WHITHER THE REGULATOR: FOOD AND DRUG LAW, THE NATURAL HEALTH PRODUCT REGULATIONS AND THE EROSION OF SAFETY, EFFICACY AND QUALITY

by

Michael D. Taylor

Submitted in partial fulfilment of the requirements
for the degree of Doctor of Philosophy

at

Dalhousie University
Halifax, Nova Scotia
November 2023

DEDICATION

To Michelle for her love and endless support, Bill for his patience and Mom for her memory.

I would also like to thank, Dalhousie Law School, the Canadian Institute of Health Research Program in Health Law and Policy, and the HERA Create program for their generous contributions during my studies, without which I would not have been able to get here.

TABLE OF CONTENTS

LIST OF FIGURES

ABSTRACT

The following thesis considers whether the regime established by the Natural Health Product Regulations (NHPR) is a suboptimal framework. It explores the effects that the creation and implementation of the NHPR have had on the safety, efficacy, and quality (SEQ) standard used in Canadian food and drug law. The original regulations, largely brought in to support the licensing of traditional medicines, herbs, vitamins, and other naturally occurring substances, have with time come to be dominated by non-traditional products making poorly demonstrated health claims. Over time, the Natural Health Products Directorate (NHPD) came to focus on access and speed of approval over demonstration of products' merit or ensuring their quality and safety. The result is a set of regulations which do little to advance their original public health goals. The thesis uses a model of realistic empirical analysis (REA) in governance law to assess how the regulations have manifest in operation, with intended and unintended consequences. To achieve this goal, first, the nature, history, and regulatory issues associated with the SEQ standard and the emergence of Complementary and Alternative Medicine (CAM) are explored, in Chapters 2 and 3. Chapter 4 outlines the emergence and content of the NHPR. Chapter 5 explores the emerging policy goals of Health Canada, gaps in the NHPR and how the administration of the regulations has evolved from 2004 through 2023. Chapter 6 provides three case studies – energy drinks, homeopathics, and self-care products – which illustrate problems with the regulations. Chapter 7 looks at external sources that have assessed the regulations, such as court cases, audits, and evaluations. In Chapter 8 the deregulatory agenda in Canada as well as the concept of risk regulation are explored, which suggest that the NHPR's weakness aligns with this agenda. In conclusion, it is observed that the NHPR are a poor set of health regulations and that their normalization of a lower SEQ standard is likely having a global effect of eroding health and safety across other areas of Canadian food and drug law. It is suggested that the NHPR should be strengthened to concentrate on quality and on reducing unfounded health claims. All regulation in Canada would greatly be improved by a more accurate assessment of its manifestation in line with concepts of really responsive regulation.

LIST OF ABBREVIATIONS USED

ADR – Adverse Drug Reactions

CAM – Complementary and Alternative Medicines

DEL – Drug Establishment License (drug)

FD – Food Directorate

FDA – Food and Drug Act

HPFB – Health Products and Food Branch

HPFBI – Health Products and Food Branch Inspectorate

MHPD – Marketed Health Product Directorate

NAPRA – National Association of Pharmaceutical Regulatory Authorities

NDS – New Drug Submission (drug)

NDMAC – Non-Prescription Drug Manufacturers Association

NHPD – Natural Health Product Directorate

NNHPD – (after 2014) Non-prescription drug and Natural Health Product Directorate

NHPR – Natural Health Product Regulations

OTC – Over the Counter Drug

PLA – Product Licensing Application (NHP)

SEQ – Safety, Efficacy and Quality

SCF – Self-Care Framework

SL – Site License (NHP)

TPD – Therapeutic Product Directorate

WHO – World Health Organization

CHAPTER 1 - INTRODUCTION[1]

Before embarking on the daunting task of reading several hundred pages about a seemingly obscure component of Canada's vast food and drug regulatory network, it is fair to ask why you should care about the *Natural Health Products Regulations* (*NHPR*).[2] Aside from curiosity and a desire to learn about this area of Canadian law, I might start with two quick stories. These stories illustrate that the application of the *NHPR* is not just an esoteric question, or one that affects products that are innately benign. They reveal that this regulatory system has health impacts that can affect Canadians' lives in drastic ways. I will cover both narratives in greater detail in my case studies, but a sneak peek at this stage may help the reader understand the significance of the *NHPR*.

The first story involves a death that may have occurred as the result of taking an NHP. In 2006 Health Canada received a report that a teenager had died from over-consuming an energy drink (ED). Brian Shepard, 15 years old at the time, had been at a Red Bull paintball tournament in Ontario, and after a day of exertion, died from a heart attack. Brian had consumed half a dozen sample cans of Red Bull as his only source of hydration. I had the rare opportunity as a co-op student of being an observer with the group making the health and safety assessment of the event at Health Canada. There had been other cases of teen death associated with energy drinks in Canada and abroad,[3] but nothing was conclusive. Energy drinks contained high quantities of

[1] Some of the content of this introduction mirrors the arguments and text approved by my Thesis Committee as part of my thesis proposal defense.
[2] *Natural Health Product Regulations, SOR 2003-196*, hereinafter *NHPR*.
[3] See Kaur, A., Yousef, H., Ramgobin-Marshall, D. and Jain, R., "Energy Drink Consumption: A Rising Public Health Issue" (2022) *Pub Med* 23(3), online at: https://pubmed.com. Bruser, D., *Energy Drinks Suspected to Have Caused Deaths of 3 Canadians*, (Toronto Star, November 18, 2012), online at: https://www.thestar.com.

guanine, *taurine* and *caffeine,* which were known to be stimulants and could be linked to heart issues, as well as acting as diuretics, which exacerbated dehydration. Both the energy drink industry and Brian's grieving father waited on the outcome of Health Canada's assessment.

Ultimately, the assessment panel decided that Brian's death could not conclusively be linked only to his consumption of energy drinks. There was a "suspected connection between a product and side effect but no medical proof that one caused the other."[4] While the energy drink was likely a mitigating factor, existing heart issues and Brian's exertion that day may also have caused his death. As a student, I was surprised by the regulator's reticence to proactively pronounce that these products might be unsafe for consumption by teenagers based on the potential risks, particularly because Brain's death seemed so unnecessary. Prior to 2004, energy drinks were prohibited from the Canadian market as foods because of safety concerns. After 2004, in order to be licensed as NHPs they were marketed as a sub-class of drug which should have prohibited[5] their distribution as samples. The regulations also required them to be sold in a fixed dosage form (a 250 ml can consumed only once per day) and recommended that they not be sold to children. Yet, the ambiguities in the regulations meant that none of these specific criteria were actively being enforced. Even more troubling was the question: what was the added merit to health provided by energy drinks that justified their entry to the market in 2004 if there were known risks?

The second narrative starts in 2015 when the Canadian Broadcasting Corporation's (CBC) investigative program *Marketplace* conducted an experiment. Looking at the requirement

[4] *Ibid.*

of the *Food and Drug Act* for NHPs, [6] they asked: how hard would it be to license a made-up NHP? They created a product for children called *Nighton Children* (an anagram of nothing), which claimed to reduce "fever, pain and inflammation."[7] They sought out a homeopathic reference text in a public library, chose two ingredients at random with a wide range of listed curative properties, photocopied the pages, and sent them off to the *Natural Health Product Directorate* (NHPD). The product proposed to have no ingredients beyond highly diluted doses of homeopathic active ingredients but claimed to relieve pain, fever, and colds. CBC producers then created a false set of packaging, shown below, submitted an application, and a few weeks later received an approved product license.

Figure 1: Fake NHP 'Nighton' created by CBC-Marketplace [8]

In theory, if the producers had been able to find a manufacturer, they could have introduced the product, directed at children, to Canadians. Nighton would have sat on pharmacy shelves next to over-the-counter drugs treating the same symptoms. Most consumers would have found distinguishing between the two products difficult. Upon contacting the Minister of Health's office, the CBC was told that the product was appropriately licensed because it was deemed

---

[6] *Food and Drug Act*, R.S.C., 1982, hereinafter *FDA*, section 14 which is supported by the *Food and Drug Regulations*, *C.R.C., C.870*, hereinafter *FDR*. The *NHPR* is a subordinate set of regulations under the *FDA* making them a sub-class of drug.
[7] Canadian Broadcasting Corporation (CBC) – Marketplace, *License to Deceive – Nighton*, (CBC, 2015), online at: https://www.cbc.ca/player, hereinafter *CBC Nighton*.
[8] *Ibid*.

"low-risk,"[9] even though it is a product that was designed to treat fever in children with no scientifically demonstrated merit.

As troubling as both examples are, they are not isolated incidences of weaknesses in the regulations. The public may expect that when Health Canada creates a regulatory regime for products, it will do something to promote or protect health. Energy drinks are only one of a wave of products that had previously been prevented from either making health claims without clinical evidence or that were outright prohibited for safety reasons prior to 2004 by other regulatory regimes under the *Food and Drug Act* (*FDA*). Homeopathics, on the other hand, represent a class of products that have reduced safety and efficacy requirements but, until recently,[10] were approved by Health Canada in a form that made them almost indistinguishable from drugs approved through the more rigorous process. The NHP regime has arguably varied the efficacy, safety, and quality standards for products regulated as part of food and drug law in a substantive way, a development of which few Canadians are aware.

A quick tour through most people's lives will also illustrate how ubiquitous NHPs have become. The scope of products that have been licensed as NHPs in the past 19 years is astounding; they include traditional medicines, energy drinks, lip balms, homeopathic remedies, yogurts, small-batch herbal remedies, cosmetics, vitamins produced by large multinational corporations, and many others. Even if you do not use complementary or alternative medicines (CAMs), it is likely that you use a product making health claims such as toothpaste,

[9] *Ibid*.
[10] Health Canada, *Evidence for Homeopathic Medicines,* (Heath Canada: Ottawa, 2022), online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines.

antiperspirant, fortified juice, shampoo, cosmetics, or vitamins that are or have been licensed as an NHP. Presently, in Canada, there are an estimated 100,000 products legally classified and marketed as NHPs.[11] It is estimated that a full two-third of Canadians regularly use NHPs,[12] and in general, these products are perceived as being more natural and safer when compared to conventional drugs.[13] Yet, it could be argued that these products are neither safer, natural, or effective.

Natural Health Product Regulation in Canada

The *Natural Health Product Regulations*[14] *(NHPR)* came into force in January 2004. The intent of these regulations was to ensure "that all Canadians have ready access to [NHPs] that are **safe, effective, and of high quality**, while respecting **freedom of choice** and **philosophical and cultural diversity**."[15] These goals can operate at odds. Traditionally, health products have been regulated based on what is called the SEQ (safety, efficacy, and quality) standard.[16] The SEQ standard developed in Canada over the 20th century in response to what was seen as an unregulated and unsafe consumer market for health products at the beginning of the century. This background will be explored extensively in Chapter 1. Safety relates to a product's toxicity

[11] Health Canada, "Licensed Natural Health Product Database," online at: https://www.canada.ca/en/health-canada/services/drugs-health-products.
[12] Health Canada/Ipsos Reid, *Natural Health Product Tracking Survey*, (Health Canada:Ottawa, 2010), online at: http://www.int4life.ca.
[13] Boon, H., Kachan, N. and Boecker, A., "Use of Natural Heath Products: How Does Being 'Natural' Affect Choice?" *PubMed* (2012), online at: https://pubmed.ncbi.nlm.nih.gov.
[14] *NHPR,* supra note 2.
[15] Health Canada, The Approach to Natural Health Products, (Health Canada: Ottawa, 2013), online at: https://www.canada.ca, hereinafter *Approach*.
[16] M. Taylor, "Chapter 2: A Background to Drug Regulation in Canada" in *A Bitter Pill to Swallow - LLM Dissertation* (Halifax: Dalhousie University, 2010), hereinafter *Taylor LLM*.

(is the substance in the dosage and formulation sold toxic);[17] efficacy relates to the claims around the product (does the substance do what it is purported to do);[18] and quality relates to manufacturing (has the product been manufactured without impurities, adulteration, or misrepresentations in labelling).[19] In Canada, pharmaceuticals are required to demonstrate a relatively high bar of evidence to prove SEQ, including clinical trials, demonstrations of good manufacturing practices, product testing, manufacturing site inspections, and ongoing safety monitoring.

Regulatory systems for complementary and alternative medicine (CAM), like the *NHPR*, struggle with the SEQ standard.[20] A sweeping pronouncement that they are all low risk is problematic. There is limited scientific evidence to demonstrate efficacy for most of these products. Products with older, traditional uses can rely upon a history of cultural or paradigm-based use to establish safety.[21] For more modern CAM products, evidence justifying use is based on very recent subjective observations or beliefs, making it difficult to assume that safety and efficacy are justified. Other concerns range from how to regulate a belief-based health effect (for traditional or cultural forms of medicine), what to do when dealing with traditional products that are unsafe, to how to deal with a surprisingly large number of NHPs on the market that are

[17] *Ibid*, see also Lemmens, T. and Bouchard, R. A., "Regulation of Pharmaceuticals in Canada" in Downie, J., Caulfield, T. and Flood, C. M. eds., *Canadian Health Law and Policy*, 3rd c (Markham: LexisNexis Canada Inc., 2007).
[18] *Ibid*.
[19] *Ibid*.
[20] See E. Ernst and K. Smith, *More Harm than Good? The Moral Maze of Complementary and Alternative Medicine* (Springer International Publishing: Switzerland, 2018), hereinafter *More Harm* and M. H. Cohen, *Complementary & Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (John Hopkins University Press: Baltimore, 1998), hereinafter *Cohen*.
[21] *Ibid*.

adulterated.[22] It should be possible to establish quality through adherence to good manufacturing practices, much like other products (i.e. there is no reason that there should be low manufacturing standards for NHPs).

In 2009, the NHPD conducted a mandated review of the *NHPR*,[23] undertaken as part of HPFB's *Blueprint for Renewal* initiative.[24] The consultation paper for this review and final report[25] captured many existing regulatory and health and safety issues for NHPs that resulted from the *NHPR*: a lack of clear provisions prohibiting or allowing advertising; lack of clarity around compounding; inadvertent inclusion of biologics in the NHP definition; poor identification of how to make distinctions between various product classes; lack of a system for ensuring good manufacturing practices (GMP) for NHPs; and lack of clarity around how to deal with sampling of NHPs.

Five years later, an evaluation of the NHP program conducted by Health Canada's Office of Audit and Evaluation (March 2016) covering the period 2011-2015 still found that "questions remain about the efficacy and quality of some NHPs, and that this could have an impact on safety."[26] The report went on to find that "some [NHPs] make claims that are not supported by

---

[22] Genuis, S. J., Schwalfenberg, G., Siy, A.J., et al., "Toxic Element Contamination of Natural Health Products and Pharmaceutical Preparations" (2012) *PLoS ONE* 7(11). *OAG, infra* note 26.
[23] Health Canada, *Charting a Course: Refining Canada's Approach to Regulating Natural Health Products*, (Health Canada: Ottawa, 2007), hereinafter *Charting a Course*.
[24] Health Canada, *Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food* (Health Canada: Ottawa, 2006), hereinafter *Blueprint*. See also Health Canada, *Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food* (Health Canada: Ottawa: 2007).
[25] Health Canada, *Final Report – Online Consultations: Natural Health Products Regulatory Review* (Health Canada: Ottawa, 2008).
[26] Health Canada, *Evaluation of the Natural Health Products Program 2010-2011 to 2014-2015* (Health Canada, Ottawa, 2016), hereinafter *2016 Evaluation*. Health Canada, *Final Report: Audit of the Management of the Natural Health Products Program* (Health Canada, Ottawa, 2015), hereinafter *2015 Audit*.

scientific evidence and that lack of an on-site inspection program in conjunction with the current attestation model do not do enough to verify the quality of products manufactured both domestically and outside of Canada."[27] The evaluation also identified that significant challenges have been created, including "product classification issues; accessibility of information issues; limited follow-up on recalled products; and post-market activities that tend to be generally reactive, and not proactive."[28] The majority of these identified issues are a direct result of intentional decisions about how the regulations were being implemented, including emphasizing NHPs as low-risk products meriting lower regulatory supervision. This, in turn, has meant interpreting, in guidance, the regulations as permissive, and allowing for reduced evidential standards for SEQ.

More recently, in the spring of 2021, the Office of the Auditor General of Canada (OAG) again found that there were serious deficiencies in how NHPs were regulated, concluding that "Health Canada did not ensure that natural health products offered to Canadians were safe, effective, and accurately represented on the basis of appropriate evidence."[29] The OAG acknowledged that the regulators were using some form of logic around evidence to make regulatory decisions on safety and efficacy, but that advertising and health claims made by manufacturers frequently did not adhere to their licensing conditions. All the products tested by the OAG were found to be adulterated. The OAG went on to further find that "Health Canada did little to prevent poor information from being given to consumers about licensed natural

[27] *Ibid*.
[28] *Ibid*.
[29] The Office of the Auditor General (OAG) - Commissioner of the Environment and Sustainable Development, *Report 2- Natural Health Products*, (OAG, Ottawa: 2021), online at: https://www.oag-bvg.gc.ca, hereinafter *OAG*.

health products."[30] Even more troubling was the finding that the regulator had few mechanisms in place to ensure good manufacturing practices for these products or to monitor them once they were licensed. In conclusion, the OAG found that NHPs were "unchecked after they entered the market"[31] and that the regulator was "not always successful in responding to serious problems"[32] in a timely manner. Given the breadth of products regulated as NHPs and the volume of these products consumed by Canadians every day, these findings are troubling and warrant further exploration.

There is little substantive research looking at the *NHPR*. In 2020, Jeremy Ng, in affiliation with his work as part of the Canadian government-funded *Natural Health Product Research Society of Canada,*[33] conducted a systematic review of over 1,700 articles related to NHPs in Canada to determine if there had been any peer-reviewed studies evaluating the NHP regulatory regime.[34] He found one study from 2012. Most studies did not meet the criteria of being peer reviewed, impartial, or comprehensive. The single article identified, by Walji and Wiktorowicz,[35] focused primarily on some of the growing pains of the new regulations in the first eight years of their operation. There has been no additional research in the past decade on the NHP regulatory framework and no systematic analysis of these regulations from a legal perspective. Ng called for greater research into the effectiveness and impact of these regulations.

---

[30] *Ibid*.
[31] *Ibid*.
[32] *Ibid*.
[33] See online at: https://www.nhprs.ca.
[34] Ng, J., and Luong, M., "Evaluation of the Canadian Natural Health Product Regulatory Framework: A Scoping Review" (2020) *European Journal of Integrative Medicine*, 37, online at: https://www.sciencedirect.com, hereinafter *Ng*.
[35] Walji, R. and Wiktorowicz, M., "Governance of Natural Health Products Regulation: An Iterative Process" (2019) *Health Policy* 111(1), online at: https://www.sciencedirect.com, hereinafter *Walji & Wiktorowicz*.

I propose that there is a need for an outcome analysis of NHP regulations. In a recent speech, outgoing Secretary of the Treasury Board of Canada Secretariat, Peter Wallace, flagged that one of his key concerns around government regulations are "not just the intended, but [the] unintended consequences of how they are administered."[36] Traditionally, law and legal scholarship has looked at regulation in an administrative context, usually as a result of litigation and the application of court-made administrative law.[37] This tends to create a point-in-time approach to legal analysis where decision-makers are either asked to pronounce on a procedural component of a regulatory regime or a specific case of disputed application of regulatory oversight.[38] While it can be argued that this form of analysis does produce lessons and helps guide regulatory development, it provides an episodic and far-from-comprehensive view of how regulations work, and the intended and unintended consequences they create. As part of my CIHR fellowship in Health Law, Policy, and Ethics, we were called upon to look at health systems in context and how the policy around them impacts Canadians.

Abraham identified a more comprehensive form of legal and regulatory assessment using a model he calls **realistic empirical analysis** (REA).[39] Using REA a researcher establishes the rules of a system in detail, identifies the interests which surround the actors, and examines how this affects the development of policy and outcomes in the system. Abraham's research focuses

[36] Peter Wallace, a speech provided to the Priorities and Planning Sector of the Treasury Board of Canada Secretariat on December 6, 2018.
[37] Scott, J. and Stum, S. P., "Court as a Catalysts: Rethinking the Judicial Role in New Governance" (2007) 13(3) *Columbia Journal of European Law;* Spiller, P. T., "A Positive Political Theory of Regulatory Instruments: Contracts, Administrative Law or Regulatory Specificity?" (1995) *69 S. CAL Reve 47;* Lahey, W., "New Governance Regulation and Managerial Accountability for Performance in Canada's Health Care Systems" in Kouri R. P. and Régis, C. eds., *Grand Challenges in Health Law and Policy* (Cowansville: Editions Yvon Blais, 2010).
[38] *Ibid*.
[39] Abraham, J., "Sociology of Pharmaceutical Development and Regulation: A Realist Empirical Research Program" (2008) *Sociology of Health & Illness* 30(6) 869.

on establishing those drivers and the interests of the U.K. pharmaceutical regulatory regime. He was able to create a holistic assessment of how "bias manifests itself at the micro-social level of science-based pharmaceutical testing and regulatory decision-making."[40] I would like to add to this type of assessment a detailed description of the operational realities, including those derived from guidance and directives, to frame the regulation of NHPs. From this we can gain a view into the interests, obligations, and policy decisions that have been made around NHPs. This would provide a description not only of how the regulations are intended to operate, but how they have ultimately manifest in execution.

Real-world legal and governance analysis of food and drug law has been rare in Canada, partially because legal researchers have left the mapping of non-judicial aspects of these regulatory systems and their administration to other academic disciplines. Political scientists,[41] sociologists,[42] and even medical researchers[43] have done a better job than legal experts of describing how food and drug law is created and operates in Canada. It is also rare because it has not been seen to fit within the analytical categories of the common law.

Regulatory systems are intentional constructs developed and framed by regulators. As Avorn notes, in making these decisions:

---

[40] *Ibid*. at 874.
[41] Wiktorowicz, M.E., "Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France" (2003) *Journal of Health Politics, Policy and Law* 28(4) 615.
[42] Mintzes, B., Morgan S. and Wright J., "Twelve Years' Experience with Direct-to-Consumer Advertising of Prescription Drugs in Canada: A Cautionary Tale" (2009) *PloS One* 4(5) at 1.
[43] La Rochelle, P., Lexchin, J. and Simonyan, D., "Analysis of the Drugs Withdrawn from the US Market from 1976 to 2010 for Safety Reasons" (2016) *Pharmaceutical Medicine* 30 at 277.

> … [The regulatory] system shapes decisions for good or for ill – the incentives that drive behaviour, the culture of expectations about information or standards of practice, the regulations that do or don't exist and how thoughtfully they're enforced.[44]

Governments and their regulators play a key role in establishing and reinforcing the parameters under which drug regulation unfolds. As Wiktorowicz notes:

> by facilitating some courses of action or making others more difficult, government institutions shape the manner and degree to which organized interests exert influence and thus determine where the balance lies between interest group demands and the programmatic goals of government.[45]

Regulators are not impartial or passive actors and intentionally create the regulatory environment in which decisions about therapeutic products are made, with far-reaching health outcomes for Canadians.

In their text *Understanding Regulation: Theory, Strategy, and Practice,*[46] Baldwin, Cave and Lodge mirror this sentiment by proposing that new regulatory models need to develop a framework of **really responsive regulation** (RRR). This newer form of regulatory theory calls for an assessment of regulatory systems over the long term. They note that a regulatory system will evolve based on five key factors: (i) the behaviour, attitudes, and culture of regulated and regulators, (ii) the institutional setting of the regulatory regime, (iii) the interactions between the different tools and parts of the regime, (iv) the regime's "own performance over time,"[47] and (v) finally, being adaptable to changes. They also add the need to have (vi) a strong compliance regime to provide objective real-world data on whether the program is meeting its policy

---

[44] Avorn, Jerry, *Powerful Medicines: The Benefits, Risks, and Cost of Prescription Drugs* (New York: Knopf, 2004), hereinafter *Avorn*, at 18.
[45] *Wiktorowicz, supra* note 41.
[46] 3rd ed, (Oxford University Press: Oxford, 2012), hereinafter *Baldwin et al*. See also Black, J. and Baldwin, R., "Really Responsive Risk-based Regulation" (2010) *Law & Policy* 32 at 181, herein after *Black*.
[47] *Ibid*

objectives. I will discuss regulatory theory and its evolution in Canada in greater detail later, but a more comprehensive analysis of the context and operation of the *NHPR* would be a valuable starting point.

Another model for regulatory outcomes comes from the European Union, where there is much more analysis of regulation as manifest in execution, and the patterns of rules, formal and informal, that emerge. It falls under the general rubric of **governance studies or governance law.** Moller[48] identifies this as a broader shift that has taken place in legal studies, from government to governance, where administrative law is understood as being made in the execution of regulatory activities, and not only by courts and legislatures. In this framing of legal governance, "legal knowledge becomes a descriptive tool rather than a normative one."[49] This form of legal scholarship moves beyond doctrinal analysis to the assessment of institutions and their execution of regulatory activity. Kingsbury et al. argue that governance law must "be analyzed as administrative action: rulemaking, administrative adjudication between competing interests, and other forms of regulatory and administrative decision-making."[50] It is a model that asks how administrative structures can ensure that they are accountable as they manifest in operation.

Under governance law, there is a theoretical approach to administrative law that sees the design, structure, and function (administration) of a regulatory system as part of administrative

[48] Moller, C., "European Governance: Meaning and Value of a Concept" (2006) 43 *Common Market Law Review* 313 at 36.
[49] *Ibid.*
[50] Kingsbury, B., Krisch, N. and Stewart, R. B., "The Emergency of Global Administrative Law" (2005) *Law and Contemporary Problems* 65(8) at 17.

law. Moeller, in the EU context, has seen this as the emergence of a new form of governance law where, "a governance perspective transforms legal knowledge from questions of legality to questions of optimal institutional management."[51] As Baldwin et al. note, this includes the "culture of the actors, institutional settings, interaction between regulatory tools, a regulatory regime's performance over time, and changes in any of these elements."[52] This perspective considers law in the real-world operation of regulatory organizations. In this framework, the law is the "pattern of regulation"[53] that exists in its execution.

My thesis argues that a system with lower safety, efficacy, and quality standards, initially designed to regulate traditional and herbal products, has expanded to cover a wide range of new products. The initial regulatory scope was too broad, and new products were able to seek regulation under reduced standards meant for traditional and alternative medicine. This was due to gaps in regulations and the inherent difficulty in defining the evidential base and parameters of complementary and alternative medicine (CAM) products. As a result, regulators struggled to cope with the high volume of new products and were forced to extend exceptions to safety, efficacy, and quality standards. This led to a flood of products making poor-quality health claims and a shift towards accepting poorly proven claims. These changes have had a wider impact, reducing the safety, efficacy, and quality norms of all food and drug law in Canada. This shift towards risk-based regulation and economic considerations as the primary drivers of food and drug regulation has resulted in minimal compliance enforcement for non-compliant natural

[51] *Moeller, supra* note 48 at 38.
[52] *Baldwin et al*, *supra* note 46.
[53] *Abraham, supra* note 39.

health products (NHPs), leading to an overall degradation of safety, efficacy, and quality standards, and less protection for Canadians provided by Health Canada.

To date, there has been no systematic legal assessment of the Natural Health Product Regulatory Regime from a legal, policy, and institutional perspective. It is intended that my thesis be the first in-depth legal assessment of this regime, applying the broader concept of administrative law I have described above. Furthermore, I will use this analytical framework to assess the qualities and implications of applying risk-based regulation to a health and safety regime. This is a task that becomes even more important as the "lessons" learned from NHPs are used to justify an expansion of a "risk-based" regulatory system to other areas of food and drug law. It is hoped that the reader can use the following both as a grounding for understanding NHP law in Canada and as a critical appraisal of this regulatory system.

A General Disclaimer

The experience of healing and health are very subjective. The choice which underlies the use of complementary or alternative medicines (CAMs), natural health products (NHPs) or any form of unconventional medicine or therapy is not the focus of this thesis. The focus of my thesis will not be to assess the cultural values that underlie long-standing traditional or cultural practices, nor should that be the focus of a legal dissertation. I will focus on the effectiveness of the legal regime around natural health products. Does this regulatory system do what it purports to do? Or more specifically, does the regulatory model adopted in Canada for these types of products achieve its stated public health policy goals and best protect Canadian consumers? At the end of my thesis, I will offer some proposals to make these types of regulatory regimes more effective.

In doing so, I will review some of the theories underlying these therapies to better understand the regulatory problem, but it is not the goal of this thesis to weigh in on the heated debate between those who support the use of CAMs and those who advocate for conventional medicine.

Within the broad class of CAMs there is a collection of practices based on long-standing traditional belief systems. Many of these systems are founded on cultural practices that are thousands of years old. These traditional belief systems should be respected within the cultural and historical context in which they exist. The text *Mi'kmaq Medicines - Remedies and Recollections,* by Laurie Lacey,[54] encapsulates an example of traditional Indigenous medicine in Nova Scotia. In describing the underlying theory of these traditional practices, Lacey states:

> When we travel the forest fields, or canoe the lakes, rivers and streams, we are surrounded by healing energies that nourish the body, mind and spirit. When the medicine maker declares that we are surrounded by medicines, it means that we are surrounded by medicinal plants and trees, and also that we live in this ocean of healing energy.[55]

Part of the root of this healing practice is a well-developed system of belief and cultural tradition. My thesis is in no way designed to pass judgement on traditional belief-based practices, nor should it be the purpose of any regulatory regime to curtail or pronounce on the beliefs underlying these various systems. The specific cultural or faith-based systems underlying traditional medicines are outside the ambit of a legal thesis and my expertise. I will assess the nature of the evidence required by regulatory systems for licensing alternative remedies, especially those making new claims, but I will not assess the beliefs associated with this evidence.

---

[54] Laurie, L., *Mi'Kmaq Medicines* (Nimbus Publishing: Halifax, 2012).
[55] *Ibid*, at xi.

RESEARCH QUESTION

In my thesis, I will ask: what lessons can be learned for regulatory theory and food and drug law from the evolution of the Canadian regulatory regime for NHPs? **My thesis is that the current natural health product regulations (soon to include self-care products) is a suboptimal framework**. In addressing this question, I will explore several subordinate arguments:

a. That the legal framework for *NHPR* has created an overly broad regulatory pathway allowing for unintended products to seek legal approval.
b. That there are a series of structural issues with the *NHPR* (around product licensing, site licensing, quality assurance, adverse event reporting, advertising, etc.) that make it suboptimal.
c. That the low standards and proof required in NHP licensing and the changes in the regulatory system over the past 19 years to focus on market access over safety or efficacy stand in opposition to the rest of the drug regulatory system.
d. That the overly broad regulatory pathway, structural issues, and minimal standards (a, b & c) are being used as a model to justify the expansion of this system (the self-care framework) to replicate these errors more broadly under the food and drug regime for a host of new products.

I will also look at the *NHPR* as an example of modern regulation to determine the lessons that can be learned for future health and safety regulation, food and drug law, and regulatory theory in general.

METHODOLOGY

In my master's thesis, I examined the institutional and legal system for drugs, and provided a systematic description of institutional actors, policy drivers, and most importantly, requirements existing under the law. In my PhD dissertation, I intend to complete a mapping of the regulation and outcomes associated with the *NHPR*. I will use this approach to administrative law to provide a detailed comprehensive and analytical description of how Canada's *NHPR* system functions and is evolving, using my own experience in the system, and by incorporating into my description not just the regulations (the hard law) but the relevant guidelines and directives (the soft law), as well as the interaction between relevant actors who are part of the regulatory system. This will also serve as the first roadmap to the *NHPR* regulation in operation for the legal reader. In short, I will provide an in-depth description of *NHPR* as a system of governance that itself functions within a broader system of regulation that includes Canadian food and drug law, the government's broader thinking about and approach to regulation, and the world of ideas about regulation that influences regulation everywhere, and most particularly, that equates good regulation with risk-based regulation.

The second chapter of my thesis will include a historical description of the emergence of the dominant legal and public health tool in food and drug regulation: the safety, efficacy, and quality (SEQ) standard. This will be followed by a description of the legal requirements in place for pharmaceutical drugs to meet SEQ standards, which includes product licensing, drug establishment licensing, safety testing, quality assurance, and clinical testing for efficacy. It is a unique point of law that NHPs are a sub-class of drug, while many of the legal obligations existing for drugs have been modified by the *NHPR*. Other product classes which overlap with

NHPs will be briefly discussed and then I will review the current literature on emerging issues and critiques of the drug regime in Canada.

In Chapter 3, I will explore the unique nature of complementary and alternative medicine (CAM) products, first as an issue of nomenclature (the scope of CAMs is very hard to define) and then by reviewing the historical development of CAM as a health-care model in opposition to conventional medicine. Rather than providing a complete definition of CAM products, I will identify several principles that can be used in guiding how they can be classified. This will lead to a discussion of the legal and ethical issues that these products present to regulators, especially in trying to apply the SEQ standard.

In Chapter 4, I will outline the *NHPR* legal regime, and relevant guidance that has emerged to help solidify how the SEQ standards are applied for these products. The discussion will start with some international comparators for the regulation of CAM products, in particular the EU, U.S., and Australia, which represent the spectrum of approaches for regulating CAM products. I will next describe the Parliamentary and committee processes which led to the recommendation for the new regulations and established the goals of the new regime. I will describe the *NHPR* regulatory regime, including relevant guidance, particularly as they apply to good manufacturing practices, evidential requirements, and pre-clinical testing, in contrast to those systems for conventional medicines described in Chapter 1.

In Chapter 5, I will briefly summarise the evolution of Health Canada drug policy. I then will then outline several gaps that existed in the initial construction of the regulations. I will

work through several issues that were identified early in the *NHPR*'s operation (the scope of the *NHPR* definition, combination products, GMP standards, advertising, etc.) that have had long-term implications for how the *NHPR* has been operationalized and has affected the regulation of other products under the *Food and Drug Act*. Finally, I will look sequentially at the evolution of the *NHPR* and how it has demonstrated a gradual trend to adopting guidance that creates a *deminimus* standard associated with pre-market review.

In Chapter 6, I will employ case studies of several products, examining how they have progressed or been treated under the *NHPR* regime to illustrate the policy and regulatory gaps of both the current and proposed self-care system. I have chosen products based on their illustration of different strengths and weaknesses of the *NHPR* regime. These products are:

- Energy drinks as a demonstration of a new class of products that could not be licensed under the food and drug regime prior to 2004, and one which the regulatory regime was required to adapt to by adjusting health and safety standards.
- Homeopathy as an example of a long-standing form of complementary and alternative medicine, with little demonstrable efficacy, that the regime was required to incorporate. It is also a class of products that raises significant legal and ethical issues because it has little to no provable health benefits.
- Non-prescription drugs, which are pharmaceuticals, with known health and safety concerns, that are currently regulated as drugs but will be subject to a much lower health and safety standard under the proposed self-care model.

In Chapter 7, I will conduct an evaluation of how successful the *NHPR* has been in meeting its original public health goals and maintaining a robust, or at least coherent, system for establishing SEQ for products. In the first section, I will provide an overview of the minimal case law associated with *NHPR*, which has generally re-asserted that the regulations are valid under the *FDA* and that their primary goal should be the protection of health. Next, I will review existing evaluations of this regime, two by Health Canada and one by the Auditor General of Canada (AG), which over the past decade have consistently found the *NHPR* system is not performing well in ensuring that quality and safe products are coming to market. I will then look at several factors that can be used to assess good versus bad regulation and assess how the *NHPR* has performed.

In Chapter 8, I will ask which regulatory drivers, both government-wide and within Health Canada, have led to the acceptance of a mode of regulation that accepts this low standard of regulatory oversight. First, I will review the evolution of the government de-regulatory agenda. This will be mapped in combination with several initiatives at Health Canada that have sought to implement these regulatory initiatives in the health context. This has been demonstrated by a shift in the focus in the goals of product regulation away from health and safety towards market access and reducing burden on industry. Finally, I will explore the concept of risk regulation, pointing out its strengths and weaknesses, and how it has become a mechanism used by successive governments, potentially incorrectly, to justify de-regulation in the food and drug law space.

Finally, in my conclusion (Chapter 9) I will summarize my observations and pronounce on my research questions. I will then provide some suggestions for improving NHP regulation and the regulatory agenda in Canada.

CONTRIBUTION OF THIS THESIS

To date there has been no comprehensive evaluation of the natural health product (NHP) regime. Nor has there been a review of the implications of this regime on the safety, efficacy, and je of therapeutic products overall. This thesis will represent the first review of how the SEQ standard has been impacted by the *Natural Health Product Regulations* (*NHPR*). It will also represent the first mapping, from a policy and legal perspective, of the implications of regulating complementary and alternative medicine products in Canada.

The *NHPR* were originally conceived as a regime to provide a greater degree of oversight for traditional medicines (including herbal remedies, vitamins, minerals, and homeopathics) while at the same time allowing for a reduced SEQ standard to account for their history and cultural context. An overly broad definition of NHP has meant that most of the products being approved by this regime are non-traditional products making poorly proven claims. Yet, Health Canada has viewed this regime as a low-risk regulatory success story that it is expanding to other product categories (including cosmetics, over-the-counter drugs, personal care products, advanced therapeutics, and medical disinfectants).

There are health and safety concerns associated with this erosion of the SEQ standard. It represents the adoption of a regulatory agenda that seeks to align the goals of health product regulation with economic ones. I will also describe how this shift in regulatory priorities has occurred at Health Canada but also as an intentional program to change the way regulations are created, managed, and implemented in Canada. In the end my analysis will lead to conclusions

about how better to regulate CAM products in Canada, how to ensure that the SEQ standard is not eroded, and how better to align Canadian food and drug regulation with public health goals.

The Regulation-Making Process in Canada

Before getting too far into discussions around the nature of regulatory theory, I will begin with a starting question: what exactly are regulations, how are they made, and what is their importance? At their most basic, regulations are a subordinate set of legal instruments to support a piece of legislation. They are normally passed and implemented by the government in power, not by Parliament. As the Department of Justice (DOJ) describes them:

> Because our **society is** so **complex**, it would be nearly impossible if lawmakers had to deal with all of the details of all the laws. To help with this, Parliament and provincial and territorial legislatures often pass laws to give departments or other government organizations the authority to make specific laws called **regulations**.[56]

Under the *Statutory Instruments Act*[57] they are more formally defined under Section 2.1 as:

> a statutory instrument made in the exercise of a legislative power conferred by or under an Act of Parliament, or for the contravention of which a penalty, fine or imprisonment is prescribed by or under an Act of Parliament.[58]

Subordinate to these regulations is a broader class of statutory instruments including: rules, orders, directives, guidance, and tariffs that are adopted to guide compliance with and administration of regulations.[59]

From a broader perspective, the act of regulating or being regulated can be seen as "sustained and focused control executed by a public agency over activities that are valued by a

---

[56] Government of Canada - Department of Justice, *Infographic: How New Laws and Regulations are Created*, (DOJ, Ottawa), online at: https://canada.justice.gc.ca/eng/laws-lois/infograph.html. See also Government of Canada – Privy Council Office, *Guide to Making Federal Acts and Regulations*, (PCO, Ottawa), online at: https://www.canada.ca/content/dam/pco-bcp/documents/pdfs/fed-acts-eng.pdf.
[57] *R.S.C., 1985, c.S-22.*
[58] *Ibid*, at *s.2.1.*
[59] *Infographic, supra* note 56.

community,"[60] under the direction of an authority. Regulatory systems can be seen as manifesting certain characteristics: (i) exercising a specific set of commands where "regulation involves the promulgation of a binding set of rules to be applied by a body designated to that purpose;"[61] (ii) involving deliberate state influence on policy and behaviour such as "economic institutions, contractual powers, deployment of resources, franchises, supply of information or other technologies;"[62] (iii) other forms of social or economic influence where there is "no requirement that the regulatory effect or mechanisms are deliberated or designed;"[63] and can include a broad host of activities by "other bodies including corporations, self-regulators, professional trade bodies or voluntary organizations."[64] In effect, the act of regulating involves all the activities undertaken by a regulator and the regulated, whether direct or indirect, and whether these are intended or unintended as a result of the existence of a set of regulations.

As was noted above, supporting regulations are a collection of subordinate tools generated by regulators to clarify the execution of the regulations. These are normally generated by the institution doing the regulating, and while not strictly legal or carrying legislative authority, they do have quasi-legal authority over the regulated. In descending order of authority, these include policies, directives, standards, guidelines, and tools.

[60] *Baldwin et al, supra* note 46 at 3.
[61] *Ibid.*
[62] *Ibid.*
[63] *Ibid.*
[64] *Ibid.*

Table 1 – Structure and description of Treasury Board policy instruments

Instrument	Description	Usual Audience	Application
Policy Framework	Formal statement that provides context and broad guidance with respect to policy themes or clusters. Also provides the supporting structure within which specific Treasury Board policies and other instruments can be understood in strategic terms. Explains ***why*** Treasury Board sets policy in particular area.	Ministers, Deputy Heads	Architectural
Policy	Formal direction that imposes specific responsibilities on departments. Policies explain ***what*** deputy heads and their officials are expected to achieve.	Ministers Deputy Heads	Mandatory
Directive	Formal instruction that obliges departments to take (or avoid) specific action. Directives explain ***how*** deputy heads' officials must meet the policy objective.	Managers & Functional Specialists	Mandatory
Standard	A set of operational or technical measures, procedures or practices for government-wide use. Standards provide more detailed information on ***how*** managers and functional specialists are expected to conduct certain aspects of their duties.		Mandatory
Guideline	A document providing guidance, advice or explanation to managers or functional area specialists.		Voluntary
Tools	Examples include recognized best practices, handbooks, communications products and audit products.		Voluntary

Figure 2: TBS Hierarchy of Policy Instruments[65]

Various players in the Canadian federal system have a role in the formal regulatory development process. **Departments and their Ministers** are responsible for bringing forward regulatory proposals related to their mandate and responding to political requests regarding new regulations The **Privy Council Office** (PCO) ensures examination and registration as required by the *Statutory Instruments Act (SIA)*[66] and provides policy advice to the **Prime Minister** and **Cabinet** on regulatory proposals. The **Department of Justice** (DOJ) is in charge of ultimately drafting the text of regulations, reviewing them for consistency, general legal compliance, and ensuring legality with the *SIA*. The **Treasury Board Secretariat of Canada** (TBS) provides support with regulatory submissions and "reviews authorities, conducts regulatory design, and

[65] Government of Canada – Treasury Board of Canada Secretariat, *Foundational Framework for Treasury Board Polices*, (TBS, Ottawa), online at: https://www.tbs-sct.canada.ca/pol.
[66] *SIA, supra* note 57.

analyzes and supports Treasury Board Ministers"[67] in validating the regulations. As will be described later, the role of TBS has expanded in recent years to include a challenge function to departments bringing forward new regulations as well as taking a lead in implementing new regulatory initiatives. **Public Services and Procurement Canada** (PSPC) is responsible for publication of the regulations in the *Canada Gazette Part I* and *Part II.*[68]

In 2006 the regulatory challenge and oversight unit was moved from the PCO to TBS under the newly created **Regulatory Affairs Sector** (TBS-RAS). RAS has increasingly had a hand in triaging submissions and overseeing how regulations are drafted. The authority for approving regulations was also shifted from Cabinet itself to **Treasury Board (TB),** with TB acting as the cabinet committee responsible for considering Governor in Council matters, including regulations. RAS plays a role in setting regulatory policy and leading regulatory modernization initiatives. Meetings of TB called Part B oversee final approval of subordinate laws, regulations, and orders in council (OiCs). On average, TB reviews 100 to 200 regulatory proposals per year from various departments across government.[69]

The drafting of regulations in Canada follows a series of steps within the administrative system of the government. Yet, the *SIA* stipulates, the only procedural criteria which must be applied is ensuring regulations are validated (by the Clerk of the Privy Council).[70] Section 10 of

---

[67] Government of Canada – Treasury Board of Canada Secretariat, *Treasury Board of Canada Secretariat Organization – Regulatory Affairs Sector*, (TBS, Ottawa), online at: https://www.canada.ca/en/treasury-board-secretariat, hereinafter *Role of RAS*.
[68] Government of Canada, *About the Canada Gazette*, online at: https://www.gazette.gc.ca/cg-gc/lm-sp-eng.html.
[69] *Role of RAS, supra* note 67.
[70] Under Section 3.2 of the *SIA* the Clerk of the Privy Council… shall examine the proposed regulation to ensure that (a) it is authorized by the statute; (b) it does not constitute an unusual or unexpected use of the authority; (c) it does not trespass unduly on existing rights and freedoms (d) the form and draftsmanship of the proposed regulation are in accordance with established standards.

the *SIA* also requires that new regulation must go through a gazetting process before finally coming into force. This leaves most of the process for developing and approving regulations in the hands of the government of the day. This discretion includes formulating what administrative processes will be involved and determining the criteria to be applied in generating new regulation. On average the development of a set of regulations takes from 18 to 24 months, depending on the complexity and political will associated with the regulations.[71] The development of the *NHPR* from the original issuance of the Minister's mandate took 56 months to come into force.[72]

The development of a set of regulations starts when Parliament passes a piece of legislation that may require new regulation or with the identification of a new problem, usually at the operational or stakeholder interface within a department. This will be followed by policy work which considers various options to address the issue. If it is determined that the best option is a new set of regulations, the department will work with the Department of Justice to develop a Memorandum to Cabinet (MC) requesting both policy and funding approval to develop a new regulatory program. (In certain cases a new regulatory program may be announced in the budget which can be followed by an MC seeking authority to access funds and enact policy). If given approval, the department will then engage in consultations with external and internal stakeholders and DOJ on the forms and options for the regulations.

TBS-RAS continues to be engaged at this stage to triage the regulatory proposals. TBS-RAS will be engaged throughout the early stages of the process to provide advice on meeting the

[71] *Role of RAS, supra* note 67.
[72] The Minister's mandate was issue in March 1999 and the regulations came into force on January 1, 2004.

policy objectives of the government in structuring any new regulations. The role of TBS in this policy challenge will include asking questions related to statutory authorities, applying several policy lenses put forward by the government, examining the need for the regulations, and proposing other tools for implementing the appropriate level of oversight. In the case of new legislation it can work the other way as well, with central agencies, PCO or TBS-RAS, putting pressure on line departments on behalf of the government to get regulations in place where they are key to implementing the government's legislation.

If the proposed regulations pass the early challenge and template stage with RAS, they will then be discussed with DOJ and a formal set of drafting instructions will be put forward with which DOJ will then begin drafting the regulations. DOJ has a special drafting unit which will draft the regulations and review them with specific lenses, including constitutionality, statutory authority, common regulatory language, and concordance between French and English versions of the text. Draft regulations will then be shared back to the department which will go through a series of negotiations on specific wording until both DOJ and the department are satisfied. RAS and other affected departments will also be consulted on the wording of the regulations. At this time there may also be formal and informal engagement with stakeholders (both internal and external) on the structure of the regulations. As the regulations move closer to finalization, Ministers' offices will be briefed on the wording of the regulations as will Cabinet if they have significant potential political implications.

Once wording has been finalized, the draft regulations will be submitted again to TBS-RAS for the preparation of a TB submission for the regulations to be approved for pre-

publication by Treasury Board (TB). It will eventually be reviewed by Ministers at TB Part B and given approval or sent back for reconsideration. As part of the submission, DOJ, the sponsoring department, and TBS will also work on a **Regulatory Impact Analysis Statement** (RIAS)[73] that describes the purpose of the regulations and relevant considerations, including the issues being addressed, potential risks, and concerns raised by the government of the day.

Once TBS has approved a prepublication of the regulations, they will be given a final validation check for language concordance by DOJ and then published by PSPC in the ***Canada Gazette Part 1***[74] which allows for 90 days of public input and comment. Comments are received by PSPC and shared with the sponsoring department. Departments are expected to respond and address substantive comments and engage both TBS-RAS and DOJ in any required edits or amendments to be made to the text of the regulations. If required, because of substantial changes, an additional TB submission is prepared outlining the comments and revised wording of the final regulations. Once TB Part B provides approval of the finalized regulations they are published in ***Canada Gazette Part II***.[75]This publication constitutes approval and the regulations become law pending any later coming-into-force dates. A standing committee of Parliament (the **Standing Joint Committee for the Scrutiny of Regulations**)[76] regularly reviews and provides guidance on needed updates to the regulations, often noting required technical updates.

[73] Government of Canada, *Policy on Regulatory Development*, (2018), online at: https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations.
[74] Government of Canada, *Canada Gazette*, online at: https://www.gazette.gc.ca/accueil-home-eng.html
[75] *Ibid*.
[76] Parliament of Canada, *The Standing Joint Committee for the Scrutiny of Regulations*, (Library of Parliament: Ottawa, 2022), online at: https://lop.parl.ca.

There are some important factors to note about the above-described process. The first is that the regulatory-making power is subordinate to the government of the day and does not need to return to Parliament to be voted on for approval. Parliament approves the legislation upon which regulations are based, but generally does not vote on new or amended regulations. The second is that departments are only the sponsors of a set of regulations, but DOJ is the ultimate drafter and representative of the Crown in making the regulations. Central agencies, in particular since the 2006 creation of TBS-RAS, play a crucial role in providing policy oversight and guidance in the creation of regulations. As such, while departments develop regulations, they are subject to centralized political direction, including aligning regulatory development to the mandate of the government of the day. TBS-RAS analysts have a high degree of discretion in how they provide their challenge function on a particular set of regulations. TBS-RAS also plays a particular role in this respect, by triaging, challenging, and enforcing central agencies' perspectives throughout the regulatory development process. This can also apply in the inverse when seeking to modify or remove a set of regulations.

Re-ordering Regulatory Theory

There has been a tendency over the past two decades for governments to increasingly embrace new forms of regulatory theory. This has been partially driven by a liberalization agenda, resource constraints, and an expansion of government oversight.[77] It is also the product of a trend in regulatory theory towards the rationalization of regulation. Advocates of these approaches have sought to apply a more nuanced perspective to regulatory oversight in contrast

[77] *Baldwin et al, supra* note 46.

to the "stale disputation between the proponents of deterrence and compliance models of enforcement."[78] This process began in the mid-1990s and picked up steam around the turn of the millennium. There are several core theories and "waves" of regulatory thinking that have built on one another to have a great impact in changing the regulatory landscape.

Responsive Regulation

A starting point for much of this change is John Braithwaite's 2002 text *Restorative Justice and Responsive Regulation,*[79] which argued that the key to successful regulation was to "establish a synergy between punishment and persuasion."[80] From this, they proposed a graded pyramid of regulatory strategies that could be applied to regulatees.

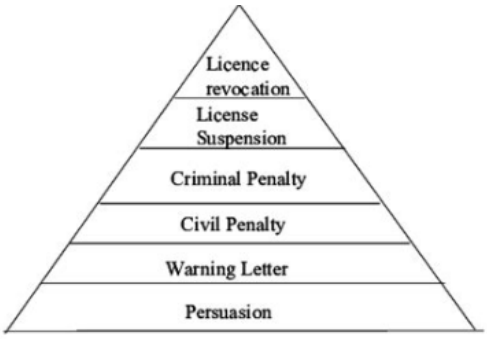

Figure 3: Braithwaite's Enforcement Pyramid for Responsive Regulation[81]

Under responsive regulation, enforcement becomes a graded process with increasing severity based on degree of non-compliance. Aligned with the enforcement pyramid is a revised concept of the degree of regulation, or different regulatory strategies, which should be applied.

[78] *Ibid.*
[79] (Oxford University Press: Oxford, 2002)
[80] *Ibid*
[81] *Ibid.*

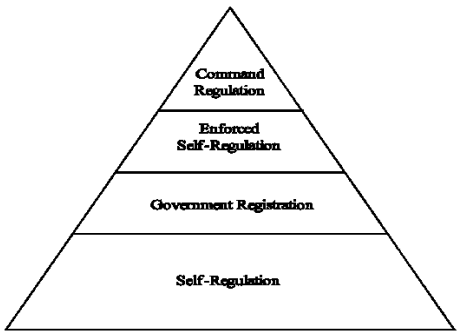

Figure 4: Braithwaite's Enforcement Strategies Pyramid for Responsive Regulation[82]

Under this model, regulatory intervention should be proportional to the risk of the activity which must be regulated. This model has immediate appeal for the regulated and regulators, as it is argued that for the vast majority of activities, self-regulation, enforced self-regulation, and command regulation with discretionary punishment would be the norm.

Responsive regulation immediately leads to several questions.[83] The first centres on how determinations will be made about where to place activities along the pyramid. From this, a required methodology for risk quantification emerges, which in turn leads to concepts around risk regulation that will be discussed later. Yet, as Baldwin et al. note, "where potentially catastrophic risks are being controlled, it may not be acceptable to enforce by [slowly] escalating up the ladder of the pyramid."[84]A second issue centres on defining the rules that will be used to determine which activities will be undertaken for enforcement. These risk determination rules themselves can become the focus of regulation and can be subject to brokering and rule-setting

[82] *Ibid.*
[83] *Baldwin et al, supra* note 46.
[84] *Ibid.*

between regulators and regulatees. As Baldwin at al. note, "behaviour however, is often driven not by regulatory pressure but by the culture prevalent in the sector."[85]

This is a gap between Braithwaite's theory and the regulatory reality. There is nothing inherently incorrect about Braithwaite's conception of varied regulatory compliance action by risk, but in execution it can become distorted and used to justify not graded regulation, but a form of deregulation. A host of factors influence what types of regulatory enforcement and enforcement strategy will develop:

> Agency resource levels, the size of the regulated population, the kinds of standards imposed and how these are received, the observability of non-compliance, the costs of compliance, the financial assistance available for compliance, and the enforcement structure.[86]

Some argue that a poor application of Braithwaite's principles will result in a general trend where regulatory activity is pulled towards lower levels of intervention to reduce regulatory and political friction:

> Agencies may lack the tools or resources to progress to more punitive strategies, it may fear the political consequences of progression and may not have the judicial, public or political support for escalation, it may be reluctant to trigger an adverse business reaction to deterrence strategies; it may find it difficult to assess business reaction to deterrence strategies; it may find it difficult to assess the need of a regulated firm's response to existing controls, and it may be disinclined to escalate unless it has sufficient evidence to make a case for the highest level of response.[87]

There are also legal issues associated with the high degree of discretion that strict responsive regulation allows. This discretion could be subject to review unless the rules are very clear about when and how a regulator chooses to apply enforcement. The application of this regulatory

---

[85] *Ibid*.
[86] *Ibid*.
[87] *Ibid* at 263.

theory has formed the basis of a massive transformation in regulatory compliance and enforcement practices, particularly in financial, transport, and resource regulation. Health Canada's own compliance framework virtually mirrors Ayers and Braithwaite's enforcement pyramid.

Smart Regulation

The limitations of responsive regulation call for a system which helps clarify the gray areas between the layers of the pyramid and encompasses additional actors. The proponents of smart regulation such as Lodge[88] and Gunningham,[89] put forward a model which included additional actors as a mitigation of the relationship between the regulator and the regulated (often meaning between industry and regulators). Third parties are intended to help mediate the process and support the placement of compliance activities along the continuum of the pyramid. In this conception, "regulation can be carried out not merely by the state (and opens up) the possibility of regulating using a number of different institutions."[90] Third parties can help detect, inform, and standardize the criteria along each step of the compliance pyramid.

What emerges is a three-sided triangle including regulator, regulated parties, and third parties, with third parties providing assurance and mediation between the two. This additional information can supplement the of compliance being observed without immediately requiring intervention from the regulator. As Baldwin et al. note, "seeing regulation in terms of these three

[88] Lodge, M., "Accountability and Transparency in Regulation: Critiques, Doctrines and Instruments," in Jacint, J. and Levi-Faur, D. eds., *The Politics of Regulation* (Cheltenham, 2004).
[89] Gunningham, N. and Grabosky, P., *Smart Regulation* (Oxford, 1998), hereinafter Gunnigham.
[90] *Baldwin et al, supra* note 46.

dimensions allows the adaptation of creative mixes, or networks, of regulatory enforcement instruments and of influencing actors or institutions."[91] The result of smart regulation was a proliferation of new regulatory tools and arrangements such as self-regulation supported by rating agencies, enforcement mediated by third parties, and rule-setting based on joint standards development held between regulated and regulators, mediated by a third party of international standard makers. For drug regulation it was related to the emergence of third-party standard safety organizations (ICH, [92] CIOMS,[93] WHO[94]) as well as the incorporation of third-party compliance monitoring (GMPs, site licensing inspections).

Smart regulation has its critics.[95] If the balance between regulators, regulatees, and third parties providing information or support is not correctly balanced, it can create problems in administration. A third party which merely reinforced the perspective of the regulatees may distort the risk criteria employed in assessing compliance. This relationship between third-party rating agencies and the banking sector, which provided low-risk ratings on overleveraged complex derivative products, was cited as one of the gaps in oversight that led to the 2008 financial crisis.[96] Similarly, the use of an escalating pyramid of compliance can become "more difficult when complex mixes of strategy and institutions are involved."[97] This may become increasingly difficult when looking at sharing information between different institutions (governmental and non-governmental) that may have different modes and standards of information sharing. Baldwin et al. also identify gaps in smart regulation that may result from

---

[91] *Ibid*.
[92] International Council for Harmonization, online at: https://www.ich.org.
[93] Council for International Harmonization of Medical Sciences, online at: http://www.cioms.ch.
[94] World Health Organization, online at: www.who.int.
[95] *Gunnigham, supra* note 89.
[96] *Baldwin et al, supra* note 46 at 267.
[97] *Ibid*, at 267.

issues with "information management, clarity of messaging to regulatees, resource and time constraints,"[98] and may result in even more acute concerns related to "consistency, fairness and accountability."[99] Looking at the adoption of a SMART regulatory agenda in the Canadian health context, Janice Graham was even more critical:

> In only a few years, a grammar of "smart" has exploded onto the national and international scene. We hear of smart communities, smart drugs, smart labels, smart risk, smart weapons, smart cars, smart hydro and smart marketing, but we are blocked from getting answers to necessary questions: What sort of smart analysis determines the balance between cost-effectiveness and health impact? Whose evidence do the regulators use to evaluate these data? How effective and safe are the vaccines or therapies that might be fast-tracked through a reformed regulatory process? Which populations, communities and people are protected? Who is left out? Who profits and who benefits from therapeutic intervention programs?[100]

Problem-Centred Regulation

In response to some of the criticisms of smart regulation, a new paradigm of even more targeted, bespoke regulatory activities emerged, known as problem-centred regulation. This form of regulation "define problems precisely, determine how to measure impact, develop solutions or incentives, implement the plan, and then monitor review and adjust the plan accordingly."[101] In this conception, regulation becomes a form of targeted risk management that is highly targeted and responsive. Each regulatory issue becomes a specific project to be managed in the short or long term. This conception focuses the bar of when regulation should be used to currently observed phenomena which can be identified as a known risk. Oversight is tailored to minimal

[98] *Ibid*, at 267.
[99] *Ibid*.
[100] Graham, J., "Smart Regulation: Will the Government's Strategy Work?" (2005) *CMAJ* 173(12).
[101] *Baldwin et al, supra* note 46 at 267.

interventions to address a specific issue. Ideally this model would emphasize the application of activity to address the biggest problems.

Problem-centred regulation helps target regulatory interventions in a more tactical approach than Braithwaite's pyramid, yet it does little to help with deciding how to select the appropriate level of intervention. Problem-centred regulation is criticized because it can lead to a heavy reliance on established risk criteria and other forms of risk calculus which will be described later in this chapter. As Baldwin notes:

> It is rarely the case that risk-based regulators can identify the targeted risk unproblematically. They usually have to make difficult decisions about the types of risks that they will target and how these are to be constructed.[102]

Conceiving of regulatory issues as purely projects to be managed can lead to the removal of important contextual information from regulatory decision-making. There is a caution here because "perhaps too readily regulations can be parceled into [discrete] problems and projects to be addressed by teams."[103] This approach may result in overlooking many of the broader causal factors that contribute to a regulatory problem. It will also favour limiting regulation to a snapshot in time of existing regulatory or non-compliance issues, which can ignore the emergence of systematic or temporally unknown risks. Similarly, how the risks or biggest problems are defined will always involve a certain amount of subjective judgement that may be swayed by policy and political factors (i.e., should a drug regime be driven by economic goals or health and safety ones). Defining the problem defines the regulatory priorities.

---

[102] *Ibid* at 268.
[103] *Ibid*.

Really Responsive Regulation

Baldwin et al. suggest that regulations must evolve to be much more contextual. Putting forward a model they call really responsive regulation, they argue that in "designing, applying, and developing regulatory systems, regulators need to adapt their strategies to more than the behaviours of the regulatees."[104] When considering the development and creation of a regulatory regime, regulators need to be:

> … attentive and responsive to five key factors: the behaviours, attitudes, and cultures of regulatory actors, the institutional settings of the regulatory regime; the interactions between the different logics of regulatory tools and strategies; and the regime's own performance over time; and, finally, changes in each of these elements.[105]

To this could also be added the emergence of new risk knowledge that comes with regulating, including the gathering of information over time, the emergence of new technologies or the intentional analysis of relationships by academics.

Behaviour and attitudes are important because they will frame how a regulated party is likely to respond, because "the motivational postures, conceptions of interest, and cognitive frameworks of regulated firms (and regulators) vitally affect the regulatory relationship and the regulator's capacity to influence regulatees' behaviour."[106] Institutional settings are important because they frame the distribution of power, influence, and action of the various players and

[104] *Ibid.*
[105] *Ibid,* at 269.
[106] *Ibid*, at 270.

"[are] vitally affected by the position that each organization (regulator or regulated concern) occupies with regard to other institutions."[107]

In cases of enforcement, agencies with an asymmetry of power with regulatees are likely to receive little response to requests for direct enforcement. The interaction of the various regulatory tools is also vitally important because their coherence and interdependence can frame whether a regulatory regime is effective. A self-regulation system with low compliance enforcement and low third-party validation, for instance, may not be effective. It becomes very important for regulators to "manage tool and strategy interactions and to avoid undesirable confusions of logic."[108] It is also essential that regulators can measure performance to ensure it is "capable of measuring whether tools and strategies in current use are proving successful in achieving desired objectives."[109] This requires not just an assessment of rates of compliance or regulatory activity (say, approval of submissions) but demands "a quantification of performance in achieving agency objectives."[110] Finally, regulations must be able to change in relation to the various operational realities noted above. As Baldwin notes, "regulators who cannot assess the performance of their regimes cannot know whether their efforts (and budgets) are having any positive effect in furthering their objectives."[111]

Another component of really responsive regulation is that it should have mechanisms in place to detect both non-compliance and broader factors affecting the effectiveness of the

[107] *Ibid.*
[108] *Ibid*
[109] *Ibid*, at 271.
[110] *Ibid.*
[111] *Ibid.*

regulatory regime. I will discuss risk-based regulation later but in contrast to really responsive regulation they tend to:

> Look more directly towards objectives but [also] tend to look towards a given set of risks and a given approach to these – they tend to under-emphasize the need to detect new and 'off-the-screen' activities of a non-compliant or undesirable nature.[112]

In contrast, really responsive regulation would "seek to detect such [off-the-screen] matters and develop ways to assess how reliable its detection processes are."[113] After gaining a full awareness of effectiveness and "knowing their reliability of detection and indeed other process drivers,"[114] regulators can accurately evaluate levels of compliance and determine whether the regulations are achieving their original objectives. I will revisit some of these concepts when discussing how to frame the *NHPR* in the concluding chapter.

[112] *Ibid,* at 272.
[113] *Ibid.*
[114] *Ibid.*

CHAPTER 2 - FOOD AND DRUG LAW IN CANADA

In this chapter I will set the stage for the rest of this thesis by explaining the development and core elements of food and drug law and regulation in Canada. The current chapter is intended to be largely descriptive and to serve as a grounding for the rest of the thesis as a food and drug law primer with emphasis on the regulation of drugs. Here I do not challenge the current assumptions of this field of research. As such, the chapter will outline the Canadian legal frameworks, the institutional players, and the history of food and drug regulation in Canada. It will also outline the current criticism of the area (poor transparency, the undue influence of industry, and a focus on access and economic factors over SEQ), many of which can by analogy be extended to the *NHPR* regime.

Part 1 - Food and Drug Regulation in Canada

(i) Drugs in Canada

As of March 29, 2022, there were 54,756 pharmaceutical drugs licensed to be on the market in Canada. Of these, there are over 13,000 actively marketed drugs available for sale.[115] (This is contrasted with over 100,000 NHPs that have been licensed since 2004.)[116] Canada is the ninth-largest pharmaceutical market in the world.[117] As of 2019, the last pre-pandemic period for which numbers were accurately collected, Canadians spent over $42 billion on pharmaceutical

[115] Health Canada, *Drug Products Database (DPD),* online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html, hereinafter DPD, accessed July 15, 2022.
[116] Health Canada, *Licensed Natural Health Products Database (LNHPD),* online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions.html, herein after LNHPD, accessed on July 15, 2022.
[117] See Industry Canada, *Profile the Pharmaceutical Industry*, (ISED, Ottawa), online at: https://www.ic.gc.ca.

drugs,[118] accounting for over 15% of all health expenditures.[119] The top classes of pharmaceutical drugs purchased included those used to treat rheumatoid arthritis (8.1%), age-related macular degeneration (5%), and autoimmune diseases (3.37%).[120] Ensuring the safety, quality, and utility of these products is an important task.

Over the last century and a half, a system has developed where therapeutic products,[121] including pharmaceutical drugs, have been regulated based on a pre-market demonstration of what has been deemed the SEQ (safety, efficacy, and quality) standard.[122] As briefly noted earlier, safety relates to a product's toxicity (is the substance in the dosage form provided not toxic),[123] efficacy is related to the claims around the product (does the substance do what it is purported to do),[124] and quality relates to the product's purity and manufacturing conditions (has the product been manufactured without impurities, adulteration, or mislabelling).[125] The SEQ standard is intended to give the public the confidence that they are consuming what is advertised, that the product will not have adverse consequences or cause unintended health issues and that products will have the health effect that is claimed. In more recent times, a fourth pillar has been added to create the SEQ+(P) standard, where P (representing pharmacovigilance) relates to the ongoing monitoring of a drug's safety and efficacy post-market.[126]

---

[118] The University of British Columbia, *Industry Overview: Complementary and Alternative Medicines in Canada*, (UBC: Vancouver, 2019), online at: https://sba.ubc.ca/industry-overview-complementary-and-alternative-medicine-canada.
[119] Canadian Institute for Health Information, *Prescription Drug Spending in Canada – 2019*, online at: https://www.cihi.ca/en/national-health-expenditure-trends.
[120] *Ibid*.
[121] Therapeutic products include drugs, medical devices, and any combination thereof.
[122] *Taylor LLM, supra* note 16.
[123] *Ibid*, see also Lemmens, T. and Bouchard, R. A., "Regulation of Pharmaceuticals in Canada" in Downie, J., Caulfield, T. and Flood, C. M. eds., *Canadian Health Law and Policy*, 3rd ed. (Markham: LexisNexis Canada Inc., 2007), hereinafter *Bouchard*.
[124] *Ibid*.
[125] *Ibid*.
[126] *Ibid*.

(ii) Considerations in Food and Drug Law

There is no magic bullet when it comes to managing our ills. The use of any therapeutic product, including NHPs, has inherent risks and potential benefits. In every regulatory decision about those products and their use there is a balancing of concerns. As I note in my LLM thesis:

> how much risk to accept in return for benefit when dealing with a specific drug is never reducible to an empirical formula. It involves the assessment of competing concerns and predictive judgments often based on unclear or ambiguous data.[127]

Jerry Avorn in his book *Powerful Medicines: The Benefits, Risk and Cost of Prescription Drugs*[128] argues that "every drug-use decision is a small Faustian Bargain, with risk and benefits."[129] He goes on to note that:

> A pharmaceutical manufacturer must decide whether to proceed with the costly and cumbersome development of a new molecule that could be a blockbuster product or dead end…An experimental subject must decide whether to volunteer for a trial of a drug that could improve her health or cause unknown hazard. A regulator must decide whether the new product should then be allowed on the market. A physician must decide whether its promised therapeutic value will outweigh its potential for harm. Ultimately, the patient must decide (sometimes several times each day) whether it's worth taking [a] drug as prescribed.[130]

Previously, I argued that the "role of a drug regulator is to help make these Faustian decisions more informed,"[131] more balanced, and more evidence based. The regulatory process and the science that surrounds it are ways to try to minimize the unknowns in these decision-making processes. In situations where those unknowns cannot adequately be defined, the goal of a regulator should be to help mitigate or minimize the associated unknown impacts while

---

[127] *Taylor LLM, supra* note 16 at 7.
[128] *Avorn, supra* note 44.
[129] *Ibid,* 34 at 142
[130] *Ibid*.
[131] *Taylor LLM, supra* note 16 at 98.

improving health outcomes. There is no perfect point where all risks associated with a health intervention can be removed, but health professionals and regulators generally have an obligation to try. In the case of drugs and NHPs, regulators have an obligation to rely upon evidence where it exists or to identify the parameters of how they will be making decisions when evidence does not exist.

(iii) The Pendulum of Drug Regulation

Drug regulation is subject to several opposing policy concerns that will come up repeatedly when considering the regulatory decision-making process.[132] The first is a competing push and pull between the safety of drugs and access to drugs. As will be discussed in greater detail later, the need of a manufacturer to bring a product to market as quickly as possible is often at odds with the need to gather evidence that products are safe or meet the purposes for which they are marketed. Waiting too long to bring products to market can have detrimental effects on patients seeking care, while moving too fast can lead to patients being exposed to unnecessary, harmful, or ineffectual treatments. The rhetoric around access is couched in terms of freedoms and a patient's right to determine their own treatment in the face of unnecessary and inefficient regulatory burdens.[133] On the other side of this argument[134] is the perspective that without good science demonstrating a drug's safety and efficacy, the public may be exposed to unnecessary,

---

[132] *Ibid,* conclusion.
[133] Graham, J., *A Lethal Guardian: The Canadian Government's Ban on Prescription Drugs*, (Fraser Institute: Vancouver, 2005), online at: https://www.fraserinstitute.org, hereinafter Graham.
[134] Habibi, R., Guenette, L., Lexchin, J., Reynolds, E., Wiktorowicz M., and Mintzes, B., "Regulating Information or Allowing Deception? Pharmaceutical Sales Visits in Canada, France and the United States" (2016) *Journal of Law, Medicine* and Ethics 44(4) at 602. Hammitt, W., et al, "Precautionary Regulation in Europe and the United States: A Quantitative Comparison" (2005) *Risk Analysis* 25(5) at 1215.

harmful, or ineffectual treatments. NHPs are seldom breakthrough treatments, but they do suffer from much the same rhetoric around their merit and the right of patients to choose treatment.

A second policy polarity is around whether the locus of gathering evidence about a product's risks and benefits should be done pre- or post-market. The precautionary argument is that there are certain harms which are so large and irreversible that they should be prevented, unless there is a very good demonstration that those risks have been considered and addressed.[135] Under this drug regulatory approach, the bar for new drugs is set high, requiring several rounds of clinical trials to demonstrate efficacy and safety before a product is licensed. An argument for monitoring risks post-market postulates that a product's true nature and impact can only be determined by observing it under real-world conditions. This conception of regulation accepts a potential harm as a trade-off for garnishing additional safety information. A more extreme version of this perspective even holds that the market itself should form the corrective mechanism for adverse events.[136]

Part 2 – An Outline of the History of Food and Drug Regulation

Historically, the development of modern drug regulation has swung between periods of low intervention in the market and the introduction of increased regulatory safeguards following a very public health failure.[137] It is important to understand the roots of why the SEQ standard is

[135] Soule, E., "The Precautionary Principle and the Regulation of U.S. Food and Drug Safety" (2004) *Journal of Medicine and Philosophy* 29(3) 333.
[136] Graham, J., Nuttall, R., "Faster Access to New Drugs: Fault lines between Health Canada's Regulatory Intent and Industry Innovation practices" (2013) *Ethics in Biology, Engineering & Medicine – An International Journal* 4(3) at 231-239.
[137] *Taylor LLM, supra* note 16.

employed in most current drug models. Each of these criteria is the result of a long process of legal changes that were designed to ensure that health goals are being met in order to protect the public from unsafe or poorly prepared products. An early driver was the prevention of fraud, but also ensuring the purity and quality of products advertised for sale. Eventually this would be backed by an expectation that some form of scientific proof is brought to bear in assessing the utility of products, including human safety testing and clinical trials. These legal developments were the product of an intentional program of regulatory development focused on public safety.

When I turn to the regulatory system for NHPs later in my thesis, it will be useful to observe that many of these longstanding protections have been lowered in the past two decades for this new class of products. The result has been an increase in observed cases of adulteration, concerns around safety, and a class of products which de-couple the making of general health claims from any form of demonstrated proof with clinical evidence of efficacy. Some would argue this represents a slip back into a system where poor-quality products making unfounded claims are saturating the market.[138] It is useful to remember that the SEQ standard was developed to improve consumer safety and inform health choices, and while imperfect, generally represents a success in public health law.[139]

[138] Wiktorowicz, M. E., Lexchin, J., et al, *Keeping an Eye on Prescription Drugs, Keeping Canadians Safe* (Ottawa: Health Council of Canada, 2010), La Rochelle, P., Lexchin, J., Simonyan, D., "Analysis of the Drugs Withdrawn from the US Market from 1976 to 2010 for Safety Reasons" (2016) *Pharmaceutical Medicine* 30 at 277, Lexchin, J., "Quality of Evidence Considered by Health Canada in Granting Full Market Authorisation to New Drugs with a Conditional Approval: a Retrospective Cohort Study" (2018) *BMJ Open* 8 at 20.
[139] *Bouchard, supra* note 123.

(i) Beginnings: The 19th Century Experience

The current era of drug regulation began in the mid-19th century, coinciding with two events: the rise of the modern state and the emergence of scientific interest in public health.[140] The starting point of modern food and drug regulation can be traced to the *Adulteration Act*[141] of 1860 in England. This legislation was concerned with the adulteration or altering of the advertised composition of foods and other consumables. It followed a well-publicized series of private scientific reports in England[142] and the U.S.[143] that showed many common foods and other consumables were adulterated. Manufacturers "cheapened the most common items of food such as coffee, milk, and beer and sometimes even laced their food products (especially confectionery) with poisonous substances to enhance color and weight."[144] For instance, in the 1880s it was estimated that a high proportion of the "milk" consumed in London (70 to 80 thousand pounds annually) was mostly adulterated water or a mixture of other substances, with

---

[140] London, J., "Tragedy, Transformation, and Triumph: Comparing the Factors and Forces That Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act in the United States" (2014) *Food & Drug Law Journal* 69(2) at 315, hereinafter *London*. See also Curran, K. C., "British Food and Drug Law-A History" (1952) *Food Drug Cosmetic Law Journal* 6(4) at 247, Stieb, E. W., *Drug Adulteration: Detection and Control in Nineteenth-Century Britain* (University of Wisconsin Press: London,1966), Hutt, P., "A History of Government Regulation of Adulteration and Misbranding of Food," (1984) *Food, Drug and Cosmetic Law Journal* 39(2) at 33, Spiekermann, U., "Redefining Food: the Standardization of Products and Production in Europe and the United States, 1880-1914" (*2011) History and Technology* 17(11) and Steib, E. W. and Quance, E. J., "Drug Adulteration: Detection and Control in Canada" (1972) *Pharmacy History* 14(1) at 18.

[141] *23 & 24 Vict. c 84* (1860), hereinafter *Adulteration Act 1860*.

[142] Crellin, J. K., "Drug Adulteration, Detection and Control in Nineteenth-Century Britain" (1968) *Medical History* 12(2) at 212.

[143] Fredric Accum, *A Treatise on Adulterations of Food and Culinary Poisons: Exhibiting the Fraudulent Sophistications of Bread, Beer, Wine, Spirituous Liquors, Tea, Coffee, Cream, Confectionery, Vinegar, Mustard, Pepper, Cheese, Olive Oil, Pickles, and Other Articles Employed in Domestic Economy, and Methods of Detecting Them* (Longman: London, 1820), online at: Interactive Library, https://archive.org, accessed on May 24, 2022.

[144] London, J., "Tragedy, Transformation, and Triumph: Comparing the Factors and Forces That Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act in the United States" (2014) *Food* and *Drug Law Journal* 69(2) 315 at 318. Rioux, S., "Capitalist Food Production and the Rise of Legal Adulteration: Regulating Food Standards in 19th Century Britain" (2018) *Journal of Agrarian Change* 19(1) at 64 , hereinafter *Rioux*; where he notes Accum identified three criteria that were related to adulteration (a) adding weight and bulk; (b) enhancing colour; and (c) improving smell, flavour and pungency.

little actual milk included and most nutrients removed.[145] Bread was the most frequently adulterated product and contained "cheap substitutes, and even chalk, plaster, sand, sugar, lead, bone dust, pipe clay, sawdust, soap, gypsum, ground stone, and pearl ash"[146] to replace flour and bulk up the bread. Other commonly adulterated products included coffee made of a mixture of "chicory, roasted corn, ground peas, beans, potato flour [with] coffee itself absent."[147] Similarly, sugar contained "disturbing amounts of chalk, plaster of Paris, starch, flour, pipe clay, sawdust and grit."[148] Confections made with sugar contained "poisonous colouring … such as bisulphate of mercury, copper carbonate, chrome yellow, and red and white lead."[149]

To Victorians, adulteration was both an economic and health problem.[150] The market was affected by the sale of fraudulently represented goods and these products were made unhealthy by hidden impurities. Addressing the issue required establishing a standard composition for commonly consumed substances (for example, defining what milk is) and developing a system to ensure the composition could be tested (a standard chemistry for testing if milk was indeed milk).[151]

The *Adulteration Act*[152] made it an offence to sell a good that was adulterated and allowed for local officials, known as public analysts, to request and test samples of food products for purity. Because it was not fraudulent, the Act did not make it an offence to provide an impure or even

---

[145] Otter, C, "Milk and Victorians: The Problem of Adulteration" (2019) *Victorian Review* 45(2) at 192.
[146] *London, supra* note 144 at 318.
[147] *Ibid.*
[148] *Ibid*
[149] *Ibid.*
[150] *Rioux, supra* note 144.
[151] Hamence, J. H., "The 1860 Act and Its Influence on the Purity of the World's Food: Historical Introduction" (1960) *Food Drug Cosmetic Law Journal* 15(11) at 711.
[152] *Adulteration Act 1860, supra note 141.*

toxic substance for sale, so long as there was no misrepresentation with regards to composition.[153] As Hamaence notes:

> Unfortunately, the act was a failure, and this was partly due to the lack of suitably qualified men to be appointed as public analysts and also to an almost complete lack of knowledge of the chemical composition of everyday foodstuffs, which rendered the meaning of adulteration to say the least, difficult. [154]

In 1858 a particularly heinous case of adulteration paired with the crusading efforts of a series of medical researchers at the newly formed journal *The Lancet* accelerated the push towards stronger legislation.[155] The Bradford sweet poisonings[156]occurred when a series of peppermint lozenges, called humbugs, were sold adulterated with arsenic. The lozenges had been prepared by a small-batch manufacturer for resale.[157] The manufacturer, like many, used gypsum powder as a common substitute for the more expensive sugar. Unfortunately, an inattentive chemist had provided arsenic trioxide instead of the gypsum (itself a non-toxic substitute for sugar). The assistant to the sweet-maker, unaware of the mistake, cut in over half a gram (580 milligrams) of arsenic into each lozenge. Normally, more than 290 milligrams of arsenic is lethal.[158] Despite the sweet-maker and distributer both becoming ill from the batch and observing that the lozenges looked off-colour, they sold the lozenges to the public. Twenty-one individuals died and an

---

[153] *Rioux, supra* note 144.
[154] *Hamence, supra* note 155 at 714.
[155] *London, supra* note 144.
[156] Jones, I. F., "Arsenic and the Bradford poisonings of 1858" (2000) *The Pharmaceutical Journal* 265 at 938, hereinafter *Bradford.* A similar and potentially more sinister adulteration occurred in Hong Kong a year earlier involving bread and a potentially intentional adulteration. It similarly inflamed the imagination of the British public. See Lowe K. and McLaughlin, E., "Caution! The Bread is Poisoned: The Hong Kong Mass Poisoning of January 1857" (2015) *The Journal of Imperial and Commonwealth History* 43(2) at 189.
[157] Small batch manufacturing was a common practice in the 19th century where manufacturers consolidated products to be sold under their brand from a collection of smaller manufacturers. Purity testing of these products was not the norm.
[158] *Bradford, supra* note 160.

additional 100 became severely ill, many of them children. The case sparked public outrage and calls for state interventions.[159]

In response, the U.K. Parliament passed the 1868 *Pharmacy Act.*[160] The Act introduced a new professional designation of pharmacists or druggists to (i) sell, dispense, or compound poisonous substances and (ii) sell certain classes of drugs (mainly opioids). The intention was to impose clear rules for the sale of dangerous substances, including being labelled as "POISON" if they were to be re-sold to manufacturers. Drugs that were considered as having potential social harms, such as opioids, now had a controlled point of sale.[161] Accreditation as a pharmacist or druggist was the purview of the *Royal College of Pharmacists* which, under Royal Charter since 1848, set professional standards of practice and published pharmacopeia on compounding and composition of medicinal remedies, including drugs. The Act also led to the emergence of a professional class of chemists, under the Society of Public Analysts, who began to develop a new science of food and drug chemistry and published a journal, *The Analyst*.[162]

In 1875, the U.K. Parliament published the *Sale of Food and Drug Act,*[163] bringing together the concept of toxicity and purity to the manufacture of food and drugs. Section 3 of the Act made it an offence to mix injurious substances into food intended for sale. Section 4 made it an offence to sell a drug "with any ingredient or material so as to affect injuriously the **quality** or **potency** of such drug."[164] Section 6 went further and prohibited the intentional sale of a food or drug

[159] *Ibid.*
[160] *31 & 32 Vict c 121 (1868)*
[161] *Ibid.*
[162] *London, supra* note 144.
[163] *38 & 39 Vict., c. 63* (1875).
[164] *Ibid.*

"which is not of the nature, substance, and quality of the article demanded (represented) by [a] purchaser."[165] The Act also mandated accurate labelling (s.8), and prohibited altering finished products (s.9). Sections 10-12 of the Act allowed for the appointment of analysts, at the expense of the Crown or the purchaser of a product, to assess the toxicity and purity of a finished product and made it an offence (s.17) to refuse to sell a product for analysis. The Act exempted compounded medicines (a single batch prepared directly by a pharmacist) and proprietary medicines (those prepared under a patented formulation). The makers of proprietary medicines were not required to disclose or label the ingredients of their products since it would give away their "secret" patented formulations.

(ii) The North American Experience with Food and Drug Regulation

Canada was the first North American jurisdiction to pass similar legislation to address adulteration. The unwieldly named *Act to Impose License Duties on Compounds of Spirits; to amend the Act Respecting the Inland Revenue; and to Prevent the Adulteration of Food, Drink and Drugs Act (Inland Revenue Act*)[166] of 1874 brought into force many of the provisions of the U.K.'s *Sale of Food and Drug Act*.[167] It made it an offence to knowingly sell food or drugs adulterated with unsafe substances and allowed for officials to monitor the composition of food and drugs offered for sale. Adulteration was defined as "any deleterious ingredients or any material of less value than is understood by the name."[168] The 1877 report of the Commissioner

[165] *Ibid.*
[166] *37 Vict, c.8*, hereinafter *Inland Revenue Act*.
[167] *Supra,* note 163.
[168] *Inland Revenue Act, supra* note 166. See also Steib, E. W., "Drug Adulteration: Detection and Control in Canada: II. A Step Forward: The Adulteration Act of 1884" (1976) *Pharmacy in History* Vol 18 (1) at 17.

of Inland Revenue found that in data gathered from eight analysts across Canada, "51.7% of food products analyzed were found to be adulterated."[169] The most adulterated products were milk, pepper, coffee, ginger, mustard, and tea. Ninety percent of coffees were adulterated and included little or no actual coffee.

The Commissioner observed that the Act had little impact on the assessment of drug quality in the first eight years of its operation since only one drug (quinine wine – legally also a food) was analyzed by government officials.[170] It took until 1883 for officials to finally assess 96 drug samples from eight different drugs. It was found that 12 % were adulterated. By this time the Act was having an effect, as only 24% of foods were now being found to be adulterated – a significant improvement over a decade earlier.[171] Another concern raised in the first few years of the legislation's operation was that it was defective because it did not provide clear reference to compendia that could be used as a standard of composition purity for drugs.[172]

In response, Parliament in 1884 passed the *Act Relating to the Adulteration of Food and Drugs*[173] that put in place specific standards for drugs. Section 2 of the Act indicated adulteration would occur if the product did not conform to "standards of strength, quality or purity" identified in British, U.S., or other recognized standard pharmacopeia[174] or "if its strength or purity falls below the professed standards under which it is sold."[175] The Act also "distinguished between

---

[169] Government of Canada, News Release: *The Canda Communicable Disease Report – 30 Years On*, online at: https://www.canada.ca/en/public-health/services/reports-publications/canada-communicable-disease-report-ccdr.
[170] *Ibid.*
[171] *Ibid,* referencing the *Inland Revenue Report of 1883*.
[172] *Steib, supra* note 140 at 19.
[173] *An Act to Amend and to Consolidate as Amended the Several Acts Respecting the Adulteration of Food and Drugs*, S.C. 1884 c. 34
[174] *Ibid*, see Cook, E. F., "History of Pharmacopeias" (1946) *Food, Drug and Cosmetic Law Quarterly* 1(4) at 518.
[175] *Ibid.*

commercial fraud (for example, intentionally adding chicory to coffee) and adulteration injurious to health (for example, selling toxic flour)."[176] The Act established a chief analyst as part of the Department of Inland Revenue who could develop quality standards, analytical techniques, and coordinate the activities of quality-assurance analysts across Canada.

Like the earlier U.K. legislation, the Act exempted proprietary or patented medicines from the application of its new quality and toxicity standards. The chief analyst raised concerns about this exemption in his first annual report to Parliament (1886):

> no more pernicious class of goods is to be met with on the markets, buoying up by false representations the failing strength of the really afflicted, exciting fears and anticipation of evil in the minds of the hale though weak minded, and robbing the poor of his hard earn money [than proprietary medicines].[177]

Unfortunately, the late 1800s were what one author has called the era of "entrepreneurial and commercialized medicine."[178] It was also commonly known as the era of snake-oil medicine,[179] in which a wide spectrum of potions, medicines, lotions, and cure-alls were sold for any and all known ailments. These remedies were often prepared in unsanitary conditions, with little standardization, and little indication of what they contained. [180] The result was a wide number of

---

[176] *Ibid*, see also Malleck, D., "Pure Drugs and Professional Druggists: Food and Drug Laws in Canada, 1870s-1908" (2006) *Pharmacy in History* 48(3) at 103.
[177] *Ibid* at 107.
[178] *Ibid*.
[179] Note that snake oil has a long and checkered history in the U.S. Originally brought as a traditional Chinese medicine used to help with inflammation by Chinese railroad workers, it was picked up by more unscrupulous manufacturers who sold it as a cure-all. Snake oil has been shown to have high levels of omega fatty acids which are excellent at helping with general inflammation and arthritis. See Hayes, A, "The History of Snake Oil" (2015) *The Pharmaceutical Journal* 294. Zhang, G., Higuchi, T., Shirai, N., Suzuki, H. and Shimizu, E., "Effect of Erabu Sea Snake *(Laticauda semifasciata)* Lipids on the Swimming Endurance of Mice" (2007) *Annals of Nutrition and Metabolism* 51(3) at 281. Also see the excellent podcast by Code Switch, *A History of 'Snake Oil Salesman* (2013), online at: https://www.npr.org/sections/codeswitch.
[180] For an interesting social history see Young, J. H. *The Toadstool Millionaires: A Social History of Patent Medicines in America before Federal Regulation* (Princeton University Press: Princeton, 1962). Also see, Kang, L. and Pedersen, N., *Quackery: A Brief History of the Worst Ways to Cure Everything* (Workman: New York, 2017) Kindle Edition hereinafter *Quackery*.

health products being sold making fraudulent or unsubstantiated claims, with low quality and little to no protection from the state. (As I will note later, much the same concern 100 years later would lead countries around the world to look at developing regulatory regimes for many complementary and alternative medicines.)

Proprietary formulations were made by mixing a neutral substrate (such as vegetable stock) with alcohol, morphine, opium, or cocaine.[181] For instance, two common children's cough syrups (Ayer's Pectoral and Mrs. Winslow's Soothing Syrup) were found to contain high levels of opioids.[182] An investigation by the Provincial Board of Health in Ontario found that adulteration and misbranding among patented medicines was rampant. As noted in Malleck 2006, the report found that:

> Many manufactured products that claimed to have high nutritive value …were in fact nothing more than mildly alcoholic tonics with little of the advertised nutritional value. .. "Whiskol" advertised as "a non-intoxicating stimulant, whiskey without its sting" contained in fact 28.2 percent alcohol by volume… Colden's liquid tonic, which was "recommended for treatment of [the] alcohol habit" contained 26.5 percent alcohol by volume. Hoofland's German Bitters, purported to be "entirely vegetable and free from alcoholic stimulant" but contained 25.6 per cent alcohol by volume.[183]

The *Royal College of Surgeons* and the *Canadian Pharmacists' Association* began to echo the chief analyst's concerns that patented medicines posed both a health risk and were being sold using false and misleading claims.[184]

---

[181] *Malleck, supra* note 176.
[182] *Ibid.*
[183] *Malleck supra* note 176, at 110.
[184] *Ibid.* An interesting history of similar criticisms by the FDA can be found at: https://www.fda.gov/about-fda/fda-history-exhibits/80-years-federal-food-drug-and-cosmetic-act.

Around this time, a series of U.S. authors began to take aim at patented medicines. Samuel Hopkins Adams' series "The Great American Fraud: The Nostrum Evil and Quacks,"[185] printed in *Collier's Weekly* beginning in October 1905,[186] was highly influential in drawing the attention of Americans to the "harm done to the public by this industry founded mainly on fraud and poisons."[187] Adams exposed the methods and close links of patented medicines to U.S. advertising agencies and the publishing industry. Harvey Washington Wiley, the chief chemist in the U.S. Department of Agriculture, began a series of studies[188] on the adulteration of foods and drugs in the U.S. and produced a series of reports[189] to Congress that backed up the claims made by Adams.

Much as the Bradford poisonings had accelerated the introduction of food and drug adulteration laws in the U.K., the death of 13 children caused by a 1901 error in the manufacturing of a diphtheria vaccine infected with tetanus accelerated the development of U.S. safety legislation.[190] The 1906 *Pure Food and Drug Act (PFDA)*[191] made it a crime to sell or trade adulterated or poisonous foods or drugs, including patented medicines. The Act also prohibited cutting products with quantities of potentially dangerous substances such as "alcohol, morphine, opium, cocaine, heroin, chloroform, cannabis, [or] chloral hydrate."[192] The Act established a standing federal agency that had powers to seize and destroy adulterated food and drugs, mandated purity to be

---

[185] Adams, S. H., *The Great American Fraud: Articles on the Nostrum Evil and Quacks, In Two Series, Reprinted from Colliers Weekly* (Colliers Weekly: 1906), online at: https://archive.org/details/greatamericanfra00adam.
[186] *London, supra* note 144, at 320.
[187] *Ibid.*
[188] US Food and Drug Administration, *FDA History*, online at: https://www.fda.gov/about-fda/fda-history.
[189] *Ibid.*
[190] *Ibid.*
[191] *The Statutes at Large of the United States of America, from December 1905 to March 1907, Concurrent Resolutions of the Two Houses of Congress*. Washington: Government Printing Office, 1907. 768-772.
[192] *Ibid*, at s.8.

defined by U.S. pharmacopeia, and established labelling standards for all drugs. The most enduring innovation of the *PFDA* was that it made it an offence to misbrand products with "false and misleading"[193] statements about **effectiveness** and composition.

Under similar pressure to deal with patented medicines in Canada, a select Committee of the House of Commons was convened in 1907[194] to look at drafting legislation to extend the adulteration condition of the 1884 Act to all manufacturers including those of patented medicines. In 1909 the *Proprietary and Patented Medicines Act*[195] broadened the class of products subject to quality controls to include all drug products for sale, including patented medicines. The new Act prohibited the inclusion of certain substances and required that all medicines adhere to purity and toxicity controls. Unlike the U.S. *PDFA,* the 1909 Canadian legislation was silent on the making of false or misleading claims. It took until a 1912[196] amendment to make it an offence to make false, misleading, or exaggerated claims on labels, wrappers, circulars, or in advertisements for food and drug products. A 1934 amendment[197] further established a detailed list of specific health conditions for which it was illegal to advertise or offer for sale a food or drug as a treatment.

In the period between the two World Wars, Canada gradually introduced additional rules around the types of claims that could be made and the nature of products that could be marketed. Major innovations included the introduction of classes of drugs, and the licensing of drug

[193] *Ibid.*
[194] *Malleck supra* note 176.
[195] *S.C. 1908.*
[196] *Food and Drug Act, S.C. 1920 c. 27.*
[197] *1939 Amendment.*

manufacturers.[198] Still, the Canadian system remained passive.[199] Drug manufacturers were required to meet certain conditions (covering composition, purity, and manufacturing standards) and subject to periodic inspection of manufacturing sites and testing of the purity of manufactured products. Manufacturers were not required to meet any pre-market conditions or obtain pre-market approval.

(iii) Towards Safety

The next wave of regulatory changes occurred following the sulfanilamide tragedy of 1937.[200] Sulfanilamide, used to treat throat infections, had an established history as a lozenge and was widely manufactured throughout the U.S. In 1937, a Tennessee firm decided to develop a new liquid form of the treatment. A raspberry-tasting pink drink preparation was developed, composed of 10% sulfanilamide, 72% diethylene glycol (replacing ethanol) and 16% water. Corporate laboratories tested the new dosage form and it was found to meet the applicable chemical specifications (in terms of colour, composition, and purity). It turned out that the liquid dosage form was highly toxic to humans and led to the verified deaths of 105 Americans and many more cases of blindness. Prior to the release of the product, the manufacturer felt no need to assess the new liquid dosage form for safety in humans, even though the non-medicinal liquid diethylene glycol was more commonly used as an anti-freezing agent. Over 1,300 batch

---

[198] *Ibid*.
[199] J. Lexchin, *The Real Pushers: A Critical Analysis of the Canadian Drug Industry* (Vancouver: New Star Books, 1984).
[200] US Food and Drug Administration – Circular, *Sulfanilamide Disaster: Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, online at https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf/ See also Wax, P., M., "Elixirs, Diluents and the Passage of the 1938 Federal Food, Drug and Cosmetic Act" (1995) *Ann Intern Med* 122(6) 456.

shipments of finished products were distributed across the U.S. Because of poor record-keeping it was a challenge for health officials to trace, track, and recall all the poisonous products.

The U.S. responded by passing the 1938 *Federal Food, Drug and Cosmetic Act*[201] that required all new formulations of drugs and cosmetics to be tested for safety before they could be marketed. This introduced the concept of pre-market clinical safety testing (the safety component of the SEQ formula). New products and new formulations would have to be first tested on animals and then on small groups of volunteers. It also required the submission of a report on this safety testing to be provided to federal regulators before licensing, and products had to be accurately labelled with directions for their safe use.

A 1939 amendment to the Canadian legislation[202] made it an offence to knowingly sell or market toxic substances, but no pre-clinical safety testing was required. Because of the low standards compared to the U.S., one author has argued that during this period Canada became "a proving ground for the marketing of new (untested) drugs."[203] In 1951 an Order in Council (OIC)[204] was issued, making it mandatory that new drug manufacturers submit proof of safety to federal regulators (the newly established Food and Drug Division of the Canadian Department of National Health and Welfare) before they could sell their products. New manufacturers were required to demonstrate they had quality controls and processes in place for safety testing. Formal market authorization -- a notice of compliance -- could be withheld until this information was provided to regulators. In 1953, the Canadian government passed the *Canadian Food and*

[201] *21 U.S.C ch 9, 53 Stat 1040.*
[202] *1939 Amendment, supra* note 197.
[203] See Curran, R. E., *Canada's Food and Drug Laws* (Commerce Clearing House: Chicago, 1953) at 296.
[204] 1951 OiC.

Drugs Act,[205] which further expanded the powers of the federal authorities to inspect the premises where products were manufactured.

(iv) Towards Efficacy - The Emergence of the Clinical Trial

The thalidomide disaster of the 1960s was the next event to spur regulatory change, by introducing the concept of clinical trials and testing drugs for efficacy. Thalidomide, developed as a tranquilizer, was prescribed widely to pregnant women experiencing morning sickness. In the 1950s, drug manufacturers provided the drug to as wide a market as possible, including providing samples for doctors to distribute free of charge to patients. In 1961 an Australian doctor, William McBride, wrote to *The Lancet* with concerns that he had observed an abnormal increase in the birth of children with deformities from mothers he was treating with thalidomide. In the end, it is estimated that thalidomide led to as many as 10,000 children being born with congenital birth defects.[206]

In the United States, strong resistance from a group of analysts at the Food and Drug Administration (*FDA*)[207] meant the drug was never approved for the U.S. market. That did not stop the U.S. distributer, Richardson-Merrell, from marketing the drug directly to physicians, and as many as 20,000 Americans were given thalidomide as part of two unpublished clinical

---

[205] Curran, supra note 203.
[206] Stafford, N., "William McBride: Alerted the World to the Dangers of Thalidomide in Fetal Development" (2018) *BMJ* 362. McBride, W.G. ,"Thalidomide and Congenital Abnormalities" (1962) *Lancet* 2 at 1358, online at: https://www.thelancet.com.
[207] Thomas, K., *The Story of Thalidomide in the U.S., Told through Documents* (New York Times: New York, 2020), online at: https://www.nytimes.com/2020/03/23/health/thalidomide-fda-documents.html.

trials.[208] A Senate committee led by Senator Estes Kefauver produced a report[209] that was damning of the general lack of safeguards around clinical testing. In response, the U.S. enacted the 1962 amendments to the *Federal Food and Drug Act (the Kefauver Amendment*)[210] that: (i) required manufacturers to prove the effectiveness of drugs before they were on the market; (ii) this evidence had to be based on controlled clinical studies; (iii) the *FDA* was to retrospectively look at the effectiveness of drugs marketed between 1938 and 1962; (iv) the *FDA* controlled approvals of drug advertising; (v) the *FDA* could set manufacturing standards and inspect production facilities. This was the birth of the modern efficacy standard to be demonstrated through clinical trials.

While thalidomide was quickly removed from the market in the U.K., it took until 1968 for the U.K. Parliament to pass the *Medicines Act*[211] that mandated the running of clinical trials to demonstrate efficacy for new drugs. The 1968 Act established the Commission on Human Medicines that was empowered to set conditions around "licensing of new drugs, removal of licenses for existing drugs, requirements for clinical trials and powers to revoke, suspend and ask for variances to existing license[s]."[212] It took longer for Canada to introduce mandatory clinical trials. While the 1953 Act[213] allowed for the setting of conditions for the sale of a new drug, it did not allow for compelling a manufacturer to remove a product already on the market. A quick

---

[208] *Ibid.*
[209] *Ibid.*
[210] *76 Stat. 780 (1962),* hereinafter *Kefauver-Harris Amendments*.
[211] See US – Food and Drug Administration, *Kefauver-Harris Amendments Revolutionized Drug Development* (2019), online at: www.fda.gov/consumers/consumer-updates/kefauver-harris-amendments-revolutionized-drug-development. *See also Peltzman, S.,* "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments" *(1972) Journal of Political Economy* 81(5) at1049.
[212] *Kefauver-Harris Amendments, supra note 210.*
[213] *1953 Act.*

solution was provided by the creation of a Schedule[214] prohibiting certain drugs for sale, which included thalidomide.

Largely in response to thalidomide, in 1962 a *Special Committee of the House of Commons on Food and Drugs* undertook a study "concerning the safety in research and manufacturing"[215] of new and existing drugs. The committee's findings, published in a 1966 report,[216] called for sweeping changes to the Canadian drug approval process.[217] New regulations were introduced that required manufacturers to provide a pre-clinical submission with "substantial evidence of effectiveness" before marketing a new drug.[218] Yet substantial evidence of effectiveness still did not necessarily require clinical trials.

It took until 1985 for the *Food and Drug Act*[219] to be updated to require clinical trials. The new Act included provisions establishing standards for the registration of clinical trials and making these trials a condition for the pre-market licensing of new drugs.[220] The legislation also gave regulators the power to compel the license of manufacturing facilities prior to market authorization, inspect these facilities, and revoke licenses if they were found to be unsafe.[221] Over the next several decades, this point-in-time approach[222] to drug regulation was the norm.

---

[214] *Schedule A.*
[215] 1962 a *Special Committee of the House of Commons on Food and Drugs.*
[216] *Ibid*, 1966 Report.
[217] *Ibid.*
[218] *Ibid.*
[219] *FDA, supra* note 6.
[220] *Ibid.*
[221] *Ibid.*
[222] Point-in-time approach is a common term used to describe the drug review process where the regulator only has one limited intervention at assessment during the drug's life cycle. It does represent an ex-ante form of intervention, but is highly limited in its time frame. See *Taylor LLM, supra* note 16 or Wiktorowicz, M. E., "Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France" (2003) *Journal of Health Politics, Policy and Law* 28(4) 615.

Manufacturers would develop products, do safety testing, conduct clinical trials, and share that information along with manufacturing site information to regulators. Regulators would review this information and based on the evidence provided in the clinical trials, either provide or withhold a market authorization. At the time of the *NHPR* coming into force in 2004, this was the version of the Act in place. NHPs are ultimately a sub-class of drug under this Act and the provisions in the Act apply to NHPs.

(v) Towards Ongoing Safety Monitoring

It would take two more health failures to bring in the final pillar of modern drug regulation, ongoing safety monitoring for adverse events. The first was the Vioxx scare of the early 2000s. In 1999, Merck Pharmaceuticals sought to market a new non-steroidal anti-inflammatory (NSAID) product, *Vioxx Rofecoxib*, to treat arthritis.[223] Preliminary clinical trials had shown the drug's promise, and market authorizations submitted to the *FDA* highlighted these early clinical studies. Later that year, Merck began a series of additional clinical studies, the *Vioxx Gastrointestinal Outcomes Research* (VIGOR), to assess other potential benefits of the drug. Unexpectedly, the VIGOR study observed a significant increase in cardiovascular incidents in patients who were taking Vioxx rather than an existing NSAID, in this case, naproxen.[224] Merck

[223] See Angell, M. *The Truth About the Drug Companies: How They deceive us and What to do About it*, (New York: Random House, 2004), herein after Angell, Krumholz, H. M., Ross, J. S., Presler, A. H and Egilman, D. S., "What Have We Learned from Vioxx?" (2007) *BMJ* 20(334) at 120, Nesi, T., *Poison Pills: The Untold Story of the Vioxx Drug* Scandal (Thomas Dunne Books: New York, 2008), Gilhooley, M., "Vioxx's History and the Need for Better Testing" (2007) *Seton Hall Law Review* 37 at 941, online at: https://scholarship.shu.edu/cgi.
[224] National Public Radio, *Timeline: The Rise and Fall of Vioxx,* (November 2007), online at: https://www.npr.org. Canadian Medical Association, "Editorial: Vioxx - Lessons for Health Canada and the FDA" (2005) 172(1) *CMAJ* 5.

was aware of these new findings but did not submit them to the *FDA*, which was at that time reviewing their product license. Ultimately, Vioxx was approved for market.

The problematic nature of the VIGOR studies only came to light when an independent researcher brought it to the attention of the FDA.[225] The FDA struggled to integrate the additional information into the Vioxx license but did not issue a safety warning or remove the product from the market. During the next five years it is estimated that 30,000 Americans may have experienced cardiovascular events such as heart attacks from taking Vioxx.[226] These were unnecessary as Vioxx had shown little to no additional benefit over existing NSAIDs. A report commissioned by the U.S. Institute of Medicine (IOM)[227] found that regulators at the FDA were hesitant to act on Vioxx health concerns even after receiving additional risk information, and the law provided little incentive for manufacturers to bring forward all clinical information, pre- or post-market, to regulators. A 2006 study by the U.S. Government Accounting Office (GAO)[228] was more scathing, and found the "FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues."[229] The study also found that FDA officials lacked the motivation and power to compel the release of all clinical data on a drug's safety.

---

[225] *Ibid.*
[226] *Ibid.*
[227] U.S. Institutes of Medicine (IOM) – National Academies of Science, Engineering and Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (IOM: Washington, 2007), online at: https://nap.nationalacademies.org.
[228] U.S. Government Accountability Office, *Drug Safety: Improvement Needed in FDA's Postmarked Decision-Making Process* (GAO: Washington, 2006), online at: https://www.gao.gov/assets/gao-06-402.pdf.
[229] *Ibid.*

In 2007, the U.S. passed the *Food and Drug Administration Authorization Act*[230] (*FDAAA*), which gave powers to the FDA to compel additional post-market safety studies and to compel manufacturers to publicly register all clinical trials. The 2007 amendments further allowed for the imposition of mandatory post-market safety testing as a condition of licensing and imposed mandatory safety reviews for new drugs three and seven years post-market.[231] New drugs were required to have in place plans for monitoring post-market safety in the form of pharmacovigilance plans. Manufacturers were also required to impose systems to allow for adverse event reporting, plans to mitigate any known risks -- risk-management plans -- and to make clear in labelling any known risks. Amendments made to the *FDAAA* in 2012 with the *Food and Drug Administration Safety and Innovation Act (FDASIA)*[232] -- made it more explicit that manufacturers had to demonstrate post-market, and on an ongoing basis, that the benefits of licensing a product outweighed the risks.

Starting in 2010, the EU (which at the time included the U.K.) made similar changes to its administrative practices[233] to formalize components of pharmacovigilance into the drug approval and post-market surveillance activities of manufacturers. Going forward in the EU, all drugs were required to provide risk-management plans and to have in place processes for post-market surveillance.[234] The EU also made it mandatory to publish all clinical trials in a publicly available registry.[235]

---

[230] *21 U.S.C 301, 121 Stat. 823*, herein after *FDAAA*.
[231] *Ibid*.
[232] *21 U.S.C. 301, 126 Stat. 993.*
[233] *EU Directive 2010/84/EU* and *Regulation (EU) 1235/2010.*
[234] *Ibid.*
[235] *Ibid.*

Conversely, Health Canada was slow to integrate ongoing post-market clinical testing. Its first reaction was to propose a type of graduated license with ongoing safety monitoring called *progressive licensing*.[236] It was intended to be a form of pharmacovigilance that imposed more extensive ongoing and progressive safety monitoring in exchange for earlier market access. It also envisioned increased powers for the regulator to compel safety studies and to remove products from the market if there were safety concerns. These proposed changes were put forward as part of Bill C-51 in 2008, an *Act to Amend the Food and Drug Act and to Make Consequential Amendments to Other Acts*,[237] which died on the order paper with the prorogation of Parliament that year. (As will be discussed later, the reaction of the NHP lobby to these expanded powers had a significant effect on impeding the adoption of this legislation).

It took almost another decade before Canada introduced stronger post-market measures. Political will coalesced around the death of Vanessa Young, who suffered a cardiac arrest after taking *cisapride*, a common antacid.[238] It would later come out that the drug's manufacturer had conducted unpublished clinical studies that raised safety concerns around this product.[239] In 2014, the *Protecting Canadians from Unsafe Drugs Act*[240] (*Vanessa's Law*) was passed. The Act imposed a host of new conditions on drug manufacturers and finally gave the Minister power to remove licensed products from the market. The Minister could also require the publication of all clinical trials undertaken in Canada and compel license holders to conduct additional clinical

---

[236] Yeates, N., Lee, D. K. and Maher, M., "Health Canada's Progressive Licensing Framework" (2007) *CMAJ* 176(13), online at: https://www.cmaj.ca.
[237] First Reading 8 April, 2008, this Bill did not become law before the 39th Parliament ended on September 7, 2008, see Library of Parliament, *Bill C-51 Legislative Summary*, (Library of Parliament: Ottawa, 2008), online at: https://lop.parl.ca/staticfiles/Public, herein after *Bill C-51*.
[238] Arnott, W., "Cisapride and the Vanessa Young Inquest" (2001) *CMAJ* 165(4) at 395 and CMAJ Editors, "Lessons Learned from Cisapride" (2001) *CMAJ* 164(9) at 1269.
[239] *Ibid.*
[240] *S.C. 2014, C. 24*, hereinafter *Vanessa's Law.*

studies. The full scope of the new obligations will be discussed in greater detail in the next section on the existing food and drug laws in Canada. Initially NHPs were expressly exempted from inclusion in *Vanessa's Law*[241] which meant that the new powers to compel post-market safety research, remove products from market, and define regulatory pathways for products did not apply to NHPs. As will be discussed later, it would take until this year, 2023,[242] for this gap in the law to be closed.

Part 3 – Canadian Drug Regulation Today

(i) The Regulator

Health Canada has the broad mandate of "helping Canadians maintain and improve their health [including] ensuring that high-quality health services are accessible and work[ing] to reduce health risks."[243] The *Health Products and Food Branch* (HPFB) of Health Canada is the sub-branch that deals with health products and it is tasked with "evaluating and monitoring the safety, quality, and efficacy of health products (including pharmaceuticals, biologicals, radiopharmaceuticals, medical devices and natural health products)."[244] HPFB is further subdivided into a series of directorates that administer various health product lines, including the *Therapeutic Products Directorate* (TPD), which covers pharmaceuticals, the *Food Directorate* (FD), the *Medical Devices Directorate* (MDD), and the *Natural and Non-Prescription Health*

---

[241] *Ibid, s.2.*
[242] *An Act to Implement Certain Provisions of the Budget, Bill C-47, 2023,* Third Reading June 6, 2023 (Canada, 44th Parl., 1st sess.), as of June 19, 2023 it is with the Senate of Canada for pre-study, hereinafter *BIA 2023*.
[243] Health Canada, *Homepage*, online at https://www.canada.ca/en/health-canada.html. Under the current government Health Canada is part of the broader health portfolio of the Minister of Health that also includes the Canadian food Inspection Agency (CFIA), Canadian Institutes of Health Research (CIHR), Public Health Agency of Canada (PHAC) and the Patented Medicine Price Review Board (PMPRB).
[244] Health Products and Food Branch, *Homepage*, online at: https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies.

Products Directorate (NNHPD). The majority of regulation and policy-setting for new prescription pharmaceuticals occurs at the *Therapeutic Products Directorate* (TPD).[245] The TPD itself is further broken down into a series of bureaus.[246]Additionally, there is a directorate that deals with post-market surveillance of health product safety: the *Marketed Health Products Directorate* (MHPD). HPFB also has an Inspectorate (HPFB Inspectorate) for on-site and product inspections, and the *Canadian Boarder Services Agency* (CBSA) inspects imported products. The *Canadian Food Inspection Agency* (CFIA) is responsible for inspection and overseeing quality assurance around facilities producing food.

(ii) The Authorities

In Canada permission to manufacture and market new drugs is regulated at the federal level through the *Food and Drug Act*[247] (*FDA*) and the *Food and Drug Regulations*[248] (*FDR*). The *FDA* sets the condition of sale and general definition of different classes of therapeutic products. The product types captured by the Act are foods (materials sold as food or drink for human beings), drugs (used in the mitigation and treatment of disorders), devices (tools, instruments, or apparatuses used in treatment), cosmetics (mixtures used in cleansing and improving or altering appearance) and therapeutic products (an omnibus category that captures

[245] Some new drug decisions will be made in concert with the Biologics and Radiopharmaceutical Directorate (BRD) and the Marketed Health Product Directorate, specifically in cases where there is a new production method that employs biologics (such as mRNA Covid vaccines) or radiopharmaceuticals.
[246] The main new drug evaluations divisions are the Bureaus of Cardiology, Allergy and Neurological Science (BCANS), the Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD) and the Bureau of Metabolism, Oncology and Reproductive sciences (BMORS). The Bureau of Pharmaceutical Sciences (BPS) reviews the pharmacological composition of new or existing formulations of drugs to ensure their quality and chemical composition.
[247] *FDA*, *supra* note 6.
[248] *FDR, supra* note 6.

drugs, medical devices, or any combination of the two). NHPs were explicitly exempted from being classified as therapeutic products, and remain drugs under the older 1985 definition of the Act.[249]

The *FDA* sets out the authorities for the Minister of Health to impose conditions on the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage, and testing of food and drugs. Under Section 9 of the *FDA* there is a general prohibition to "label, treat, process, sell or advertise any drug in a manner that is **false, misleading or deceptive** or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."[250] This is a power enacted under the federal government's criminal law power, which authorizes laws against fraud or that enact a prohibition to protect public health and safety. [251] Section 8 of the *FDA* complements Section 9 by providing a general prohibition against the sale of any drug of **low quality** or that has been "manufactured, prepared, preserved, packaged or stored under unsanitary conditions" or that has been "adulterated."[252]

Section 30(1) of the *FDA* gives the Governor in Council (GiC) fairly broad powers to make regulations supporting the *FDA*, including under 30(1)(o)(i) to address the methods of "manufacture, preparation, preserving, packaging, labelling, storing and testing of any new drug"[253] and under Section 30(1)(o)(ii) to address the "sale or the conditions of sale of any new drug."[254] The *NHPR* is established under this regulation-making authority. Section 30(1) (r)

---

[249] *Vanessa's Law, supra* note 240 at s.2.
[250] *FDA, supra* note 6 at s.9.
[251] *Standard Sausage Co. v. Lee*, [1934] 1 D.L.R. 706; *Jamieson & Co. (Dominion) Ltd v. Canada (Attorney General)*, [1987] F.C.J. No. 826, 12 F.T.R. 167 (F.C.T.D.) and *Wrigley Can. v. Can.*, (2000) 256 N.R. 387.
[252] *FDA, supra* note 6 at s.8.
[253] *Ibid.*
[254] *Ibid.*

authorizes regulations on the requirements for market authorization, including "establishing the eligibility criteria for submitting an application for such authorization."[255] Section 30(1.2) of the *FDA* expands this authority to therapeutic products, including the "issuance of authorizations – including licenses – that authorize, as the case may be, the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product, and the amendment, suspension and revocation of such authorizations."[256] These expanded regulatory-making powers under *Vanessa's Law* also include regulations on imposing terms and conditions on licenses (s.30 (1.2) (b)), requiring licensees to come forward with new safety information (s.30 (1.2) (d)), and revoking product licenses if required (s.30 (1.2) (f)).[257]

(iii) The Food and Drug Regulations (FDR)

The *Food and Drug Regulations (FDR)*[258] contain sections for each of the product lines administered by the *FDA*: Part A deals with general administration; Part B prescribes the standards for food; Part C sets the standards for drugs; Part D sets the standards for vitamins, minerals, and amino acids; Part E sets the standards for sweeteners; and Part G sets standards for controlled drugs. Most of the text of the regulations support Part B, which provides a very comprehensive and detailed description of what can and cannot be included in foods (i.e. physical composition) by type (e.g. meats, fruits and vegetables, bread, alcohol, dairy products, etc.). Part B also includes what can be relayed to consumers about these products, including a

[255] *Ibid.*
[256] *Ibid.*
[257] *Vanessa's Law, supra* note 240.
[258] *FDR, supra* note 6.

very limited number of health claims.[259] Section D provides further clarity by listing the expected vitamin, mineral, and amino acid compositions in foods.

The drug section of the *FDR* (Part C) is broken down into a series of 10 divisions. Division 1 provides the general administrative provisions for bringing new drugs to market. Division 1A establishes the conditions for licenses for drug manufacturing. Division 2 establishes the good manufacturing practices required by these manufacturers. Divisions 3 and 4 apply to two sub-classes of drugs, radiopharmaceuticals, and biologics, respectively. Division 5 addresses the requirements for the authorization of clinical trials in Canada. Division 6 outlines the strict composition standards for a set of hormone-related drugs: conjugated estrogens, digitoxin, digoxin, esterified estrogens, gelatin, and thyroid.

(iv) The Regulation of Drugs

Division 8 of the *FDR* deals with the licensing of new drugs, including new substances, combinations or new conditions, or purposes that have not previously been authorized in Canada.[260] Section C.01.014 of the *FDR* sets out a general prohibition that "no manufacturer

---

[259] Of relevance to this thesis foods now allow for a very strict limited list of health claims (see the table under section *B.01.603 (1)*) related to diet and the maintenance of health and nutrient content claims (i.e. "low in fat", "high in energy" – see table in section B01.513(1)).

[260] Under section C.08.001 new drug include:

> (a) that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has **not been sold as a drug in Canada** for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;
>
> (b) that is a **combination of two or more drugs**, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that combination and proportion for use as a drug; or
>
> (c) with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, route of administration or duration of action, and that **has not**

shall sell a drug in dosage form unless a drug identification number (DIN) has been assigned for that drug."[261] For NHPs, under the *NHPR*, this is changed to a natural health product number (NPN) or a homeopathic NPN (HM-NPN). Under Section C08.002 (1) no person shall sell or advertise a new drug unless they have submitted a new drug submission (NDS)[262] and been granted a notice of compliance (NOC).[263] In effect, the approval of the NDS is the key to the issuance of an NOC and a DIN, which allows a pharmaceutical drug to be marketed in Canada. Under the *NHPR* a product licensing application (PLA) is submitted to Health Canada which can result in the issuance of a product license (PL).

Section 2 of the *FDA* provides a broad definition of what constitutes a drug:

> Drugs include any substances or mixture of substances manufactured, sold, or represented for use in:
>
> (a) The diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state, or its symptoms, in human beings or animals,
> (b) restoring, correcting, or modifying organic function in human beings or animals, or
> (c) disinfection in premises in which food is manufactured, prepared or kept.[264]

This definition has two core components. The first is that it is a purpose- or claim-based definition: any represented use for one of the designated purposes will make the product a drug. The second core component is that this definition captures two different types of claims: those

---

been sold for that use or condition of use in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that use or condition of use of that drug.

[261] *Section C.01.014.*

[262] Under *section C.08.002 (1)* No person shall sell or advertise a new drug unless:
(a) the manufacturer of the new drug has filed with the Minister a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission relating to the new drug that is satisfactory to the Minister.
(b) the Minister has issued, under section C.08.004 or C.08.004.01, a notice of compliance to the manufacturer of the new drug in respect of the submission

[263] Granted under *C.08.004*.

[264] *FDA, supra* note 6 at s.2.

related to diagnosis, treatment, or mitigation of illness, and those that more generally vary organic functions in humans. Disinfectants used in food production are also considered drugs.

The intent and health claims associated with a drug are core to its designation as a drug. Section 3(1) of the *FDA* strictly prohibits claims for treatment and preventative cures for a list of disorders or abnormal states listed in Schedule A-1 of the *FDA* for which there are no cures (i.e. obesity, cancer, alcoholism, addiction, etc.). Previously there were two more comprehensive schedules in the *FDA* that prohibited certain claims (Schedule A) and certain substances (Schedule F) for drugs. They were designed as an added protection to supplement the fraud preventions provision of s.9 of the *FDA*, making it clear that certain claims and substances could not be used for drugs. As will be discussed later, both Schedules were removed to enable NHPs to make these types of claims and accommodate the wide class of substances that can be considered NHPs.

As noted above, in 2014, Health Canada introduced amendments to the *FDA* in the form of *Vanessa's Law*[265] to address long-standing deficiencies related to the powers of the Minister. *Vanessa's Law* expanded the powers of the Health Minister to recall products, compel evidence from manufacturers, and impose ongoing monitoring obligations on market authorizations. It also allows the Minister to decide on what constitutes a specific type of product (e.g., medical device versus a drug) and the licensing conditions which apply to each. These amendments introduced a new omnibus product definition, "therapeutic product," that captured "a drug or

[265] *Vanessa's Law, supra* note 240. See Health Canada, *ARCHIVED: Amendments to the Food and Drugs Act: Guide to New Authorities (power to require and disclose information, power to order a label change and power to order a recall*, (Health Canada: Ottawa, 2014), online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines.

device or any combination of drug and device."[266] The definition of therapeutic product intentionally excluded "natural health product within the meaning of the Natural Product Regulations."[267] This meant that the Minister lacked the ability to deem a product which claims to be an NHP as another class of product. It also meant for much of the *NHPR*'s 20-year operation it was difficult to compel manufacturers to remove products from the market.

a. The Pharmaceutical Drug Approval Process

The release of a new drug can be conceived as occurring in three stages: (1) research and development or "pre-approval," (2) regulatory assessment or "approval," and (3) drug release to the market or "post-approval." As outlined in the diagram below, this approval process, in theory, follows a very specific series of sequential steps, from clinical studies through to approval, marketing, and a series of ongoing marketing measures.

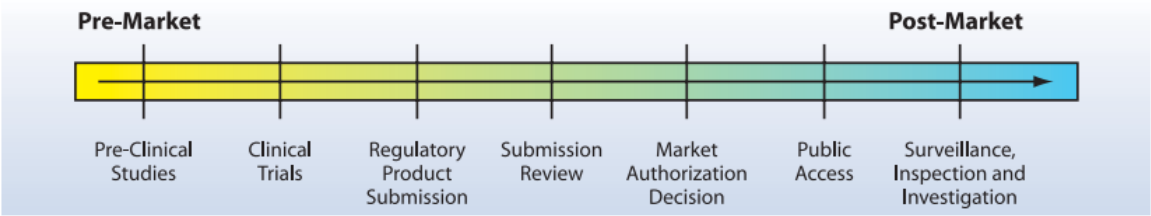

Figure 5: The Regulatory Process in Canada (Health Canada – 2007)[268]

[266] *Ibid* at s.2.
[267] *Ibid,* note it is the intention of the government to close this gap by removing the exemption in the *BIA 2023, supra* note 242.
[268] *How Drugs are Reviewed in Canada,* https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/drugs-reviewed-canada.html.

In practice, regulators have a very limited oversight of drug development, testing, and marketing. The regulator tends to be most engaged with the clinical evidence at the market authorization stage. The pre-approval generation of evidence and the post-approval monitoring for evidence is largely in the hands of manufacturers.[269]

b. Drug Development and Pre-Clinical Safety Testing

New drug development begins with the discovery of a new chemical entity (NCE) or increased understanding of the causes of disease that may lead to new or targeted applications of existing pharmaceuticals.[270] These will then be confirmed first through a series of biochemical testing (in vitro) and then through a series of testing in living organisms (in vivo) to ensure the chemical entity is, in the language of industry, "drugable," that is, can reliably be observed to create a consistent effect. Only 10 percent of chemical compounds make the transition from in vitro to in vivo animal testing.[271] This is the first step in assessing the safety in the SEQ formula. Traditional NHPs do not have a requirement to be tested in animals, or in small clinical samples before use, but instead rely upon a history of use and a listing of allowable substances captured in the *NHP Ingredients Database*.[272]

---

[269] Until *Vanessa's Law, supra* note 240 regulators had little ability to proactively impel manufacturers to generate, or share all information that they held on efficacy.
[270] For a comprehensive description of pre-clinical drug discover and testing see Hughes, P., Rees, S., Kalindjian, S. B. and Philpott, K. L., "Principles of early Drug Discovery" (2011) *British Journal of Pharmacology* 162(6), online at: https://www.ncbi.nlm.nih.gov.
[271] *Ibid*.
[272] Health Canada, *Natural Health Products Ingredients Database*, online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/natural-health-products, hereinafter *NHPID*.

c. Clinical Trials

In order to undertake a clinical trial involving humans, all manufacturers must submit a clinical trial application (CTA) to Health Canada.[273] The CTA requires the provision of information related to the intended trial's protocols (methodology and location), quality assurance and details of the manufacture or importation of the product, and details of the investigators undertaking the trials. Investigators are expected to comply with international standards for good clinical practices[274] and to have sought approval of the trial from a research ethics board (REB)[275] affiliated with the institution where the trial will be conducted. The trial is also required to be registered.[276] Sponsors are required to develop an investigator's brochure that outlines all the existing clinical or safety data related to the drug, including available clinical or pre-clinical data and the regulatory status of where and for what the drug is approved internationally. Upon approval, HC will list the clinical trial in their *Clinical Trial Database* (CTD)[277] containing general information about the trial, including protocol name, drug name, medical condition, sponsor name, and dates. The CTD does not list detailed descriptions of the methodology or findings associated with each clinical trial.

---

[273] Health Canada, *Clinical Trial Application (CTA)*, online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/applications.html.
[274] *Ibid*.
[275] *Ibid*.
[276] The World Health Organisation (WHO) recognizes two: *ClinicalTrials.gov* and the Current *Controlled Trials International Standard Randomised Controlled Trials Number Register*.
[277] Health Canada, Clinical Trail Database, online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/health-canada-clinical-trials-database.html

Clinical trials are normally conducted in four phases (I through IV).[278] The purpose of clinical trials is to progressively demonstrate with scientific evidence based on sound methodological practices that drugs are safe and efficacious for the purposes for which they will be marketed to the public. Phase II (small human trials) and Phase III (double-blind randomized controlled trials) in particular are designed to show a product is safe for human consumption and can demonstrate efficacy. As will be discussed in Chapter 3, the *NHPR* does include provisions for conducting clinical trials (Part 4) but they are seldom used.

d. New Drug Submissions

Once a pharmaceutical drug has been developed and clinical data demonstrates it is safe and effective, the manufacturer can bring forward a new drug submission (NDS) to seek market access. The NDS must include sufficient information for the regulator to evaluate:

- **(f)** details of the tests to be applied to **control the potency, purity, stability, and safety** of the new drug; (Quality)
- **(g)** detailed reports of the **tests used to establish the safety of the new drug** for the purpose and under the conditions of use recommended; (Safety)
- **(h) substantial evidence of the clinical effectiveness** of the new drug for the purpose and under the conditions of use recommended (Efficacy)[279]

---

[278] The formal phases of a clinical trial are:
Phase I trials are early research studies on humans that assess the effects of the drug on a small sample of healthy volunteers.
Phase II trials are studies in which the drug is tested in a larger sample and targeted at specific conditions.
Phase III trials are usually large-scale trials designed to test the effect of the drug in a wider population with more participants and in comparison, with existing therapies.
Phase IV seek to demonstrate efficacy of the drug in a large population post-market or as part of a licensing condition that seeks to explore potential risks over the long term.[278]

[279] *FDR, supra* note 6 at C.08.002(2). Other criteria included in the NDS are name (proper and brand name), ingredients, site and methods of manufacture, details of control testing, mock-ups of packaging and labels, how the drug will be represented for use, dosage forms and proof the product is distinct from other products with a DIN.

Substantial evidence of effectiveness will require clinical trials demonstrating that the drug's "benefits outweigh their risks."[280]

If, at the "completion of the review, the conclusion is that the benefits outweigh the risks and that the risks can be mitigated,"[281] the product will be issued a drug identification number (DIN). This will allow the product to be assessed for relative pricing by the *Patented Medicines Price Review Board* (PMPRB)[282] and the issuing of an exclusive patent under the *Patented Medicines (Notice of Compliance) Regulations*.[283] NHPs do not enjoy any patent protections as they are generally not novel substances. At the end of this process, a notice of compliance (NOC) is issued that indicates the licensing approval of the product in Canada. Once the product is approved, it will be added to the *Prescription Drug List*.[284]

e. Drug Establishment Licensing and Good Manufacturing Practices

For drugs to be licensed in Canada, manufacturers or importers (licensees) must ensure they adhere to good manufacturing practices (GMPs) and obtain a drug establishment license (DEL). Division 2 (s.C.02.001-s.C.02.030) of the *FDR*[285] sets out the obligations related to GMPs and Division 1A[286] sets out the obligations as they relate to DELs. A requirement to obtain a DEL

---

[280] *Ibid*.
[281] *How Drugs are Reviewed in Canada, supra* note 268.
[282] Patented Medicine Prices Review Board (PMPRB), online at: https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2020.html#a1
[283] *SOR/93-133*.
[284] Health Canada, *Prescription Drug List (PDL)*, online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list.html. HC regularly issues notices of additions or removals from the PDL.
[285] *FDR*, supra note 6 at Davison 2.
[286] *Ibid*, Division 1A.

and adhere to GMPs represents the quality component of the SEQ formula. NHPs have an analogous system for site licensing (SL) and GMPs with much lower standards that will be discussed in later chapters.

i. Drug Establishment Licensing (DEL)

Drug establishment licenses (DELs) are required for all facilities that "fabricate, package, label, distribute, import, wholesale or test"[287] drugs or their components. A third party that does quality-control testing on drugs must also obtain a DEL. A DEL is obtained by applying to Health Canada[288] and outlining: (i) each activity that will be undertaken at the facility; (ii) the category of drugs, dosage forms, and class of all drugs to be manufactured; (iii) the drug identification number of the drug to be manufactured; (iv) whether the facility has been inspected (by the HC Inspectorate); and (v) the location and contact information of the fabricator and facility. Each new drug, active pharmaceutical ingredient, or modification of an existing drug formulation requires a new DEL. DELs are renewed annually, and fabricators have a proactive obligation to provide an updated application for annual review.[289]

ii. Good Manufacturing Practices (GMPs)

[287] *Ibid,* s.01A.004 (1).
[288] The Health Products Compliance Division (HPCD) of the Therapeutic Product Directorate (TPD) is responsible for DEL policy.
[289] See Health Canada, *Guidance on Drug Establishment Licences (GUI-0002),* (Health Canada: Ottawa, 2020), online at https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement.

Ensuring quality in the production process by a DEL holder is done by adhering to good manufacturing practice (GMP) standards. GMP standards "ensure that drugs are consistently produced and controlled to the quality standards appropriate for their intended use, and meet the specifications required by their marketing authorization."[290] GMPs guarantee the base quality and safety of products, preventing adulteration, minimizing contamination, and ensuring purity of materials. Key to these standards is that manufacturers and importers have in place very detailed and strict processes to monitor, test, and keep records demonstrating that their manufacturing processes are done under uniform and sanitary conditions supervised by qualified personnel. As will be discussed later when compared to NHPs, the GMP standards for conventional pharmaceutical drugs provide a very high degree of certainty about the processes and conditions manufacturers must have in place to ensure the quality of products.

Drug manufacturers are expected to lay out specifications in writing, before they begin manufacturing, for "all properties and qualities of the drug, raw material, packaging material that are relevant to the manufacture, packaging and use of the drug, including identity, potency and purity."[291] Manufacturers and importers are then expected to test and retain samples of raw materials,[292] packaging,[293] and finished products[294] against these specifications. Manufacturers are required to conduct self-inspections to make sure they have in place all the elements required by their fabrication and safety requirements.[295] Manufacturers and importers must also have in place written procedures for product recall, including records of all distribution of the product.[296]

---

[290] *Ibid.*
[291] *FDR, supra* note 6 at s.C.02.002.
[292] *Ibid*, s.C.02.009.
[293] *Ibid,* s.C.02.016.
[294] *Ibid.*
[295] *Ibid*, s.C.02.012.
[296] *Ibid*, s.C.02.011.

Premises must be constructed in a manner that permits operations to be performed under clean, sanitary conditions, allows for the cleaning of surfaces, and prevents contamination.[297] Equipment must be designed and constructed to permit cleaning of surfaces, prevent contamination, and allow for functioning in accordance with intended use.[298]

Manufacturers must have in place a written sanitation program that specifies cleaning procedures for equipment and premises.[299] Manufacturers are also expected to have in place a quality management department and a highly educated and accredited official who is responsible for overseeing the quality management system (QMS), testing, and record keeping. Records must be retained demonstrating the outcomes of any testing and demonstrating for each lot that it adheres to GMP conditions, specifications, and practices. This includes the capacity to trace sourcing of all products, their raw ingredients, and accompanying tests for all components included in the fabrication. Records are to be kept for one year, and must record the date, time, and person who conducted any testing. If requested, these records must be presented to inspectors, although the Health Canada Inspectorate can do further testing if required.

f. Post-Market Surveillance

The HPFB Inspectorate routinely inspects DEL manufacturing sites for compliance with good manufacturing practices. Inspection results are tracked in the *Canadian Drug Inspection List*

[297] *Ibid*, s.C.02.004.
[298] *Ibid*, s.C.02.005.
[299] *Ibid*.

Database;[300] as of May 7, 2022, there were 98 inspections completed in 2022. Current and ongoing inspections of concern, domestically and internationally, are tracked in *Inspection Trackers: Drug Manufacturing Establishments*.[301] At this time there are 168 open files, mostly abroad, that are being further investigated for safety concerns, mostly for failing to meet standards of good manufacturing practices. Explicit details of the quality and safety concerns at these sites are not provided by Health Canada in the database. NHPs have been criticized for having no inspections or a very poor ongoing site inspection program.

Sections C.01016-C.01020 of the Food and Drug Regulations prohibit the selling of a drug on the market unless "manufacturers report all information relating to a serious adverse drug reaction within 15 days after receiving or becoming aware of the information."[302] Manufacturers must also produce an annual report "containing a concise, critical analysis of the adverse drug reactions and serious drug reactions… [including] a significant change in what is known about the risk and benefits of the drug."[303] In 2014, Health Canada implemented new guidance on ADR reporting, replacing the previous post-market reporting regime with a new set of good pharmacovigilance practices.[304] Much like GMP standards, market authorization holders (MAHs) and importers must have in place written procedures for dealing with and tracking each reported case of an ADR. The onus is put on MAHs and importers to report ADRs that "meet the

[300] Health Canada, *The Canadian Drug Inspection List*, online at: https://www.drug-inspections.canada.ca, accessed on May 7, 2022.
[301] Health Canada, *Inspection Tracker: Drug Manufacturing Establishments*, online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/compliance-enforcement/inspection-tracker-drug-manufacturing-establishments.html, accessed on May 7, 2022.
[302] *FDR, supra* note 6 at s.C.01017.
[303] *Ibid,* s.C.01018.
[304] Health Canada, Guidance, *Good Pharmacovigilance Practices (GVP) Guidelines (GUI-0102),* (Health Canada: Ottawa, 2013), online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices.

requirements of the Food and Drug Regulations."[305] Similarly, MAHs are required to do periodic self-assessments to determine that this system is working.

Part 4 - Other Classes of Therapeutic Products Regulated by Health Canada

The following section will describe other classes of products that are captured under the "therapeutic products" definition. They are regulated with many of the same mechanisms as drugs but with different approaches to the SEQ standard depending upon their perceived level of inherent potential for harm. It is important to briefly discuss these different types of products, because: (i) they overlap with other product classes (including NHPs); (ii) they represent niche classes of products that have required legal tailoring to adjust to the specific health considerations of their class; and (iii) they have been used to inform developments in regulation for other or new classes of products. As will be discussed later in this thesis, one of the major issues with the *NHPR* is that the definition for NHP is so broad it has led product manufacturers to seek licensing under this more permissive regime, or as part of a blended regime.

(i) Foods

Under the *FDA*, foods are described as "any article manufactured, sold or represented as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purposes whatsoever."[306] Food regulation tends to be focused on adulteration and purity of the products presented for sale. Currently *s.4 (1)* of the *FDA* provides the general prohibition

[305] *FRD, supra* note 6 at s.4.
[306] *FDA, supra* note 6 at *s.2*.

against the sale of foods that are "poisonous, harmful, unfit for human consumption, decaying, adulterated, or manufactured under unsanitary conditions."[307] Section 5 also has a general prohibition for selling foods where:

> No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.[308]

To prescribe purity, the *FDR* give very exact parameters for the composition, labelling, and safety conditions around manufacturing for commercially marketable foods.[309] These composition standards are very precise and generally adhere to agreed international norms found in the *Codex Alimentarius*.[310] For instance, in the case of canned vegetables (s. B. 11.002(d) (i)), no more than 15% of the product can be seasonings (e.g. dill or vinegar) and the remainder (85%) of the product must be vegetable matter. Rum is described as "a potable alcohol distilled, or a mix of potable alcohol distillate, obtained from sugar-cane product fermented by the action of yeast or a mixture of yeast and other micro-organisms, that has been aged for at least one year in small wood" (*s.B02.030*).[311] Under Section *B.05.002*, roasted coffee or coffee "shall be roasted green coffee, and shall contain not less than 10 per cent fat, and may contain no more than six percent total ash."[312]

Section *B.15.001 (1)* prohibits the inclusion of contaminants outlined in the *List of Contaminants and other Adulterated Substances in Foods*.[313] This includes pest control products,

---

[307] *Ibid,* at *s.4(1).*
[308] *Ibid,* at *s.5(1).*
[309] *Ibid,* at *Division 1-24.*
[310] WHO, *Codex Alimentarius: International Food Standards*, online at: https://www.fao.org/fao-who-codexalimentarius/en.
[311] *FDR, supra* note 6.
[312] *Ibid.*
[313] *Ibid.*

agricultural chemicals, and other substances not fit for human consumption. Section *B.16.001* also requires strict limits on food additives, such as colourings or texture modifiers, and how they are added to foods in the production process. The FDR also gives directions specifying the purpose for including food additives, which foods additives can be paired with which foods, and the percentage composition of the additives.[314] This includes specific provisions limiting the addition of vitamins, minerals, and stimulants. Prior to the *NHPR* coming into force, in 2004, these provisions prohibited most foods with additives and those making unproven health claims from the market. Sections exist outlining the use of common additives such as salt and sweetening agents, including sugar, vinegar, and other additives.[315]

Assuming a food manufacturer complies with all the conditions of composition, manufacturing, and labelling of a food, no pre-market approval of a new food product is required from Health Canada. The Canadian Food Inspection Agency (CFIA) is empowered to test products on the market for compliance with food standards, including setting conditions on importation and testing finished products. The HPFB Inspectorate can investigate and access the manufacturing conditions of any premise on which foods are made for compliance with the Act and regulations.

(ii) Medical Devices

[314] *Ibid, Division 16*.
[315] *Ibid.*

A medical device is any "instrument, apparatus, contrivance, or similar article (including components) used for therapeutic purposes,"[316] such as treatments, diagnostic tests, support of body structures, tests for pregnancy, or the prevention of conception. All new medical devices to be imported or sold must first register and be licensed by the Medical Devices Directorate at Health Canada. Products have different requirements depending on their risk categorization. Risk classification is a purpose test which includes consideration of such criteria as invasiveness of the device, whether it punctures the dermis, whether it requires a source of energy, and whether its success or failure directly affects life.

Schedule 1 of the *Medical Devices Regulation*[317] sets out the various classes of products and the risk classifications that are associated with each (Class I – IV). Class I products are considered low risk and require the use of good manufacturing practices in their production. Cotton swabs such as Q-tips are an example. At the other end of the spectrum, Class IV products are highly invasive and require prescribed conditions of use, manufacturing, and clinical trials to demonstrate their safety and efficacy before they can be marketed. Pacemakers are an example. Manufacturers are responsible for identifying the class of their products and pursuing the appropriate pathway for approval; they are also obliged to ensure that the product is safe and effective for the purposes that it is intended.

Medical devices sit on a continuum between foods and drugs. The level of intervention is based on an active pre-market assessment of the relative risks posed by the product as it is intended to be used based on a very detailed set of rules. This rule set (or risk classification

[316] *FDA, supra* note 6 at s.2.
[317] *SOR 98-282.*

system) itself was the product of very detailed consultation with stakeholders, the scientific community, and experts at Health Canada.[318]

(iii) Cosmetics

Cosmetics include products, substances, or mixtures of substances "sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth,"[319] including deodorants and perfumes. They are administered under the *Cosmetics Regulations*[320] which require manufacturers to provide notice to Health Canada that the product is being sold and to provide a full list of product ingredients. The regulator does not approve cosmetics before they are sold. It is prohibited under s.16 of the FDA to sell cosmetics that include ingredients that may cause injury when used according to direction or customary use. It is also prohibited to manufacture, prepare, preserve, pack, or store cosmetics under unsanitary conditions. Packaging must comply with the general rules applicable to all consumer products in Canada under the *Consumer Packaging and Labelling Act*.[321] Prior to the *NHPR* coming into force in 2004, cosmetics could not make health treatment claims; otherwise, they would be classified as a drug.

Part 5 – Current Academic Critiques of the Food and Drug System

[318] Health Canada, *Guidance Document - Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs),* (Health Canada: Ottawa, 2015), online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.
[319] *FDR, supra* note 6 at s.2.
[320] *C.R.C., c.869.*
[321] *R.S.C., 1985, c. C-38.*

In the early 2000s, *Vioxx* triggered a resurgence of research into the current state of drug regulation. Two notable texts, both American, are Marcia Angell's *The Truth About the Drug Companies: How They Deceive Us and What to Do about It*[322] and Jerry Avorn's *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs.*[323] Both highlighted that much of modern pharmaceutical regulation was based on poor-quality science, biased information provided to regulators, and legal standards that favoured drug manufacturers. Davis and Abraham's more detailed and academic analysis in *Unhealthy Pharmaceutical Regulation: Innovation, Politics and Promissory Science* (2013)[324] argues that much of the drug regulatory system in place over the past three decades has been couched in terms of improving patient health and safety but represents the implementation of an industry-friendly agenda.

Around the same time, there was an explosion of Canadian scholarship researching the Canadian system. Academics expressed concerns that the Canadian regulatory system was being modified to accelerate approvals,[325] relied upon poor scientific standards and unclear processes,[326] was based on industry-biased clinical information,[327] priced drugs based on little

---

[322] *Angell, supra* note 223.
[323] *Avorn, supra* note 44.
[324] (New York: Basingstoke – Palgrave Macmillan, 2013), hereinafter *Davis and Abraham*. This text also provide a host of applicable analytic frames that can be applied to food and drug regulation: neoliberal theory; capture theory; corporate bias theory; disease-politics theory (hard and soft versions) and expectations marketing theory.
[325] Paul, D., "Comparison of the Drug Approval Process in the US, the EU and Canada" (2001) *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing* 1(3) at 224, Sawicka, M. and Bouchard, R. A., "Empirical Analysis of Canadian Dug Approval Data 2001-2008: Are Canadian Pharmaceutical Players Doing More With Less" (2009) *McGill Journal of Law and Health* 85.
[326] Caulfield, T eds., *Using and Abusing Evidence in Science and Health Policy: Article Collection*, (BioMed Central: 2013), online at: www.biomedcentral.com/series /EvidenceUseAbuse). Lundh, A., Lexchin, J., Mintzes, B., Schroll, J. and Bero, L., "Industry Sponsorship and Research Outcome: Systematic Review with Meta-analysis" (2018) 44(10) *Intensive Care Medicine* 1603.
[327] Lexchin, J, "Quality of Evidence Considered by Health Canada in Granting Full market Authorisation to new Drugs with a Conditional Approval: a Retrospective Cohort Study" (2018) *BMJ Open* 8 at 20. Davidoff, F. et als., "Sponsorship, Authorship and Accountability" (2001) *CMAJ* 165(6) at 786 (PUBMED). Lexchin, J., Bero, L. A., Djulbegovic, B. and Clark, O., "Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review" (2003) 326 *BMJ* 1167.

assessment of merit,[328] allowed for clinical pathways (priority reviews) that did not reflect clinical needs,[329] was increasingly favouring post-market surveillance in favour of early-market entry,[330] and overall was favouring industry over public safety.[331] I will not go into all of this research, as my master's thesis was an attempt to categorize, capture, and scope many of these criticisms, but I will highlight a few concerns that continue to dominate the literature and can be extended by analogy to the regulatory system for NHPs.

As noted earlier, *Vanessa's Law* was designed to increase clinical transparency, expand the powers of regulators to impose conditions at licensing, compel clinical testing, and more clearly set out post-market obligations on manufacturers.[332] Two recent texts have evaluated how well these changes have addressed long-standing criticisms. Fierlbeck, Graham and Herder's (eds) *Transparency, Power, and Influence in the Pharmaceutical Industry: Policy Gain or Confidence Game?* (2021)[333] provides a score card on how "actionable and meaningful these changes [at the regulator] have been."[334] Their assessment is not favourable, and they argue that overall, there has been limited improvement in transparency around data used in drug decision-

---

[328] Goozner, M, *The $800 Million Pill: The Truth Behind the Cost of New Drugs* (University of California Press: Los Angeles, 2004) and Lexchin, J., "Drug pricing in Canada" in Z. Babar eds. *Pharmaceutical prices in the 21st century*. (Springer International Publishing: Switzerland, 2015). Zhang, R., Martin D., and Naylor, C. D., "Regulator or Regulatory Shield? The Case for Reforming Canada's Patented Medicine Prices Review Board" (2017) *Canadian Medical Association Journal* 189(14) E515.

[329] Kondro, W. ,"Health Canada Proposes New Regulatory Regime for Drugs" (2007) 176(9) *CMAJ*, (PUBMED).

[330] Dieppe, P. A., Ebrahim, S. and Juni, P., "Lessons from the Withdrawal of Rofecoxhib: Patients Would be Safer if Drug Companies Disclosed Adverse Events before Licensing" (2004) 329 *BMJ* 867. Hebert, P. C. ,"Editorial: Progressive Licensing Needs Progressive Open Debate" (2007) 176(13) *CMAJ* at 1801 (PUBMED). Wiktorowicz, M. E., "Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France" (2003) 28(4) *Journal of Health Politics, Policy and Law* 615.

[331] Egertson, L. ,"Drug Approval System Questioned in US and Canada" (2005) 172(3) *CMAJ* 317 (PUBMED). Lexchin, J. ,"Drug Withdrawals from the Canadian Market for Safety Reasons, 1963-2004" (2005) 172(6) *CMAJ* 765 (PUBMED). Mintzes, B. "Drug Regulatory Failure in Canada: The Case of Diane-35" (2004) *Women and Health Protection*, online at www.whp-apsf.ca.

[332] *Vanessa's Law, supra* note 240.

[333] (University of Toronto Press: Toronto, 2021), hereinafter *Fierlbeck et al.*

[334] *Ibid,* at 14.

making. Similarly, Joel Lexchin in his book *Private Profit Versus Public Policy: The Pharmaceutical Industry and the Canadian State* (2016)[335] suggests that Canadian drug regulation is subject to a form of client pluralism where "the state sees many of its interests as synonymous with those of the industry that it is charged to regulate."[336] He argues that this has led to industry having an unbalanced impact on the regulatory process and the development of regulatory policy that has eroded the impartiality of the regulator.[337] He argues further that public health goals in drug regulation are being supplanted by economic goals.

Generally, ongoing criticisms of the Canadian drug regulatory system can be grouped into three categories: (i) criticisms of an overall lack of **transparency and data** in the regulatory process, decision-making, and in how industry generates and reports on SEQ;[338] (ii) criticism of the **influence of industry** on the regulatory process, both in terms of framing the variables to be considered in drug approvals and exerting influence on regulators' decisions;[339] and (iii) the criticism that there is a **disproportionate push for products to be placed on the market** at the expense of generating robust SEQ data.[340] In a later chapter, I will provide a further discussion of regulatory theory and the role of regulators in formulating decisions, but for now it is sufficient to say that regulators are not passive parties in the drug regulatory process. They have a proactive obligation to make sure that they operate in the public interest. Regulators are also caught in an imperfect world, balancing valid competing concerns set by patients, practitioners, and politicians.

---

[335] (University of Toronto Press: Toronto, 2016), Kindle Version, hereinafter *Private Profits*.
[336] *Ibid.* at 437.
[337] *Ibid.*
[338] *Fierlbeck et al, supra* note 333, at Chapter 2. Herder, M., "Denaturalizing Transparency in Drug Regulation" (2015) McGill Journal of Law and Health 8(2) at S57.
[339] *Private Profits, supra* note 335.
[340] *Taylor LLM, supra* note 16.

(i) Poor Transparency and Data

In order to ensure that regulatory regimes are robust, they must be subject to a series of checks and balances that allow for assessment of regulatory decisions and the systems in which these decisions are made.[341] Boven[342] frames this argument as the need to ensure that regulatory systems are not just going through the motions of creating processes with internal logic but that they must ultimately be guided by conditions (i.e. data) in the real world and in ways that lead to improvements in the behaviour of the regulated. A key component of this is ensuring that accountability is operating in a transparent way -- that the data, activities, and decisions of those involved in the drug regulatory regime are open for review. This ensures that they can be reviewed, criticized, and validated by those without a direct interest in the process.

There is an asymmetry between the public and drug manufacturers, both in terms of knowledge about products and data around SEQ. To help balance this asymmetry, regulators are given a legal monopoly to act as the learned intermediary assessing the data put forward. In theory this analysis should be as impartial as possible and based on the best data available. Yet drug regulators are criticized for not providing very clear reasons underlying regulatory decisions,[343] for failing to disclose all discussions and interface they have with industry,[344] and

---

[341] *Baldwin et al, supra* note 46.
[342] M. Bovens, "Two Concepts of Accountability: Accountability as a Virtue and as a Mechanism" (2010) 33(5) *West European Politics* at 951, hereinafter *Bovens.*
[343] Fierlbeck, K., *"Chapter 1 – Transparency, Pharmaceuticals, and the Problem of Change" in Fierlbeck et al, supra* note 333, Lexchin, J., "Drug Withdrawals from the Canadian Market for Safety Reasons, 1963-2004" (2005) 172(6) *CMAJ* 765 (PUBMED).
[344] *Private Profits*, supra note 335.

for relying on poor data to frame decision-making.[345] The drug industry is criticized for failing to report all clinical trials and for being selective in how it presents clinical data to regulators,[346] health practitioners, and academics.

The result, it is argued, is that much of the regulatory process and evidence brought to bear in regulatory decision-making is not impartial. Ben Goldacre in his book *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*[347] is even more critical of this imbalance in information:

> Drugs are tested by the people who manufacture them, in poorly designed trials, on hopelessly small numbers of weird, unrepresentative patients, and analyzed using techniques which are flawed by design, in such a way that they exaggerate the benefits of treatments. Unsurprisingly, these trials tend to produce results that favour the manufacturer. When trials throw up results that companies don't like, they are perfectly entitled to hide them from doctors and patients, so we only ever see a distorted picture of any drug's true effects. Regulators see most of the trial data, but only from early on in a drug's life, and even then, they don't give this data to doctors or patients, or even to other parts of government. This distorted evidence is then communicated and applied in a distorted fashion. In their forty years of practice after leaving medical school, doctors hear about what works through ad hoc oral traditions, from sales reps, colleagues, or journals. But those colleagues can be in the pay of drug companies – often undisclosed – and the journals are too. And so are the patient groups. And finally, academic papers, which everyone thinks of as objective, are often covertly planned and written by people who work directly for the companies, without disclosure.[348]

Quality and safety standards are also criticized. Much of the systems in place for ensuring good manufacturing practices and good PhV practices are a form of self-regulation.[349] The regulator is

---

[345] *Gagnon, infra* note 366.
[346] Matthew Herder "Toward a jurisprudence of drug regulation" (2014) 422 *Journal of Law and Medical Ethics* 244–62.
[347] (Random House: Toronto, 2014), Kindle edition.
[348] *Ibid,* at 64.
[349] *Ibid.*

dependent upon industry to monitor and report on their observations of manufacturing processes and emerging "serious" adverse events.[350]

(ii) Undue Influence of Industry

As noted above, Lexchin has long argued that industry exerts an undue influence over the regulator in Canada, noting that:

> what industry has asked for each time is remarkably consistent and reflects its self-interest: stronger intellectual property rights, faster drug review times, higher prices, quicker access to provincial and territorial markets, a wider definition of what counts as spending on research, restrictions on how quickly generics enter the market.[351]

He argues that in each of these cases the regulator sees their role as a supporter and collaborator with industry, rather than maintaining impartiality from the party they are intending to regulate. Lexchin has charted a long historical evolution, going back to the 1930s, in which the leading drug manufacturing associations in Canada, now represented by Rx&D Canada, have worked hand in hand with regulators steering new policy reforms.[352]

Other researchers have observed the influence of industry on the framing of scientific research in Canada, [353] the funding of academia,[354] and the marketing and management of continuing education for doctors. Much of the funding at TPD-Health Canada comes from user

---

[350] *Ibid.*
[351] *The Real Pushers, supra* note 199.
[352] *Ibid.*
[353] Chappell, N., et al., "Conflict of Interest in Pharmaceutical Policy Research: an Example from Canada" (2016) *International Journal of Health Governance* 21(2) at 66.
[354] Downie, J., Baird, P. and Thompson, J., "Industry and the Academy: Conflicts of Interest in Contemporary Health Research" (2002) 10 *Health Law J.* 103. DeVries, R. and Lemmens, T., "The Social and Cultural Shaping of Medical Evidence: Case Studies from Pharmaceutical Research and Obstetric Science" (2005) *Social Science & Medicine* 62(11) at 2694.

fees charged to manufacturers.[355] Under the *User Fees Act*[356] the regulator adhered to service delivery standards that preferentially treat drug companies as clients.[357] Much of the governance structures and expert advisory committees that support drug licensing and provide expert scientific advice in Canada are made up of industry, or closely allied with industry members.[358] Researchers have also observed that the regulator has weakened much of the process for establishing standards for GMPs, PhV practices, pharmacopeias, risk-benefit standards, and clinical guidelines to industry or groups very closely associated with industry.[359]

This is not just a concern in Canada; a host of publications have mapped the perilously close relationship between the FDA and industry.[360] Both the GAO and IOM issued reports following the *Vioxx* incident that were highly critical of the FDA, noting that: officials in the FDA and industry often worked in concert on the approval of new products; the FDA structured regulatory systems frequently based on industry lobbying; and the FDA engaged in brokering or discourse with industry when assessing ADR data. This situation seems to hardly have improved

---

[355] *Taylor LLM, supra* note 16. Mitchell, A. P., Trivedi, N. U., Bach, P. B., "The Prescription Drug User Fees Act: Much More Than User Fees" (2022) *Med Care* 60(4) at 287.
[356] *S.C. 2004, c.6.* Replaced in 2017 by the *Service Fees Act, S.C. 2017, c. 20, s. 451.* For a full list of the fees that Health Canada can change and the service standards that accompany them see https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fees.html.
[357] *Ibid*
[358] *Real Pushers, supra* note 199.
[359] Lexchin, J., "Harmony in Drug Regulation, but Who's Calling the Tune? An Examination of Regulatory Harmonization in Health Canada." (2012) *International Journal of Social Determinants of Health and Health Services* 42(1).
[360] McCabe, A. R., "A Precarious Balancing Act: The Role of the FDA as Protector of Public Health and Industry Wealth" (2003) 36 *Suffolk U. L. Rev*. 787 at 804 (WL). Okie, S., "What Ails the FDA?" (2005) 352(1) *NEJM* 1063 (PUBMED). Government of the United States of America, Department of Health and Human Services, Food and Drug Administration, *Report to Congress: Changing the Future of Drug Safety: FDA Initiatives to Strengthen and Transform the Drug Safety System (*Washington: Department of Health and Human Services, 2009). United States Senate, Committee on Finance, *Report to Congressional Requesters: Drug Safety: Improvement Needed in FDA's Post market Decision-making and Oversight Process* (Washington: Government Accounting Office, 2007). Avorn, J., "FDA Standards – Good Enough for Government Work?" (2005) 353(10) *NEJM* 969 (PUBMED).

as of April 2022 when a congressional report[361] found that the consulting firm McKinsey, which was helping the FDA re-design its regulatory process for drug approval and oversight, was actively lobbying for the drug industry at the regulator, including for Purdue Pharmaceuticals of opioid infamy.

Abramson and Davis in their text *Uncertain Pharmaceutical Regulation: Innovation, Politics and Promissory Science*[362] have similarly documented the perilously close relationship between EU regulators and industry and argue that the past 40 years have been a slow process of deregulation pitched as being in the patient's interest. Similarly, Daemmrich in *Pharmacopolitics: Drug Regulation in the United States and Germany*[363] finds that the EU has tracked much the same trajectory as the U.S. in prioritizing industry growth over regulatory caution. While there have been some regulatory protections introduced in the EU to compel the publication of clinical data, the EU market is still heavily influenced by a tight relationship between manufacturers and industry.[364] In 2005, the European Medicines Agency (EMEA) set up a think-tank, the Innovative Medicines Initiative (IMI), to remove administrative and regulatory "bottlenecks" from industry's development and the approval of new drugs.[365]

---

[361] U.S. House of Representatives - Committee on Oversight and Reform, *The Firm and the FDA: McKinsey & Company's Conflicts of Interest at the Heart of the Opioid Epidemic* (U.S. House of Representatives: Washington, April 2022), online at: https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov.
[362] (Palgrave McMillan: U.K, 2013).
[363] (University of North Carolina Press: North Carolina, 2004).
[364] *Ibid*.
[365] European Medicines Agency (EMEA), *Innovative Drug Development Approaches: Final Report from the EMEA/CHMP Think-Tank Group on Innovative Drug Development*, (EMEA: London, 2007), online at: https://www.ema.europa.eu.

Gagnon[366] argues that this represents a coopting of the defined value of the determinants of drug regulatory policy by industry. In this case, industry's goal is to gain "control over industrial knowledge, and over material means to put this knowledge to use," ultimately to maximize capital earning capacity. Gagnon proposes that:

> the main activity of drug companies is not to produce drugs; it is to produce and control narratives shaping medical knowledge in a way that favours their interests. The production of the social determinants of value (medical knowledge and social demand for drugs) is much more important here than the producing value (of the drug).[367]

In other words, the goal of industry is to maximize profits and it does so by controlling the "social structure and habits of thought" around the benefits versus risks of drugs and how these affect market access. This in turn influences regulators, health systems, health practitioners, patients, and any other interested party in a pharmaceutical regulatory system's understanding of a drug's value. I will argue much the same process has taken place for NHPs.

Gagnon postulates seven different kinds of capture that industry has traditionally used to determine value and understanding in pharmaceutical systems: scientific, professional, technological, regulatory, market, media, and civil society.[368] **Scientific capture** is embodied by industry influencing the scientific discourse (clinical data) around a drug's risk and benefit, primarily by inflating the number of positive scientific publications, suppressing negative results, and neutralizing the capacity for independent validation.[369] **Professional capture** happens when companies employ strategies to "capture the technical experts of a specific sector," including

[366] Gagnon, M-A., Chapter 8: The Political Economy of Influence: Ghost-Management in the Pharmaceutical Sector, in *Fierlbeck et al, supra* note 337, hereinafter *Gagnon.*
[367] *Ibid*, at 168.
[368] *Ibid*, at 163 -177.
[369] *Ibid*, at 165.

through promotional campaigns or supporting sympathetic researchers. **Technological capture** happens when companies "establish the technological standards in their sector or develop patent portfolios to increase their bargaining capacity against competitors."[370] **Regulatory capture** occurs when industry is able to direct the intent of the regulatory agenda away from "the public interest and towards the interest of industry itself."[371] **Market capture** occurs when manufacturers are able to "develop market power and restrain market competition" from competitors, for example through patents or monopolies. **Media capture** occurs when industry is able to control the creation of a narrative around the value of a drug through the media, including academic publications, journalism, and advertising. **Civil society capture** occurs when industry is able to exert influence on civil society groups such as charities, patient advocacy groups, non-governmental organizations, social movements, and other groups with a stake in drug regulation.

Recent observations by Vural[372] noted that the consultations for amendments to the *FDA* in *Bill C-97*[373] were undertaken with a small group of stakeholders largely drawn from industry and led not by Health Canada but by the economic departments of Innovation, Science and Economic Development Canada (ISED) and the Treasury Board of Canada Secretariat (TBS). They further noted that:

> a) agenda setting and [its] formulation has been insulated from wider interest groups' participation, b) policy initiation and coordination was undertaken by a federal institution other than the regulatory authority, and c) the amendments were approved through a "fast track" legislative process.[374]

---

[370] *Ibid,* at 168.
[371] *Ibid,* at 171.
[372] Vural, I. E., Herder, M., Graham, J. E., "From Sandbox to Pandemic: Agile Reform of Canadian Drug Regulation" (2021) 125(9) *Health Policy* at 1115.
[373] Bill C-97, *An Act to Implement Certain Provision of the Budget Tabled In Parliament on March 19, 2019 and Other Measured*, S.C. 2019, c. 29.
[374] Vural, supra note 372 at 1117.

Two groups played a role in consulting on the regulatory changes: the **Advisory Council on Economic Growth** (ACEG) and the **Health and Biosciences Economic Table** (HBET). Neither of these groups has a public health mandate. Instead, their preoccupation has been to remove regulatory barriers, because, in their view, the regulatory pathways for food and drugs in Canada are overly complex, confusing, and stifling of innovation.[375]

(iii) Access and Innovation versus SEQ

A final area in which there is strong criticism of current drug regulation is around the push to shift the locus of drugs' SEQ assessment to post-market.[376] Associated with this is an argument from industry that to offer benefits, drugs need to be approved faster and with fewer conditions. Benefits are framed in terms of both access to needed new innovative treatments and the economic benefits that come from drug development. Access is also framed as a freedom of choice issue for patients. This leads to a push to speed up approvals and reduce the "backlog" of new drugs.[377] Regulators have adopted much of this logic, accepting that drug approval times represent a lag on drug development and that there is a need to reduce regulatory burden on industry.[378] As we will see, access to alternative medicines is often framed as a freedom of choice issue.

---

[375] *Ibid.*
[376] *Taylor LLM,* supra note 16.
[377] Health Canada, *Regulation and Beyond: Progress on Health Canada's Therapeutic Access Strategy* (Ottawa: Health Canada, 2005), online at: http://www.hc-sc.gc.ca/hcs-sss/pubs, hereinafter *TAS Progress*.
[378] *Ibid.*

In my master's thesis[379] I addressed these issues extensively, concluding that: most new drugs are not innovative; approval times in Canada are comparable to or faster than in other G8 countries; economic benefits from drug development are minimal given that most are imports; Canadians pay some of the highest drug prices in the developed world; drug companies are notoriously bad at post-market monitoring; and existing expedited pathways (the Special Access Program (SAP), priority reviews and notice of compliance with conditions (NOCc)) are increasingly the most used pathways for new drugs.[380] It is an exaggeration to say there is an extensive innovation and access gap in Canada.

A common criticism is that regulatory models are increasingly allowing products on the market with lower bars of clinical testing (often limited to phase II studies) in exchange for promises of post-market surveillance or additional clinical testing (in phase IV post-market studies).[381] Davis and Abraham [382] and Lexchin[383] argue that this represents a fundamental shift away from risk mitigation towards risk minimization, or a shift away from trying to prevent harm from reaching the public to accepting some harm in exchange for economic benefit.[384] As one author notes, this is a shift from a precautionary model of drug approval to one that seeks to allow access until a known risk has been identified (called the sound science argument).[385] In this case, regulators are making an explicit decision to expose the public to potentially greater

[379] *Taylor LLM*, supra note 16.
[380] Thomas, K. E., McAuslane, N., Parkinson, C., Walker S. R. and Luscombe, D.K., "A Study of Trends in Pharmaceutical Regulatory Approval Times for Nine Major Markets in the 1990s" (1998) *Drug Information Journal* 32 787 (PUBMED). Rawson, N.S., "Time Required for Approval of New Drugs in Canada, Australia, Sweden the United Kingdom and the United States in 1996-1998" (2000) *CMAJ* 162(4) 501 (PUBMED).
[381] Phase IV = Real world studies with affected patient populations, *supra* note 278.
[382] *Davis and Abraham, supra* note 324.
[383] *Real Pushers, supra* note 199.
[384] Abraham, J. and Davis, C., "Risking public safety: Experts, the medical profession and 'acceptable' drug injury" (2005) 7 *Health, Risk & Society* 379, online at http://www.tandfonline.com/doi/pdf/10.1080/13698570500390473
[385] *Ibid.*

unknown harms. Davis and Abraham[386] argues that this leads to fundamental questions of whether a drug regulator's role is to promote public health, or innovation and economic growth.

The Fraser Institute goes even further to argue that drug regulatory systems are a virtual ban on new drug access and that "lengthening the time new medicines are automatically banned only reduces the timelines of new information about their possible adverse effects." [387] According to this argument, the market should decide how best to deal with drug safety such that "informed patients could … use the drug while patients who were ignorant or more averse to risk would veer away from it."[388] As I demonstrated in my LLM research:[389] Industry has a history of distorting clinical data and exaggerating the merit of new products, while simultaneously downplaying the risk; generally, once a product is on the market, the majority of post-market research, even research that is mandated as part of conditions of approval, is never done; manufacturers are not incentivized to re-assess efficacy with new clinical studies, ADR data is often underreported; and regulators are slow to act on new safety data or lack the authority to remove drugs once they are on the market. In the U.S., a recent Congressional report[390] found that the even the FDA still does a poor job of tracking its own issued post-market commitments and a similar 2011 report from the Auditor General of Canada[391] found that Health Canada had little to no system in place for monitoring post-market commitments.

---

[386] *Davis and Abraham, supra* note 324.
[387] *A Lethal Guardian, supra* note 133 at 1, online at: http://www.fraseramerica.org, see also Skinner B. J. and Revere, M., *Access Delayed, Access Denied: Waiting for New Medicines in Canada* (Fraser Institute: Vancouver: 2010).
[388] *Ibid*. at 19.
[389] *Taylor LLM, supra* note 16, and Chapter 4: An Improper Balancing of Concerns. See also *Bouchard, supra* note 123.
[390] U.S. Senate Committee oN Fianace, Senate Report on Avandia, online at: http://www.finance.senate.gov/newsroom/chairman/release/?id=bc56b552-efc5-4706-968d-f7032d5cd2e4.
[391] *OAG, supra* note 29.

The notion that greater risks should be taken on by the consuming public in exchange for earlier access assumes that patients are being denied urgently needed new products. This is not necessarily the case; a host of literature has shown that urgently needed drugs can access accelerated approval pathways[392] and most new drugs provide little to no benefit over existing treatments. Pursuant to s.79 – 103 of the *Patent Act,*[393] the *Patented Medicines Price Review Board* (PMPRB)[394] reviews new medicines to determine their relative market value and therapeutic merit. For a drug to be "innovative" it must "contain a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient."[395] In a review of its own approvals from 2011-2020, the PMPRB found the majority of new drugs (91%) showed only moderate, slight, or no improvement over existing therapies.[396]

A more comprehensive description of Health Canada's policy and regulatory developments will be explored in later chapters, but it has shown a pattern over the past decade of increasingly adopting much of the policy and regulatory logic put forward by industry regarding a need to reduce regulatory burden, expedite approvals, and increase consumer choice. The 2007 *Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food*[397] announced the government's intention to move to lifecycle models with "continuous evaluation

---

[392] Christie, T. K. S., and Montaner, J. S. G., "The Perverted Irony of Health Canada's Special Access Programme" (2006) 174(12) *CMAJ* at 1746 (PUBMED).
[393] *R.S.C., 1985, c. P-4*
[394] Patented Medicine Prices Review Board (PMPRB), online at: https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2020.html#a, hereinafter *PMPRB 2020*.
[395] *FDR, supra* note 6 at *s.C.08.004.1*
[396] *PMPRB 2020, supra* note 394.
[397] *Blueprint II, supra* note 24.

of safety and effectiveness and quality of products before and after their introduction to the Canadian market,"[398] and in return, the removal of "traditional regulatory processes as a barrier to access."[399] Later that year, the government's *Consumer Safety Action Plan*[400] focused on improving consumer choice and spreading oversight throughout the lifecycle of a product. As the report indicates:

> The Action Plan aims to prevent safety problems by giving consumers and health professionals more and better information to make informed decisions about the safety and safe use of products and by enabling safety planning at an early stage. Enhanced targeted oversight will be achieved by new measures to support the ongoing assessment of the risks and benefits of a product over its lifecycle through a progressive licensing system and by providing modern inspection authorities.[401]

These two announcements were followed by a legislative initiative (the failed Bill C-51) that sought to adopt progressive licensing and pharmacovigilance mechanisms.[402] At the same time, Health Canada expanded the use of priority reviews (now 25% of all product reviews), increased the number of NOCC and expanded the special access program.[403]

Currently proposed future directions for the *FDA* are intended to develop **"**regulatory frameworks that are flexible and less prescriptive to better respond to innovation and emerging risks."[404] Health Canada has announced that it will be **"**taking a more agile approach by streamlining its regulatory processes."[405] The goal is to "enable the pharmaceutical industry to

---

[398] *Ibid* at page 7.
[399] *Ibid*.
[400] *Ibid*.
[401] *Ibid*.
[402] *C-51, supra* note 237
[403] *Blueprint II, supra* note 24.
[404] Health Canada, *Health and Biosciences: Target Regulatory Review*, (Health Canada: Ottawa, 2019), online at: https://www.canada.ca/en/health-canada/corporate/about-health-canada, hereinafter *Biosciences Review*.
[405] *Ibid*

bring new drugs to Canada more quickly, benefiting patients, and potentially increasing revenues for patented drug makers."[406]

Proposed amendments to the *FDR* coming into force in 2023 will "modernize the Canadian therapeutic product regulatory system towards strengthened implementation of a lifecycle approach."[407] This includes the adoption of rolling submissions (clinical data following market access) for products that meet the current criteria for priority review, the introduction of post-market risk management plans (early introduction with mitigation strategies), and an expansion of the *advanced therapeutic pathway* (ATP) (to include bespoke and agile regulatory pathways). Bill C-97,[408] which introduced the ATP, allows for early authorization by "the Minister, provided that risks can be adequately managed, controlled, and outweighed by anticipated benefit."[409] Health Canada is also exploring the use of other sources of evidence to justify introduction of products to the market, such as real-world evidence for promising therapies (i.e., no clinical trials being required).[410]

If there is a pendulum in drug regulation that swings between safety, efficacy, and quality versus access and innovation, that pendulum has swung far into the innovation and access side of the fulcrum. Health Canada and central agencies in the Canadian government have undertaken a regulatory agenda[411] that: (i) focuses on reducing regulatory barriers; (ii) frames drug regulation

---

406 *Ibid*.
407 *Canada Gazette*, part I, Volume 155, Number 31.
408 *Bill C-97, supra* note 373.
409 *Ibid*.
410 Health Canada, *Elements of Real World Data/Evidence Quality throughout the Prescription Drug Products Life Cycle,* (Health Canada: Ottawa, 2019), online at: https://www.canada.ca/en/services/health/publications/drugs-health-products/real-world-data-evidence-drug-lifecycle-report.html.
411 *Biosciences Review, supra* note 404.

as primarily an economic activity; and (iii) prioritizes market access for urgently needed products. In the post-COVID-19 era, this may be the norm, as drug companies have proven in the case of COVID-19 vaccines that they do have the capacity to develop products rapidly. Yet as many authors argue, COVID has also put industry in a position of relative advantage and power in relation to government.

For NHPs, which are subject to a high degree of consumer demand but little true clinical advances, the *NHPR* has become the most permissive product regime under the *FDA*, tending to pull the SEQ standard down for other product classes. The result has been a shift towards a very permissive conception of low risk and a very low regulatory bar for product entry. Ultimately, this can be argued to be a confluence of the three trends discussed above: an acceptance of a low bar for health claims, a preferential engagement with stakeholders largely representing the NHP industry, and equating the goal of the regulatory regime with market access instead of safety or efficacy. Before I discuss these issues, in the next chapter I will focus on the nature of complementary and alternative medicine (CAM) products, their history, and why they inherently produce challenges for regulators. This is important because NHPs can be considered a class of CAM.

CHAPTER 3 – COMPLEMENTARY AND ALTERNATIVE MEDICINES

Before exploring the legal, regulatory, and policy framework for natural health products (NHPs), it will help to establish the worldview and general characteristics of the broader class of complementary and alternative medicines (CAMs) to which these products belong. CAMs offer a counter narrative to the conventional modes of health delivery and drug development. Attempting to define some of the parameters and the qualities of CAMs is important because the practices and theoretical roots of these belief systems form the evidential basis which justifies the use and health claims used to license NHPs. This chapter will serve as a survey describing the nature, theory, and history of the worldview around CAMs. Many of the ethical, scientific, and legal issues that relate to CAMs exist in parallel to those that exist for NHPs. This in turn helps to identify some of the regulatory challenges that exist for these types of products when compared to conventional pharmaceuticals. It should be noted that "NHP" is merely the legal term used in Canada to describe the legal class of CAM products which are regulated for sale.

A 2010 Health Canada study reports that an estimated 70% of Canadians regularly use CAM products.[412] A more recent study of why Canadians use so many CAM products observed that the public perceives them as being "safer, less subject to adverse reactions, and in some way, more 'natural' than other drugs."[413] This is despite the fact that there is little to no clinical

[412] Health Canada, *Natural Health Product Tracking Survey 2010 Final Report*, (Prepared by Ipsos Reid: Ottawa, 2010) p.6, online at: http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2011/135-09/report.pd, hereinafter *Ipsos –Reid*.
[413] Barry, A. R., "Patients' Perceptions and Use of Natural Health Products" (2018) 151 *Can Pharm J* 254.

evidence supporting CAMs' efficacy[414] and that "natural means safe is not necessarily true."[415] Advocates of conventional medicine will argue that many of these products are not effective or safe, especially when taken unsupervised, as a replacement for more conventional treatments or when over-consumed.[416]

There are two fairly entrenched camps when it comes to CAM use. One sees the emergence of complementary and alternative medicine as an evolution in thinking about how health care is pursued, allowing for more holistic and traditional treatments.[417] For others it is seen as a crass commercialization of people's anxieties, and a failure to apply rigorous science to treatment.[418] Regardless, there has been an explosion of new products, new health claims, and a public increasingly putting their faith in CAM products. This represents a paradigm challenge to conventional medicine and its reliance on pharmaceuticals approved through the clinical trial processes described in the last chapter.[419] For advocates of CAMs it represents the expansion of a more holistic and faith-based system of healing into areas claimed exclusively by conventional

---

[414] Ernst E., and Smith, K., *More Harm than Good? The Moral Maze of Complementary and Alternative Medicine* (Springer International Publishing: Switzerland, 2018).
[415] *Ibid*, at page 29.
[416] For example see Navarro, V. J., Barnhart, H., Bonkovsky, H. L., et al, "Liver Injury from Herbals and Dietary Supplements in the U.S. Drug Induced Liver Injury Network" (2014) 60 *Hepatology* 1399. Budnik, L.T., Baur, X., Harth V. and Hahn A., "Alternative Drugs go Global: Possible Lead and/or Mercury Intoxication from Imported Natural Health Products and a Need for Scientifically Evaluated Poisoning Monitoring from Environmental Exposures" (2016) 11 *J Occup Med Toxicol* 49. Geller, A. I., Shehab, N., Weidle H. J., et al, "Emergency department visits for adverse events related to dietary supplements" (2015) 373 *N Engl J Med* 1531. Rao, N., Spiller, H. A., Hodges, N. L., et al "An Increase in Dietary Supplement Exposures Reported to US Poison Control Centers" (2017) 13 *J Med Toxicol* 227. Foster, B.C., Cvijovic, K., Boon, H., et al, "Melatonin interaction resulting in severe sedation" (2015) 18 *J Pharm Pharm Sci* 124. Necyk, C., Ware, M. A., Arnason , J. T., et al, "Increased bruising with the combination of long-chain omega-3 fatty acids, flaxseed oil and clopidogrel" (2013) 146 *Can Pharm J (Ott)* 93.
[417] Knoll, A. M., "The Reawakening of Complementary and Alternative Medicine at the Turn of the Twenty-First Century: Filling the Void in Conventional Biomedicine" (2004) 20 *J Contemp Health L & Policy* 329.
[418] See Ernst supra note 414 or Caufield T. & Feasby, C., "Potions, Promises and Paradoxes: Complementary and Alternative Medicine and Malpractice La in Canada" (2001) 9 *Health Law J.* 183 or T. Caufield, T., "Homeopathy and the ethics of researching magic" (February 2015) *Policy Options*.
[419] *Ibid* see also Cohen M. H., and Eisenberg, D. M., "Potential Physician Malpractice Liability Associated with Complementary and Integrative Medical Therapies" *(2002)* 136 *Annals of Internal Medicine* 596, MacDonald , C. and Gavura, S., "Alternative Medicine and the Ethics of Commerce" (2016) 30(2) *Bioethics* 77.

medicine.[420] It puts regulators in a quandary, having to balance the increasing desire for these products against the need to ensure that they are pronounced to be safe, effective, and of decent quality based on some coherent criteria.

Since 2002, the World Health Organization (WHO)[421] has been working with member states attempting to improve the use of CAMs. The primary goal of their work has been "improving equitable access to safe, quality and effective [CAMs] [which] can potentially meet communities' needs and build sustainable and culturally sensitive primary care."[422] The WHO speculates that the resurgence in the use of CAMs has several causes, including:

> an increased demand for all health services, a desire for more information leading to an increased awareness of available options, an increasing dissatisfaction with existing health-care services, and a rekindled interest in "whole person care" and disease prevention..[including] the need to focus on quality of life when a cure is not possible.[423]

Acknowledging that these products are becoming more prevalent and that their integration into conventional treatment is warranted, the WHO's *2014-2023 Traditional Medicine Strategy*[424] has identified three goals:

- To build the **knowledge base** for active management of [CAMs] through appropriate national policies[425]
- To strengthen the quality assurance, safety, proper use and effectiveness of [CAMs] by regulating products, practices and practitioners;[426] and
- To promote universal health coverage by integrating [CAM] services into health-care service delivery and self-health care.[427]

---

[420] Micozzi, M. S., *Fundamentals of Complementary and Alternative, and Integrative Medicine*, 6th Edition (Elsevier Canada: Toronto, 2018), hereinafter *Micozzi*.
[421] WHO, *Traditional Medicine Strategy 2002–2005*, (WHO: Geneva, 2002), online at: https://apps.who.int/iris/handle/10665/67163, hereinafter *WHO 2002-2005*.
[422] *Ibid,* at introduction.
[423] *Ibid*.
[424] WHO, *Traditional Medicines Strategy 2014-2023*, (WHO: Geneva, 2014), online at: https://www.who.int/publications/i/item/9789241506096, hereinafter *WHO 2014-2023*, at page 28.
[425] *Ibid*, at 44
[426] *Ibid*, at 49.
[427] *Ibid*, at 53.

As part of this and integrated into the 2018 *Declaration of Astana*[428] from the WHO *Global Conference on Primary Health Care* is a belief that health-care models need to "be driven by applying scientific as well as traditional knowledge, and extending access to a range of health-care services, which include [CAMs]."[429]

There are several principles that can be taken from the WHO's *Traditional Medicine Strategy* 2014-2023[430] According to the WHO's objectives, traditional CAM products are perceived as a valid component of modern health care and should be seen as supplementing or supporting more conventional forms of medicine. From the WHO's perspective, "in an ideal world, traditional medicine would be an option offered by a well-functioning, people-centred health system that balances curative services with preventive care."[431] A critical aspect of this work is to enhance the scientific knowledge base around the usefulness of CAM products while also respecting traditional knowledge and cultural practices. The WHO framework does not assign a level of merit to any CAM practices but instead suggests that countries must create legal-regulatory frameworks around these products and encourage more research into their safe and effective use. It is worth noting that the WHO framework concentrates on traditional CAMs, but not all or even most CAM products, practices, or practitioners in many Western countries are based on long-standing cultural traditions.

---

[428] WHO, *Declaration of Astana*, (WHO: Astana, 2018), online at: https://www.who.int/docs/default-source/primary-health/declaration/gcphc-declaration.pdf, hereinafter *Declaration of Astana*.
[429] *Ibid*.
[430] *Supra*, note 428.
[431] *Ibid*.

Part 1 - Towards a Working Definition

(i) Complementary Alternative Medicine (CAM)

Before beginning an analysis of the fundamentals underlying CAM as a belief system, a starting problem is how to define this highly varied and heterogeneous set of activities. As Kaan notes, the "threshold problem in any legal analysis [of CAMs is] the most intractable and difficult…that of definition."[432] He goes on to say that:

> There is little agreement on the terminology for many practices, disciplines and traditions, and even less on how they are to be classified: grouped together by history or in terms of allied traditions; according to functional principles; or according to how they are used in relation to "conventional" medical therapy.[433]

Jesson and Tovino in their text *Complementary and Alternative Medicine and the Law*[434] reiterate this complex starting question, indicating that:

> the term "CAM" encompasses a number of therapies that are highly diverse, both in their location and time of origin, as well as their philosophies of health and healing [which] creates one very large umbrella.[435]

CAM tends to be an inclusive category, bringing together a very wide and diverse set of practices, practitioners, and potential health products, with little attempt to provide a comprehensive ordering, hierarchy, or taxonomy. Many of the rules of ordering and nomenclature based in conventional medical traditions are difficult to apply. This is a problem that we will see regulators struggle with when they try to define NHP in the regulations.

---

[432] Kaan, T. S. H., "Traditional, Complementary and Alternative Medicine" in Joly, Y., and Knoppers, B. M., eds., *Routledge Handbook of Medical Law and Ethics*, (Routledge: New York, 2014), Kindle Edition, hereinafter *Kaan,* at 419.
[433] *Ibid.*
[434] Jesson, L. E. and Tovino, S. A., *Complementary and Alternative Medicine and the Law,* (Carolina Academic Press: Carolina, 2010), hereinafter *Jesson*.
[435] *Ibid*, at introduction.

The World Health Organization (WHO) offers a general operating definition of **complementary and alternative medicine** as "a broad set of health-care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system."[436] In other words, CAM encompasses any practices, practitioners, or products outside the dominant system of conventional medicine. In contrast, the WHO defines **conventional drugs** as "medical drugs used in conventional systems of medicine with the intention to treat or prevent disease, or to restore, correct or modify physiological function."[437] As Kaan notes,

> The bedrock of conventional medicine is an insistence on the scientific method, and the use of drugs, therapies, and interventions whose safety, efficacy, and effectiveness are backed by empirical data.[438]

In the previous chapter, I discussed how conventional drug regulation has evolved over the past century and a half, with an increasing emphasis on conducting *a priori* scientific reviews to establish the efficacy and safety of drugs. In contrast, historically most CAMs lack such regulation, oversight of quality control, or clinically tested demonstration of safety and efficacy.

The WHO also makes a distinction between CAM products, practices, and practitioners.[439] **Practitioners** include those who provide service, guidance, and professional advice related to CAMs. A wide range of practitioners are included with varying levels of expertise and training across disciplines as varied as yoga instructors, energy healers, naturopaths, and chiropractors.[440] **Practices** are mediated or self-guided activities that are

---

[436] WHO, *WHO Global Report on Traditional and Complementary Medicine - 2019*, (WHO: Geneva, 2019), online at: https://apps.who.int/iris/bitstream/handle/10665/312342/9789241515436-eng.pdf, hereinafter *WHO CAM 2019, at 8*.
[437] *Ibid.*
[438] *Kaan*, *supra* note 432 at 420.
[439] *WHO CAM 2019, supra* note 436 at 44.
[440] *Ibid.*

undertaken when implementing CAM treatments. A wide range of activities are included, from mindfulness training to yoga to acupuncture. The WHO defines **products** in a limited way, focusing on "herbs, herbal materials, herbal preparations and finished herbal products that contain parts of plants, other plant materials or combinations thereof as active ingredients."[441] My thesis will focus primarily on the regulation of the **CAM products, specifically NHPs, regulated under the Canadian *FDA* and *NHPR*.**[442] I will not touch on the regulated behaviours of practitioners or practices of CAM in Canada.

CAM proponents will often make a distinction between their forms of medicine and what they term **allopathic medicine**.[443] Allopathic medicine was originally a derogatory term developed by practitioners of CAM [444] to denote the tendency of conventional medicine to separate treatment from the holistic cause of disease (*allo* from the Greek, meaning "opposite" and *pathos,* meaning "suffering"). In opposition, CAM practitioners see themselves as practitioners of a holistic form of medicine (*homeo* meaning "whole" in Greek). I will avoid using the term "allopath," which is seen as derogatory by many practitioners of modern medicine. Instead, I will use the WHO term "conventional medicine" throughout my thesis to describe the use of the dominant form of medical treatment provided in Canada and other Western countries.

[441] *Ibid.*
[442] *Ibid.*
[443] *Micozzi, supra* note 420.
[444] *Ibid.*

Under the WHO regime, the term **traditional medicine** is used to refer to a host of long-established non-conventional medical traditions. The WHO notes that in many cases, traditional practices are older than those used in conventional medicine and represent:

> the sum-total of the knowledge, skill, and practices based on the theories, beliefs, and **experiences indigenous to different cultures**, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.[445]

Traditional health systems such as *Ayurvedic* [446]and *Chinese*[447] medicine are based on ancient concepts, practices, and texts with thousands of years of uninterrupted use. Associated with traditional practices are formal **pharmacopeias** that outline the practices and specific remedies, including composition of medicines, that should be used for illnesses. According to the WHO, to be considered a traditional system of medicine, there should be (i) a well-documented history of use (this can include oral history) that has (ii) been largely continuous and (iii) is based on a coherent system of logic or belief.[448] **Herbal medicine**[449] includes specific herbal remedies, whether wholly organic or inorganic, that are native to a specific country or region.[450] Many herbal medicines would also likely be considered traditional medicines.

---

[445] *WHO CAM 2019, supra* note 436 at 8.
[446] WHO, *International Standard Terminologies on Ayurveda*, (WHO: Geneva, 2023), hereinafter WHO Ayurveda.
[447] WHO, *International Standard Terminologies on Chinese Medicine,* (WHO: Geneva, 2022), hereinafter WHO TCM.
[448] *WHO CAM 2019, supra* note 436 at 8. All three should be present for a system to be recognized as a traditional medicine system -- for example, while well documented and based on a core belief system, there are no traditional practitioners of classical Egyptian medicine left in the world.
[449] *Ibid*. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain, as active ingredients, parts of plants, other plant materials or combinations thereof. In some countries, herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials).
[450] *Ibid*. The WHO defines Indigenous traditional medicine as the sum total of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating physical, mental and social diseases. This knowledge or practice may rely exclusively on past experience and observation handed down orally or in writing from generation to generation. These practices are native to the country in which they are practised. The majority of Indigenous traditional medicine has been practised at the primary health-care level."

Not all, or even most, CAM products are linked to traditional medicine. To the WHO definition I would also add a category of **modern, new, or non-traditional CAMs** which include the broader class of products, practitioners and practices which have emerged in the past century and a half making health claims not necessarily rooted in traditional forms of medicine or practice. These systems generally have less of a cohesive system of logic backing their practice, less of a history of use, and less of a root in existing cultural belief systems. These products may make claims based on extrapolation from existing or older traditional CAM, but they are based on new paradigms or perceived systems of beliefs. In Western countries there are many more commercial products that are based on modern/non-traditional CAM claims than there are products based on traditional claims.[451] Modern, new, or non-traditional CAMs are often associated with the concept of **wellness** that arose in the 1800s in Europe, but saw a resurgence in the 1960s as a "a condition of change in which the individual moves forward, climbing toward a higher potential of functioning."[452] While wellness is a system of belief, many[453] would argue it does not meet the criteria of a being a coherent system of logic.[454]

Integrative medicine describes a combination of therapies into an integrated treatment model. It emphasizes the use of multimodal interventions, involving two or more approaches, such as conventional treatment, lifestyle changes, physical rehabilitation, psychotherapy, and complementary health practices. The goal is to address the needs of the individual as a whole. The boundaries of these various definitions are porous, "allowing therapies to transition from one

[451] For instance, in Canada, of the 100,000 thousand licensed NHPs, many more are licensed as modern or non-traditional NHPs than traditional NHPs. It is at a ratio of almost 9 (new) to 1 (traditional).
[452] Dunn, H. L., "What High-Level Wellness Means" (1959) 50(11) *Canadian Journal of Public Health* at 447.
[453] Tim Caulfield, "Remedies – Big Pharma and the Colon Cleansers" in *The Cure for Everything!* (Viking: Toronto, 2012), hereinafter *Caulfield*. *Ernst, supra* note 418.
[454] *Ibid*.

group to the other."[455] **Traditional and complementary medicine (TCM)** is used as a catch-all term where the distinctions between traditional and newer complimentary-alternative medicine blur, which they often do.[456] Alternative therapies can become conventional practices as they gain wider acceptance or broader cultural recognition, the way mindfulness meditation and yoga have. Alternatively, commonly accepted components of the dominant health-care system can fall out of favour and be relegated to the status of alternative medicine, e.g., bleeding as treatment for fever.

For many around the world, there is little perceived delineation between traditional, complementary, and even conventional medicine. CAMs, particularly herbal medicines, are the most prevalent and familiar forms of medicine in the developing world.[457] As Kaan suggests, "for a large portion of humankind, traditional and CAM medicine is not only the main form of medicine, but it is essentially the only kind of primary medical care readily available."[458] According to the WHO, the resurgence in the use of CAMs has several causes, including:

> an increased demand for all health services, a desire for more information leading to an increased awareness of available options, an increasing dissatisfaction with existing health-care services, and a rekindled interest in "whole person care" and disease prevention... [including] the need to focus on quality of life when a cure is not possible.[459]

CAM treatments are preferred because they are more affordable, can be provided by non-medically trained practitioners, can be easily accessed, and may allow for self-administration of treatments.

---

[455] *Jesson, supra* note 434 at 9.
[456] *WHO CAM 2019, supra* note 436 at 8.
[457] *Ibid.*
[458] *Kaan, supra* note 432 at 424
[459] *WHO 2014-2023, supra* note 424 at 28.

(ii) A Rough Typology of Complementary and Alternative Medicine

Trying to define the quality of CAMs is important; while this thesis will not be assessing these individual therapies, the practices and theoretical roots of these belief systems form the evidential basis which justifies specific health claims used to license NHPs. In 2022, the Cochran Collaboration conducted an analysis of a wide range of peer-reviewed and other quality-assessed information sources to try to develop a comprehensive operational definition of what they term "complementary, alternative and integrative medicine."[460] Their goal was to "support the harmonization of CAM-related research through the provision of a standard of classification, as well as support improved collaboration between different research groups."[461] Their analysis produced an exhaustive list of 1,561 unique practices that could be grouped under 604 distinct types of CAMs. Practices ranged from the traditional use of saffron, to regression therapy, to sauna treatments, to voodoo.[462] While a laudable goal, an operational definition composed of 1,561 unique categories grouped under 604 sub-categories is unwieldy for comparative analysis. This attempt captures one of the core difficulties when dealing with CAMs, which is concretely defining what is in or out of the definition and how to define an ever-expanding category. This in turn affects the evidence or system of knowledge that can be brought to bear in assessing their utility.

---

[460] Ng, J. Y., et al, "A Comprehensive Search String Informed by an Operational Definition of Complementary, Alternative, and Integrative Medicine for Systematic Bibliographic Database Search Strategies" (2022) 22 *BMC Complementary Medicine and Therapies*, online at: https://bmccomplementmedtherapies.biomedcentral.com at 2.
[461] *Ibid.*
[462] The full alphabetized list can be found here: https://bmccomplementmedtherapies.biomedcentral.com, accessed on June 2, 2022. It should be noted that even this was not a study without controversy. Researchers left out many traditional practices and authoritative texts, including herbal medicines and other traditional pharmacopeias. Sources of information surveyed included: 1) Peer-reviewed articles from MEDLINE, EMBASE, AMED, Psyc INFO, CINAHL, etc.: 2) "Aims and Scope" webpages of peer-reviewed CAIM journals: 3) Highly-accessed online encyclopaedias and 4) Highly ranked websites.

A simpler framing was provided in the 2000 *Report to the National Institutes of Health on Alternative Medical Systems and Practices in the United States: Alternative Medicines – Expanding Medical Horizons* (the Chantilly Report).[463] This report identified seven types of CAM practices: (i) alternative systems of medical practice; (ii) pharmacological and biological treatments; (iii) herbal medicines; (iv) diet and nutrition; (v) manual healing methods; (vi) bio-electromagnetic applications; and (vii) mind-body interventions.

Figure 6: Specific Modes of Complementary and Alternative Medicine as Defined in the Chantilly Report[464]

Type of CAM Practice	Mode of Action	Examples
1) Alternative systems of medical practice	Care based on existing cultural beliefs in an established traditional practice not dominant in conventional medicine.	Acupuncture, herbal medicine, traditional Oriental medicine, Ayurvedic medicine, homeopathy, naturopathy.
2) Pharmacological and biological treatments	Assortment of drugs and vaccines not accepted by mainstream medicine.	Peptide treatments, processed blood products, hormone injections.
3) Herbal medicines	Established practices that use plants and plant products.	Dried or whole plants, in combination or in natural form, phyto-medicines, herbal teas.
4) Diet and nutrition	Modifying health through the consumption of specific foods or nutrients.	Diet, mineral, and vitamin supplements, specific dietary lifestyles (e.g., veganism).
5) Manual healing methods	Touch and manipulation of the body to address dysfunction and improve global health.	Osteopathy, chiropractic and massage therapies.
6) Bio-electromagnetic applications	Modifying or altering the electromagnetic or electrical fields around the body.	Application of non-thermal, non-ionizing electromagnetic fields, magnetic, energy healing.
7) Mind-body interventions	The connection of mind and body and the power of each to affect the other.	Psychotherapy, meditation, hypnosis, biofeedback, yoga, dance therapy, music therapy, art therapy, prayer.

[463] U.S. National Institutes of Health, *Report to the National Institutes of Health on Alternative Medical Systems and Practices in the United States: Alternative Medicines – Expanding Medical Horizons* (the Chantilly Report) (National Institutes of Heath: Washington, 1992), accessed via nova net. The goal of the report was to provide a survey of CAMs to begin "establish[ing] an information clearinghouse on alternative medicine so that the public, policy-makers, and public health express can make informed decisions about their health care options" related to CAMs.

[464] *Ibid.*

The Merck Manual[465] builds on the Chantilly Report to divide practices into five categories: whole alternative medical systems; biologically based therapies; manipulative and body-based practices; mind-body medicine; and energy therapies.

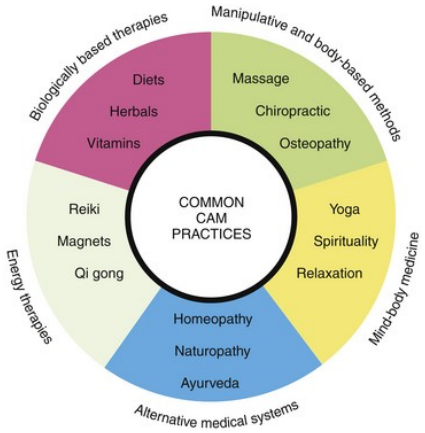

Figure 7: Merk Manual Classification of CAMs [466]

According to the Merck Manual:

- ***Alternative medical systems*** are based on a defined philosophy and explanation of disease, diagnosis, and therapy.
- ***Biologically based therapies*** use "naturally occurring substances" to treat disease (such as botanical medicine, NHPs, diet, etc.).
- ***Manipulative and body-based practices*** treat illness "through bodily manipulation"[467] such as massage, chiropractic therapy, yoga, and cupping.
- ***Mind-body medicine*** is based on the theory that mental and emotional factors affect physical health and "behavioural, psychological, social and spiritual methods" (such as hypnotherapy, medication, biofeedback, and yoga) can help prevent or cure disease.
- ***Energy therapies*** "focus on the energy field" around the body and the use of therapies to influence these fields through practices such as reiki, magnets, and therapeutic touch.[468]

---

[465] The Merck Manuals are the leading authoritative texts on medical and pharmaceutical practice in use in Canada and the U.S. Millstine, D., *Types of Complementary and Alternative Medicine - Special Subjects*, (Merck Manuals Consumer Version: 2022), online at: https://www.merckmanuals.com/en-ca.
[466] *Ibid.*
[467] *Ibid.*
[468] *Ibid.*

Merck does not consider these discrete categories; rather, it takes the view that many practices can and do overlap in classification and treatment. For example, qigong can be considered part of a tradition of Chinese medicine as well as an energy therapy.

The U.S. National Institute of Health (NIH), under the U.S. National Centre for Complementary and Integrative Health (NCCIH), has tried to situate some of the most common CAM practices within the boundaries of conventional medicine and conventional therapeutics (drugs and medical devices), in the following diagram.

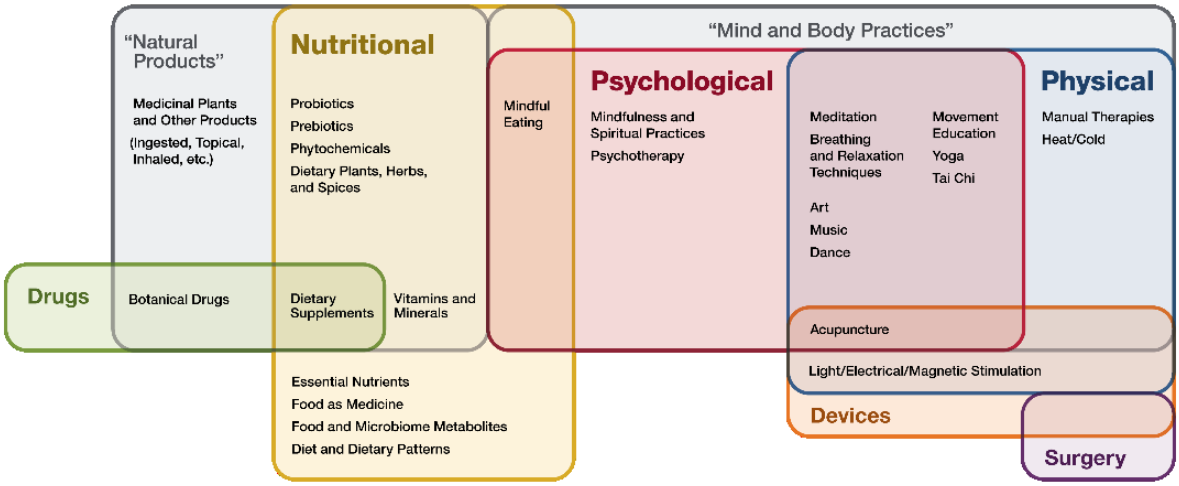

Figure 8: NCCIH – CAM Classification [469]

The mission of the NCCIH is to "through rigorous scientific investigation [assess] the fundamental science, usefulness, and safety of complementary and integrative health approaches and their roles in improving health and health care."[470] Accordingly, the NCCIH takes a conventional or integrative scientific approach, trying to situate CAMs in parallel to

[469] U.S. National Centre for Complementary and Integrative Health (NCCIH), *Complementary, Alternative, or Integrative Health: What's In a Name?*, (NCCIH: Washington), online at: https://www.nccih.nih.gov.
[470] *Ibid.*

conventional medicine. Its classification tries to capture several overlapping elements: (i) mode of action (asking: does the practice affect the nutrition, psychology, or physical state of a patient); (ii) whether the product is a mind-body practice versus one based on natural products; and (iii) federally regulated products like drugs,[471] medical devices, and surgery.

None of these classification systems are discrete and many CAMs fall within overlapping categories. For instance, under the NCCIH system, meditation and yoga are both psychological and physical mind-body practices. Probiotics are a nutritional practice based on consumption of "natural products" to affect gut bacteria. Acupuncture includes elements of psychology and physical therapy while also employing devices in the form of acupuncture needles. While again useful for comparison to conventional medicine and by mode of action, the NCCIH framework excludes many types of traditional medicine and does not easily situate the 604 types of CAMs identified by the Cochrane Collaboration into one complete framework.

(iii) Some Criteria Common to CAMs

In *Nature Cures: The History of Alternative Medicine in America,*[472] James Whorton outlines some general traits that can be helpful in situating most CAMs. First, as noted above, the term encompasses a very **inclusive class of products**, practices, and treatments that can make it difficult to create simple taxonomies with clear boundaries. Second, CAM treatments, products, and practices are **based on a holistic conception of health** focused on the whole

[471] As will be discussed later in the US only dietary supplements, vitamins and naturally derived drugs are regulated by the FDA.
[472] Whorton, J., *Nature Cures: The History of Alternative Medicine in America*, (Oxford University Press: New York, 2002), hereinafter *Whorton.*

patient, not just disease, with a goal of seeking longer-term balance and equilibrium. Third, these products are cast as being **more natural and** less invasive, calling on the fundamental healing powers of nature. Fourth, in CAM, **the patient's subjective experience** of their health is at the centre of treatment. Fifth, the sources of proof brought forward by practitioners of TCM **allows for non-clinical forms of evidence**, including subjective, historical, and even allegorical evidence. Finally, much of CAM is **belief-based**, which can put it at direct odds with any conventional systems used to justify use or any laws which seek to restrict access.

a. An Inclusive Category

As was noted above, the boundaries of defining what is or is not a CAM can be difficult to determine. Micozzi notes that, "CAM remains a largely undifferentiated amalgam of non-biomedical practices and much of CAM-as-presently-spoken-of is not actually focused on medical care, but rather on sickness prevention and wellness care."[473] As an advocate of inclusivity, Micozzi argues that any form of classification is a "historical and cultural social construct" that ignores the plurality of CAM treatments.[474] Kaan similarly notes that the ambiguous edges of CAM results in a "classification in which traditional Chinese medicine and Ayurvedic medicine are lumped together with crystal therapy, dowsing, and radionics in a catch-all list."[475] In *Fundamentals of Complementary and Alternative and Integrative Medicine (6th Ed),*[476] Micozzi suggests that CAM definitions should be principle-based, looking at shared characteristics of practices and systems of thought, such as a focus on holistic healing, lifestyle,

[473] *Micozzi, supra* note 420 at 1702.
[474] Ibid at 330.
[475] *Kaan, supra* note 432 at 421.
[476] *Micozzi, supra* note 420.

subjective experience, non-observable outcomes, less direct intervention, and more links to innate sources of healing. It is difficult as a starting point to exclude any practice related to health in which people are placing their faith as not being a CAM.

One important distinction in CAM, briefly noted above, is that made between those which have "practices that are many years or centuries old and have a large body of practitioners and practices and a well-developed fund of clinical 'wisdom' that is encoded in the beliefs of a particular society or subgroup of people" [477]versus "practices that have been developed recently by one or a few practitioners in isolation from peers and without scientific testing [or] clinical studies."[478] Traditional systems tend to be "intellectually coherent with and practically responsive to the cultures in which they initially developed,"[479] while many of the newer practices rely primarily upon supposition and minimal new clinical evidence. In regulatory systems, this may lead to a two-track system of oversight, one for those linked to existing traditional or established practices and one for those making new claims about existing or new types of products.

b. The Holistic Experience of Health

Under much of CAM, there is an emphasis on overall health and healing rather than on the treatment of a specific etiology or symptoms. It is a system-based healing approach, focusing both on re-establishing the body's equilibrium and placing the patient within an environmental

[477] *Ibid.*
[478] *Ibid.*
[479] Bivins, R, *Alternative Medicine* (Oxford University Press: Oxford, 2007) Kindle edition at 43, hereinafter *Bivins*.

context. This approach considers how wellness is experienced and ultimately treated. As Micozzi notes:

> Wellness in the context of [CAM] is more than the prevention of disease. It is focused on engaging the inner resources of each individual as an active and conscious participant in the maintenance of his or her own health. By the same token, the property of being healthy is not conferred on an individual by an outside agency or entity, but rather results from the balance of internal resources within the external natural and social environments.[480]

CAM practitioners would argue that in opposition to conventional approaches, their goal is "restoring [a] natural state of balance rather [than conventional medicine] that interferes with normal as well as abnormal biological processes, produces side effects and reduces symptoms without addressing the causes of illness."[481] Joseph Hahnemann created homeopathy in opposition to conventional medicine, which, in his view, only "treated disease by opposing symptoms [and not] preventing illness or addressing root causes of disease."[482] To many CAM proponents, illness has multiple causes and can be approached through a variety of different practices, "biochemical, environmental, social, physical, behavioural and spiritual,"[483] to re-establish equilibrium.

CAM is also perceived as promoting patterns of behaviour and treatment that are less invasive. CAM practitioners typically argue that conventional medicine can attack disease "so brashly as to indiscriminately overwhelm the patient too."[484] CAM practitioners make a distinction between curing the symptoms of a disease and healing the patient. As Micozzi puts it:

---

[480] Micozzi, supra note 420, at 1266.
[481] Cohen, M. H., *Complementary & Alternative Medicine: Legal Boundaries and Regulatory Perspectives,* (John Hopkins University Press, Baltimore: 1998), herein after Cohen at 244
[482] *Ibid.*
[483] *Ibid.*
[484] *Whorton, supra* note 472 at 4.

> Curing involves the eradication of disease at the physiological level. Healing involves a movement towards wholeness, growth, or greater balance on physical, mental, emotional, and social levels rather than a focus on curing a given disease or disorder.[485]

CAM is seen by its adherents as both having longer-term effects and being more sustainable for the patient. CAM practitioners "focus on social and psychological dimensions of illness and individual responsibility for the healing process."[486] As such, many CAM practices may be highly attractive to patients who can experience more attention, care, and perceived concern for addressing environmental factors during treatment.[487]

c. Natural Modes of Healing

CAM adherents also commonly claim their approaches are more natural, less invasive and assist in more natural forms of healing. In this perspective, nature is the source of healing, and treatment moves patients back to a more fundamental natural state of health. As Bivins suggests:

> These models proposed that diseases had a natural course through which they would inevitably progress, ending in a 'crisis' during which the patient's vital force would either be exhausted or be restored to a state of healthy balance.[488]

Therefore, the natural healing goal of much of CAM is to "enhance the body's own innate [natural] recuperative powers."[489] For early 19th-century practitioners of natural medicine, nature "was a good, kind angel, hovering over the bed of sickness …who regularly saved the life of many a poor patient, who is near being drugged to death by some ignorant quack, or some over-

[485] *Cohen, supra* note 481 at 183.
[486] *Ibid*, at 241.
[487] *Ibid.*
[488] *Bivins, supra* note 479 at 90-91.
[489] *Cohen, supra* note 481 at 4.

dosing doctor."[490] For many 19th-century practitioners, nature was also synonymous with spirituality or some form of the divine.[491] For many modern practitioners of CAM, there continues to be a spiritual element associated with the natural as a form of purity in greater harmony with the environment.

To tap into these innate resources, CAM emphasizes the use of natural (organic or herbal) sources instead of synthetic ones. To this end, CAM practitioners focus on the "use of natural products, employ natural forces as treatments and are devoted to treating their patients naturally."[492] The term "natural" is broadly defined and implies a more fundamental form of healing.[493] According to this reasoning, a product sourced from nature is better than one created chemically by humans. The inclusion of the word "natural" in natural health products is an attempt to capture this concept. As Ernst notes, nature is "pictured as benign, and natural remedies are therefore not just intrinsically superior but also safer."[494] However, as Ernst also points out, "not all forms of CAMs are natural"[495] and "nature is by no means always benevolent."[496]

---

[490] *Ibid,* at 6
[491] *Ibid*.
[492] Ernst, E and Smith, K., *More Harm than Good: The Moral Maze of Complementary and Alternative Medicine* (Springer: Exeter, 2018) Kindle Edition here and after *Ernst Maze*.
[493] *Ibid*.
[494] *Ibid*.
[495] *Ibid*.
[496] *Ibid*.

d. The Primacy of the Subjective Experience of Health

CAM systems do not emphasize physiologically measurable outcomes, but rather how a person feels because of treatment. Patients are to be seen as a "whole person, a unique individual with his or her own inner resources."[497] As such, CAM models are focused on the experience of the individual: their subjective experience of treatment and a person's perception of their overall health. This can incorporate not just the status of their physical health, but elements of their beliefs, feelings, or spiritual experience during illness. This subjective experience is seen as an aggregate experience of one's overall quality of life, not just at acute moments of treatment. CAM adherents would argue that this is contrasted with conventional medicine, where a "client's subjective experience [is] subordinate to the objective evidence of pathology discernable by the doctor."[498]

Under this conception, the effectiveness of using CAM is not based on a set of externally validated observations, but on how the individual has framed their experience. In this way, the use of CAMs takes on value resembling a belief system. Putting the placebo effect aside for the moment, the subjective experience of health can have a significant effect on individual health outcomes. For regulators, it is very difficult to quantify or police belief; it is equally difficult to challenge subjective experience. For many traditional medicines, belief in their effectiveness is rooted in cultural or spiritual systems with a long history. In newer forms of CAM, there is a similar development of products that align to current cultural norms or dominant beliefs.[499]

---

[497] *Micozzi, supra* note 420 at 1351.
[498] *Whorton, supra* note 472 at 302.
[499] *Ernst Maze, supra* note 492.

Treatments can be seen as helping to confirm our existing biases rather than challenging them. Or as Kang puts it:

> Our own biases—confirmation bias, in-group bias, post-purchase rationalization, and a host of others—all have heady effects on our ability to systematically evaluate treatments as varied as herbal cough drops, electronic cancer zappers, or pricey plasma-injected facials.[500]

Since these products hold significant personal value for their users, they will frame any restriction or criticism as an infringement on their right to choose and the freedom to direct their own treatment. As we will see later, Canadians are not immune to these concepts in relation to the freedoms associated with NHP use.

e. Rejection of Conventional Medicine and Clinical Proof

This focus on the subjective experience of health also leads to a wide variety of evidence being put forward to demonstrate CAM's merit. As Whorton notes:

> To a considerable degree alternative medicine has followed an alternative science, one requiring no sophisticated reasoning and abstruse theory, or expensive laboratories and extensive experimentation, but intuition, common sense, patience and close observation.[501]

The argument is that if the subjective experience is most essential, then the subjective perception of improved health should be valid proof of a treatment's effectiveness. This can lead to a "belief that orthodox medicine [is] overly rationalistic, placing too much confidence in theory and not trusting sufficiently in experience."[502] Such a framing can lead to scorn or rejection of the methods of scientific validation for treatment. This also means a high degree of skepticism

---

[500] *Quackery, supra* note 180 at 94.
[501] *Whorton, supra* note 472 at 11.
[502] *Ibid.*

regarding conventional medicine's burdens of proof. If a patient perceives themselves to be feeling better, that demonstrates improvement.

While some CAMs have sought to engage in clinical-style demonstrations of their efficacy, most have not.[503] This creates a natural division between conventional medicine and CAM in terms of establishing and assessing health outcomes. While some CAM outcomes can be measured, such as the physical and emotional improvements observed in practices like yoga and meditation, the spiritual energy, or metaphysical healing provided by these practices cannot. Much of the modern history of pharmaceutical regulation, described in the previous chapter, has been an evolution in improving the scientific assessment of the claims made by products used for health treatment. The safety, efficacy, and quality (SEQ) standard developed in response to a multitude of "snake oils" being sold at the turn of the century. As a result, belief-based practices become difficult to fit into a scientific model. Ernst is less kind, stating that "alternative medicine is not a field governed by rationality. It is not based on rationality. It is a religion. And because it is a religion, I've come to realize the evidence doesn't matter."[504]

[503] *Cohen, supra* note 481.
[504] *Caulfield, supra* note 453 quoting Ernst at 2560. The Quote goes on "He [Ernst] recognized, he said, that "strong financial pressures govern the science in the area of pharmaceuticals." But he thinks the distorting forces are worse in the world of alternative medicine because, as he says, "a quasi-religious perspective governs, and that is a more powerful force than even money."

Part 2 - Theoretical Beginnings – A Brief History of CAMs

(i) Common Origins

To understand the origins of the beliefs, methods, and theoretical underpinnings of CAMs and how they relate to conventional medicine, itis helpful to look briefly at their historical origins. What has constituted the "dominant health system" has varied extensively in the past, and the subjective belief at the heart of CAM is nothing new. Starting with the roots of Western history, curative systems in both classical Egypt and Greece were the purview of religious institutions calling on hidden powers of healing to supplant physical care. Writing of ancient Egyptians, Guido Majno notes in his text *The Healing Hand: Man, and Wound in the Ancient World,*[505] "there was no clear-cut distinction between so-called rational medicine and magic: drugs and incantations were administered in all possible combinations, and by the same or by different practitioners."[506] Authority for prescribing any form of treatment was derived from the religious authority of practitioners.

Some of the earliest Western records of treatment for illness come from Greek temples where priests assisted patients seeking intervention from the gods. Majno describes the experience of pilgrims who would arrive at the temple of Asklepios to seek healing:

> The ritual would be simple: relax on the holy grounds, take in the beauty of the surroundings, listen to the hymns, and wait for the night. Then each patient would be required to lay down in the sacred hall called the *abaton* (place of no walking) and wait for the god to appear and give advice in a dream. The priest would assist, receive a small gift for the god (perhaps a cake or a votive tablet), and maybe act as guides to the

[505] (First Harvard Press: Cambridge, 1975) hereinafter *Majno.*
[506] *Ibid,* at 125.

> amenities that came with the temple: the baths, the theater. But all the medical gestures would be up to the gods.[507]

Patient testimonies were transcribed on metal plaques, hundreds of which survive. One describes an elderly soldier, Gorgias, who sought out a temple:

> when all else had failed, when the wounds simply refuse to heal, and no *iatros* [local healer] could think of a new and different plaster; when [he] had carried the [illness] in his lungs for a year and a half… and nobody could help him.[508]

For Gorgias, after a night sleeping in the temple and dreaming of a god pulling the illness like an arrow from his lungs, he purportedly walked out of the temple well. We have no proof the treatment worked, but someone believed in the effect of the treatment enough to advertise it upon a plaque at the front of a temple which we can read over 2,000 years later.

These examples illustrate how the foundations of Western medicine are rooted in a religious or spiritual form of belief. Much of the medical literature which remains from the Greek world is heavy on observation and practical technique, but low on methodology or exploration of the actual mechanisms underlying illness. They did not employ scientific methods in the generation of treatment or wisdom around the effectiveness of treatment. Instead, they "accepted for a fact what we would instantly recognize as a hypothesis"[509] and concentrated on abstraction over clinical observation. What modern clinicians would criticize as unsubstantiated inferential reasoning (a hypothesis), Greek medicine took as theoretical or spiritual truth, and seldom sought to test it. This system of medicine reinforced dominant social and religious norms instead of challenging them.

---

[507] *Ibid,* at 203.
[508] *Ibid.*
[509] *Ibid,* at 176

Hippocrates, who both CAM and conventional practitioners claim as the root of their modern practices, advocated a form of holistic medicine based on diet, exercise, and living well. The goal of these health regimens was to balance competing forces/fluids in the body (*chymoi* or the four humours: black bile, phlegm, yellow bile, and blood). For Greek doctors, dissection was forbidden by law and religion, so "the body's hidden workings had to be deduced largely from what went in and what came out... [and] with internal physiology hidden, disease might be conjecturally explained."[510] There are few proponents of pure humoral treatment today, yet "taken as a whole package, Greek humoralism was [a] powerful explanatory framework of health and disease."[511] For a society that could not conduct dissection or had no understanding of bacteria, this system explained observed physical phenomena such as flushed skin, a running nose, sweating, diarrhea, or discoloured urine. It also gave a simple rule of thumb to practitioners: "bleed to get rid of bad humours, starve to prevent new, and purge to get rid of the rest."[512]

In addition to his theoretical framework, Hippocrates laid out a practical regimen to prevent disease and treat the lifestyle of the patient, related to diet, exercise, massage, recuperation after illness, and maintaining hygiene and cleanliness.[513] These simple ministrations alone likely went a long way to promote healing. Hippocrates ascribed most healing to the power

[510] Porter, R., *The Greatest Benefit to Mankind: A Medical History of Humanity* (W.W. Norton & Company: New York, 1999) Kindle Edition a 56, hereinafter *Porter*.
[511] *Ibid*.
[512] *Majno, supra* note 505 at 178.
[513] *Ibid*.

of nature (*vix medicatrix naturae*), that the body's own nature will seek to return to a state of balance:

> the doctrine of the healing power of nature gave rise to two of [his] most important aphorisms: "Natural forces are the healers of disease," and "As to diseases, make a habit of two things – to help, or at least do no harm."[514]

This concept of *vitalism* is one of the cornerstones of many CAM therapies. Hippocrates also advocated "medicine at the bedside [where doctors] waited and watched their patients, talking, winning trust and giving a helping hand to the 'healing power of nature.'"[515] This was again a call to the holistic, observational medicine tailored to the patient.

The call to holistic practice and the balancing of bodily systems has parallels in two much older classical medical traditions: *Traditional Chinese medicine* (TCM)[516] and *Ayurvedic* medicine.[517] These are two of the oldest recorded systems of medicine in the world and have been in continual use for thousands of years.[518] As Ray Porter in *The Greatest Benefit to Mankind: A Medical History of Humanity*[519] notes, these ancient forms of medicine were a complexly interwoven set of teachings where:

> Health depends on the preservation of harmony within the body, and harmony between the body, the environment and the larger order of things. Healing is a question of knowing how harmony can be restored; and the task of the physician is as much philosophical as technical.[520]

---

[514] Bynum, W., *The History of Medicine: A Very Short Induction* (Oxford University Press, Oxford, 2008) hereinafter Bynum at 442.
[515] *Porter, supra* note 510 at 1167.
[516] *WHO TCM, supra* note 447.
[517] *WHO Ayurveda*, supra note 446.
[518] *Bivins, supra* note 479.
[519] *Porter, supra* note 510.
[520] *Ibid,* at 2859.

There is a focus on balancing the physical body, mind, and spirit. A very simplified explanation of TCM would be that the body is seeking to balance its internal energies (*qi*) and the balancing of opposing forces *yin* (external) and *yang* (internal). TCM has a highly developed collection of herbal practices.[521] Ayurvedic medicine is similarly based upon the concept of balancing vital energies, classically the three bodily humours or *disas*: wind, bile, and phlegm. Ayurvedic medicine was also "a code of life and consisted of practical advice concerning all aspects of life, from washing to diet… [for] maintenance of the balance of the soul."[522] Both TCM and Ayurvedic medicine were codified in texts that include extensive herbal and practice guidelines for making medicines.

Much of what we know about classical Western medicine comes from the Roman writer Galen (129-219). He worked first as a ringside triage medic treating gladiators, and later as physician to the emperor Marcus Aurelius in the second century AD. Galen was a prodigious writer[523] and provided extensive guidance for treating ailments, especially acute physical traumas. He believed in clinical experience and a very rudimentary form of experimental anatomy using animals as a proxy since human dissection was illegal. To Galen, Hippocratic medicine should be "set within a wider anatomo-physiological framework, [and] that anatomy, logic and experience fitted together."[524] As Porter notes, Galen created a new system based on observation where:

> Gross anatomy and experiments offered paths to understanding, but Galen did not restrict himself to sensory perceptions. By combining his observations with Platonic speculations about the macrocosm at large, he formulated models of concealed bodily structures. Each

[521] *WHO TCM, supra* note 447.
[522] *Porter, supra* note 510.
[523] Over 350 existing texts exist with themes from the philosophical to stitching wounds. *Ibid* and *Bynum, supra* note 514.
[524] *Porter, supra* note 510 at 1515.

> part functioned only when its basic elements were properly adapted, and any change would result in functional failure or disease. The unknown was thereby explained in terms of a structural/functional physiology.[525]

Galen's system had a symmetry and a logic and provided guidance for many treatments, but it was also patently wrong in its anatomical speculation.[526] Yet, Galen's ministrations and projective physiology served as the basis of most medical treatment in the West for the next 1,700 years.

Another classical source, Dioscorides (40-90 AD), tried to capture the known details of the herbal treatment of disease.[527] Dioscorides was a Roman military doctor who had travelled extensively throughout the Empire gathering details on herbs and other remedies. In his *De Materia Medica*[528] he described the characteristics of each plant, its habitat, and its use in treatment. As one article notes:

> The five volumes of *De materia medica* include 827 items: 651 plants and plant products, 87 animal products and 89 minerals. The text is written in a consistent and orderly fashion with plants grouped by type and by action. For each entry, the name(s), botanical description and sources, therapeutic usage, medicinal preparations and warnings are given.[529]

This text stayed in print throughout the Middle Ages and forms the basis of the "creation narrative" of herbal medicine.[530] It would become doctrinal and form the basis of most pharmacological healing in Europe for the next 1,500 years.

---

[525] *Majno, supra* note 505 at 178.
[526] *Bynum, supra* note 514.
[527] Francia, S. and Stobart, A., *Critical Approaches to the History of Western Herbal Medicine: From Classical Antiquity to the Early Modern Period* (Bloomsbury Academics: London, 2014). Pedanius, D. (Dioscorides), *De Materia Medica*, see a Medieval version by Laguna, Andres, *Acerca de la materia medicinal y de los venenos mortiferos*, (Jean Laet: Antwerp, 1555), online at the Library of Congress: online at https://www.loc.gov/item/2021666851/
[528] *Ibid.*
[529] *Ibid,* Chapter 10.
[530] *Ibid.*

(ii) The Obscure Middle Ages

In the West, for much of the Middle Ages, theories of medicine and treatment become difficult to track. The various written records we do have, from Byzantine, Western monastic, and Jewish sources, across "widely separated geographical and cultural milieus all shared one characteristic: a veneration of the medical wisdom of the Greeks, and a desire to base their own medical theories and practices on these ancient precepts."[531] From Greek medicine, three core principles became doctrine: the humoral system, a basis in herbal treatments, and a belief in the intercession of spiritual (or unseen) forces.[532] For most Europeans, medical treatment became a very local matter intertwined with mysticism and the Christian Church. Christian teachings saw illness as an extension of spiritual ills, and healing mediated by intercession of the Divine.[533]

A gift of Islamic medicine in the 9th to 12th centuries was an evolving discourse, both written and transferred through a series of educational institutions, around treatment and the gathering and ordering of existing texts. Eventually this led to the establishment of formal training centres of *Unani* medicine which became part of established universities.[534] Scholars such as Rhazes (8th C), Avicenna (10th C), and Averros (12th C) mixed theology, philosophy, Greek theory, and observed practice to generate a more detailed compendia of known medicine and new knowledge.

---

[531] *Bynum, supra* note 514 at 521.
[532] *Ibid.*
[533] *Ibid.*
[534] *Ibid.*

Figure 9: Early Islamic Copy of De Materia Medica[535]

This included some of the first and most complete compendia of herbal and other remedies. As Porter notes, these pharmacopeias contained a wide variety of synthesized knowledge:

> The medical formulary of al-Kindi (*Yaqub ibn-Ishaq al-Kindi*, c. 800–870) served as a source for Arabic treatises on pharmacology, botany, zoology and mineralogy. Ibn al-Baytar (d. 1248) astonishingly listed over 3,000 items, including 800 botanical drugs, 145 mineral drugs, and 130 animal drugs. His writings contained many Persian, Indian or Oriental drugs unknown to the Greeks. Al-Biruni described more than a thousand samples in his *Kitab al-Saydanah fi al Tibb* [Book of Pharmacy in the Healing Art]. The *Minhaj al-Dukkan wa Dustur al-'yan* [Handbook for the Apothecary Shop], written in Cairo in 1259 …. included drug synonyms, recipes for syrups, remedies to aid digestion, fumigations and liniments and pharmaceutical weights – and also covered the duties and shop practices of the pharmacist.[536]

It is not surprising that the first recorded pharmacies (apothecaries) and professional guilds for training standard methods of compounding were in Baghdad in the 9th century.

[535] A Folio from a 13th century Islamic copy of the *De Materia Medica*, Metropolitan museum of Art, online at: https://theherbalacademy.com/de-materia-medica/
[536] *Porter, supra note* 510 at 1968.

(iii) The Emergence of Conventional Medicine

Systems of medicine began to emerge in Europe between the 11th and 13th centuries with the establishment of universities, starting first in Italy (Salerno, Bologna) and Spain (Seville, Salamanca), that focused on translating Arabic and Greek texts.[537] Mirroring Islamic universities and closely tied to the Church, the initial training that developed is what Bynum[538] calls:

> library medicine [where] the teaching was initially based [strictly] on texts, of classical and Islamic authors, and disputation rather than practical training or experiment was the key.[539]

Early European medicine was highly doctrinal, inferential, and untested. Associated with these universities was the emergence of hospitals, first as religious institutions to treat the poor, and then as more secular training centres. In the 11th century, universities began the stratification of professional practice; those individuals granted degrees were now formally doctors with a claim to expertise.[540]

In the 13th century, starting in Paris, universities began a form of observational and practical medicine that sought to catalogue clinical phenomena as well as reconcile doctrinal ideas from classical medicine.[541] Over the next several hundred years, there evolved a rudimentary observational medicine. For instance, *The Grand Surgery* (1280)[542] is divided

> into sections on general principles, and on anatomy, embryology, ulcers, fistulas, fractures, baldness and skin diseases, phlebotomy and scarification, cautery and diseases of various organs. There is also a lengthy section on herbs and pharmacy.[543]

---

[537] *Bynum, supra* note 514.
[538] *Ibid.*
[539] *Ibid* at 620.
[540] *Porter, supra* note 510.
[541] *Ibid.*
[542] Lanfranc of Milan, *Chirurgia Magna* (1280), as sited in *Porter, supra* note 514 at 2232.
[543] *Porter, supra* note 510 at 2234.

Guy de Cahuliac's *Chiurgia Magna* (1363)[544] was a compendium covering "anatomy, inflammation, wounds, ulcers, fractures, dislocations and miscellaneous diseases…[with] 3,299 references to other works, including 890 quotations from Galen."[545] These works were not only compendia they also added new practices and even challenged doctrinally based library medicine. Starting in Italy, urban areas began to register public physicians (*medici condotti*) who provided commercial or civically sanctioned services outside the university. By the mid-1500s, civic doctors were being appointed in most of northern Europe.[546]

Universities and the expansion of practice led to the development of new forms of medical knowledge. The development of anatomy, starting in Italy with the first public dissection in Bologna in 1315,[547] led to direct challenges to the Galenic explanations of physiological function. Increasingly, doctors were asked to assess "not only the cause of the illness but all aspects of the patient."[548] Vesalius began to dissect human cadavers and disprove the anatomy of Galen.[549] Paracelsus (1493-1541) began to expound the idea that medicine should be based on observation, specifically that the effect of treatment should be clinically validated by observing body chemistry.[550] Thomas Sydenham (1624-89)[551] believed that treatment and disease should be systematically classified by describing diseases, remedies, and

[544] Guy De Chauliac, *Chirurgia magna (1363)* as sited in *Porter, supra* note 510 at 2232.
[545] *Porter, supra* note 510 at 2246.
[546] *Ibid.*
[547] *Ibid.*
[548] *Ibid.*
[549] Zampieir, F., El Maghawry, M., Zanatta, A., Thiene, G., "Andrea Vesalius: Celebrating 500 Years of Dissecting Nature" (2015) *Global Cardiology Science Practice* 66, online at: https://www.ncbi.nlm.nih.gov.
[550] Stillman, J. M., "Paracelsus as A Reformer in Medicine" (1919) *The Monist* 29(2) at 526, online at: https://www.jstor.org/stable/27900766.
[551] Sloan, A. W., "Thomas Sydenham, 1624-1689" (1987) *S Afr Med J* 72(4) (PUBMED).

outcomes, and that only after "correctly diagnosing a disease [should] remedies be empirically sought."[552]

Pharmacology also underwent a renaissance. First, scholars sought to translate and capture all the ancient compendia and integrate pharmacology with what was learned in the Arabic world, and then they sought to append their own observations.[553] Teachings that had until then relied upon classical descriptions of herbs, or "leaves, seeds, fruits, bark, roots of plants, shrubs and trees"[554] emerged into a new study of botany that strived to catalogue all plants and their potential healing properties in exacting detail. A series of lavishly illustrated texts followed, which sought to accurately capture the origin, appearance, properties, and uses of known plants. Added to these were plants and remedies that began to arrive from the New World, completely unknown to the ancients.[555]

Figure 10: Folio from P. Mattioli's Lavishly Updated Materia Medica (1565)[556]

[552] *Bynum, supra* note 514 at 738.
[553] *Ibid.*
[554] *Porter, supra* note 510 at 2246.
[555] *Ibid.*
[556] Online at https://philaprintshop.com, visited May 20, 2022.

These records and an increase in the available medicines led to the first organized professional associations of apothecaries: *The Masters, Wardens, and Society of the Arts and Mystery of the Apothecaries of the City of London* in 1607. It also led to a systematization of the acceptable treatments for certain diseases.[557]

With the emergence of large-scale hospitals, first in France in the 1700s, there began to develop a core of practice based on clinical observation and outcome. As Bynum has noted, what emerged was a medical practice where "[n]o theory and much practice were the orders of the day."[558] This system was based on three pillars: "physical diagnosis, pathologic-clinical correlation, and the use of large numbers of cases to elucidate diagnostic categories and to evaluate therapy."[559] That said, most medicine as practiced by doctors at the time remained fairly brutal and ineffective. It was reliant on ancient precepts of purging and prescribing herbal remedies, often removed from concepts such as sterilizing instruments, tracking a patient's progress or standardizing practice. Seeing a doctor at the time was expensive, and often left the patient worse off than before treatment.[560]

(iv) The Emergence of Modern CAM

The changes that gave birth to modern alternative medicine were rooted in a reaction to "trends in medical thought and practice, as well as in the broader culture."[561] Alternative

[557] *Bynum, supra* note 514 at 738
[558] *Ibid*, at 826.
[559] *Ibid,* at 838.
[560] *Quackery, supra* note 180.
[561] *Whorton, supra* note 472 at 25.

practitioners saw much of the emerging field of medical practice as ineffective and harmful to patients.[562] In opposition, there arose a class of health practitioners who sought to place holism and the powers of the human body at the centre of treatment. This rejection of conventional medicine also had its roots in a pushback against the decoupling of mind and body by emerging Enlightenment medicine.[563] CAM practitioners sought a holistic link between mind and body, developed practices based on limited or subjective observations of health, and rejected clinical or experimental assessment of treatments.[564] They sought a link between the spiritual and physical.

One of the early North American practitioners of this new model of holistic therapies was Samuel Thomson (1769-1843). Thomson was an "unlettered man whose common sense told him physicians were incompetent and who learned what he believed to be the effective way to cure through personal observations and practical trials."[565] Based on his observations of the emetic qualities of the herb *lobelia*, noting that it causes nausea and violent vomiting in fellow farmhands, he developed a system of herbal medicine. Thomsonianism put forward that the body was like a furnace and vital body heat needed to be regularly released, like a valve on a furnace, using purgatives. These treatments were not far from the expensive purgative treatments provided by most doctors of the day. Two other core tenets of Thomsonianism were that patients could heal themselves and that all cures could be found in nature. For his adherents, healing could be achieved primarily by taking his tonic, mostly made up of lobelia extract and going through the regular, painful process of purging their bowels and stomach.

---

[562] *Ibid*.
[563] *Ibid*.
[564] *Ibid*
[565] *Ibid* at 28.

Thompson's system was a popular success because it was marketed as a natural alternative to the medicine of the time and because he was able to develop products which could be sold directly to the consumer. Thomsonianism treatment:

> was a continuation, on a higher plane, of the domestic medicine, or folk practice and self-care, historically used by people for whom professional medicine was inaccessible or too expensive or mistrusted. Its simple theory seemed reasonable to the farmer and mechanic; its straightforward therapy clearly accomplished what theory said it should. A man could feel his innards being scrubbed by lobelia and could hardly doubt after a cayenne enema that heat had been added to his body.[566]

Thomson expanded his popular natural medicine with an effective marketing scheme that recruited local "agents" to speak on the merit of his tonic, sell products, and recruit new agents.[567] The popularity of his product was aided by the fact that much of medicine at the time still relied upon the purgatives prescribed by Galen, so his treatment was similar and cheaper than that offered by most doctors.

Another popular modern alternative practice, homeopathy, developed in the 1880s as a European reaction to the limits and reasoning around existing medicine.[568] In Germany, Samuel Hahnemann observed that if he took a cure for malaria -- cinchona bark, which contains *quinine* -- while healthy, he developed many of the symptoms of malaria. Putting aside whether he was experiencing a self-induced drug overdose, Hahnemann reasoned that taking products that produced symptoms similar to ailments was a form of inoculation. Contrary to medicine which sought to treat the disease by eliminating symptoms, homeopathy produced symptoms "based on

---

[566] *Ibid*, at 42.
[567] *Ibid*. Arguably the first recorded case of a multi-level marketing (MLM) scheme recorded in the United States.
[568] Loudon, Irvine, "A Brief History of Homeopathy" (2006) *J R Soc Med* 99(12) at 607, online at: https://www.ncbi.nlm.nih.gov.

the administration of [toxic] remedies that produced effects similar to those of disease."[569] Hahnemann recruited several hundred healthy patients who voluntarily underwent his treatment and recorded their perceived reactions. From these subjective reports, he then developed a program of treatment that sought to provide patients with a variety of noxious substances to prophylactically produce negative effects.[570] A further refinement was made after he discovered that his treatments were, unsurprisingly, making his patients ill or killing them; he began diluting the noxious substances to trace amounts. Following these treatments, adherents continued to self-report that they stayed healthy.

The theory underlying homeopathy is that this observed effect, as attested by patients, was the result of some medium other than matter.[571] How else could Hahnemann account for patients continuing to observe positive health effects when the products (and their noxious components) were so diluted? His conclusion was that the "body was endowed with life and that its physiological functioning was governed by a non-material vital force or vital spirit… that operated beyond the realm of chemistry and physics."[572] Treatments served to balance or maintain this vital spirit and could displace the negative effects of disease.

In 1810, Hahnemann consolidated his ideas into *Organon der Rationelle Halkunde* (Origin of Homeopathic Medicine),[573] and a European lecture tour. His treatment was a popular hit among the aristocracy (serving as a favourite of the British Royal Family) and the public.

---

[569] *Whorton, supra* note 472.
[570] *Ibid*.
[571] *Ibid.*
[572] *Ibid, at 58*.
[573] Hahnemann, S., *Organon Der Rationellen Heilkunde*, (Arnoldischen Buchhandlung: Dresden,1810), online at Interactive Archive, https://archive.org , visited June 7, 2022.

Again, a large portion of Hahnemann's appeal was based in his rejection of conventional medicine and rooting his treatments in popular sentiment. By the time of his death in 1843, his system of medicine was widespread across Europe and accepted as part of conventional medicine. It jumped to North America with the establishment of the *Homeopathic Medical College of Philadelphia* in 1848. For the next 50 years, there were more schools of homeopathic medicine in North America than of conventional medicine.[574]

Both Thomsonianism and homeopathy manifest some of the common characteristics of CAM systems of treatment. They were both based on subjective experience and inferential logic. They linked themselves to the restorative powers of nature and the innate vital forces of the body. They saw themselves as more holistic and balanced in treatment than conventional medicine. They were also based on systems of belief that could not be tested. As was noted by one author, these early CAM practices were "intellectually coherent with and practically responsive to the cultures in which they were developed."[575] Homeopathy and Thompson's naturalism proved widely popular in the 19th century. These approaches were less interventional than conventional medicine at the time, allowing for accessible self-care and reflected beliefs of the larger culture, which was still highly religious and rural. This raises the question of whether at the time these may have represented a more conventional form of practice than doctor-provided medical care.

Other common forms of alternative medicine began to emerge around the same time. **Osteopathy** developed in the 1870s based on a belief that interventional pharmaceutical modes

[574] *Whorton, supra* note 472 at 25.
[575] WHO 2019, *supra* note 440.

of treatment should be rejected in favour of manual manipulation of the body to bring its natural healing properties back into alignment.[576] A different form of manipulation therapy, **chiropractic medicine,** developed in the 1880s, was also based on concepts of balancing the body's "tone or degree of vigour, tension, activity and strength."[577] **Naturopathy** was established in the 1890s as a form of returning to the "nature-intended mode of life"[578] through diet, lifestyle, a reliance on herbal remedies, and focusing on removing physical impurities from the body.

At the start of the 20th century, the medical profession began to lean heavily upon professionalization, experiment, and peer review to validate practice. Professional associations began to develop with the intent of regulating the practice of medicine in the U.K., U.S., and Canada.[579] Similarly, medical universities -- or medical schools in universities -- began to be established in the U.K., U.S., and Canada to provide training in a standard curriculum of knowledge and skills to new physicians. Professional associations regulating the professions of pharmacists and medical chemists began to emerge. New sciences to assess the process of therapeutic treatments began to arise, standardizing surgery, public health, differential diagnosis, epidemiology, and pathology. The early-1900 identification of the root of much disease and new measures to deal with diseases like typhoid, polio, and dysentery led to a resurgent faith in conventional medicine.[580] As was described in the last chapter, new systems of testing and ensuring the quality and safety of drugs began to emerge.

---

[576] *Whorton, supra* note 472 at 147.
[577] *Ibid,* at 169.
[578] *Ibid,* at 194.
[579] *Porter, supra* note 510.
[580] *Bynum, supra* note 514.

Organized medicine also began an assault on all forms of non-empirically based care. The medical profession ascribed the right to a higher moral ground to conventional medical reasoning because it was based on science. As Whorton notes, beginning in the early 1900s:

> the medical profession assiduously cultivated the image of the new doctor as a highly educated, critical-thinking scientist with lifesaving powers, an enlightened physician who had no truck with the ignorance and superstition of a former time.[581]

Conventional medicine began to make a clear distinction between its practices and those of "alternative" medicines. This was aligned with increasing state involvement in the regulation of treatments and the licensing of professional associations.[582] Conventional medicine began to mandate clinical training and licensing to ensure that practicing doctors had the same base of knowledge and were applying similar practice guidelines in care.[583] Laws tended to favour standardization and uniform practice, aligning themselves with the agenda of medical associations. Access to hospitals was also aligned with the medical professionals licensed by professional associations.[584]

While conventional medicine was expanding its legitimacy and authority through the early 19th century, the CAM community continued to rely upon individual experience and non-empirically tested practice.[585] Conventional medicine sought to debunk many of the foundational theories of CAMs and their value as therapies, arguing that they were unfounded. The 1932 text *The Healing Cults,*[586] published by the *Committee on the Cost of Medicare*, took direct aim at the

---

[581] *Whorton, supra* 472 page 222.
[582] *Ibid, at Chapter 10: From Medical Cultism to Alternative Medicine* at 221.
[583] *Ibid.*
[584] *Ibid.*
[585] *Ibid.*
[586] Reed, L. S. *The Healing Cults; a Study of Sectarian Medical Practice: its Extent, Causes, and Control* (Committee on the Cost of Medical Care - University of Chicago Press: Chicago, 1932).

"cultish practices" of many CAM practices. The critique was that most CAMs were perpetuated by "narrow and simple-minded believers in the all-encompassing truths of their healing revelation…clinging to beliefs with a fervor more characteristic of an evangelist than a scientific group."[587] The emergence of regulatory regimes designed to dissuade "snake oils" and adulteration described in the last chapter was led by concerned medical practitioners armed with the new tools of chemistry and scientific testing for SEQ. The impact of these efforts was profound, with a loss of public faith in most forms of CAM. As Whorton notes, in the U.S. context, "while there were twenty-two homeopathic schools at the beginning of the 19th century, only two were left by 1930."[588] In response, much of CAM practice scrambled to catch up to conventional medicine, by establishing professional associations and developing more standardized and clinically assessed practices.[589] Yet, for much of the 20th century, CAM was largely a niche market.

(v) The Resurgence of CAM

Much of this changed with the counter-culture movement of the 1960s. CAM practitioners were suspicious of conventional medicine and argued that it was pushing "every form of suffering… into its narrow biomedical construct of disease [and] ignoring the human facet of illness."[590] They argued that medicine had developed in such a way as to ignore the needs of the patient. Medicine had lost the thread of spirituality, vitalism, and holistic healing

[587] *Whorton, supra* note 472 at page 221.
[588] *Ibid*, at 222.
[589] Notably other Osteopathy and Chiropractic practitioners sought to ground much of their practice in standardized clinical practices, *Ibid*.
[590] *Whorton, supra* note 472.

that was at the root of patient-centred healing. CAM practices appealed to the public because of "an understanding of human beings as organisms whose mental, emotional, and spiritual powers were fully integrated with and affected the function of their bodies."[591]They were critical of medicine for failing to communicate with patients, separating the "mind" from the body, and of the way that the specialization of many medical practitioners led them to treat their patients with indifference.[592] CAM practitioners were also critical of an increased "fragmentation of care resulting from medical specialization."[593]

This was followed by an emergent cultural criticism of the norms of medicine as a system of control. Michel Foucault's *The Birth of the Clinic*[594] criticized medicine as a system of standardization and social control using clinical knowledge. Rick Carlson's *The End of Medicine*[595] argued that conventional medicine had begun to treat patients indifferently as machines without feelings, minds, and spirits. The book *One Flew over the Cuckoo's Nest*,[596] and the widely successful movie[597] which followed, argued that modern institutional psychiatry was an attempt to segregate the reasoned person from society. At the same time, counter-culture began to popularize traditional practices that had existed for millennia such as yoga, acupuncture, energy healing, and meditation.[598] The new holistic medicine adopted the earlier

[591] *Micozzi, supra* note 420.
[592] *Ibid*.
[593] *Whorton, supra* not 472 at 248.
[594] Foucault, M., *The Birth of the Clinic: An Archeology of Medical Perception* (Vintage: Toronto, reprint 1994).
[595] Carlson, R. J., *The End of Medicine* (Wiley: New York, 1975) Internet Archive, online at: https://archive.org/details/endofmedicine00carl.
[596] Kesey, K., *One Few over the Cuckoo's Nest* (Viking Press: New York, 1963).
[597] Forman, M., *One Few over the Cuckoo's Nest* (1975) United Artist.
[598] Knoll, A. M., "The Reawakening of Complementary and Alternative Medicine at the Turn of the Twenty-First Century: Filling the Void in Conventional Biomedicine" *J of Contemporary Health Law & Policy* 20(2) at 329.

lessons of Thompson by appealing to the public's sensibilities and making treatments seem approachable.

In the 1990s, a detente between practitioners of CAM and conventional medicine started to emerge. There was a recognition by conventional medicine that for many types of treatment, particularly for those patients with long-term or terminal illness, alternative forms of therapy could support conventional treatments.[599] This led to the "complementary" concept extending conventional medicines to include many CAM practices. Increasingly, clinical practice sought to blend the two types of treatment into a more long-term holistic form of treatment. Since the beginning of the 21st century, this has evolved into a concept of integrative medicine that sees CAM and conventional medicine as joint sides of treatment.[600] There has been an explosion in demand and use of CAMs, especially CAM products. As will be discussed in the next chapter, this has left regulators of health products scrambling to find ways to ensure these products can be accessed in a manner that is safe, efficacious, and ensures quality.

Cooter[601] argues that populism has paired with commercialization in the development of an emergent wellness industry in the United States, Europe, and Canada. Whorton suggests that this represents the shift into a "holistic hodgepodge"[602] form of alternative medicine, with newer concepts of spiritualism being blended with ideas around vitalism, holism, and existing CAM therapies. What emerges is a commercialized and popular form of alternative medicine removed

[599] Zollman, C. and Vickers, A., "What is Complementary Medicine?" (1999) *BMJ* 319(7211) at 693.
[600] Rosenbaum, C. C., "The History of Complementary and Alternative Medicine in the US" (2007) *Annals of Pharmacotherapy* 41(7-8).
[601] Eds., *Studies in the History of Alternative Medicine* (Macmillan Press: Oxford, 1988)
[602] Whorton, supra note 472 at 280.

from any pretence to empiricism and often ignoring the nuances of older, traditional forms of CAM.[603] Comparing it to treatments and drugs that were debunked at the turn of the century with the emergence of the SEQ standards discussed in Chapter 1, Whorton goes on to state that:

> much that passed itself off as alternative medicine …. [is] no better than eighteenth-century science. The benevolent aura of holism translated into market appeal, and the proponents of any would-be scheme of healing, no matter how far-fetched or hare-brained, were certain to label their practice "holistic."[604]

The result has been an explosion of new CAM therapies and treatments that "intermingled the sound with the spurious, the down-to-earth with the extra-terrestrial."[605] Many of these practices not only rejected empirical or clinical modes of validation, but outright rejected the legitimacy of conventional medicine.

More recently, much of this has morphed into a billion-dollar wellness industry.[606] Fariha Roisin in her 2022 text *Who is Wellness For,* [607]argues that much of this new wave of CAM is a form of cultural appropriation, where traditional practice and "thought in a modern context has been coopted to serve Western minds and egos."[608] This wave has created a host of new therapies, practices, and products that are based on older paradigms but that distort or fetishize the underlying reasoning and purpose of the original treatments. Others argue that what has developed is a crass form of commercialization of alternative medicine for profit.[609] In his scathing critique *McMindfulness: How Mindfulness Became New Capitalist Spirituality,* [610]

---

[603] *Ibid,* at 282.
[604] *Ibid*.
[605] *Ibid*.
[606] Caulfield, T., *The Science of Celebrity* (Penguin: Toronto, 2015), Kindle Edition, hereinafter *Sci Celb*.
[607] Roisin, F, *Who is Wellness For? An Examination of Wellness Culture and Who It Leaves Behind* (Harper Wave: New York, 2022), hereinafter Roisin.
[608] *Ibid*, at 42.
[609] *Sci Celb, supra* note 606 and *Caulfield, supra* note 457.
[610] (Repeater: 2019) Kindle Edition.

Ronald E. Purser claims that the massive wellness industry, in particular that part related to mindfulness, has been co-opted as a form of self-rationalizing neo-conservative religion.

Part 3 – Regulatory and Ethical Issues Associated with CAMs

In the next section I will discuss some of the regulatory, ethical, and legal issues that arise when it comes to considering how regulators deal with CAMs. I will primarily be concerned with the challenges that are created in applying traditional SEQ standards to CAMs. There is a paucity of academic literature in this area, as most legal research on CAMs has focused on the liability of practitioners[611] or flaws in existing regulatory systems related to CAMs in other jurisdictions.[612] This literature is representative of a polarity between those who are critical of an overly burdensome regulatory regime for new CAM products[613] and those who are highly critical of the lack of scientific rigour imposed by regulators on these products.[614] This rejection of science and clinical standards of proof can create specific legal and policy problems for CAM regulators. On one side, regulators are seeking to impose better standards of proof around these products and discourage unsubstantiated health claims. On the other side, any regulatory system will have to be designed in such a way as to not curtail reasonable access to products that are desired based on belief systems (including personal, traditional, and new practices based on an emergent system of beliefs). There is a very fine line that needs to be walked in this context, between ensuring that a regulatory system has a purposeful impact on SEQ based in empiricism, and

[611] *Jesson, supra* note 434.
[612] *Kaan, supra* note 432.
[613] *Micozzi, supra* note 420.
[614] *Ernst, supra* note 418 and *Ernst Maze, supra* note 492.

allowing for products that are generally benign in nature to be used by those who choose to do so.

Building on the work started by the WHO,[615] around the turn of the century a series of countries began to struggle with the issue of how to regulate the exploding market for CAM products. This process started with a report by the National Centre for Complementary and Integrative Health in the U.S. in 1995 with the *Workshop on the Regulations of Herbal Medicines: A Report*.[616] In 1997 a Canadian Parliamentary committee was asked by the Minister of Health to begin looking at the development of a legislative and regulatory system for CAM products.[617] In the U.K. the House of Lords Science and Technology Committee (1999-2000) began looking at "whether good structures of regulation to protect the public are in place."[618] In the EU the Commission issued a *Green Paper on the Promotion of Herbal Medicinal Products* (2001).[619] A similar *White House Commission on Complementary and Alternative Medicine* was established in 2000 to "develop legislative and administrative recommendations that would help public policy maximize potential benefits to consumers and American health care of complementary and alternative medicine (CAM) therapies." Similar investigations were undertaken by legislators in Japan, Brazil, New Zealand, Ireland, China, India, South Africa, Brazil and many others.[620]

---

[615] *WHO 2002-2005, supra* note 421.
[616] National Centre for Complementary and Integrative Health in the U.S. in 1995
[617] The Standing Committee on Health received a letter form Allan Rock on November 13, 1997. The report that was produced *Natural Health Products: A New Vision: Report of the Standing Committee on Health, infra* note 713, was shared with the Minister of Health in November of 1998.
[618] The final report was published 1999
[619] *Green Paper on the Promotion of Herbal Medicinal Products* (2001).
[620] *White House Commission on Complementary and Alternative Medicine* was established in 2000.

(i) Threshold Policy Questions

Most of the government reports struggled with similar concerns. A primary question was whether to regulate these products at all and, if so, at what level of regulatory intervention. Generally, it was agreed that better regulation was necessary to protect the public and expand the knowledge base on the utility of these products. Regulatory systems, where they existed, were not specifically tailored to CAM products or had been licensed under older systems based solely on a history of use. Jurisdictions tended to agree that traditional practices should be recognized and validated but also placed under some form of regulatory regime. The reports attempted to position these products along an existing continuum between foods (a registration system) and conventional drugs (an *a priori* review of clinical evidence). Foods, typically based on established international standards in the *Codex Alimentarius*, were subject to mostly post-market inspection regimes. Conventional drugs, to varying degrees across jurisdictions, adhered to pre-market assessments of safety, efficacy, and quality. It was generally agreed that CAM products should fall somewhere on a continuum between these two points. Safety and efficacy should consider existing traditional practices and established histories of use, but also needed to assess, where possible, the efficacy of new products and restrict intrinsically harmful products from licensing. Quality, where possible, should not be varied or reduced simply because these products were CAMs unless explicitly related to a traditional compounding process.

(ii) Specific Issue: Defining the Products to Be Regulated

A second policy question relates to which activities should be regulated and which specific types of products would be subject to regulation. Both food and drug licensees engage in a wide host of activities, from manufacturing to processing, importing, exporting, handling, marketing, and storing products. In the case of drugs, the SEQ standards are prescribed in regulation and include comprehensive processes for establishment of safety, product testing, and monitoring manufacturing processes to ensure product purity and no adulteration. For foods, many of the standards are based on common processes established by industry with comprehensive composition standards to ensure purity and a lack of adulteration. Different jurisdictions proposed different approaches to this problem, but all have attempted to capture the scope of regulated CAM products based on two criteria: (i) a function, or claim-based criteria (what the product is purported to do), and (ii) the substance or nature of the product (whether it originates from nature or is synthetic). Generally, these products have also been considered as suitable for safe consumption without a practitioner, implying that they are not complicated to use, can be self-administered, and can be consumed safely *ad libidum* (at the user's discretion).

Most of the jurisdictions recognized the need to integrate CAM better into conventional systems, which reflects the perspective of the WHO that such integration is crucial to "build[ing] sustainable and culturally sensitive primary care."[621] However, regulators must walk a very difficult policy line between conventional medicine and CAM advocates who may have different views on the purpose of the regulation. Conventional medicine is likely to advocate for the

[621] *WHO 2014-2023, supra* note 424.

validation of health claims based on evidence, with regulations intended to inform consumer choice about the efficacy of products. Conversely, CAM producers and practitioners may seek validation of their practices and methods through regulation, with a desire for recognition and legitimacy like that of conventional medicine.

Deciding the scope of products to be regulated is the threshold question. In most cases, these regulatory systems restrict the substances included in the definition to a very limited range of herbal or naturally occurring substances, as well as limiting the types of claims allowed. Clear delineations are made between existing regulatory pathways for foods, drugs, and devices, cosmetics, etc. and any new regulatory pathway for CAM products. If the criteria of what is being regulated is not clear, there is a risk of confusion and overlap between product categories (i.e., CAM-food products) or a regulatory category with an ever-expanding scope.

(iii) Specific Issue: Traditional versus New

Keeping in line with the WHO's goals, regulators must also show sensitivity towards the traditional belief systems of various CAM practitioners. In cases where products are not inherently harmful, this means allowing for the continuation of traditional beliefs and practices, whether indigenous or new to a jurisdiction, as well as respecting valid emerging belief systems based on these traditions. At its most basic, this requires some recognition of traditional practices and potentially carving out how SEQ will be applied for these products. This will likely include respecting traditional sources of evidence, but some system will need to be put in place to validate which sources will be allowed (usually traditional pharmacopeias) and how this will be translated

into required evidence for SEQ. Similarly, regulators should be sensitive to the extent that new forms of CAM can appropriate traditional practices and products from indigenous practitioners.[622]

The regulation of new products making new claims is more complicated. Lacking any historical demonstration of safe use, regulators have to decide where to set the bar for SEQ for these products. Since these systems have less of a claim as a cultural or historical practice, they should be treated with greater scrutiny. Many of these systems will be based on beliefs or lifestyle choices, but they do not have the same evidential or policy weight as traditional forms of CAM. The systems put in place for new products cannot mirror that of traditional products, especially when it relates to efficacy or a history of use, because that data does not exist. New or varied sources demonstrating safety and efficacy will have to be established. Differentiating between traditional and new can be difficult. If the product lacks a cultural history or a history of use then evidential standards for safety and efficacy should be higher, until an established pattern of safe use can be observed. It is problematic to license products with no reliable evidence on SEQ.

(iv) Specific Issues: Quality

There are genuine concerns related the quality of CAM products. In 2014 Wardell[623] outlined many of these concerns, and more recently in 2020, Lamb[624] completed a systematic review of CAM issues related to quality. CAM products are particularly susceptible to poor manufacturing.

---

[622] *Roisin, supra* note 607.

[623] Wardel, J. and Adams, J., "Indirect and Non-Indirect Risk Associated with Complementary and Alternative Medicine Use: An Integrative Review" (2014) *European Journal of Integrative Medicine* 6 at 409, hereinafter Wardel.

[624] *Lamb, supra* note 755.

This can include contamination or adulteration with other substances, poor chemical stability of CAM products leading to degradation, and low bio-availability due to products being insoluble in water. Additionally, there is a high degree of variability between different product batches. In the case of botanical or herbal remedies, the "content of active compounds may vary, which could be dependent on season, climate, temperature, humidity, soil, storage condition and other factors."[625] There can also be issues associated with the products themselves, such as capsules rupturing, poor expedient use, and incorrect use of medicinal ingredients. In Canada, CAM products, NHPs, have consistently been found to be adulterated and of low purity.[626] This adulteration has included being laced with substances not listed on the label, incorrect dosage forms, and even the inclusion of unlicensed pharmaceutical substances.[627]

As previously mentioned, the starting point for any type of CAM regulation is the demonstration of quality. I believe that it is important to ensure that CAM products meet the same quality standards as similar consumer products. It is crucial to ensure that these products are not adulterated with harmful substances and that they are what they represent themselves to be, to make any claims of efficacy or safety meaningful. The quality standard for CAMs should be at least equal to that for foods, but likely higher, to protect the public. Food and drug law establishes detailed criteria for what can and cannot be included in a food product, which producers are largely left to implement. On the other hand, drug laws prescribe detailed rules *a priori* to ensure that manufacturing processes, packaging, and handling meet applicable standards. There is an ideal place between food and drug manufacturing standards for CAM products. If there is not a heavy *a*

[625] *Ibid.*
[626] *Ibid.*
[627] *Ibid.*

priori review of SEQ, as is the case for drugs, then there should be a robust post-market inspection regime.

(v) Specific Issue: Safety

CAM products must be inherently safe; this means that they can be used safely for the purposes for which they are intended. Most CAM products are benign. However, some CAM products, such as St. John's Wort and Belladonna[628] may not be safe when taken with other medicines as they have been traditionally prescribed. Other products may interfere with existing conventional medicines.[629] Still others may be safe when taken in limited dosages, but overuse can have serious health consequences. With hindsight, some traditional practices can also prove to be of little use and potentially harmful, such as bloodletting, for example. Newer CAMs often lack proof of safe use. Therefore, it is essential to ensure that CAM products are properly evaluated for safety and that consumers are provided with accurate information about their use and potential risks.

Regulators will have to decide what level of risk is acceptable for CAM products. As these products are typically used without the supervision of a health-care professional, dosage forms will need to be clearly prescribed. Like drugs, safety testing in humans may be necessary for some products, but this may not be practical for the majority. A history of known safe use can act as a surrogate for safety testing, but this will not exist for newer products. In the absence of a history of safe use, regulators may need to prohibit certain toxic substances, create allowable ingredient lists

[628] See Reader Digest, *Magic and Medicine of Plants*, (Readers Digest: New York, 1986). It provides a very useful description of the reputed properties of many plants, including highlighting those which can be dangerous.
[629] Mayo Clinic, Pres release, *Herbal Supplement and Heart Medicines May Not Mix*, online at: https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/herbal-supplements/art-20046488

or ask that new products undergo safety testing. Regardless, regulators will have to delineate some form of system to ensure that dangerous CAM products are not reaching the public and that toxic substances are not allowed in new CAM products.

(vi) Specific Issue: Efficacy

Wardell[630] and Lamb[631] have outlined some harms that may result from the low efficacy of CAM products. If a patient uses a CAM treatment exclusively for long-term acute or curable illness and the treatment is ineffective, the consequences could be dire, including missed opportunities for more effective treatments. The same issue can occur if a patient is taking a CAM treatment and delays seeking a needed diagnosis. While CAM treatments can be used to supplement conventional treatment, they also reduce adherence to a full spectrum of more effective treatments.[632] For instance, CAM use has been identified as a major factor in resistance to vaccine uptake during public health emergencies and the rejection of treatments, such as COVID-19 vaccines.[633]

According to Ernst,[634] when CAM products are placed under regulatory oversight, the regulator has a duty to assist the informed choice of the public regarding their efficacy. He also argues that pharmacists, doctors, and other health professionals have an obligation to not present CAM treatments they know are ineffective to patients.[635] He goes on further to argue that in those cases

---

[630] *Wardel, supra* note 623.
[631] *Lamb, supra* note 624.
[632] *Ibid.*
[633] National Institutes of Health, Press Release, *Dietary Supplement in the Time of Covid-19*, online at: https://ods.od.nih.gov/factsheets/COVID19-HealthProfessional.
[634] *Ernst, supra* note 418.
[635] *Ibid.*

where the regulators validate ineffective treatments, they may be complicit in a form of fraud being perpetuated on the public. Many CAM therapies are associated with lifestyles or health fads that are highly marketed. This is important because research has demonstrated that legislative oversight means Canadians tend to perceive CAM products as being "safe, effective and natural."[636] According to Morta,[637] with the explosion of CAM markets, there is a danger of public health goals associated with CAMs being superseded by economic goals, one where the purpose of regulations ceases to be health promotion and instead becomes the validation of CAM therapies to help promote their commercialization.

Cohen (2014) provides a controversial rubric for how clinicians should assess the utility of CAMs when faced with high patient demand.[638] His simple rubric is to weigh the desire of the patient to use the product versus its negative effect if the treatment does not work. In this way a patient's wishes can be met but not at the expense of health outcomes. Under these criteria, efficacy is also not just a demonstration of actual clinical effectiveness but a function of how much a treatment aligns to a belief system. This flips the paradigm of efficacy to align with subjective desire for use of low-risk products, rather than clinical effectiveness alone. For regulators this leads to a question of whether they will support a system with little to no efficacy, to meet public demand.

[636] *Ipsos-Reid, supra* note 416.
[637] *Morta, supra* note 565.
[638] *Cohen, supra* note 481.

CHAPTER 4: THE *NATURAL HEALTH PRODUCT REGULATIONS*

Part 1– International Comparators in CAM Product Regulation

(i) The Global Regulation of Complementary and Alternative Medicine

According to the WHO *Global Report on Traditional and Complementary Medicine* in 2019,[639] the last date pre-COVID data was gathered, 170 member states (88% of respondents) acknowledged the use of complementary and alternative medicines (CAMs). Of these, 107 (63%) had a national office that dealt with CAMs and 98 (58%) had a "national policy" of some form overseeing CAMs.[640] To be included in their survey, a "national policy" was required:

> [to] include a definition of the role of the government in the development of CAM in the health-care delivery system, safety and efficacy may be stated as guiding principles and the policy may also include vision and mission statements as well as goals and objectives.[641]

Of these 98 (58%) countries with national policies, only 36 (21%) have stand-alone CAM policies; the remainder roll these into other national health policies (e.g., for drugs or public health measures). One hundred and nine (64%) report having national or state-level laws or regulations affecting CAMs in some form, and many of these laws are worked into other national or state health laws (such as food and drug laws or criminal law). This is a significant increase over the last two decades, when only 49 (29%) countries acknowledged having any form of regulatory system that touched on CAM in place in 1999.

---

639 *WHO 2019, supra* note 440.
640 *Ibid*.
641 *Ibid*.

The 2019 WHO report also noted that regulation systems in place may cover specific products (herbals or natural products), but they may also be more expansive and cover other areas of health care such as allowable practices, licensing education of providers, and whether CAMs are covered by health insurance.[642] The WHO observed that the most commonly listed forms of CAM in use (in descending order) were: acupuncture, herbal medicines, indigenous traditional medicine, traditional Chinese medicine, chiropractic therapy, osteopathy, Ayurvedic medicine, Unami medicine, and others.[643] CAMs were most likely to be recognized in the European region,[644] the African region, and the Americas region. They were least likely to be acknowledged being used in the Eastern Mediterranean (Middle East) and South-East Asia. In these last two areas CAMs may be linked to long-standing traditional forms of medicine which do not distinguish these practices as alternative treatment, but as part of conventional treatment.

(ii) International Comparators - The Regulation of CAM Products in Other Jurisdictions

In the next section I will discuss several international systems which exist for the regulation of CAM products. While there are legal systems which have dealt with these products for a long time in parallel to the regulation of conventional products -- India, China, and Japan come to mind[645] -- I will focus on regulatory systems in the West that were developed around the same time as the *NHPR*. The three examples I will discuss, Australia, the EU and the U.S., were the regimes for CAM regulation that would have informed Canadian legislators when drafting the

[642] *Ibid.*
[643] *Ibid.*
[644] *Ibid.*
[645] *Ibid,* The WHO does a very good job summarizing how these systems have dealt with long-standing traditional systems in parallel to new regulations for pharmaceutical and modern CAM products.

new regulations. These jurisdictions represent some of the largest players and those with the greatest influence in the international regulatory environment around food and drug law. They also represent a spectrum of approaches, from a full SEQ system modelled on drugs in the EU, to a hands-off approach with post-market intervention analogous to food in the U.S., and Australia somewhere in between with a graded registration system.

a. The United States – Vitamins, Dietary Supplements and Caveat Emptor

In the United States most CAM products are regulated as dietary supplements (a class of foods) and have no requirements to demonstrate SEQ to regulators. This is the result of 1994 amendments to the *Food Drug and Cosmetic Act (FDCA)*[646] introduced by the *Dietary Supplement Health and Education Act* (*DSEA*)[647] that limited the ability of the U.S. *Food and Drug Administration* (FDA) to set pre-market assessment conditions on any dietary supplements. *DSEA* made it the prerogative of manufacturers to make determinations that products were safe to be on the market. *DSEA* further limited the intervention of the FDA to only those cases where severe harm or adulteration can be proven after the product is on the market.. In the U.S. there is no special carve-out for traditional products; they are either a drug or a dietary supplement.

For most of the 20th century, vitamins and dietary supplements were regulated by the FDA under the *FDCA* as either foods or drugs, depending on the type of product (composition) and the nature of claims being made about the product. Grassroots reaction to an FDA proposal to impose

[646] *Public Law No. 15-717, S. 52-1040*, hereinafter *US-FDA*.
[647] *Public Law No. 103-417, S.784 -103* (1993-1994), hereinafter *DSEA*.

basic evidentiary standards on vitamins led to an amendment to the *FDCA* in 1970 with the *Rogers Proxmire Act*,[648] which prohibited the FDA from regulating vitamins and minerals with the same system used for pharmaceutical drugs. In 1990, under growing pressure that these products were making false and misleading claims, the FDA put forward new legislation, the *Nutrition Labelling and Education Act*,[649] which would require "significant scientific agreement for a food making a health claim."[650]

Catherine Price in *Vitamania: How Vitamins Revolutionized the Way We Think About Food*[651] described how the dietary supplements industry reacted with a massive legal and public relations campaign targeted at discrediting the new legislation. One of their key tactics was enlisting consumers in a campaign framing the new legislation as an attempt to curtail Americans' freedom by state control.[652] One TV commercial at the time sponsored by industry[653] showed a SWAT team storming actor Mel Gibson's house and arresting him as he held a bottle while pleading, "guys you know they are just vitamins – like in Vitamin C."[654] Gibson then admonishes viewers, "if you don't want to lose your vitamins, make the FDA stop. Call the U.S. Senate and tell them that you want to take your vitamins in peace."[655] The video ends with an ominous message: "Protect your right to use vitamins and other supplements."[656]

---

[648] *Pub. L. No. 94-278, Stat. 401 90* (1976).
[649] *Pub L. No. 101-535, Stat. 1040 2353.*
[650] *Ibid.*
[651] Price, C., *Vitamania: How Vitamins Revolutionized the Way We Think about Food* (Penguin: New York, 2015) Kindle Edition, hereinafter *Vitamania*. See also *Jesson, supra* note 434 "Chapter 6 Regulation of Dietary Supplements and the Food and Drug Administration," hereinafter *Jesson Supplements*.
[652] *Ibid.*
[653] Vitamania Podcast, the video can be accessed, online at: https://www.youtube.com/watch?v=IV2olDA0w8U.
[654] *Ibid.*
[655] *Ibid.*
[656] *Ibid.*

The broader campaign worked. Because of a letter-writing campaign to legislators, first the FDA suspended implementation of the new labelling rules, and then in 1994, Congress passed the *DSEA* amendment to the *FDCA*. *DSEA* defined a dietary supplement as:

> a product (other than tobacco) intended to supplement diet that bears or contains one or more of the following dietary ingredients – a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above.[657]

DSEA solidified these products not as drugs but as a specific type of food. Adulteration occurred only if they "presented a significant or unreasonable risk of illness or injury"[658] (i) under recommended conditions of use or (ii) under ordinary conditions of use.[659] *DSEA* added the caveat that "the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated."[660] As Jesson and Tovino note:

> Under this amendment, dietary supplement manufacturers (unlike manufacturers of drugs and complex medical devices) make the determination that a product is sufficiently safe to be put on the market. The FDA then has the burden of proving otherwise in order to remove that product from the market. For dietary supplements, all compliance activity had to take place post market and the onus to prove an infraction of safety warranting withdrawal or compliance activity was placed on the regulator.[661]

In theory, dietary supplements can only make very limited general claims related to health improvement, structure/function, and nutrient content. Manufacturers are responsible for assessing the nature and sufficiency of evidence that will be required to validate these claims. This may or may not involve scientific evidence. The same applies to ensuring quality; the manufacturer is responsible for making a judgement if products are safe, including deciding what

---

[657] *DSEA*, supra 647.
[658] *Ibid.*
[659] *Ibid.*
[660] *Ibid.*
[661] *Jesson Supplements, supra* note 651.

GMP standards will be in place. If a manufacturer makes a statement about diagnosis, treatment, cure, or prevention of a disease, the FDA cannot prevent them from putting a product on the market, but the product must bear the disclaimer: "this statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."[662]

The bar is high for the FDA to prove adulteration or to prove a significant or unreasonable risk of illness or injury. In those cases where it has tried, there has been stiff resistance from manufacturers to removing the product from the market.[663] The first compliance action the FDA took against dietary supplements was for *Ephedra*, a naturally occurring substance that acts in a manner similar to amphetamines, and which was being marketed for weight loss, increased energy, and enhanced athletic performance. The U.S. Center for Disease Control (CDC) at the time reported that *Ephedra* accounted for 60% of reported ADRs, including strokes, heart palpitations, tremors, insomnia, and deaths.[664] The FDA was unable to obtain safety information from manufacturers and was required to conduct its own investigation and issue an order that all products containing *Ephedra* were adulterated.[665] One of the major proprietary users of *Ephedra*, Nutraceuticals Corporation of America, was unwilling to voluntarily remove it from the market and litigated the matter for almost a decade. It was finally decided that the FDA had the power to do its own independent assessment of product safety, and manufacturers should provide to regulators any known ADR data they had in their possession.[666]

---

[662] U.S. Food and Drug Administration, *Dietary Supplement Labelling Guide: Chapter VI. Claims*, (FDA: Washington, 2005), online at: https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide-chapter-vi-claims
[663] *Vitamania, supra* note 653.
[664] Rao, N., Spiller, H. A., Hodges, N. L., et al "An Increase in Dietary Supplement Exposures Reported to US Poison Control Centers" (2017) 13 *J Med Toxicol* 227.
[665] *Ibid.*
[666] *49 B.R. 333* (S.D.N.Y. 2006)

In 2006 Congress passed an amendment to the *FDCA*[667] that requires manufacturers to proactively provide safety data to the FDA, but as the *Ephedra* case has shown, it has been an uphill battle to remove products from the market. In 2007 the FDA proposed updated guidance on the safety requirements for dietary supplements[668] that would have provided guidance on the types of acceptable safety and efficacy information. Under pressure from Congress, these guidelines have only remained in draft form. In 2009 the *U.S. Government Accounting Office* (GAO) released a scathing report[669] calling on the government to increase oversight of dietary supplements. While the FDA has issued over 1,000 notifications to manufacturers in the past decade, it still lacks the mandate to force removal of products from the market without a very high bar of proof. In 2019 the new director of the FDA did indicate that he was going to increase enforcement against these products, [670]but there has been little additional regulatory action since the onset of the COVID-19 pandemic. The 2022 Supreme Court decision in *West Virginia v. EPA*[671] limited regulatory agency from acting with discretion. This will likely further limit the likelihood that the FDA will undertake new measures without express direction from Congress, so the regime for dietary supplements will likely remain the same for the immediate future.

---

667 *Pub L.109-462.*
668 U.S. FDA, *Complementary and Alternative Medicine Products and their Regulation by the Food and Drug Administration,* Docket 3FDA-2006-D-0102.
669 U.S. Government Accounting Office (GAO), *Dietary Supplements: FDA Should Take Further Action to Improve Oversight and Consumer Understanding* (GAO, Washington, 2009).
670 U.S. FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., On the Agency's New Efforts to Strengthen Regulation of Dietary Supplements by Modernizing and Reforming FDA's Oversight*, (US FDA: Washington, 2019).
671 *West Virginia v EPA*, 985 F, 3D 914.

b. The European Union Full Registration with Accommodation for Member States

In the EU, CAM products are regulated as a special class of product called herbal medicinal products (HMPs). The EU has a two-level system with centralized registration and rule-setting at the EU level, and a localized system for approving market access and more specific conditions set at the state level. Approval at the state level is registered at the EU level and then applicable to all member states. The centralized process is administered by the European Medicines Agency (EMEA), which also issues EU-wide directives and standards, and registers the EU-wide approval of medicines. The EU system also has an exemption for existing medicinal products, herbal products, and homeopathies which historically existed in member states before EU unification.

EU Directive 2001/83/EC[672] defines a herbal medicinal product (HMP) as a "substance or combination of substances presented as having properties for treating or preventing disease in human beings"[673] and "administered to humans with a view to restoring, correcting or modifying physiological function by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis."[674] This purpose-based definition has two components: a representation (claim) component and an effect component. An HMP must also be a substance of origin derived from human, animal, vegetable, or chemical sources (naturally occurring or by synthesis).[675]

[672] Online at: https://health.ec.europa.eu/publications/directive-200183ec_en.
[673] *Ibid.*
[674] *Ibid.*
[675] *Ibid.*

Initially under the 2001 directive, market authorization was required to be issued by the EMEA or a competent state authority before a product could be placed on the market. The market authorization must include a high degree of detail about the specific HMP, including "qualitative and quantitative particulars of all constituents of the HMP,"[676] which includes an evaluation of any environmental risks, description of manufacturing methods, therapeutic indications, contra-indicators, adverse reactions, and description of manufacturing controls in place.[677] Manufacturers are also required to provide results of pharmaceuticals (chemical tests), pre-clinical tests, and clinical trials.[678] Similar to drugs, manufacturers must also have risk management and pharmacovigilance plans in place.[679] In effect, the initial pathway for HMPs was similar to that of drugs with the exception that efficacy information could be demonstrated by existing clinical data.

In 2004, under pressure from member states, the EU introduced a new directive[680] with a simplified procedure for harmonization between member states. The directive exempts HMPs from the need for clinical trials and pre-clinical trials where member states are licensing products that "have a well-established medicinal use with a recognized efficiency and an acceptable level of safety."[681] The system was established to allow for two new categories of HMPs: those for traditional use and those with a well-established use. For traditional use registration, "no clinical tests and clinical trials on safety or efficacy are required as long as sufficient safety data and plausible efficacy are demonstrated."[682] This process involves the "assessment of mostly

---

[676] *Ibid.*
[677] *Ibid.*
[678] *Ibid*
[679] *Ibid.*
[680] *EU Directive 2004/24/EC,* online at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004L0024.
[681] *Ibid.*
[682] *Ibid.*

bibliographic safety and efficacy data"[683] with a history of 30 years of use, with at least 15 of those in the EU, and does not require supervision of a medical practitioner. The well-established use application reduces the need for clinical data when "scientific literature establishing that the active substance of the medicinal products has been in well-established medicinal use within the EU for at least ten years, with recognized efficiency and an acceptable level of safety."[684]

The EU supports the centralized process by generating EU monographs that "carry the therapeutic uses and safe conditions of well-established and/or traditional use for herbal substances and preparations"[685] which can be used to assist applicants in meeting safety and efficacy licensing requirements. Similarly, the EU maintains a list of herbal substances which captures substances commonly allowed for humans as HMPs.[686] These and other guidance issued at a centralized level are administered by the Committee on Herbal Medicinal Products (HMPC).[687]

In effect, the EU has a three-stream system, operating at two levels of evaluation. The EU system sets much higher requirements for GMPs, akin to drug manufacturers, but allows for a reduced standard of efficacy (quantitative and qualitative). There are strong critiques of the EU system for HMPs, the biggest being that the variance at the state level means that different

---

[683] *Ibid*.
[684] *Ibid*.
[685] EMAE, *Procedure for the Preparation of Community Monographs for Traditional Herbal Medicinal Products, Reference*, EMEA/HMPC/182320/2005 Rev. 2, online at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline.
[686] *Ibid*.
[687] *CHMP*, online at: https://www.ema.europa.eu/en/committees/committee-herbal-medicinal-products-hmpc.

standards are applied to determine how a traditional HMP is defined, and varying evidential standards are used to support demonstrations of safety and efficacy.[688]

c. Australia: A Graded Registration System

Australia was one of the first Western jurisdictions to establish a domestic system for the regulation of CAM products. Australia has a regulatory environment similar to that of Canada; it is a former British colony with common law, an Indigenous population with a long history of their own traditional medicines, and a large immigrant population that has brought additional forms of traditional practices. The *Therapeutic Goods Act (TGA)* of 1989[689] and the *Therapeutic Goods Regulation (TGR)* of 1990[690] established a new category of products called complementary medicines. The definition of complementary medicines (CMs) has two components: one based on "a clearly established identity and traditional use"[691] and a substance component, "being composed of a designated active ingredient captured in Schedule 14"[692] of the regulations. Schedule 14 is notable for including mainly naturally occurring substances, including amino acids, plant or herbal materials, homeopathies, microorganisms, plant fibres, enzymes, algae, etc.[693] Therefore, to qualify as a CAM, a product must be distinct in identity with a traditional use and made up of a substance drawn from natural sources. This definition did not allow for newer products which do not meet these criteria.

---

[688] Wiesner, S., Salamonsen, A., and Fonnebo, V., "Which risk understandings can be derived from the current disharmonized regulation of complementary and alternative medicine in Europe?" (2018) *BMC Complementary and Alternative Medicine* 18(11).
[689] *No. 21, 1990, hereinafter TGA.*
[690] *Statutory Rules No. 236, 2002, hereinafter TGR.*
[691] *Ibid.*
[692] *Ibid.*
[693] *Ibid.*

All therapeutic products in Australia, including pharmaceutical drugs and medical devices, are regulated by the *Therapeutic Goods Administration* (TGA)[694] which has a two-tiered system for product regulation based on identified risk. All marketed products must be included in the *Australian Register of Therapeutic Goods* (ARTG).[695] For "low-risk" products, this is a registration process to be **listed** on the ARTG, in which manufacturers attest to the GMP standards and attest that they have evidence on hand to demonstrate any claims made for the product. Higher-risk products are required to go through a more comprehensive evaluation by the TGA, confusingly called **registration**, which involves a comprehensive assessment/validation of GMP processes and scientific evidence demonstrating the efficacy of the product.

Listed complementary medicines must meet the two threshold criteria of the CM definition (traditional and on Schedule 14), and can only be for "low-risk ingredients"[696] and "make indications for health maintenance, health enhancement or for non-serious self-limiting conditions."[697] Low-risk ingredients are those not included in a list of high-risk ingredients provided by the TGA.[698] The sponsor must also under s.26 (a) of the Act demonstrate "the medicine is safe for the purpose for which it is to be used"[699] and attest that the "applicant holds information (evidence) to support the claim."[700] This information, which is held by the manufacturer, must be made available to the TGA upon request.

---

[694] See online at: https://www.tga.gov.au.
[695] See online at: https://www.tga.gov.au/resources/artg
[696] *TGR, supra* note 690.
[697] *Ibid.*
[698] *TGA, Ingredient Search Database, online at: https://www.tga.gov.au/ingredients-search.*
[699] *TGA, supra* note 693.
[700] *Ibid.*

The TGA *Evidence Guidelines: How to Demonstrate the Efficacy of Listed Medicines is Acceptable*[701] sets out the conditions around the types of evidence manufacturers are expected to have on hand to demonstrate safety and efficacy. Under Section 2.1.1, evidence of traditional use is demonstrated by a history of use which "provides an accumulated repository of systematic observations and underpins the safe use of the medications in a traditional system."[702] Factors which will be relevant to this consideration include: (i) time over which the medicine or active ingredients have been used, (ii) continuity of its use, (iii) geographical extent of its use, and (iv) a record of use in traditional sources.[703] A well-established tradition is defined as 75 years of continual use or "extensive records in international (traditional) evidence sources."[704] Sources of traditional use include *material medica*,[705] official pharmacopeias and monographs, publications of international regulatory authorities, texts of traditional paradigms, and well-recognized reference texts.[706] Alternative sources of evidence can be used, including non-referred textbooks, modern textbooks, independent written histories, and oral evidence sources confirmed in multiple sources.[707]

Products which are higher risk, "based on their ingredients of the indications made for the medicine," are evaluated for SEQ by the TGA. High-risk indicators include those "intended to treat severe medical conditions that require medical supervision, those not suitable for self-medication and those for which the medicine may have significant adverse effects, contra

[701] Online at: https://www.tga.gov.au/resources/resource/guidance/evidence-guidelines.
[702] *Ibid.*
[703] *Ibid.*
[704] *Ibid.*
[705] *Ibid.*
[706] *Ibid.*
[707] *Ibid.*

indications or drug interactions."[708] The registration pathway then follows the same evaluation criteria as for any new conventional drug.[709] The guidance does allow for variance in the pathway if it is only a reference to a product previously approved by another competent authority or regulatory jurisdiction (e.g., if it has regulatory authorization in Canada).

In 2017 the TGA introduced a third licensing pathway, the *Assessed Listed Medicinal Pathway* (ALMP) that was intended to be a midpoint between the full registered pathway and self-attested licensed pathway.[710] This new pathway allowed a set of intermediate indicators for preventative and reduction claims for general claims (e.g., helps promote heart health).[711] These claims were assessed based on the seriousness of the ailment they were addressing and the claim having a low, intermediate, or high rating. High-risk ratings, where indications refer to the "prevention, alleviation or cure of a serious disease"[712] are required to go through the full registration process. Intermediate, non-serious disease with low-risk indicators or low-risk claims were subject to a blended licensing process and lower evidential (SEQ) standards.

The Australian system is notable for a few elements. It is primarily a registration system that places the liability for ensuring SEQ on the manufacturer. It is also very limiting of what is or is not a CM product; if a product is not a traditional medicine of composed of natural substances, it is regulated as a drug. This stratification means that products making non-traditional claims are drugs. The guidance is also very prescriptive of what types of evidence will be allowed to

---

[708] *Ibid.*
[709] *Ibid.*
[710] See TGA, *Assessed Listed Medicines: Assessed Listed Medicines Pathway for Complementary Medicines*, online at: https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-non-prescription-medicine/assessed-listed-medicines.
[711] *Ibid.*
[712] *Ibid.*

demonstrate traditional use. In the end, the system is largely a mechanism for the registration of new products that allows for the restriction of certain types of claims. It does not allow for the introduction of products making modern claims.

Part 2 - The Emergence of the Natural Health Products Regulations in Canada

(i) The Report of the Standing Committee on Health on CAMs

In the mid-1990s, Canada was facing public pressure to create a more comprehensive regulatory system for CAM products. In 1997 the Minister of Health asked the Parliamentary Standing Committee on Health to commission a study on what the framework would look like for a new regulatory system dealing with CAM therapeutic products. The mandate established by the standing committee was to:

> make recommendations regarding the legislative and regulatory regime governing traditional medicines (including, but not limited to, traditional herbal remedies, traditional Chinese, Ayurvedic and Native North American medicines), homeopathic preparations and vitamin and mineral supplements.[713]

In completing these tasks, the committee was to consult broadly, including associations, consumers, and manufacturers, and consider the legislative and regulatory regimes existing in other jurisdictions. Furthermore, they were to try to balance the objectives of "consumer freedom of choice and access while ensuring the quality and safety of such products."[714]

---

[713] Standing Committee on Health, *Natural Health Products a New Vision: Report of the Standing Committee on Health*, (November 1998), online at: http://www.parl.gc.ca/InfoComDoc/36/1/HEAL/Studies/Reports/healrp02-e.htm, hereinafter *New Vision.*

[714] *Ibid.*

The committee members noted that this would be no easy task because of the intense debate over the regulation of CAMs and the need to accommodate pressure from both industry and consumers. They were also aware of the "diverse nature of both the manufacturing and distribution sectors of [the industry]"[715] which included a spectrum ranging from large industrial companies to small manufacturers producing only small batches. At the time of the committee's launch, they were primarily concerned with six classes of products: vitamins, mineral supplements, herbal remedies/teas, homeopathic preparations, nutraceuticals, and the amorphous "other" which captured products not easily fitting into one of the previous categories. These represented the most commonly used CAMs in Canada at the time, with vitamins (at 45%) and mineral supplements (22%) making up the bulk of products. The "other" category, which includes wellness products, dietary supplements, and any other products, was expected to account for only 5% of the products to be regulated and was not intended to be the primary focus of the regulations.

In their formal terms of reference, the committee established a goal for themselves of proposing a regulatory framework for CAMs that protects the health of consumers, respects consumer access to products, and guarantees product safety and quality. After discussion, the committee supplemented these initial goals with a few more: CAMs must be seen as "different in nature and form [so] not be treated strictly as either a food or pharmaceutical, placing them in a regulatory grey area between food and drugs,"[716] and CAM products must, as a primary goal, establish standards of quality to prevent adulteration. Other principles included a respect for cultural diversity, transparency of decision-making, and informed choice for consumers. For over

[715] *Ibid.*
[716] *Ibid.*

18 months, the committee met with over 150 witnesses, representing a range of voices from interested in CAM products.

In November 1998 the standing committee tabled its final report, *Natural Health Products: A New Vision*,[717] with Parliament. The report made 53 recommendations proposing either a new regulatory regime for CAM products as part of the existing regimes for either foods or drugs, or as a stand-alone regime. A new agency should be housed within either existing regulatory agencies (the Food Directorate or the TPD) or in a stand-alone regulatory agency. It should be supported by an expert advisory group created explicitly to regulate this new class of products (the future NHPD).[718] The new agency and advisory committee was to "develop new regulations, revise legislation and [set] out appropriate policies."[719]

The committee also recommended that the new system be focused as a first principle on safety and quality. The new regulatory authority was to assume primary responsibility for ensuring safety by considering information from "a range of sources; historical and recent, traditional knowledge and contemporary science."[720] The committee suggested that the new regulations should develop a "revised risk/benefit system that is more stringent than the one currently in place for foods, but less stringent than the one applied to drugs."[721] Quality (manufactured purity and GMPs) varied widely across the NHP industry along with the sophistication of these manufacturers, so there was to be a new establishment licensing (EL) and a

[717] *Ibid.*
[718] *Ibid.*
[719] *Ibid.*
[720] *Ibid.*
[721] *Ibid.*

good manufacturing process (GMP) regime for these products. The new EL system was to be supported by specific quality controls and testing regimes in place with inspection activities performed "consistently and on a regular basis"[722] by knowledgeable inspectors.

Claims (efficacy) were to be assessed to ensure that there is reasonable evidence to support the claim. The reasonable evidence provided to demonstrate the validity of health claims was to be related to "the type of claims being made,"[723] not the clinical standard in place for pharmaceutical drugs. The committee suggested sources of evidence should be flexible and include "generally accepted and traditional references, professional consensus, clinical evidence including, but not limited to double-blind trials and other types of clinical or scientific evidence."[724] This was a fairly wide bar for demonstrating efficacy. They also encouraged the creation of monographs, and a compendium of evidence related to specific products that would contain a standardized product description and allowable claims. Finally, they asserted that all products needed clear labelling with the nature of the claim and product description to inform consumer choice.[725]

As the regime was largely intended to apply to traditional products, respect was to be given to existing sources of evidence. In order to assist in determining the reasonableness of the evidence provided, the committee recommended a new licensing framework "based on a risk management approach that emphasized the margin of safety associated with a particular

[722] *Ibid*.
[723] *Ibid*.
[724] *Ibid*.
[725] *Ibid*.

product."[726] The expert advisory committee was to assist the new regulator in developing a series of product classes (like that for medical devices)[727] based on the inherent safety of products. The degree of post-market surveillance was to be supported by the "margin of safety" associated with various products.[728]

The report also made a host of additional recommendations. The new regulatory agency should be allowed to use cost recovery from product applicants to cover product assessment costs.[729] The regulator should develop an appeal process for rejected licensing decisions. Health Canada should begin supporting academic research to back the generation of new evidence on the efficacy of CAMs, which in turn would support the development of monographs.[730] The new regulations should exempt compounding by practitioners and traditional healers.[731] Transitional provisions should be included in a new regulatory regime that allowed for the gradual licensing of products already on the market (those with an existing DIN, homeopathies, vitamins, and certain products captured under the *FDR* as either drugs or foods).[732]

In setting up the new regulations, Health Canada was given no simple task. They were to create a system that established new standards for SEQ but was also sensitive to the unique needs of the stakeholders associated with these products. These stakeholders were hardly uniform and included small manufacturers, homeopaths, naturopaths, traditional practitioners, gemologists, food producers, major multinationals, and everything in between. They had also been tasked with

---

[726] *Ibid*.
[727] *Ibid*.
[728] *Ibid*.
[729] *Ibid*.
[730] *Ibid*.
[731] *Ibid*.
[732] *Ibid*.

developing a system that would categorize products based on "inherent risks" and, accordingly, requiring varying degrees of evidence. This meant, in theory, drawing comparisons across varying and different systems of CAMs with equally varying systems of belief, practice, and evidence justifying products. This would require the development of a comprehensive risk classification system for these products overlaid with the risk claims and the risk of substances. As was noted earlier, the nature of evidence underlying many CAMs is grounded in non-clinical forms of observation, subjective observation, and traditional patterns of use and belief systems.

a. A Quick Note on Claims

Before launching into discussion of the *NHPR*, I would like to address health claims as they were intended by the standing committee. These will become important in the exploration of health claims and the demonstration of efficacy later in this thesis. As noted in Chapter 1, general claims for curatives (curing disease) were prohibited in the *FDA Schedule* A[733] under the general maxim that a product on the market was a treatment, not a cure. Any product which was to claim specific clinical effects should be able to demonstrate those outcomes using clinical trials, and would normally be regulated as a pharmaceutical drug.[734] The standing committee, on advice from a Health Canada expert advisory panel, suggested that any new regime should include three types of health claims: 1) ***structure function claims*** that "report the effect of a product on a structure or physiological function in the human body,"[735] 2) ***risk reduction claims*** related to reducing the risk of developing a "disease or abnormal physiological state,"[736] and 3) ***therapeutic***

[733] *Ibid*.
[734] *Ibid*.
[735] *Ibid*.
[736] *Ibid*.

treatment claims which purport to produce "action on a specific disease or abnormal state." Health Canada added another class in their response to the standing committee: 4) ***nutritional support claims*** that "established function of a particular nutrient(s) [on] normal physiological function or as a source of essential nutrients."[737] Both structure function claims and risk reduction claims represent a very general form of health claim, specifying a global effect which is hard to observe. Therapeutic claims are very specific and can be observed using clinical observation. Nutritional support claims are analogous to nutritional claims that were allowed for certain foods.

An important reminder is that the standing committee recommended a focus on a limited number of specific products (vitamins, supplements, etc.) and traditional medicines. This was likely partially spurred by the failure of other jurisdictions to regulate some of these products effectively (notably the U.S. with *DSEA* as discussed earlier).[738] The intent would then have been on establishing claims for mostly traditional products. Other classes of modern or non-traditional claims were only expected to account for a small percentage of claims (somewhere around 5%).[739]

(ii) The Health Canada Response to the Committee[740]

In March 1999 the government tabled its response, accepting most of the recommendations in the report and in May 1999 established a transition team to establish the new stand-alone directorate. In January 2000 Phillip Waddington, an Ontario Doctor of Naturopathy,

[737] *Ibid*.
[738] *Ibid*.
[739] *Ibid*.
[740] On March 26, 1999, Health Minister Allan Rock accepted the recommendations of the Standing Committee.

was appointed the first director general (DG) of the new Natural Health Products Directorate (NHPD). The new DG reported directly to the ADM of the Health Products and Food Branch of Health Canada (HPFB). Over the next three years (1999-2002) the transition team conducted Canada-wide consultations [741]and began drafting the new regulations. An initial draft was formally circulated to stakeholders in 2001-2002,[742] and a final draft of the regulations was published in Canada Gazette Part II in June 2003.[743] While the final regulations (discussed below) lost some of the intent of the standing committee, in particular relating to defined categories of risk, stronger testing for efficacy, and defining the full role of monographs, they largely addressed the committee's recommendations. Yet, as will be discussed later, some of the choices made at this time, in particular around clarity of the definition of NHPs and risk categorization, and the evidential requirements for non-traditional products would have long-term consequences for the implementation of the regulations.

Part 3 - The Natural Health Product Regulations

The *Natural Health Product Regulations* (*NHPR*)[744] came into effect on January 1, 2004. They were intentionally structured to mirror the drug sections (Part C) of the *FDR*. At first glance, it appears that the drafters were attempting to distill the relevant components of Part C, adapting them to the new class of products. The regulations consist of parallel sections covering

[741] See, The Transition Team of the Office of Natural Health Products, *A Fresh Start: Final Report of the ONHP Transition Team*, (March 31, 2000), online at: https://web.archive.org/web/20020220170016/http://www.hc-sc.gc.ca/hpb/onhp/FinalReport.PD, herein after *Fresh Start.*
[742] *Natural Health Products Proposed Regulatory Framework*, online at: https://web.archive.org/web/20020611082527/http:/www.hc-sc.gc.ca/hpb/onhp/regs_cg1_cover_e.html
[743] *Canada Gazette Part II*, Vol. 137, No. 13.
[744] *NHPR, supra* note 2.

product licensing (Part 1),[745] site licensing (Part 2),[746] good manufacturing practice (GMP) (Part 3),[747] clinical trials (Part 4),[748] miscellaneous administrative requirements and amendments (Part 5),[749] transitional provisions (Part 6), and a general interpretation and application section fronting the regulations.[750]

As noted in the Regulatory Impact Analysis Statement (RIAS) provided with the regulations, the *NHPR* contains:

> requirements for the manufacture, packaging, labelling, storage, importation, distribution and sale of NHPs. These Regulations are intended to provide Canadians with **ready access** to natural health products that are **safe, effective, and of high quality**, while respecting **freedom of choice and philosophical and cultural diversity.**[751]

In this description, I will focus on the *NHPR* as they were at the time they came into force. I will reference subsequent guidance issued to update SEQ requirements where applicable. A more detailed chronological description of how the regulations evolved subsequently will be covered in the next chapter.

(i) What is in a Name: Defining Natural Health Products

The first task of the regulators would be to define "natural health product." As noted above, the standing committee had given the task force the tall order of capturing in a definition both the risks inherent in CAM products and the risks in the intended use of CAM products.

---

[745] *Ibid.*
[746] *Ibid.*
[747] *Ibid.*
[748] *Ibid.*
[749] *Ibid.*
[750] *Ibid.*
[751] The *RIAS* appeared as part of *Canada Gazette Part I*, Vol 135, No. 51, 4912.

After extensive consultations, the regulator chose to develop a definition with two components: purpose and composition. The regulations define a natural health product as:

> a substance set out in Schedule 1or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic preparation or a traditional medicine, that is manufactured, sold or represented for use in
>
> > (*a*) the **diagnosis, treatment, mitigation or prevention** of a disease, disorder or abnormal physical state or its symptoms in humans;
> > (*b*) **restoring or correcting organic functions** in humans; or
> > (c) **modifying organic functions** in humans, such as modifying those functions in a manner that **maintains or promotes health**.
>
> However, a natural health product does not include a substance set out in Schedule 2 or any combination of substances that includes a substance set out in Schedule 2. [752]

Products which are manufactured, sold, or represented for use as (a) treatments or prevention measures, (b) restoring or correcting organic function, or (c) maintaining or promoting health or otherwise modifying organic function are all considered to be making NHP claims. Part (a) and part (b) of this definition are pulled directly from the definition of "drug" in the *FDA*.[753] Like drugs, the definition is intended to capture under the first two criteria therapeutic claims and risk reduction claims respectively. The new type of claim promoting health by modifying organic structure is analogous to the structure function claim proposed by the standing committee but goes further to include the potential for general health maintenance claims. This makes the applicability of the type of claims that can be made under (c) very broad.

The second criterion is that the product must be composed of substances listed in Schedule 1 of the regulations and must not contain any substance listed in Schedule 2. Schedule

[752] *NHPR, supra* note 2 at s.2
[753] *FDA, supra* note 6.

1 includes the 14 identified isolated vitamins[754] recognized as needed for human health. Schedule 1 also includes substances commonly found in nature such as minerals, amino acids, and essential fatty acids. In addition, Schedule 1 includes probiotics, an emerging product class in the early 2000s.[755] The "natural" component of NHPs refers to the inclusion of "a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material"[756] and "an isolate or extract [of these substances] the primary molecular structure of which is identical to that which it had prior to extraction or isolation"[757] of these substances. The definition also includes "a synthetic duplicate" [758] of any of the substances (except minerals and probiotics) described above. This means that virtually all ingredients, synthetic or natural, can be NHPs. This makes the *NHPR* definition far more expansive than that in place in either the EU or Australia. Schedule 2[759] excludes classes of drugs spelled out in Schedules C and D of the *FDA*, which includes radiopharmaceuticals, biologics, controlled substances, cannabis, antibiotics, and substances administered by puncturing the dermis.

A final noteworthy component of the definition is an explicit inclusion of homeopathic medicine and traditional medicine. As will be discussed later, this set up a dichotomy between traditional and newer forms of NHPs, and similarly, a dichotomy in the evidence needed to be brought to bear to reflect SEQ for licensing. This also creates a problem in defining what is and what is not included in traditional medicine and the evidence that is considered to support claims by the regulator. Schedule 1 similarly was an attempt to list a series of "naturally" occurring

[754] *NHPR, supra* note 2 at *Schedule 1*.
[755] *Ibid.*
[756] *Ibid.*
[757] *Ibid.*
[758] *Ibid.*
[759] *NHPR, supra* note 2 at *Schedule 2*.

substances, plant materials, their extracts, vitamins, minerals, amino acids, and essential fatty acids, etc., that reflect the common natural components used in traditional forms of medicine. The inclusion of criteria that allowed for synthetic duplicates meant that it could be argued that virtually any substance making a health claim could be an NHP.

It is important to note that NHPs were a sub-category of drug as defined in the 1985 *FDA*,[760] as the definition of NHPs exists only within the regulations. Therefore, products that fall under this category are subject to the provisions of the *FDA* that apply to drugs. These provisions included rules related to advertising, sampling, inspections, exports, and relevant schedules (A-H) that prohibit certain claims, substances and controlled substances. On the other hand, under Section 3 of the *NHPR*,[761] NHPs are specifically exempted from the *Food and Drug Regulations (FDR)*,[762] which set out conditions for drugs and foods, unless otherwise specified.

(ii) *NHPR* Part 1: Product Licensing

a. The General Prohibition

Section 4 of the *NHPR* sets out the general prohibition against "selling a natural health product unless a product license is issued."[763] Because NHPs are still a sub-class of drug under the 1985 *FDA*, this prohibition is backed by the broader prohibition in the *FDA* s.9(1) and (2) against marketing drugs "in a manner that is false, misleading, or deceptive or is likely to create

[760] *FDA, supra* note 6.
[761] *NHPR, supra* note 2
[762] *FDR, supra* note 6.
[763] *NHPR*, *supra* note 2 at s.4.

an erroneous impression regarding its character, value, quantity, composition, merit or safety,"[764] which is in turn backed by the federal criminal law power.[765] *NHPR* Section 4(3) (a) and (b) place an obligation to stop sale if directed under one of the sections of the regulation (s.17), or when a license is suspended (s.18 or s.19) or cancelled (s. 20(b)). General grounds for a stop sale order are a "contravention of the regulations or any provision of the Act"[766] or the making of "false or misleading statements in the application submitted."[767] As will be discussed in later, NHPD has seldom been able to enforce these provisions.

Under Section 5 of the regulations, anyone seeking a product license (PL) must apply to the Minister by submitting a product licensing application (PLA). Product licensing applies to anyone wishing to sell, distribute, import, store, manufacture, package, label, or handle an NHP. Much like a new drug submission (NDS), as described in Chapter 1, the application includes a core collection of information related to the NHP's composition, medicinal and non-medicinal ingredients, intended conditions of use, claims, labelling, brand name, an attestation to manufacturing conditions, and under Section 5 (g) "information that supports the safety and efficacy of the natural health product when it is used in accordance with the condition of use."[768]

The PLA for NHPs is notable for two variations when compared to an NDS for pharmaceutical drugs. First, in relation to safety and efficacy, the PLA does not require detailed information on testing to be conducted to establish safety and purity under the *FDR* (C.08.002

[764] *Ibid.*
[765] *Ibid.*
[766] *Ibid.*
[767] *Ibid.*
[768] *Ibid.*

(f)) or "substantial evidence of clinical effectiveness" (C.08.002 (g)).[769] Instead, the *NHPR* initially required the PLA to include "information that **supports** the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use."[770] The use of the term "support" creates some ambiguity around what will meet this criteria. [771] This would later be changed to information that **demonstrates** efficacy when it is used in accordance with conditions of use,[772] because many product licensing applicants argued they did not have a need to meet any efficacy standards.[773] Secondly, unlike for drugs, PLAs do not require the submission of information about where products are to be manufactured or that the location has a valid site license (SL).[774] This is in contrast to the requirement under the *FDR* s.08.001 (3) that an NDS include details on procedures, processes, and personnel who will ensure GMP practices for the new drug.

Manufacturers are proactively responsible for notifying NHPD of any updates to their product licence application which is being reviewed, most importantly, updates to dosage, labelling, or conditions of use. If an amended application is received, the service standard of 60 days for review is reset. If reviewers have substantive questions about a PLA, the clock stops for 15 days while applicants are responding to these questions. As will be discussed in the next chapter, policy has developed over the 19 years of the operation of the *NHPR* attempting to clarify the evidence required to demonstrate SEQ.

---

[769] *FDR, supra* note 6.
[770] *NHPR*, *supra* note 2 at s.2.
[771] *Ibid,* at s.4.
[772] *SOR/2022-146 June 21, 2022*
[773] See next chapter.
[774] SL are issued under Part 2 of the *NHPR*. SL and PLA were originally linked in the draft of the regulations at Canada Gazette Part 1 but were removed because manufacturers argued this information would not always be available at the time of a PLA being submitted, see *RIAS*, *supra* note 751.

Assuming the application passes review and is approved, NHPD will issue a product license and a Natural Health Product Number (NPN or HM-NPN) which is analogous to the DIN issued for drugs. Licensed NHPs will also be added to the *Licensed Natural Health Product Database* (LNHPD), [775] which lists the product's brand name, license holder, ingredients (medicinal and non-medicinal), dosage form, recommended use, and NPN. If a PLA is not approved, NHPD will issue a notice of refusal that "sets out the reasons for refusal" of the application.[776] The applicant is given 30 days to request a reconsideration of their application and has a "right to be heard in respect to the application," followed by a second reconsideration of the application.[777] If the application is still refused, the regulator can issue a final notice that sets out the reasons for refusal.

(iii) *NHPR* Part 2 - Site Licensing

Sections 26 through 39 of the regulations deal with the requirements for site licensing. Under Section 27(1), there is a general prohibition to not "manufacture, package, label, import or sell" an NHP unless the manufacturer has applied for and received a site license[778] from the regulator and the manufacturer employs good manufacturing practices (GMPs).. The application is similar to the drug establishment license (DEL) required for a drug but is an attestation that does not require prior inspection or validation of premises by Health Canada as is required for drugs under the *FDR*. The application for an SL is simplified when compared to a DEL,

[775] *Supra,* note 11.
[776] *NHPR, supra* note 2.
[777] *Ibid.*
[778] *Ibid.*

requiring the contact and location details (name, address, telephone, etc.), a statement specifying which activities will be undertaken at each location, and an attestation that GMP standards will be used. A quality assurance person (QAP) is required to provide assessment of the sites and GMP practices in place via a quality assessment report (QAR) submitted with the SL. QAPs can be employees of the manufacturer, an importer or distributer, or more often the case, they are contracted agents from a third-party organization which specializes in providing QAR reports.

NHPD will issue an NHP SL if it is factual, not deficient in detail, and all relevant information is provided. SLs can be issued even if they are not linked to any existing NHPs being manufactured. The regulator is required to inform the applicant within 30 days of reasons for refusal in writing and to provide an opportunity for the applicant to seek reconsideration of their application.[779] Issued SLs are valid for one year and initially were to be renewed annually. The renewal process is paper-based and does not require a reconsideration of GMPs or an inspection of facilities.[780] The attestation from the applicant and the QAR report from the QAP is all that is required for renewal. Manufacturers have the onus to inform the regulator of any variance in the original conditions or details provided with their approved SL.[781] This includes informing the regulator of any changes in manufacturing, packaging, labelling, processing, or importing, and any changes in the types of NHPs being handled.

The provisions of the Act have been supplemented by guidance[782] which outlines some additional criteria that will be applied in the issuance of an SL. It reiterates that other than site,

[779] *Ibid.*
[780] *Ibid*
[781] *Ibid.*
[782] NHPD, *Good Manufacturing Practice Guidance Document*, (Health Canada; Ottawa, November 2003).

contact, and planned type of activity details, the primary criteria for site licensing is having attested GMP standards in place. As noted above, applicants must submit a site licensing application (SLA) form supplemented by the QAR form and completed by a designated official who will attest to GMP standards being in place. If the QAP is a third party, a common practice, applicants must also submit a designated party authorization form, which allows the third party to act as their agent in the SL licensing process.

Over time, the site-licensing provisions have built in some exclusions. Pharmacies, Indigenous healers, and traditional Chinese practitioners compounding single-batch products at the request of patients are exempt from holding an SL.[783] Unlike for drugs, distributers and resellers who do not manufacture, package, label, or import are also exempt from holding an SL. Those who grow, harvest, clean, sort, and/or import raw materials are exempt. Those who are producing products solely for a clinical trial under Part 4 of the regulations are exempt. Unlike for drugs, laboratories testing NHPs are not required to hold an SL.[784]

(iv) *NHPR* Part 3 - Good Manufacturing Practices (GMPs)

The more substantive criteria for manufacturers relates to good manufacturing practices. Part 3 of the regulations (Sections 43-62) lay out what is required to establish NHP GMPs. Section 43 provides the general prohibition against selling an NHP that is not manufactured, labelled, imported, distributed, or stored in accordance with GMP standards that are equivalent to those outlined in Part 3. Section 5(i) on product licensing requires that the specification of the

[783] *SOR/2022-146* June 21, 2022.
[784] *NHPR, supra* note 2.

NHP be provided and s 5(j) reinforces the requirement to provide an attestation, via a quality assurance report (QAR), that the GMP standards will be met. Section 44(a) outlines the requirements to establish the specifications of a product including: (i) detailed information regarding the purity of the NHP, (ii) for each medicinal ingredient, "detailed information respecting its quantity per dosage limits and its identity," (iii) detailed information for labelling the potency of medicinal ingredients, (iv) and describing methods, if any, that will be used to test or examine the NHP.[785] These criteria are to be reviewed and attested to by the QAP, who has responsibility for ensuring GMP standards are in place and adhered to during licensed activities.[786]

More specific details for GMPs were laid out in the guidance[787] addressing the manufacturing process (premises, equipment, sanitation programs, operations, and quality assurance).[788] These sections mirror the *FDR* sections on GMPs, but with much less detail and fewer obligations for specific activities on SL holders. Compared to the *FDR*, notably absent are manufacturers' obligations to retain samples of raw, finished, and packaged materials and obligations to test raw and finished products. Similarly, the proactive GMP obligation for drugs to ensure all premises are sanitary is replaced by a requirement to have a sanitation plan in place. No quality control department is required; instead, the QAP has responsibility for attesting to a wide variety of activities, from quality of final lots, to addressing recalls, to attesting to the quality of raw materials.

---

[785] *Ibid.*
[786] *Ibid.*
[787] NHPD, *Good Manufacturing Practice Guidance Document*, (Health Canada; Ottawa, November 2003).
[788] *Ibid.*

The *NHPR* represented one of Canada's first paper-based self-regulation processes for ensuring quality.[789] This placed the onus on SL holders to maintain records that demonstrated their GMP activities are in place; the QAP validates the records and this meets the regulatory obligation. Inspections were possible by Health Canada, but these would be risk-based and would mostly seek the existence of the records maintained by the SL holder.[790] The QAP, on behalf of the SL holder, takes on much of the responsibility for ensuring GMP process are documented. The *NHPR* requirements for recordkeeping are broken down by the various activities SL holders might be undertaking: requirements cover manufacturers (s.53), packagers (s.54), labellers (s.55), importers (s.56), and distributers (s.57). Manufacturers have the highest requirements for records retention, including lists of ingredients, records demonstrating each lot was manufactured in accordance with specifications, and records of tests, if any, conducted on NHP lots. In all cases SL holders must have a copy of the sanitation program, list of NHPs being handled at the site, and clear records allowing for product recall.

The GMP provisions were supplemented with the *Good Manufacturing Practices Guidance Document*[791] that outlines in greater detail the GMP practices that must be in place to support the QAP assessment of SL activities. The guidance breaks down these additional requirements based on places, people, processes, and products. The guidance does note that "it is recommended that applicants follow the GMP practices described in the document, but "the NHPD will consider alternative means of complying with the regulations when an acceptable rationale is provided."[792] The places portion captures premises and equipment and includes

[789] Others would follow – CFIA, Drugs, Transport Canada and other.
[790] See the *NHP Compliance Guide* issued by Health Canada in 2003.
[791] NHPD, *Good Manufacturing Practice Guidance Document*, (Health Canada; Ottawa, November 2003).
[792] *Ibid*.

details to allow for cleaning and preventing cross-contamination. Personnel includes the qualifications of the QAP and a list of activities that they have responsibility to oversee and attest to, including ensuring they have "education, training or practical experience" that makes them qualified.[793] The QAP also oversees the establishment of standard operating procedures (SOPs) and ensures that the specifications of the products are being met at each stage of manufacturing. The process section includes requirements for having a documented sanitation program, health and hygiene program, process to monitor SOPs, and documenting details to allow for recalls. SOPs for manufacturers should include material controls (overseeing handling and packaging of raw materials and batches), process controls (ensuring processes are in place and followed), and inspection controls, if any, for third-party manufacturers (do they also have GMP practices in place). Product controls must be in place to assist the QAP in assessing whether specifications are being met and any tests are "accurate and consistent in [their] results."[794]

(v) *NHPR* Part 4 - Clinical Trials

Part 4 of the *NHPR* deals with the process for applying to the regulator to complete clinical trials involving NHPs. This section of the *NHPR* parallels the clinical trial provisions of the *FDR*. At the time of their release, Part 4 was heralded as encapsulating many of the needed updates to the *FDR* in relation to clinical trials,[795] including the explicit incorporation of Research Ethics Boards (REBs),[796] the requirement to provide details on all clinical trials

[793] *Ibid.* Unlike for drug GMP monitoring no formal education is required for a QAP.
[794] *Ibid.*
[795] *NHPR, supra* note 2, Part 4.
[796] *Ibid.*

underway,[797] the full implementation of good clinical practices, [798]and the need to report the cessation of clinical trials[799] and reason for doing so to the regulators. The regulatory provisions are in the *Guidance on Clinical Trials for Natural Health Products*[800]which outlines in greater detail requirements for clinical trial protocols, safety precautions during clinical trials, and the application of good clinical practices.

I only will briefly touch on the clinical trial provision of the *NHPR*, but it is important to remember that the majority of NHPs do not require clinical trials to demonstrate safety or efficacy. Associated historical use, traditional evidence, or existing references (clinical or non-clinical) were generally sufficient for licensing traditional products. Only for newer products wishing to make claims for treatment of severe conditions were they required. In most of these cases, if the product is clinically very effective, manufacturers would likely be incentivised to license it as a pharmaceutical drug, with the period of market exclusivity that they receive. As will be discussed later, with time, NHPD has reduced these standards for non-traditional or modern products. For products that have a pathway to licensing, a failed clinical trial would likely make their product unable to obtain a license. The regulations are also clear that for those already licensed to be on the market, product license holders do not need to apply to the regulator to conduct phase IV post-market clinical trials;[801] they merely must inform the regulator that the trials will be taking place. The result is that the clinical trial provisions of the *NHPR* are much underutilized.[802]

---

[797] *Ibid.*
[798] *Ibid.*
[799] (Health Canada: Ottawa, 2003), hereinafter *Clinical Trail Guidance 2003*.
[800] *Ibid.*
[801] *Ibid.*
[802] *Ibid.*

For those who wish to conduct a clinical trial, whether PL holder or a third-party researcher, the regulations under Section 64(1)[803] prohibit the sale or importation of an NHP for use in a clinical trial, unless under s.68[804] the sponsor is already licensed to use the product for that purpose in Canada. Section 69[805] allows for clinical trials aligned to an existing PL, by informing the regulator of the dates and purpose of the clinical trial 15 days before it is to start. The guidance also notes that clinical trial applications are not required for purely observational studies, which can be used as evidence for licensing of medium- and low-risk claims.[806] If the NHP is a foreign product there needs to be a Canadian party who will be responsible for overseeing the clinical trial and providing the NHP to participants.[807]

Section 66 of the regulations parallels the clinical trial requirements in the *FDR*, outlining what is required before a clinical trial application (CTA) will be approved. These include the trial's protocol, dates of the trial, the investigator's brochure, and clinical trial attestation.[808] Notably the *NHPR* is explicit that an attestation must include written approval from each Research Ethics Board (REB) in the locations where the clinical trial will be conducted. An REB must review both the protocol and clinical and informed consent forms that are to be sought from each participant in the clinical trial. Furthermore, the clinical trial must outline "the risks and anticipated benefits arising to the health of clinical trial subjects as a result of their participation in the clinical trial."[809] The investigative brochure also calls on the applicant to provide

---

[803] *Ibid.*
[804] *Ibid.*
[805] *Ibid.*
[806] *Ibid.*
[807] *Ibid.*
[808] *Ibid.*
[809] *Ibid.*

"chemical and pharmacological properties of the NHP and other pharmokenetics, toxicology and contra-indications if known."[810] This places an onus on the clinical trial applicant to bring forward any known negative clinical or otherwise safety data.[811]

The clinical trial guidance outlies conditions when an NHP clinical trial would be appropriate and should be submitted to NHPD. This might include instances when a product is being tested for a use not included on the product label, NHPs that require additional evidence to demonstrate safety and efficacy, or NHPs with no prior use in humans (i.e., isolates or new extracts). Instances when a manufacturer may choose to conduct clinical trials include determining the long-term effects of the product on the health of patients, for comparison to or support of a conventional pharmaceutical, or a single participant trial (one subject compared over a period of time on two treatments). NHP clinical trials should not be conducted if the product would not be appropriate to be used in self-care.[812] NHP clinical trials are not appropriate when paired with a pharmaceutical being used outside of its approved use or if the NHP contains a medicinal ingredient that would require a prescription.[813]

The guidance suggests that pre-clinical trial application meetings are recommended for investigators and the NHPD Clinical Trail Unit (CTU) to discuss the product and planned protocol. Applicants are expected to have most of their initial trial details developed before meeting with NHPD, to ensure they do not rely on the regulator to draft the trial for them.[814]

---

[810] *Ibid.*
[811] *Ibid.*
[812] *Clinical Trail Guidance 2003, supra* note 799.
[813] *Ibid.*
[814] *Ibid*

Applications must include a full protocol and a *Protocol Synopsis and Evaluation Review Template* (PCERT) which summarizes the protocol for evaluators. Sponsors are also expected to provide a *Quality Overall Summary* (QOS-NHP) template that outlines, if known,

> … a description of the investigational product including the chemical and/or structural formula, if known, the relevant physical, chemical and pharmaceutical properties; chemistry and manufacturing information; dosing information; and instructions for the storage and handling of the dosage form.[815]

Applicants must also submit a summary of any known existing pre-clinical and clinical data or studies as well as market experience (including known safety data) from jurisdictions where it is licensed.[816] The guidance goes into further detail, even more than is required in the general GMP guidance, on requiring information related to the process of manufacture, material chemistry, and quality data required of unlicensed NHPs before they can be used in a clinical trial.

If the Minister finds that the use of the NHP for the purposes of the clinical trial: (1) will not endanger the health of the "clinical trial subjects (or other persons), and (2) the clinical trial is "not contrary to the best interest of the clinical trial subject,"[817] and the "objective of the clinical trial will be achieved,"[818] the Minister shall authorize the selling and import of an NHP for the purpose of the clinical trial.[819] Sponsors are required to submit within 15 days any changes to the trial's protocol, chemical properties, or manufacturing processes associated with the NHP to the regulator. Clinical trials are not allowed to amend a series of conditions outlined in *s.71(1)*[820] related to the study design, selection of subjects, and evaluation criteria for safety

---

[815] *Ibid*
[816] *Ibid*
[817] *NHPR, supra* note 2, Part 4.
[818] *Ibid*.
[819] *Ibid*.
[820] *Ibid*.

and efficacy. Section74 outlines some good clinical practices (GCP), including that the trial is "scientifically sound, informed consent is obtained from participants, [and] those involved in the clinical trial are qualified by education and training, and under the supervision of a qualified investigator."[821] The clinical trial sponsors also have a proactive obligation to notify the regulator if they observe any serious adverse reactions[822] or discontinue the trial for any reason.[823] Clinical trial sponsors must maintain records of each clinical trial[824] and the Minister may request samples of any NHPs used in the clinical trial, even if the clinical trial is suspended.[825]

The Minister may suspend the authorization for sale/import of the NHP for the purpose of the clinical trial if the sponsor fails to comply with the requirements of the Act,[826]in particular if the CTA was false or misleading,[827] or if the clinical trial sponsor is not complying with the good clinical practices required by the Act and guidance.[828] The regulator is required to give the sponsor reasonable opportunity to amend or correct any deficiencies, unless they have "reasonable grounds to believe it is necessary to prevent injury."[829] As with other parts of the *NHPR*, the regulator is required to provide the sponsor reasonable opportunity to respond and correct any deficiencies.[830]

---

[821] *Ibid*.
[822] *Ibid*.
[823] *Ibid*.
[824] *Ibid*.
[825] *Ibid*.
[826] *Ibid*.
[827] *Ibid*.
[828] *Ibid*.
[829] *Ibid*.
[830] *Ibid*.

(vi) *NHPR* Part 5 - General Administrative Provisions

Part 5 of the *NHPR* provides several general administrative guidance, including those on labelling, explicitly incorporating sections of the *FDR* and any major amendments or additions to the regulations since their coming into force in 2004. Sections 84 and 85 allow for electronic signatures and electronic records. Sections 86 through 97[831] deal with packaging and labelling of NHPs. Section 86 provides the general prohibition against selling NHPs unless they are packaged and labelled in accordance with the requirements of the *NHPR*. Section 87[832] outlines these requirements, including the recommended conditions of use, common and proper names of all ingredients (medical and non-medical), description of source material, and product number,[833] which, under Section 88, must be displayed clearly and prominently and be readily discernable under customary conditions.[834] Under Section 93, the product must also include an inner label that has much more detail, including dosage form, amount in the container, name and address of the PL holder, breakdown of all ingredients, recommended dose and duration, lot number, expiry date, and other information. Section 94 sets conditions for small packages if an inner label is not possible. Section 95 mandates the use of secure packaging for NHPs, unless they are lozenges.

Sections 96 through 103 explicitly incorporate sections of the *FDR*[835] that will apply to NHPs. Under s. 96, if pressurized containers are used, they must meet the same conditions in place for foods under the *FDR*, requiring clear labelling and hazard warnings. Under s.97,

---

831 *NHPR, supra* note 2, Part 5.
832 *Ibid*.
833 *Ibid*, *s. 91*.
834 *Ibid*.
835 *Ibid*.

cautionary statements, and child-resistant sections of the *FDR*[836] related to packaging apply when the products contain certain substances which can be hazardous when consumed by children (such as acetaminophen, acetylsalicylic acid, etc.). Similarly, under Section 98, claims about the "site, rate or extent of release to the body"[837] of medicinal ingredients must be backed by investigations that demonstrate these chemical activities.[838] Section 99 adopts the provisions and powers for Health Canada inspectors under the *FDR* that allow them to inspect premises, retain samples, and generally investigate cases of non-compliance. Sections 100 and 101 adopt *FDR* provisions related to product import and export certification respectively.

Although not included in the original regulations, Section 103 includes several amendments to the *NHPR*. Section 103.1 allows for the use of an NHP for emergency treatment of a specific patient analogous to that allowed for a drug by providing "the name of the new drug and details concerning the medical emergency for which the new drug will be imported."[839] Section 103.2 and 103.3 allow for the advertising and sale of products making preventative but not curative claims for diseases listed in the new Schedule A.1 of the Act. Sections 103.4 through 103.5 allow for pharmacists and practitioners to distribute samples under specified conditions. Section 103.6 allows for the distribution of samples of low-risk products to anyone over 18 if "[the] natural health product has a localized effect and is for administration either in the oral cavity or on the skin or is a throat lozenge"[840] and meets other classification requirements established in guidance.[841]

---

[836] *Ibid*.
[837] *Ibid*.
[838] *Ibid*.
[839] *Ibid*.
[840] *Ibid*.
[841] *Ibid*.

(vii) *NHPR* Part 6 - Transitional Provisions and Coming into Force

Part 6 of the *NHPR* contains transitional provisions for delaying compliance enforcement after the coming into force date of the regulations. Most of these transitional provisions have long lapsed, but they provided an extension to continue using existing DINs and for products to be exempt from labelling provisions for the first five years (until December 31, 2009).[842] Products with existing DINs were grandfathered from providing additional safety and efficacy information, and were except from the s.5 (g) PL requirements.[843] Similarly, products approved for clinical trials prior to the regulations coming into effect were allowed to continue.[844] Products being manufactured,[845] distributed,[846] or sold as batch lots[847] before the regulations came into force were allowed to continue doing so without an SL until December 31, 2005. The section also indicated that regulations were to come into force on January 1, 2004.

[842] *NHPR, supra* note 2, Part 6.
[843] *Ibid*.
[844] *Ibid*.
[845] *Ibid*.
[846] *Ibid*.
[847] *Ibid*.

CHAPTER 5 - THE EVOLUTION OF THE *NHPR* AND CANADIAN DRUG POLICY

Part 1 -The Evolution of Health Canada's Policy Agenda

Over the past three decades, Health Canada has introduced several department-wide initiatives to modernize the way it does business. A starting point for these changes was the program review initiated by Prime Minister Paul Martin in 1995, which called for a reduction of Health Canada and HPFB's budget by almost 40%.[848] The initial implication resulting from this program review was the rationalization of administrative processes within Health Canada. This meant reducing the overall number of officials involved in the drug review process and changing many of the administrative steps required for drug reviews. Part of this also involved exploring ways for the regulator to do more with less.

(i) The Health Canada Decision-Making Framework (2000)

Prior to 2002, the main tool for Health Canada's decision-making, including the generation of regulatory policy and program design, was the *Health Canada Decision-Making Framework*.[849] The framework was designed to help Health Canada and its partners better manage risks for the health of Canadians. It was framed by a focus on iterative learning based on

[848] Wiktorowicz, M.E., "Shifting Priorities at Health Protection Branch: Challenges to the Regulatory Process" (2008) *Canadian Public Administration* 43(1) at 1, hereinafter *Shifting Priorities*.
[849] Health Canada, *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* - August 1, 2000, (Health Canada: Ottawa, 2000), online at: https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework, hereinafter *Decision Making Framework*.

issue identification, analysis, and risk assessment, option identification, implementing a strategy, and adjusting activity following evaluation.

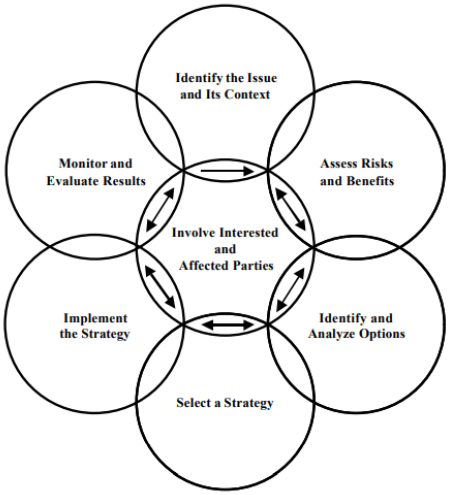

Figure 11: Health Canada Decision-Making Framework (2000)[850]

The main goal of the framework was to "to provide a common, general basis for risk management decision-making throughout the Department."[851]

The framework was based upon a series of underlying principles, primary of which was ensuring that "maintaining and improving health is the primary objective."[852] Or as the guidance notes:

> Give health and safety precedence in making risk management decisions, over economic and other considerations. Balance Health Canada's mandate to protect the health and safety of Canadians, with the right of individuals to make personal choices. Where these two interests are at odds, decisions must always favour the former over the latter.[853]

The guidance also highlighted that "Health Canada has a responsibility to inform and educate Canadians about risks to their health, and the process that is being used to assess and manage

[850] *Ibid.*
[851] *Ibid*, at ii.
[852] *Ibid*, at 5.
[853] *Ibid.*

these risks."[854] When making decisions, regulators should consult widely and assess other determinants of health, but "this can only be achieved by making effective use of sound science advice." Regarding the use of sound evidence the framework notes:

> [It is] in the best interests of Canadians, that science advice is credible, and that decision makers are confident that this advice is based on a rigorous and objective assessment of all available information. In order to achieve these goals, the decision-making process must include measures to ensure the quality, integrity and objectivity of science advice.[855]

When faced with uncertainty resulting from this scientific evidence, the framework asserted that Health Canada should use a precautionary approach. As the framework indicates:

> A precautionary approach to decision-making emphasizes the need to take timely and appropriately preventative action, even in the absence of a full scientific demonstration of cause and effect. It concludes that a lack of full scientific certainty should not be used as a reason not to take preventive measures when reasonable evidence indicates that a situation could cause some significant adverse health effect.[856]

Faced with uncertainty, or an unclear demonstration of risks and benefits, Health Canada should favour precaution until certainty can be assured. This included making decisions about the approval of new products.

(ii) Health Canada's Therapeutics Access Strategy (2003)

In 2003HPFB launched the *Therapeutic Access Strategy* (TAS) with the intention of "speeding up the regulatory process for drug approvals to ensure that Canadians have faster access to the safe drugs they need and creating a better climate for research on drugs."[857] This wording closely mirrors the argument that had been raised by industry and lobbyists, which

---

[854] *Ibid,* at 6.
[855] *Ibid.*
[856] *Ibid.*
[857] Health Canada, *Therapeutic Access Strategy* (TAS), (Health Canada: Ottawa, 2003), hereinafter *TAS*.

framed the regulatory system as a barrier to access and innovation. In the 2003 budget, TAS received a $190-million investment to be spent over five years, to "transform the way HPFB does business."[858] TAS had three specific objectives:

- To make pre-market regulatory decision-making more efficient, timely and transparent, while maintaining high standards of safety.
- To pay greater attention to safety and therapeutic effectiveness once products reach the market.
- To promote optimal drug use, including better practices in prescribing drugs, better management of products and drug plans, and making medicines more affordable.[859]

Improving decisions meant "wipe out the backlog of new drug submissions, consistently meet our performance targets for drug reviews, support better submissions, and improve our review practices and standards."[860] Paying greater attention to products on the market would be achieved by "collecting more information about how safe and effective products are pre and post market."[861] Optimal drug use was to be implemented by investments to "expand knowledge about the links between how drugs are used and health outcomes,"[862] as well as taking "measures to manage drug costs and plans."[863]

In their 2005 progress report on TAS, Health Canada highlighted a number of immediate and long-term actions underway. Foremost was the goal of "beating the backlog [through] process improvements and meeting established performance targets."[864] This represents a significant reframing of the approval process for drugs (including NHPs) around speed rather

[858] *Ibid.*
[859] *Ibid.*
[860] *Ibid.*
[861] *Ibid.*
[862] *Ibid.*
[863] *Ibid.*
[864] *TAS Progress, supra* note 377.

than accuracy, recasting the complexity of submissions as the management of a backlog. Researchers at the time noted that, for drugs, Canada's approval times were equal to or faster than most other G8 countries,[865] and the majority of new drugs seeking approval were neither innovative[866] nor particularly needed new therapies.[867] Other planned process improvements included the standardization of new guidance documents, introducing new review templates, allowing electronic submissions, and establishing an ombudsman's office to mediate disputes between industry and the regulator.[868] To tackle the backlog, submissions were recast as not an assessment of the scientific information but instead a process of project management with benchmarks and performance targets. Researchers at the time worried this would change the assessment process from a robust and independent scientific evaluation to one focused on the meeting of project targets and timelines.[869]

Health Canada also made moves to strengthen the information HPFB provided by promising to become "more transparent, responsible and accountable."[870] This involved provisions to improve the availability of information used in reviews and publishing more accurate drug information. Health Canada planned to include a host of new additional information in publicly available formats, including: new online monographs, online summary basis of decisions, a Notice of Compliance Database and publication of quarterly and annual performance plans.[871] Aligned with the practices of smart regulation, HPFB also promised to increase the number of science and management advisory committees it used to support

---

[865] *Ibid.*
[866] *Ibid.*
[867] *Ibid.*
[868] *Ibid.*
[869] *Ibid.*
[870] *Ibid.*
[871] *Ibid,* at 10.

decision-making. This included expanding the membership advisory committees to include representatives from patient and consumer groups as well as industry.

To improve safety, HPFB pledged to make a one-stop public safety and information portal for Canadians.[872] A new unit was proposed within HPFB, the *Marketed Health Product Directorate* (MHPD), which would "assess the therapeutic effectiveness of health products after they reach the market."[873] In reality, HPFB never truly developed the capacity to independently assess efficacy; it merely evolved into the agency responsible for tracking ADRs. HPFB also planned to greatly expand their "post-market inspection strategy to assess how well manufacturers are complying with the *Food and Drug Act*."[874] New tools were also introduced, including a website which tracked ADR data, new procedures were planned for reporting ADRs, and discussions began about improving international cooperation and harmonization around drug approvals. Many of these changes were not realized when the government changed in 2006.

(ii) Health Canada's Blueprint for Renewal (2006 - 2016)

a. Blueprint for Renewal I (2006)[875]

In 2006 the new government launched a more aggressive health agenda to "reorient the regulatory system to better align with modern realities."[876] From their perspective, the TAS did

[872] *Ibid*
[873] *Ibid*
[874] *Ibid*
[875] *Blueprint I, supra* note 24.
[876] *Ibid.*

not go far enough. Under the new plan, the *Blueprint for Renewal*, they sought to completely change, or "modernize," the rules the regulator employed by addressing:

- an outdated regulatory toolkit that is increasingly limited and inflexible in responding to today's health products and food environment;
- the regulatory system's current incapacity to consider a given product through its entire lifecycle, from discovery through to examining the "real-world" benefits and risks of a health product or a food on the market;
- the impact of social and economic changes, such as accelerating scientific and technological advances, the rise of trans border health and environmental threats, and a more informed and engaged citizenry;
- a regulatory system that currently works in isolation from the activities and policies at the stage of research and development, and those of the broader health-care system; and
- a regulatory system with insufficient resources for long-term efficiency and sustainability.[877]

The government further articulated that this modernization was needed because, noting Braithwaite's pyramid of needs, HPFB had an "outdated toolkit that is increasingly limited and inflexible."[878] As the *Blueprint* notes, "Health Canada requires regulatory tools that support, rather than hinder, its ability to fulfil its health protection and promotion mandate."[879] The report goes on to argue: "these challenges suggest a need to fundamentally change our regulatory approach as a necessary prerequisite to meet the rising expectations of Canadians."[880] This reframes the goals of food and drug regulation to consider a series of external drivers other than just public safety and health concerns, when administering and drafting regulations.

To achieve these goals, the *Blueprint* proposes a number of specific changes to the regulatory system. The first was moving to a product lifecycle approach that would "mark a major shift in regulatory practices to allow for a continuous evaluation of the safety,

[877] *Ibid*, at 6-7.
[878] *Ibid*.
[879] *Ibid*, at 8.
[880] *Ibid*.

effectiveness and quality of products before and after they are on the market."[881] This includes introduction of smart regulatory tools related to risk management and linking to harmonization of standards. The second was the introduction of the concept that regulators should be "moving to regulatory interventions proportional to risks."[882] The proposal was to "revamp the product categorization system so that regulatory interventions are proportional to risk and program investments are focused on higher-risk products."[883] This represents the clear adoption of a system of risk regulation.

In this framing, the *Blueprint* draws analogy to the risk categorizations in place for medical devices. In this context, the *Blueprint* explicitly mentions the *NHPR* review, and how these low-risk regulations need to be harmonized with other portions of the *FDA*. Unlike for medical devices, it is simply assumed that risk categorization for these products is low, and there is no intention of establishing a similar scientific process for vetting the various categories in place. Assuming NHPS are low risk is a policy decision about the appropriate level of regulatory intervention, not one based upon any scientific assessment of these products. Instead the regulator's capacity to address the backlog likely led to a *deminimus* standard, which in turn led to NHPs being re-cast as low risk. It is unlikely that the consuming public is aware of the fine distinction between a scientific and policy rationale for designating a NHPs as low risk.

Another component of the *Blueprint* was to introduce "a more proactive and enabling regulatory system."[884] This was intended to include greater engagement with stakeholders and

[881] *Ibid.*
[882] *Ibid.*
[883] *Ibid,* at 18.
[884] *Ibid.*

regulators to proactively forecast the needs of industry. Discussions with industry on safety and efficacy concerns were to occur "early in the development process and [be] enabling rather than creating obstacles to the commercialization of products."[885] This represents a further reframing of the purpose of health regulation to expand access and facilitate commercialization rather than solely ensuring health and safety. It also embeds the needs of industry at the forefront of the drug review process.

Health Canada also emphasized that other types of evidence than clinical trials were to be considered in product evaluation, such as "surrogate endpoints (substitutes) for clinical trials and their subsequent validation [with] real world safety and therapeutic effectiveness."[886] This, in turn, meant looking at drug approvals based on evidence "aimed at accommodating food (and other product) innovation."[887] For NHPs, this would mean an expansion of the types of acceptable evidence used in product approvals, and the abandonment by NHPD of the development of scientific compendia (monographs) by a unit at NHPD independently researching external sources of information.

In order to achieve these goals, HPFB would develop a "21st century toolkit of legislation, regulatory instruments," adopt international benchmarked regulatory practices and processes, adopt risk management practices, and enhance strategic international regulatory cooperation and partnerships. Part of this would also involve a suite of new regulations and the employment of new regulatory instruments. In selecting these instruments, Health Canada "will

[885] *Ibid.*
[886] *Ibid.*
[887] *Ibid.*

assess a range of tools, based on effectiveness, legality, compliance, fairness and socioeconomic impacts, prior to selecting the appropriate instrument."[888]

b. Blueprint for Renewal Part II (2007)[889]

Although the *Blueprint* had initiated significant changes, one year later, Health Canada released the *Blueprint II - Modernizing Canada's Regulatory System for Health Products and Food* (*BP II*).[890] It was intended to be a "more comprehensive articulation of Health Canada's plans," giving explicit detail on "how [Health Canada] will concretely move forward to design a regulatory system that further protects the health and safety of Canadians."[891] A large part of the *BP II* was the announcement of regular reviews across all product lines. This included: expanding the special access program for new drugs, reviewing the framework for clinical trials, reviewing the existing regimes for blood products, vaccines and radio pharmaceuticals, reviewing the veterinary drugs program, revamping the medical devices program, and explicitly making the NHP regulatory review more responsive to industry and consumer needs. The goal of each of these reviews was to move towards regulatory processes that would be proportional to risk and remove impediments preventing products from reaching the market.

[888] *Ibid,* at 27.
[889] *Blueprint II, supra* note 24.
[890] *Ibid.*
[891] *Ibid.*

c. The New Health Canada Compliance Framework

One of the changes following the *BP II* was the introduction of the new *Health Canada Compliance Framework*.[892] Informed by the responsive regulatory compliance pyramid of Braithwaite, it introduces a wide number of different compliance tools and allows for discretion in responding to cases of non-compliance. These would range from "reviewing records and collaborating and consulting with regular parties"[893] all the way to "recommending prosecution and criminal investigation."[894]

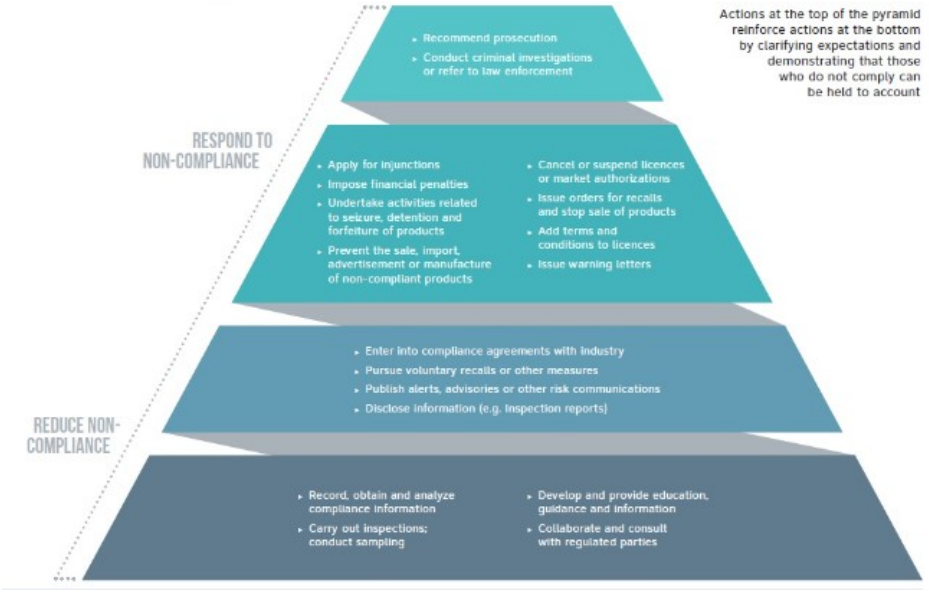

Figure 12: The Health Canada Compliance and Enforcement Pyramid[895]

Resembling Braithwaite's compliance pyramid,[896] the majority of compliance actions would fall somewhere in the middle, involving less aggressive compliance measures such as entering into

[892] Health Canada, *Compliance and Enforcement Policy Framework*, online at: https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/compliance-enforcement-framework.html, hereinafter *Compliance Framework*.
[893] *Ibid.*
[894] *Ibid*
[895] *Ibid.*
[896] *Ibid.*

compliance agreements with industry, issuing written warning letters, and adding terms and conditions to licenses to make necessary changes and improve their processes.

Under the Compliance Framework, these activities were to be mitigated by other considerations such as: (i) health and safety factors; (ii) behaviour of the regulated parties (non-compliance being accidental vs. deliberate); (iii) the compliance history of the regulated party; and (iv) other factors (scope of the issue, distribution of the product, likelihood that the issue will occur again, likely success of compliance, or other mitigating concerns). This new version introduced a high degree of discretion for regulators deciding to act on cases of non-compliance. As with all responsive regulation, it had the potential to shift the locus of regulatory activity to the decision on what compliance activity would be imposed. It was also open to criticism that it would serve industry by allowing a high degree of non-compliance. It ran the risk of being interpreted, at least in the case of lower-risk products, as sanctioning a certain degree of non-compliance. In the case of NHPD it would eventually lead to a "risk-based" compliance approach.[897]

d. The Food and Consumer Safety Action Plan[898]

In 2007, as part of *BluePrint II*, Health Canada also launched the *Food and Consumer Safety Action Plan* (FCSAP) with the goal of updating legislation and regulations to "improve industry oversight, respond more quickly to risk, and provide better product information to

[897] *Ibid.*
[898] Health Canada, *The Food and Consumer Safety Action Plan*, (Health Canada: Ottawa, 2007), hereinafter *FCSAP*.

Canadians."[899] The FCSAP reiterated the need for a lifecycle model that focused efforts on the highest-risk products, an affirmation that risks should largely be mitigated post-licensing. This would include an increased use of "systematic and rigorous pre-submission meetings with companies in order to identify safety concerns at an early stage and work with industry to develop an approach forward (with submissions)."[900] One of the most significant changes brought in by the FSCAP was the introduction of new legislation to update the four-decades-old *FDA*. The failed *Bill C-51* (2008)[901] was intended to fully adopt a progressive licensing model for therapeutic products, introduce new options for expedited approvals, and expand the Minister's compliance and enforcement powers. *Bill C-51* died on the order paper with the prorogation of Parliament in 2008.

e. The Consumer Products Safety Act

In 2011, the government reintroduced many of the provisions of *Bill C-51* for non-therapeutic products (i.e., consumer products and foods, but excluding drugs, including NHPs and medical devices) under the *Canadian Consumer Product Safety Act* (*CCPSA*).[902] This more general act increased the powers of the Minister and placed a premium on post-market inspection by the HPFB Inspectorate and CBSA. The *CCPSA* also came with guidance on choosing which tools to use in developing new regulatory frameworks, captured in the *Instrument Choice Framework for the Canadian Consumer Product Safety Act.*[903] This guidance outlines smart

[899] *Ibid.*
[900] *Ibid.*
[901] *Supra*, note 237.
[902] *S.C. 2010, c. 21.*
[903] Health Canada, online at: https://www.canada.ca/en/health-canada/services/consumer-product-safety/legislation-guidelines/guidelines-policies/instrument-choice-framework/summary.html.

regulatory principles to be considered when developing regulations or compliance tools. Regulators are to consider "a range of regulatory and non-regulatory instruments" to manage consumer product risks. In assessing the selection of regulatory tools and ways to address and identify risks, regulators were to favour solutions that:

- Achieve effective management of consumer product risks while minimizing the regulatory burden and costs to suppliers and consumers
- When appropriate, address risks through the use of non-regulatory instruments or the Prohibition by aligning requirements with existing standards or international requirements, rather than establishing new regulatory requirements[904]

This guidance placed the risks related to health on par with risks derived from increased regulatory burdens and the risks associated with reducing economic activity.

f. Health Canada's Consumer Health Products Framework (2014)

In 2014 the Conservative government relaunched their efforts to modernize the legislative and regulatory system for therapeutic products with the *Consumer Health Products Framework* (CHPF).[905] The goal of the CHPF was to "establish a consistent and aligned approach to the regulation of health products for consumers."[906] The headline of this initiative was to be an updated *FDA* as embodied in *Vanessa's Law*. Other components of this initiative would include modernizing the *Food Regulations*, updating the *Medical Devices Regulations* and an overhaul of the *Veterinary Drug Regulations*. Improving the operation of the *NHPR* was included in the initiative, but no intention to modernize the regulations was formally included in the plan. Another goal of the CHPF initiative was to create a new regulatory system for products

[904] *Ibid.*
[905] Health Canada, online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/natural-health-products/framework-consumer-health-products.html.
[906] *Ibid.*

that the regulator deemed to have similar low risks. In particular, the initial goal was to address issues around "non-prescription drugs, which are regulated using the same outdated set of regulations as prescription drugs."[907]

Part 2 - Regulatory Gaps in the NHPR

In 2007, Health Canada produced the consultation paper *Charting a Course: Refining Canada's Approach to Regulating Natural Health Products*.[908] The paper outlined regulatory issues that had arisen in the first few years of regulation. Identified issues included those relating to combination products, the lack of a link between site licenses and product licenses, the absence of advertising provisions in the *NHPR*, questions of how to deal with high-risk NHPs, and even a request from industry to have NHPs designated as a class of exclusively "self-care" products.[909] There are additional gaps that were explicitly excluded. Primarily among these was the broad definition of NHP, an underestimation of the scope and number of products which would be captured under these regulations, and the explosion of products making modern/non-traditional claims. In the following section, I will outline some of the identified and emerging issues that became apparent as the NHP regulations came into force.

(i) Definition: Everything is an NHP

The first and most significant issue with the *NHPR* is its broad definition of an NHP under s.2, which can be interpreted to include just about any product making a health claim. Originally,

---

[907] *Ibid.*
[908] *Charting a Course, supra* note 23.
[909] *Ibid.*

the standing committee's recommendations were directed towards a small class of products such as herbal remedies, vitamins and minerals, homeopathic drugs, and other traditional medicines. The regulations were also intended to focus on existing claims for these types of products.[910] However, the inclusion of a new type of claim under part c of the definition "modifying organic function in humans"[911] exceeded the types of claims which were allowed for a drug. It also made the definition of NHP one of the most inclusive in the world. Together with the broad scope of what is captured under the composition of NHPs (Schedule 1), including "a plant or a plant material, an algae, a fungus, or a non-human animal material, an extract or isolate and a "**synthetic duplicate** of a substance,"[912] there are few products making a claim, natural or otherwise, that could not argue they were an NHP.

The broad definition of NHP was further compounded by the provisions of Section 3, which exempted products meeting this definition from the application of any provisions of the *FDR*. This meant that foods, cosmetics, some drugs, medical devices, and even veterinary products claiming to be NHPs could try to use this licensing regime. It also allowed products that had previously failed to obtain a license under one of these other regimes to try again using the *NHPR*. The result, whether intended or not, was an explosion of new products seeking licensing under the more permissive NHP regime. A wider consequence was the sudden creation of a very large market of consumer products making health claims, such as antiperspirants, cosmetics, foods, toothpaste, energy bars, and others, that were prohibited before 2004.

---

[910] *New Vision, supra* note 713.
[911] *NHPR, supra* note 2 at *s.2*.
[912] *Ibid,* at *Schedule 1*.

(ii) Whither the Evidence of Efficacy

At the time that the *NHPR* came into force, products making traditional claims continued to use the same evidential criteria to demonstrate safety and efficacy that had been in place to obtain a DIN. These criteria, originally created to license herbal remedies, were expanded to capture more forms of traditional medicines with clear guidance. Additional evidence was not required for products that had previously submitted this information to Health Canada to obtain a DIN. For new traditional claims, evidence required would include a history of use, a citation referring to traditional sources of information (monograph or pharmacopeia), and a claim that the product poses no known safety issues. However, the criteria that would be applied to products not relying on traditional claims was less clear. Section 9 of the *FDA* would require that these modern/non-traditional products not make claims that were "false, misleading, or deceptive or... likely to create an erroneous impression regarding [their] character, value, quantity, composition, merit or safety."[913] For new conventional drugs, this requires a clear demonstration of safety and efficacy with clinical studies or other sources of scientific evidence.

As will be discussed in the next section, it would take almost two years for the NHPD to issued clear guidance on the type of evidence required for modern/non-traditional claims. This was further exacerbated by the flood of new or existing products seeking to use the *NHPR* as a pathway to market. Early in its mandate, NHPD made reference to a "pyramid of evidence,"[914] but did not provide specific details about the type and nature of evidence required to license modern/non-traditional claims. Notionally, evidence should be higher for non-traditional

[913] *FDA, supra* note 6 at *s.9*.
[914] *Charting a Course, supra* note 23.

products, because they lacked a cultural justification for using other sources. Additionally, there were very few full compendial descriptions of products in the form of monographs available when the *NHPR* launched, and only a few more were completed in the first few years that the *NHPR* was in operation. This made it difficult for applicants to rely upon Health Canada's guidance to determine what constitutes scientifically validated claims. It also made it unclear which criteria regulators were using to make risk-benefit decisions around licensing of newer products.

(iii) Combination Products

The regulatory obligations for NHPs were seen as less burdensome while allowing for a greater range of health claims than existing regulations. This was particularly notable for products which were limited in composition or claim by a set of older regulations the *Cosmetic Regulations*, the *Medical Devices Regulations*, *Veterinary Regulations*. By allowing applications for these products to become NHPs there was a potential for creating a two-tiered system where similar products were regulated under different regulations and marketed using different SEQ standards.

a. Food NHPs

Many of the early product licenses that NHPD received were for foods that had previously only been allowed to make a small number of nutrient content claims under the *FDR* as foods. The *NHPR* allowed for a much broader collection of structure function claims. The Food

Directorate (FD) had limited the allowable claims because they had determined that there was limited scientific evidence to justify most health claims on foods. Furthermore, the FD had decided that certain products, such as energy drinks and fortified foods, should not be allowed on the market for safety reasons or because health claims were not justified. The safety reasons included these products containing substances that could only be safely consumed in a specific dosage form. As was noted in the 2007 *NHPR* regulatory review consultation paper:

> Canadians may tend to consume these products freely without taking into consideration the recommended conditions of use and the fact that they contain medicinal ingredients which, if over-consumed, increases the risk of potential adverse effects.[915]

The FD long held that any food on the market must be safe for *ad libitum*[916] consumption, meaning that it can be safely consumed at will and without limit.

NHPD came to call foods seeking licensing under the NHP regulations "food-like NHPs." These products claimed, based on either additives (e.g., fortified with vitamins) or inherent properties (e.g., herbal teas), to produce health effects. This new class of product included fortified foods (those with additives), functional foods (those with inherent health properties), nutraceuticals (those with nutritive health claims), and other foods that made specific or general health claims. Food-like NHP manufacturers sought expanded health claims, but with less evidence than would be required by FD to justify these claims.

The original intent of Health Canada was to propose amendments to the *NHPR* "to exclude food-like NHPs from the purview of the *NHPR*…this regulatory amendment would

[915] *Charting a Course, supra* note 23 at page 31.
[916] Latin for *at will* or *with freedom*.

make it clear that these products are not regulated as NHPs."[917] However, the regulator sought a compromise that would allow for each product to be evaluated by an expert advisory committee to determine the appropriate regulatory pathway. In practice, the guidance led to most products being classified as NHPs. This process ultimately led the FD to update their regulations to allow for broader claims. In certain cases, such as energy drinks, this was done with no new evidence that these products were any safer or that the health claims which the FD had not allowed prior to 2004 were any more valid.

In 2017, new classification guidance was issued,[918] which amended the earlier criteria to focus on several factors such as product composition (food versus Schedule 1 substances), product representation (whether the product is primarily sold as a food or drug), product format (whether it has packaging which is more emblematic of a food or NHP), public perception (what would a sampling of the public think of the product) and its history of use (has it historically been sold as a food or drug).[919] However, even these criteria are likely to be affected by the advertising, packaging, and claims that a manufacturer chooses to use.

Health Canada also issued a series of new guidance for specific products that carved out a regulatory pathway for them that was distinct (*Guidance Document for Preparing a Submission for Food Health Claims* – 2009).[920] Again, none of these products had submitted additional

---

[917] *Charting a Course, supra* note 23.
[918] Health Canada, *Guidance Document: Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats*, https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/classification-products-at-food-natural-health-product-interface.html
[919] *Ibid.*
[920] Health Canada, online at: https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-claims/guidance-documents-preparing-submission-food.html.

information to demonstrate their safety or provide additional evidence to support their claims. The distinction between specific classes of products was likely lost on the public consuming items such as probiotic yogurts, vitamin waters, herbal teas, and energy boosters, where the required level of evidence to demonstrate their nutritional and physiological effects had been lowered. Even more concerning were products that had previously been excluded from the market due to health and safety concerns, such as energy drinks, which were now on the market and indistinguishable from many other beverages.

b. The Cosmetic – NHP Interface

The second-largest class of combination products consisted of NHP-cosmetics. Prior to 2004, cosmetics were allowed to make a very limited number of health claims because most claims could not be supported by scientific evidence. To make substantive health claims, these products would have been classified as drugs and would have required a full set of clinical trials. However, the *NHPR* allowed NHP-cosmetics to make a broader range of health claims if they met certain packaging and labelling requirements such as secure packaging and inclusion of dosage forms and an NPN. The *Canadian Cosmetic, Toiletry and Fragrance Association* (CCTFA) argued that a carve-out for the *NHPR* and *Cosmetic Regulations* should be created for a new class of **personal-care products** (PCP) which would be exempt from certain labelling and GMP standards, while still employing the more permissive regulatory requirements of the *NHPR*.[921] This exemption would apply to a vast number of products including deodorants, sunscreen, toothpaste, and lip glosses, etc. The CCTFA recognized that allowing these products

[921] *Charting a Course, supra* note 23.

to be paired with health claims would create a lucrative market while reducing regulatory barriers.

In 2009, Health Canada issued the *Guidance -Classification of Products at the Cosmetic Drug Interface*[922] to classify products as cosmetics or NHPs. The guidance sets upcriteria that could be used to classify products as cosmetics or NHPs based on product composition, level of action, inherent risk, and previous decisions. However, the dominant criterion for making the decision would likely be perception, or whether the product would be perceived "by consumers to have characteristics of a drug."[923] Perception criteria would include:

> … the purpose for which the general public uses the product and whether it is likely to be understood by consumers to have characteristics of a cosmetic or drug. Perception is further influenced by the extent or level of action promised by a product, in addition to the consumer's expectations for the level of regulatory control applied... To a lesser extent, placement and location of sale may also be taken into consideration. While perception would not be considered the sole basis for a decision, in certain cases, it may have an influence on how a product is used by consumers.[924]

The new guidance acknowledged the new class of personal-care product "as a substance or mixture of substances which is generally recognized by the public for use in daily cleansing or grooming. Personal-care products may fall into one of three regulatory categories in Canada: cosmetics, drugs, or natural health products."[925] The result is that most commercial cosmetic products making health claims became NHP personal-care products.

[922] Health Canada, online at: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/guidance-document-classification-products-cosmetic-drug-interface.html.
[923] *Ibid.*
[924] *Ibid.*
[925] *Ibid.*

The updated guidance resulted in an explosion of cosmetic products making a host of modern/non-traditional health claims seeking licensing as NHPs, despite no new evidence being submitted showing that these products had greater efficacy or health value to the public. Personal-care products represent the first class of NHPs that were allowed to make claims and that Health Canada approved with less evidence because the regulator had deemed them low risk. There is a fairly extensive literature demonstrating that many personal-care products, cosmetics in particular, are not low risk, and that as a class of products they are severely under-regulated.[926] Still, Health Canada without a scientific assessment has deemed them low risk and is focused on "improv[ing] the current legislation affecting these products so that they are regulated in a timelier, less onerous, and consistent manner."[927]

(iv) Quality Concerns: A Reduced Standard for SL and GMPs

The *NHPR* uses site licensing (SL) as the primary mechanism to assess a product's quality. This process involves manufacturers attesting that they are implementing good manufacturing practices (GMPs). However, the standards for site licensing and GMPs for NHPs are much lower than those required for a drug establishment license (DEL). The criteria for a DEL includes a comprehensive list of all products to be manufactured, quality assurance personnel with professional designations, and more detailed GMP standards. Drug standards require final product testing, testing of all ingredients, regular sanitary and safety testing, extensive details about manufacturing and records, as well as samples of finished and unfinished

[926] Sheikh, K., *Many Personal Care Products Contain Harmful Chemicals. Here's What to Do About It* (New York Times: February 15, 2023), online at: https://www.nytimes.com.
[927] Health Canada, *Next Steps on The Self-Care Products Initiative*, online at: https://www.canada.ca/en/health-canada/services/self-care-framework.html.

products throughout the manufacturing process. In contrast, GMP standards for NHPs are far lower and require less product testing, fewer sanitary measures, and rely more on a paper-based attestation of a quality assurance official.

According to the guidance released at the time of the *NHPR* coming into force, the *Good Manufacturing Guidance Document,*[928] assessments for GMPs would typically only be conducted when an SL is requested, or sites could be inspected by HPFBI if the Inspectorate had concerns regarding compliance with GMPs. Observed GMP non-compliance was divided into three risk categories based on "the deviations from good manufacturing practices, as well as the number of occurrences."[929] In contrast to drugs, non-compliance and revocation of an SL for NHPs was not automatic; instead:

> …observations during an inspection may result in a non-compliance rating. However, if the factor causing the risk is not widespread or occurs only occasionally, Health Canada may not take these actions automatically.

Type 1 risk includes "observations of a situation likely to result in a natural health product not complying with the *NHPR*, or to create an immediate or latent health risk."[930] This would usually result from "observations of fraud, misrepresentation and/or falsification of product or data."[931] When risks in this category are observed, a license will not be issued, or an inspector may take immediate actions (e.g., seizure or voluntary detention of the product). Type 2 risk involves "observations that may result in the production of a natural product that does not meet its market authorization." This generally implies adulteration. Type 3 risk would be any other type of variations from GMPs, for which a compliance rating would be provided.

---

[928] *Supra,* note 791.
[929] *Ibid*.
[930] *Ibid.*
[931] *Ibid.*

When Type 2 or 3 risks were reported, "NHPD will still issue a site licence or the inspector gives a compliance rating"[932] that would not immediately result in suspension of an SL. Many Type 2 and Type 3 risks would not be allowed for manufacturers making drugs or foods. Some kinds of Type 2 risks for NHPs that would not immediately violate GMP criteria include:

> grounds around manufacturing buildings not suitably maintained to protect against adulteration of the product, equipment not operating to specifications, equipment locations not preventing cross contamination, QAR officials not being qualified, no written procedures or documentation of manufacturing process, not having a sanitation program in place, raw materials stored under inappropriate conditions, no self-inspection program, samples not kept of finished products.[933]

A violation of any of these criteria for a drug or food manufacturing facility would likely lead to compliance action, such as license suspension, product warnings, or recalls.[934] In effect, NHPD was sanctioning a lower level of GMPs for NHPs than any other therapeutic product and a higher bar for compliance action when violations were detected.

(v) Decoupling Site Licenses, GMPs and Product Licensing

One of the main issues with NHP site licenses was that they were not linked to product licenses. This linking had been included in an earlier version of the regulations at CGI,[935] but was removed from the final version due to stakeholder feedback that it would be difficult to have this information at the time of submitting a PLA.[936] As a result, PLs were issued without specifying where the product would be manufactured and SLs were issued without specifying

---

[932] *Ibid.*
[933] *Ibid.*
[934] *Ibid.*
[935] *Canada Gazette I, supra* note 407.
[936] *Canada Gazette II, supra* note 743.

which products would be produced at the site. Both drugs and food manufacturers automatically track products and relate them to manufacturing sites. This meant it could be very hard to track non-compliance. This is an issue NHPD has still not resolved to this day. If a non-compliant site is identified, there is no simple way for the regulator to trace quality concerns to all products (PLs) made at that location quickly. Similarly, if a specific product is found to be adulterated, it cannot be automatically linked to the SL where it was manufactured. This makes compliance and enforcement activity difficult, and the regulator must rely on voluntary recalls and manufacturers relaying SL or PL information to the regulator.

(vi) Lack of Post-Market Powers

At the time of the regulation launch, both NHPs and drugs faced a significant gap in post-market enforcement. Health Canada did not have the legal authority to enforce post-market conditions on all marketed drugs or to compel the recall of products once they were licensed, except in clear cases of fraud or in cases where the regulator believed there was an imminent danger to human health. Health Canada had to negotiate with PL holders to voluntarily remove a product from the market, as most NHPs do not meet the criteria of posing an imminent harm to human health. Unfortunately, this issue persists to this day. As noted elsewhere, in 2014, *Vanessa's Law*[937] expanded the Minister's power to remove marketed products. However, NHPs were explicitly exempted from the updated *FDA* provisions of *Vanessa's Law* until 2023[938]

[937] *Supra* note 240.
[938] *BIA 2023, supra* note 242.

The degree to which any post-market adverse event reporting regime for NHPs would function was also unclear. The *NHPR* did specify the requirements to provide adverse drug reports (ADRs), including reporting any serious or unexpected ADRs to Health Canada after they come to a PL or SL holder's attention. It also imposed obligations on hospitals or health professionals who became aware of NHP ADRs, which would normally include pharmacists, doctors, and NHP practitioners. Yet, as self-care products, the majority of NHPs would be taken without the intervention of a practitioner. A process was established for patients to self-report adverse events, but it involved using a complex portal to file a report with the regulator. This means that a critical component of the long-term health-and-safety profile of these products is lacking. Only in the most extreme cases of hospitalization or when death occurs and a practitioner or institution intervenes would high-risk ADRs come to light.

(vii) Schedule A and Schedule F

At the time the *NHPR* came into force, many products licensed under the new regime would potentially be in violation of *Schedule A* and *Schedule F* of the *FDA*. In relation to *Schedule A*,

> 3(1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.[939]

Schedule A itself listed a set of diseases such as alcoholism, asthma, cancer, epilepsy, dysentery, hypertension, liver disease, sexual impotence, tumors etc.[940] They represent the most common

[939] *FDA, supra* note 6 at *Schedule A*.
[940] The full list of *Schedule A* conditions include: Arthritis, Asthma, Alcoholism, Alopecia, Anxiety States, Appendicitis, Arteriosclerosis, Arthritis, Asthma, Bladder Disease, Cancer, Convulsions, Depression, Diabetes, Disease of the Prostate, Disorder of Menstrual Flow, Dysentery, Edematous State, Epilepsy, Gallbladder Disease,

conditions for which patented medicines were fraudulently sold to the public during the snake oil era of the early 20th century. The idea behind *Schedule A* was to prohibit the sale of substances making claims that needed to be mediated both by proving SEQ through product review and requiring prescription. Most of the conditions listed in *Schedule A* are considered severe and cannot be treated without the intervention of a health-care practitioner.

NHP manufacturers wanted to make treatment claims for many of these disorders. Health Canada initiated consultations on the removal of prohibitions for NHPs making *Schedule A* claims. This would eventually lead to a push to remove *Schedule A* from the *FDA* altogether. There is not much evidence that most NHPs would be effective in treating *Schedule A* diseases, but the belief was that the general prohibition at the level of the *FDA* for making false and misleading statements (s.5 and s.9) should serve as the key authority for preventing fraud around these products. It was argued that NHPs would be backed by a robust product review that could validate the truthfulness of the claims being made and a robust post-market surveillance regime to detect fraud and non-compliance. As a result, *Schedule A* would be redundant. This places a large amount of credence on the strength of the evidence that would be brought forward during product reviews of NHPs. Regardless, in anticipation of the *NHPR* coming into effect, Health Canada began a process to repeal *Schedule A*.

Gangrene, Glaucoma, Gout, Heart Disease, Hernia, Hypertension, Hypotension, Impetigo, Kidney Disease, Leukemia, Liver Disease, Nausea and Vomiting of Pregnancy, Obesity, Pleurisy, Rheumatic Fever, Septicemia, Sexual impotence, Thrombotic and Embolic Disorders, Thyroid Disease, Tumor, Ulcer of the Gastro-intestinal Tract, Venereal Diseases.

Schedule F,[941] on the other hand, prohibited medicinal ingredients from being sold unless they were by prescription. Part I of *Schedule F* listed medicinal ingredients that were prohibited from sale to both animals and humans, and Part II listed medicinal ingredients that would require a prescription for human use. As a result, many naturally occurring substances in NHPs could be prohibited by *Schedule F*. For example, the inclusion of *yohimbine* in *Schedule F* meant that *yohimbine bark* (commonly used to improve athletic performance or as an aphrodisiac) would be prohibited from sale. A more extreme example is that *Schedule F* also listed *uracil* with no qualifications. *Uracil* is a common amino acid found in the RNA of all living things; this could be interpreted to mean that all natural products which contain RNA might be in violation of the Act. *Schedule F* was a residual of the general prohibition of certain substances not being allowed in any products, without a prescription, to prevent adulteration. Initially NHPD would propose qualifiers to *Schedule F* that related to the dose, quantity, or route of administration, but eventually the push would be to remove *Schedule F* completely from the *FDA* to assist in the licensing of NHPs. Another layer of protection for the consumer related to prohibited substances was removed to allow for NHPs.

(viii) Advertising and Sampling of NHPs

The *NHPR* came into force with no provisions that spoke to the advertising or sampling of NHPs. Under the *FDA,* drugs can only be advertised directly to consumers under very restrictive conditions, not breaching the requirements of s.3 (1) and s.9 (1) against false and misleading information. *Section C.08.002* of the *FDR*[942] required that the terms of market

[941] *FDA, supra* note 6 at Schedule F.
[942] *FDR, supra* note 6.

authorization of a drug be established before any sale or advertising, meaning only market authorized products can be advertised in Canada. The process for the clearance of advertising for drugs allows for a limited form of print or broadcast advertising as defined by guidance[943] released by the *Advertising Standards Council* (ASC) of Canada. This advertising was also required to go through a clearing process administered by the ASC which reviewed it for compliance before release.

Conversely, the *NHPR* is silent on what type of advertising would be allowed or what the review process would be for proposed advertising. This led to initial challenges for NHPD to place any controls on the form and content of advertising for NHPs. On one hand, some argued that the lack of express provisions in the *NHPR* meant that NHPs were not authorized for advertising, and that any direct-to-consumer advertising violated the *FDA*. On the other hand, others argued that without specific prohibitions or conditions in the *NHPR*, there were no restrictions on NHP advertising, and that any compliance activity lacked the force of law. As a result, there was confusion and an explosion of commercial advertising for NHPs, including notable examples such as probiotic yogurt commercials featuring Jamie Lee Curtis[944] and the infamous slogan "Red Bull gives you wings."[945]

The same ambiguity existed around product sampling. *Section 14(1)* of the *FDA* prohibits the distribution of drug samples.[946] *Section 14(2)* of the *FDA* allows for an exemption for

---

[943] See Health Canada, *Regulatory Requirements for Advertising*, online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising.html.
[944] Watch online at: https://www.youtube.com/watch?v=uY4fxLbnWBk.
[945] Watch a Red Bull advertisement from 2005 at: https://www.youtube.com/watch?v=QFvYneUYwtY.
[946] *FDA, supra* note 6.

sampling to health-care practitioners under prescribed conditions, as outlined in *Sections C.01.048* and *C.01.049* of the *FDR*.[947] Initially, there were no similar provisions for sampling under the *NHPR*. The practitioner groups associated with NHPs, such as traditional or alternative health practitioners, were not included in any of the exemptions under the *FDR*.NHP manufacturers were looking for provisions that would allow them to sample directly to consumers, as they considered their products more akin to consumer products. Without clarity, it could again be argued that all NHPs that were provided as samples could be in violation of the Act.[948] Many NHP manufacturers, especially those of food or cosmetic combination products, provided samples, including energy drinks, cosmetics, and fortified foods. The HPFB Inspectorate was not clear on the compliance actions that should be taken, if any. This ambiguity would eventually lead to Health Canada expanding the type and form of product that can provide samples directly to consumers.

Part 3 – The Evolution of the NHP Regulatory Regime 2004-2023

As of 2023, there are over 100,000 NHP products on the market. This is compared to 13,000 actively marketed drugs.[949] The majority of these NHPs were licensed in the last decade. However, despite the efforts of NHPD to model their processes and evidential criteria after those of the drug regime, such measures have largely been abandoned. This has resulted in a proliferation of NHPs making poorly proven health claims, many of which would not have been allowed two decades ago. With time, this has expanded to affect the standards that are applied to

[947] *Ibid*
[948] *Ibid.*
[949] *LNHPD, supra* note 116.

both food and drugs under the *FDR*. The overall effect is that NHPs have fundamentally changed food and drug law in Canada by making it more permissive of unproven health claims. The main driver for this is not public health concerns, but economic concerns related to creating a market for NHPs.

As will be discussed in the following chapters, the evaluation of the NHP regulatory system by auditors and the courts suggests that it is performing poorly as a public health protection measure. Regulators have rationalized most of these changes as risk-based and designed to support the economic goals of Canadians.[950] The key shift is that the regulations are now framed not as a mechanisms for assessing safety, efficacy and quality but as supporting the marketing of innovative new products. In the next section, I will outline how the administration of the NHP regulations has developed over the past 19 years, with a primary focus on how NHPD has changed the application of the SEQ standard for these products. It should be noted that most of the policy documents described do not have the force of law,[951] but they are the best available representations of administrative intent we have from the regulator.

[950] See Chapter 7.

[951] Most NHP Guidance documents include a form of the following disclaimer, "This document does not constitute part of the Food and Drugs Act (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies," taken in this case from the Health Canada, *Drug and Natural Health Products Recall Guide*, online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/recalls.

(i) The NHPR Coming into Force (2003-2007)

When the regulations were introduced, NHPD was expecting to deal mostly with traditional medicines, vitamins, minerals, and homeopathic products. As the Minister of Health reasserted in announcing the new regulations, "the products that fall within the new regulations include herbal remedies, homeopathies medicines, vitamins, minerals, traditional medicines, probiotics, amino acids and essential fatty acids."[952] The standing committee had estimated that 50 percent of the newly regulated products would be vitamins, 30 percent would be herbs and botanicals, the other 20 percent would include homeopathies and a small percentage would be "other products."[953] Most of the new products were expected to make traditional use claims or claims building on existing traditional uses. Other traditional products would be transitioning from already having been issued a DIN (licensed traditional herbal medication,[954] most vitamins and minerals). For products which had never been regulated, this would be the first time they were subject to manufacturing controls (SL and GMP standards) and seeking pre-market approval. Modern and non-traditional products, such as dietary supplements, would find it challenging to demonstrate effectiveness or a basis in traditional systems, and would not be licensed without further evidence. Health Canada's goal was to assure the public "that what is on

---

[952] *Minister McLellan announces the adoption of new regulation for natural health products*, online at: https://web.archive.org/web/20030623235828/http://www.hcsc.gc.ca/enghttps://web.archive.org/web/20030623235828/http://www.hcsc.gc.ca/english/media/releases/2003/2003_47.htm, hereinafter *Minister*.

[953] *RIAS, supra* note 751.

[954] As noted in *New Vision, supra* note 713, "For traditional herbal medicines, submissions to obtain DINs ... Firstly, traditional herbal medicines must present no safety concerns. Secondly, each submission must include traditional herbal references, Lastly, the indications for use must be consistent with the principles of self-medication: consumers must be able to clearly understand the purpose of products. Manufacturers wishing to market herbal medicines for the treatment of more serious ailments must provide supporting scientific and clinical data."

the label is what is in the bottle, and that health claims are supported by appropriate levels of evidence."[955]

Starting in November 2003, in anticipation of the regulations coming into force in January 2004, NHPD released limited guidance documents. These guidance documents covered conditions that had to be met to obtain a product license (the *Product Licensing Guidance Document* v.1.0),[956] conditions which had to be met to obtain a site license (the *Site Licensing Guidance Document*),[957] specific guidance on what would be required to establish quality (*Evidence for Quality of Finished Natural Health Products*),[958] safety and efficacy (*Evidence for Safety and Efficacy of Finished Natural Health Products* v1.0) [959]and GMP standards (*Good Manufacturing Practices Guidance Document*).[960] This was to be supported by the development of product monographs (outlined in the *Natural Health Product Compendium of Monographs*),[961] which were to be compendial sources of knowledge for NHPs that synthesized the known information from traditional and scientific sources about a certain substance. These were gathered in an *NHPD Compendium of Monographs* that could be referenced "in support of the safety and efficacy of the product as part of the product licensing application."[962] Guidance was also developed in the *Overview of the Natural Health Products Regulations Guidance Document*,[963] to help manufacturers determine if the regulations would apply to their products.

---

[955] *Ibid,* at 4927.
[956] Health Canada, *Products Licensing Guidance Document*, (Health Canada: Ottawa, 2003), herein after *PL 2003*.
[957] Health Canada, *Site Licensing Guidance Document*, (Health Canada: Ottawa, 2003).
[958] Health Canada, *Evidence for Quality of Finished Natural Health Products*, (Health Canada: Ottawa, 2003).
[959] Health Canada, *Evidence for Safety and Efficacy of Finished Natural Health Products* v1.0, (Health Canada: Ottawa, 2003).
[960] Health Canada, *Good Manufacturing Practices Guidance Document*, (Health Canada: Ottawa, 2003).
[961] Health Canada, *Natural Health Product Compendium of Monographs*, (Health Canada: Ottawa, 2003).
[962] *Ibid*.
[963] Health Canada, *Overview of the Natural Health Products Regulations Guidance Document*, (Health Canada: Ottawa, 2003).

This was supported by a compliance policy (*Compliance and Enforcement Policy – POL 0001*)[964] that outlined how the HPFB Inspectorate would be prioritizing compliance activities for products that were not licensed or had submitted a product licensing application.

The compliance policy and the evidence guidance mainly focused on prioritizing products that were already licensed, those holding DINs, or the licensing process for products making traditional claims. Evidential criteria for *traditional claims* would be related to the provision of information from existing traditional sources, establishing a history of human use and ensuring they were prepared in accordance with traditional methods.[965] For *non-traditional claims,* applicants were expected "to provide evidence that supports the conditions of use based on scientific evidence."[966] In reviewing any non-traditional claims, NHPD noted that "the evidence …to support a non-traditional use claim will be more stringent than what is required to support a traditional use claim."[967] These products lacked the justification for flexibility in evidential standards as they did not have a similar history of use or a cultural basis in established systems of knowledge or belief.

NHPD did not provide many specifics on how it would assess additional evidential sources for new non-traditional claims. Instead, it created a "strength of evidence grading system"[968] with criteria levels I-IV for non-traditional products and level V for traditional

[964] Health Canada, *Compliance and Enforcement Policy – POL 0001*, (Health Canada: Ottawa, 2003).
[965] *PL 2003, supra* note 956.
[966] *Ibid.*
[967] *Ibid.*
[968] *Ibid.*

products, (see below):

Levels of Evidence	Type of Evidence from Human Studies
I	Well-designed systematic reviews and meta-analyses of randomized controlled trials or other clinical trials, or at least one well-designed randomized controlled trial (preferably multicentred)
II	Well-designed clinical trials without randomization and/or control groups
III	Well-designed descriptive and observational studies, such as correlational studies, cohort studies and case-control studies
IV	Peer-reviewed published articles, conclusions of other reputable regulatory agencies or previous marketing experience, expert opinion reports
V	References to a traditional use

Figure 13: NHPD Strength of Evidence Grading System[969]

The adequacy of evidence would be considered alongside additional criteria such as whether the "evidence is from reputable and well recognized sources, it is the relevant level of evidence as outlined in the table, and the evidence is relevant to the claim."[970] Generally, newer claims would need to be based on scientific evidence rooted in clinical trials, observational studies, or peer-reviewed published articles.[971]

In theory, the model conceived before the regulations came into force was eloquent and made sense. Previously licensed traditional remedies would migrate their DINs to NHPs, providing valuable information to expand monographs. Traditional claims could be made for existing or new traditional products, referencing existing sources of traditional information. This information could be used to create new monographs. Standardized methods of manufacture would be adopted, and for the first time all products would be subject to some GMP standards to ensure sanitation and prevent adulteration. It was expected that there would be a small number of

[969] *Ibid.*
[970] *Ibid.*
[971] *Ibid.*

new product applications, but the evidential bar for these would be high. Similarly, unlicensed products already being sold where there was no link to a traditional use or no scientific information justifying their claim, such as dietary supplements resold from the United States, would have difficulty obtaining a license to remain on the market. If there was insufficient evidence to justify a new claim, applicants could apply to NHPD to conduct a clinical trial.

In execution, the reality proved to be a much greater challenge for NHPD in the first few months of 2004. The breadth of products captured by the NHP definition paired with the ambiguity of the scientific evidence required by Section *5(g)* of the *NHPR* (where evidence was merely required, information that **supported** the safe and effective use of the product) meant that there was a flood of PLAs. Contrary to expectations, most product license applications that NHPD received were not for traditional medicines, vitamins, minerals, or homeopathies. Instead, they were for new products making non-traditional claims. This includes many combination products that had been prohibited under the *FDR*. Within the first few months of being in operation, NHPD had received several thousand new non-traditional product license applications,[972] including for energy drinks, fortified foods, vitamin drinks, a vitamin cocktail to treat bipolar disorder (tested on pigs),[973] treatments for erectile dysfunction, cosmetic products, and many others.

Applicants were quick to realize that due to the broad definition of NHPs, ambiguity around evidence required to establish an NHP claim, and exclusion of NHPs from the application of the *FDR*, the new regime might be an easier regulatory pathway to market. Similarly, once on

[972] *Charting a Course, supra* note 23.
[973] *Truehope, infra* note 1318.

the market, if exempted from the conditions of the *FDR*, NHPs would have much lower ongoing safety requirements. Forum shopping created an unforeseen issue for regulators, greatly expanding the number of product licenses that NHPD received. Some of the first NHP product license applications had previously been rejected as unsafe under the food provisions of the *FDR*, such as energy drinks and dietary supplements. Other products previously regulated under the *Cosmetic Regulations*, which only allows very limited claims, sought licensing as NHPs. Products which had previously been regulated as foods and only allowed very limited claims, such as probiotic yogurts and fortified foods and juices, sought expanded claims as NHPs.

This led Health Canada to issue a new compliance policy[974] in March 2004, just four months after the regulations came into force. The policy outlined how NHPD would prioritize the processing of PLAs in queue. Prioritization was to be based on scientifically generated criteria which identified those products that would pose the greatest risk to human health until reviewed. In order from ascending priority, this included:

> 1) NHPs that were **currently regulated as drugs** because of a "lack of, or inadequate, information on their safe use." These products were prioritized because they would now be available without the intervention of a practitioner. This review was to be completed by June 2004.
>
> 2) **Isolates** of amino acids, fatty acids, and concentrated oils for internal use as they "could be consumed in a higher dosage than would normally occur with a whole organism" (plant). This review was to be completed by January 2005.
>
> 3) **Algae, bacterial, probiotic, fungal**, and non-human animal materials because, like biologic drugs, "problems may arise as a result of improper concentration, inadequate ingredient identification," and variances between batches. This review was to be completed by June 2005.
>
> 4) **Plants, plant material, extracts prepared by traditional methods**, which were lower risk, because "intrinsically plant material presents less risk than their extracts or isolates." This review was to be completed by June 2006.

---

[974] Health Canada, *Compliance Policy for Natural Health Products*, (Health Canada: Ottawa, March 2004), hereinafter *2004 Compliance Policy*.

5) **Vitamins and minerals** because "most are well known with regards to safe conditions of use." This review was to be completed by January 2007.

6) **Homeopathic medicines** because "most do not contain a material dose of medicinal ingredients and standards for product quality are well established." This review was to be completed by June 2007.[975]

Not included on the list were modern and non-traditional claim products or combination products (food or cosmetics), as they were not seen as a priority for licensing.

This was supported by the HPFB Inspectorate's new compliance approach for NHPs as outlined in the *Natural Health Products Compliance Guide* (NHPCG)[976] which was also issued in March 2004. The HPFB Inspectorate would prioritize compliance activity when dealing with the large number of newly unlicensed or unprocessed NHPs. The compliance approach was based on a scientific assessment of those "products that pose unacceptable risk to the health of Canadians."[977] The Inspectorate set out a series of priority criteria, which considered questions such as: does the product have a DIN? Will it be used with the mitigation of a professional? Does the product have ingredients prohibited by Schedule F of the *FDR*? Does the product make claims prohibited by Schedule A of the *FDR*? Is the product intended to be used by pregnant or breastfeeding women or children aged 12 or under? Is the product in a sterile dosage form? Is the product prohibited or restricted? In those cases where the Inspectorate had concerns but none of the criteria above applied, it could ask NHPD to complete a health hazard evaluation (HHE).[978]

---

[975] *Ibid.*
[976] Health Canada, *Natural Health Products Compliance Guide*, (Health Canada: Ottawa, March 2004), hereinafter *2004 Compliance Guide.*
[977] *Ibid.*
[978] *Ibid.*

To support this guidance, NHPD and the Inspectorate were creating a "risk-based" approach for NHPs using a scientific health assessment. The primary criteria were which products had the greatest potential for causing harm to humans. NHPs were not all low risk; rather, their composition and conditions of use blended to make them varied in their risks. This risk-based approach, like that for medical devices, was based on scientifically generated criteria related to harm. As noted in the *Compliance Policy for NHPs*, "the compliance approach [was] prioritized on a risk mitigation basis in order to most appropriately apply departmental resources and capacity."[979] In this case, the risk-based approach was based on a strong foundation of scientific consultation and consideration of the SEQ impact of these products on the public. With time, NHPD would come to define all NHPs as low risk based increasingly less on scientific criteria and more on a policy perspective that these products were a lower regulatory priority. I will discuss this conception of risk as a criteria of resource allocation versus risk as a defined criteria of scientifically identified harm in a later chapter.

By January 2005, NHPD had only processed just over 900 of the 7,983 applications received.[980] The vast majority of NHPs on the market remained unlicensed, and most unprocessed product licence applications were for new non-traditional NHPs. Instead of adjusting the overly broad definition of NHPs to limit the type of products that would be allowed, the NHPD began to remove barriers to licensing. In 2004, it started consultations to allow Schedule A claims to be made,[981] long prohibited by the *FDR* because they included

[979] *2004 Compliance Policy, supra* note 974.
[980] *Charting a Course, supra* note 23 and NHPD, *Status Submission Report Q1 & Q2* (April 1, 2008 to September 30, 2008).
[981] *Ibid.*

conditions for which no therapeutic products (conventional drug or otherwise) can claim to cure, such as cancer.

By the beginning of 2006, NHPD had received 12,129 applications, of which only 1,602 had been reviewed.[982] The majority of applications, totalling 9,779, continued to be for non-traditional claims. By 2008, the number of unprocessed PLAs would increase to 14,833, of which13, 584 continued to be for non-traditional products. In 2006 NHPD updated its *Product Licensing Document* (version 2.0),[983] and the *Evidence for Safety and Efficacy of NHPs*[984] guidance. The key changes were an expansion of the evidence that could support claims. The list of pharmacopeias and other sources allowed for the support of traditional claims was expanded. Non-traditional claims could now rely upon a reduced set of criteria, including "scientific evidence (e.g., clinical trials) …supplemented by other forms of evidence."[985] The guidance introduced new classes of applications: **compendial**, (a simple class based on monographs with one-ingredient traditional claims) and **non-compendial,** (a complex class because they were non-traditional claims or traditional claims containing more than one ingredient). Information required to be submitted with applications was greatly simplified;[986] applications no longer required literature search strategies, lists of all relevant evidence, or characterizations of evidence sources.

[982] *Ibid*.
[983] Health Canada, *Product Licensing Document version 2.0*, (Health Canada: Ottawa, 2004).
[984] Health Canada, *Evidence for Safety and Efficacy of NHPs version 2.0*, (Health Canada: Ottawa, 2004).
[985] *Ibid*.
[986] *Ibid*.

The new guidance was produced by Health Canada with the stated intent to "ensure that the requirements are rigorous enough to protect public health and increase consumer confidence, yet flexible enough for industry to develop useful NHPs while accommodating scientific developments."[987] The revised guidance would take into consideration "all relevant sources to support safety and efficacy."[988] The nature of this required evidence would now "depend on the type of claim being made and the severity of any named symptoms or conditions."[989] This set up the potential for varied evidence sources for different types of health claims made on new non-traditional products, something prohibited for drugs.

In particular, the new guidance would allow non-traditional products to make risk-reduction claims (reducing risk of developing a specific disease or condition) based on observational, non-clinical studies. These sources included descriptive and observational studies, pre-clinical studies, expert opinion reports, and previous market experience in other jurisdictions.[990] Other type of claims, such as therapeutic, diagnosis and treatment, disease mitigation and prevention, and specific structure function claims remain prohibited. Certain general non-specific (general structure function type) claims would also be considered, but "only in cases where there is adequate evidence to demonstrate safety." In assessing new general claims, NHPD states that these:

> …consist of broad statements that the products will promote overall health [and] it should be noted that NHPD favors the use of specific claims that provide consumers with more information to help them make better choices.[991]

---

[987] *Ibid.*
[988] *Ibid.*
[989] *Ibid.*
[990] *Ibid.*
[991] *Ibid.*

While NHPD opens the door to general claims, they indicate that it is preferable that these only be granted by exception.

(ii) Stop C-51! The Push for a Consumer Health Right to NHPs (2007-2008)

As part of the Progressive Licensing Project in 2007, Health Canada initiated discussions on an updated version of the *Food and Drug Act*. Introduced in 2008, *Bill C-51: An Act to Amend the Food and Drug Act*[992] (2008) was intended to rectify several long-standing deficiencies in the previous 1985 version of the *FDA*. Chief among these was expanding the Minister's powers to withdraw products from the market, impose steeper fines and conditions on those who violate the Act, and deem products to be part of a specific class (i.e., food, medical devices, drugs, NHPs, etc.). The unexpected negative reaction from several NHP product associations and consumer product groups exploded into one of the strongest public reactions to a piece of legislation in recent history. It culminated in rallies, TV commercials, mobilization of thousands of protesters, and a massive letter-writing campaign to the Minister of Health and Parliamentarians.

The Stop C-51 campaign was spearheaded by a coalition of advocacy groups led by the *Natural Health Products Association* (NHPA) and the *Canadian Coalition for Health Freedom* (CCHF). Stop C-51 activists argued that the new legislation was an attempt to roll the NHP regulations back into the drug regime because a definition of NHP would be added to the Act. The new definition went back to the simpler criteria-based definition, which was intended to

[992] *Supra, note* 240.

make all products therapeutic products at the level of the Act.[993] This would also allow for the new provision on compliance and deeming and compelling information to clearly apply to NHPs. Advocacy groups argued that NHPs needed to remain a distinct regime from drugs.

The reaction of the Stop C-51 lobby was intense. Activists opposed the new definition and perceived it as a threat to the independence of the NHP regime. One proponent, Shawn Buckley, claimed the new regulations would allow for Health Canada to arbitrarily search and seize NHPs in private homes, seize bank accounts, and unilaterally seize and destroy property. The CCHF created a website with resources for Canadians to draft letters and petitions to their members of Parliament and the Minister of Health. These rambling letters read:

> Regarding Bill C51 and Health Canada's (HC) regulation of Natural Health Products (NHPs), please take the time to consider the following before addressing my questions below… [then ended] Have you read Bill C51 – Yes or No? If so, do you acknowledge that in giving Health Canada the power to seize private property without court supervision, without any legal accountability, and without offering the owner any legal recourse, Bill C51 is unconstitutional, violates the Canadian Charter of Rights and Freedoms, and that the powers it provides could easily be abused by HC?[994]

At public rallies held across Canada, a common cry claimed that "Health Canada was attempting to unlawfully change over 50,000 low-risk, cost-effective and essential for health [herbs, vitamins, minerals, healthy dietary supplements, foods, beverages, nutrient rich foods] into

---

[993] "therapeutic product" means
(a) a drug,
(b) a device,
(c) cells, tissues or organs that are distributed or represented for use in
(i) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, or
(ii) restoring, correcting or modifying the body structure of human beings or animals or the functioning of parts of the bodies of human beings or animals, or
(d) a combination of two or more of the things referred to in paragraphs (a) to (c).

[994] CCHF, *Stop C-51 Petition letter*, online at: https://nhppa.org/wpcontent/uploads/2008/06/bill_c51_letter_to_ottawa.pdf.

heavily federally regulated new drugs."[995] One blogger, Truman Tuck,[996] went so far as to create a widely circulated list of the top reasons C-51 needed to be stopped, because:

> …we do not want our Canada to be a modern corporate feudal socialist fascist police state in which the several thousand years of developing the finest legal and political system in recorded history is destroyed.[997]

Tuck's top 12 reasons included the fact that: Health Canada has become more powerful than any other government department; operating with police powers outside of any rule of law; that Canada is adopting a 'Mexican Napoleonic Code' of justice to replace the rule of law; that C-51 violates the Bill of Rights; it is a power grab by Health Canada bureaucrats; [and] that Health Canada is seeking criminal law powers to prosecute and imprison Canadians.[998]

Having been at NHPD at the time, I can confirm that none of these were the drivers behind C-51. Instead, the aim was to formalize NHPs as a product class. NHPs were only a minor addition to this complex piece of legislation. Despite this, the Stop C-51 campaign captured the imagination of a significant segment of the Canadian population. Over 300,000 letters were sent to Parliamentarians and the Minister of Health. Anti-C-51 rallies, attended by thousands, were held in Calgary, Vancouver, Quebec City, and provincial capitals. Lobbying of MPs blocked the first planned vote on the new bill in Parliament.[999]

---

[995] CBC, *Criticism of Natural Health Bill C-51 Mount* (May 2008), online at: https://www.cbc.ca/news/science/criticism-of-natural-health-products-bill-c-51-mounts-1.719529 and CBC, *Bill C-51: Targeting Natural Health Products?* (June 2008), online at: https://www.cbc.ca/news/science/bill-c-51-targeting-natural-health-products-1.748783

[996] Truman Tuck was called to the Standing Committee of Health to express his opinions of C-51 on May 8th, 2008.

[997] *Ibid.*

[998] *Ibid.*

[999] *Supra*, note 999.

What was intended as a bill to update deficiencies in the two-decades-old *FDA* and only a minor amendment on NHPs had become a political headache for the government. Things became so heated that officials from NHPD and Health Canada conducted a series of information sessions across the country to articulate that the regulation of NHPs would not be affected by the new legislation. Health Canada even issued several communiques, including a frequently asked questions (FAQ) document answering questions about the impact of C-51 on the regulation of NHPs. The FAQ document addressed basic concerns, such as clarifying that "Bill C-51 will not regulate your herb garden, health food stores will not require a special license to sell NHPs, and inspectors will not be able to enter private homes without permission or warrant."[1000]

C-51 never made it into law, as it died on the order paper when Parliament was prorogued in 2008. However, the Stop C-51 campaign had far-reaching consequences. First, it had a chilling effect on NHPD, Health Canada, and various Ministers of Health in introducing any new legislative measures that could be seen as curtailing consumer freedoms associated with these products. This included explicitly excluding NHPs from future bills seeking to update food and drug law, such as *Vanessa's Law*.[1001] It also meant that NHPD and policymakers would be reluctant to introduce more stringent conditions or put forward amendments to the regulations which might restrict access to NHPs. This would include the application of higher safety and efficacy standards for non-compendial NHPs. Instead, Health Canada and NHPD would increasingly take on language reflecting the position of the C-51 movement, portraying these products as new and necessary.

[1000] Health Canada, *Bill C-51 and Natural Health Products – the Fact*, online at: https://www.sfu.ca/.
[1001] As noted elsewhere, this would leave NHPs subject to the weaker compliance conditions of the 1985 *Food and Drugs Act*, including limited powers to compel the removal of a licensed product from the market, for over a decade.

The second effect of the Stop C-51 campaign was to cement a "health freedoms" conception of NHPs in the Canadian public consciousness, and to solidify the activities of specific lobby groups advocating for a low regulatory bar for NHPs based on freedom of health choices. This parallels the highly successful public relations campaigns enacted by the dietary supplements industry in the U.S. in advance of *DSHEA*.[1002] It created a perception with the regulator that many consumers, especially those compelled to political action, were likely to support an overall reduction of evidential standards applied to new products. There have been several court cases[1003] challenging the legitimacy of Health Canada's right to regulate these products, with varying degrees of success, which show the ongoing militancy of this constituency. Lobbyists such as Shaun Buckley, president of the *Natural Health Products Protection Association* (NHPPA), continue to argue that any amendments to the *NHPR* are designed to restrict public freedoms. NHPPA defines its ongoing role as "identifying and responding to threats facing the Natural Health Products and dietary supplements industry."[1004] This has recently included opposing planned amendments in 2023 to the *NHPR*.[1005]

(iii) Backlog: Post C-51 (2008-2009)

The increasing pressure from the public and political groups advocating for health freedoms and the accumulation of outstanding non-traditional product license applications,

---

[1002] *Vitamania, supra* note 653.
[1003] *Mancuso, infra* note 1319.
[1004] Natural Health Products Protection Association (NHPPA), online at: https://nhppa.org/.
[1005] NHPPA, *Discussion Paper on 2023 Health Canada Initiatives*, online at: https://nhppa.org/wp-content/uploads/2023/06/Discussion-Paper-On-2023-Health-Canada-Initiatives-C-47-Cost-Recovery-and-Burdens-New-Powers.pdf.

contributed to a change in approach by NHPD. Outstanding non-traditional PLAs were increasingly referred to as a "backlog."[1006] NHPD began providing quarterly updates of approved product licenses aimed at addressing this backlog. NHPD also initiated a new internal process called S.T.E.P.S.[1007] that aimed to speed up the assessment of product applications by accepting more "pre-cleared"[1008] information to supplement or replace the monograph process. NHPD did not clearly define what it would accept or use as pre-cleared information. One of the aims of S.T.E.P.S. was to speed up the assessment from 70 to 700 approved product applications per month.[1009] However, the focus on quantity of approved applications over the quality of reviewed applications was a potential cause for concern.

In May 2008, NHPD issued a new streamlined process for compendial[1010] applications that relied heavily upon pre-populated information (drawing on pre-cleared information) that could be used in a new online submission system. It is at this point that an active shift in the regulations can be identified, away from a focus on licensing traditional claims (which continued to represent only 10% of PLAs) to a focus on licensing new claims. To do this, NHPD began to vary the evidential standards applied to these products. It initiated consultations on a new process that would accelerate the approval of non-compendial products licensed. Health Canada set for itself a goal of addressing 60% of the backlog by March 31, 2009, and the remaining 40% by March 31, 2010.[1011] In effect, this would mean approving 20,000 products in less than a year,

---

[1006] Natural Health Products Directorate, *Quarterly Report (Spring/Summer 2005)*, (Health Canada: Ottawa, October 2005)
[1007] Health Canada, *S.T.E.P.S – Standardize claims for NHPS and Pre-Cleared Information, Transparency and Openness, Electronic Solution, Process Improvements, Service Delivery*, www.healthcanada.gc.ca/nhponline.
[1008] *Ibid*, NHPD was not clear at this time what would constitute pre-cleared information.
[1009] *Ibid*.
[1010] Health Canada, *Compendial Products Licence Applications*, (Health Canada: Ottawa, 2008).
[1011] *Ibid*.

compared to the 10,344 it had approved to date. The majority of these would be non-compendial (non-traditional) applications that, in theory, would have a higher degree of complexity and should require more time to validate safety and efficacy claims.

To speed up this process, NHPD accelerated the issuance of monographs, which changed officially from a full description of known information about a product to a description of existing pre-cleared information.[1012] This was a shift toward including claims that had been previously approved for similar non-compendial products. These claims increasingly were general and risk-reduction claims that NHPD was now allowing for new combination products, new cosmetics, and new non-traditional (non-compendial) products. In 2009, NHPD issued the guidance *Classification of Products at the Food NHP Interface*[1013] that would make most food-like NHPs subject to the *NHPR*. NHPD also created an expedited pathway for products relying upon pre-cleared information or monographs, established abbreviated labelling standards, and expanded the criteria that could be self-selected in the new online product licensing process.

(iv) The Unprocessed Product License Applications Regulations - UPLAR (2010)

By September 2009, it appeared that the changes made by NHPD were unlikely to address the backlog of non-compendial applications. By that point, there were still around 18,000 outstanding applications, most of which were for new non-traditional applications.[1014] Health Canada announced its intention to introduce a set of regulations that would completely flip the

[1012] *Ibid*.
[1013] (Health Canada: Ottawa, 2009).
[1014] NHPD, *Status Submission Report Q3* (Health Canada: Ottawa, July, 2008).

narrative of *a priori* SEQ assessment for these products. The *Unprocessed Product Licensing Application Regulations* (*UPLAR*)[1015] would allow all NHPs to access the market, if they submitted a product license application to NHPD by February 2010. Products that were exempted would be issued an exemption number that could be used to demonstrate their application was in queue for review. The products would be given an exemption to be on the market for the next 30 months (until December 2013), without a product license being issued. It was estimated this would allow for a review of an estimated 20,000 outstanding PLAs.[1016]

The primary stated reasons for the changes in both NHPD materials and the Cost Benefit Analysis accompanying the regulations were economic. The Analysis noted the regulations would "preserve $245 million or more of … sales for affected products in the first year of its implementation."[1017] It was estimated that this would equal $935 million in sales over the full 30-month period. There was no mention of the potential impact on consumers due to the sale of these products without any safety and efficacy assessment. The primary benefit listed for consumers was to preserve "continuing access to marketed NHPs."[1018] There was no mention that most of these products did not exist or were prohibited prior to 2004.

The result of the *UPLAR* regulations was a surge in applications. By March 2010, NHPD had received over 47,000 new product licensing applications, which was an increase of 27,000 applications in a few months.[1019] Many manufacturers were aware that they could use an

---

[1015] *SOR/2010-171, s.8*
[1016] Health Canada, *Cost and Benefit Analysis: Natural Health Products (Unprocessed Product Licence Applications) Regulations*, (Health Canada: Ottawa, 2009), hereinafter *UPLAR Cost v. Benefit.*
[1017] *Ibid.*
[1018] *Ibid.*
[1019] Health Canada, *Status of Applications Quarterly Report, Q2* (Health Canada: Ottawa, July2012).

expedited pathway to bring their products to market without compliance activities for 30 months. NHPD also announced that it would initiate a process to expedite approvals.[1020] Most of these applications were non-traditional PLAs. Instead of correcting the gaps in the regulations to restrict the product definition to be closer to the original intent of the regulations or adhere to a higher standard of efficacy and safety for products making new claims, the regulator did the opposite. The *UPLAR* assumed that there was merit to having these products on the market, based largely on their economic impact. The regulations were now a highway for the licensing of non-traditional products.

NHPD promised to develop new criteria to assess non-compendial applications. In 2010, NHPD released new guidance on the *Management of Product License Applications (PLA) for Natural Health Products*.[1021] The guidance established strict review times for NHP product reviewers. Review time for products requiring a full review (Class 3) would be complied in 180 days. Products requiring a partial review (Class 2) would be completed in 180 days as well. Products which were completely relying upon an existing NHP monograph (Class 1), including pre-cleared information, would be completed in 60 days.[1022] There would be an even greater reliance on pre-cleared information and less time allocated to product reviews. NHPD reviewers would be encouraged to batch reviews that were based on the same criteria and make decisions which could be used to augment the existing store of pre-cleared information. In August 2010 the

[1020] *Ibid*.
[1021] Health Canada, *Management of Product License Applications (PLA) for Natural Health Products*, (Health Canada: Ottawa, 2010).
[1022] *Ibid*.

HPFB Inspectorate also issued new guidance that exempted products under the *UPLAR* regulations for any compliance activities.[1023]

Some organizations did not respond favourably to the *UPLAR* regulations. The National Association of Pharmaceutical Regulatory Authorities (NAPRA) sent a letter to pharmacists advising them not to sell products marketed using the *UPLAR* procedure.[1024] NAPRA expressed concern that a large class of products might enter the market that could have potential safety concerns. Additionally, they raised concerns that the *UPLAR* regulations could permit products that should be provided only under prescription to be available on the market. In the letter, NAPRA advises pharmacy professionals not to sell any products that are subject to the *UPLAR* regulations until they have been authorized for sale by Health Canada and have a valid NPN or DIN.

(v) A New Approach to Licensing NHPs (2012-2013)

In 2012, Health Canada announced it would be taking "a new approach to Natural Health Products."[1025] This was driven by "a need for increased access to products while maintaining consumer safety, and the reduction of unnecessary administrative burdens for companies trying to bring safe products to market."[1026] Two years into the *UPLAR* regulations, NHPD had licensed over 50,000 products, but believed licensing conditions were still too onerous for manufacturers.

[1023] Health Canada, *Health Products and Food Branch Inspectorate, Natural Health Products Compliance Policy (POL-0044)*, (Health Canada: Ottawa, 2010).
[1024] See *UPLAR Cost v. Benefit,* supra not 1016.
[1025] Health Canada, *A New Approach to Natural Health Products*, (Health Canada: Ottawa, 2010).
[1026] *Ibid*.

It would again expand the concept of pre-cleared information to be "how much we know about a product's benefits and risk relying upon a library of information amassed from the authorization[s]."[1027] NHPD would introduce a new three-tiered system, significantly reducing how much time they would allocate to application reviews based on certainty associated with the product.

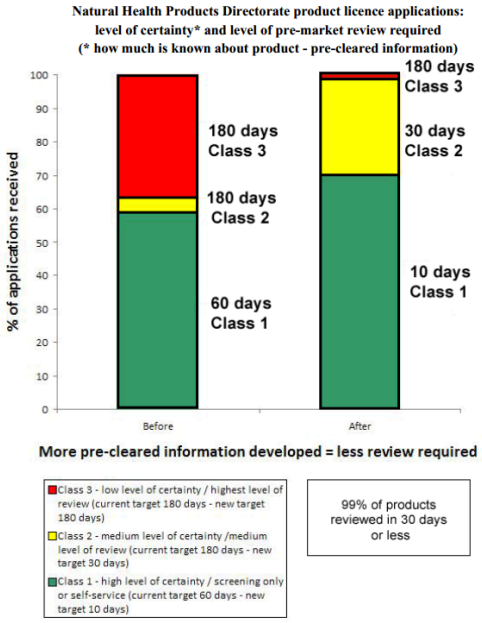

Figure 14: New product processing timelines announced by NHPD in 2012[1028]

Most products (an estimated 70%) could now be based on pre-cleared information as Class I and would self-attest to product safety and efficacy. These applications would be approved within 10 days, down from 60 days. Class 2 PLAs would be limited to previously approved product licensing applications and would take 30 days, down from 180 days. Finally, a few applications (only 10%) would be considered as having a low level of certainty and require a full evaluation, which could take as long as 180 days. Not only was the pre-market bar being set very low, but

[1027] *Ibid.*
[1028] *Ibid.*

the goal of the regulator was switching to approving as many applications as possible in as short a time as possible. Ten days hardly gives the regulator any time to assess applications or SEQ.

In December 2012, NHPD issued updated guidance on the evidence required to support traditional claims (*Pathway for Licensing Natural Health Products used as Traditional Medicines*)[1029] and non-traditional or modern claims (*Pathway for Licensing Natural Health Products Making Modern Health Claims*).[1030] This guidance replaced the 2006 guide and introduced new criteria for demonstrating the safety and efficacy of NHPs. For traditional claims, the same standards were maintained. For modern, non-traditional products, the updated guidance allowed for expanded types of claims and shifted the risk of efficacy away from whether a product worked to the impact of making the claim and it not working. This shifted completely the intent of efficacy under the SEQ standard.

a. Traditional Claims

Traditional medicines maintained the same standards, which were required to demonstrate a long history of use to establish safety (non-toxicity in humans) spanning at least two generations (later updated to 50 years) of continuous use. This use was to be referenced to a time-specific event (e.g., "used in the time of King Edward II to alleviate cough").[1031] The history of use was also to be "in the context of a particular cultural belief system or system of traditional medicine"

[1029] Health Canada, *Pathway for Licensing Natural Health Products used as Traditional Medicines – Version 2.0*, (Health Canada: Ottawa, 2010), hereinafter *Trad Claims v.2*.
[1030] Health Canada, *Pathway for Licensing Natural Health Products Making Modern Health Claims*, (Health Canada: Ottawa, 2010), hereinafter *Mod Claims*.
[1031] *Trad Claim, supra* note 1029.

in existence for at least two generations. The guidance recognized two existent sources of listed traditional medicine sources in the EU and Australia.[1032] Traditional claims had to be specific, referring to the system, paradigm of treatment, and specific dose composition (medicinal and non-medicinal) of the treatment.

Traditional medicines with multiple ingredients could rely upon claims to demonstrate safety if they were composed of ingredients recognized within a single system of traditional medicine as a whole formulation or a modification that aligned to this system.[1033] Medicinal ingredients and the logic for their combination should be documented within that system of medicine (i.e., no blending of Chinese or Ayurvedic medicines). Efficacy should be based on the belief system's theories, and/or experiences specific to the relevant traditional healing paradigm and "a clear and logical rationale should be provided to support the presence of each medicinal ingredient."[1034] The intent was to allow for an expansion of claims within each tradition, but to prevent the blending of systems or use of traditional claims for new products outside that tradition.

For traditional claims, efficacy would be demonstrated by citing a pharmacopeia from a traditional source or other type of evidence, including copies of relevant pages or a reference to an existing monograph or monograph of another recognized regulatory agency (e.g., Australia, France, China). Appendix B[1035] of the guidance provides a partial list of a few recognized

[1032] Such as the *EU Directive 2004/24* or the *Australian Therapeutic Good Administration Guidelines for Levels and Kinds of Evidence to Support Indication Claims*.
[1033] *Trad Claim, supra* note 1029.
[1034] *Ibid*.
[1035] *Ibid*.

pharmacopeias (including sources from traditional Chinese medicine, Ayurvedic, and Indigenous herbal medicines), but was not intended to be exhaustive. Additionally, "two independent references"[1036] could be used, or if only one written reference exists, it also could be supplemented by an expert opinion from someone trained in the field or healing paradigm. The guidance introduced a risk consideration that traditional medicines should not be used for "serious diseases or conditions" or be based on "interpolation or extrapolation [for] conditions that cannot be diagnosed within the traditional system."[1037]

b. Modern Claims

The guidance created a new class of "modern claims." For modern products the guidance made greater changes, shifting risk away from a clear demonstration of safety and efficacy to "the level of evidence [to be] provided to support the safety and efficacy of an NHP varying depending on the proposed health claim(s) of the product and the overall risk profile of the product or its ingredients."[1038] This creates a graded system for the evidence required to validate health claims that is distinct for NHPs. Efficacy is valued according to the claims being made for the product. The guidance spells out three risk categories: low, medium, and high.

Risk is aligned to four key risk criteria: (i) the ingredient's chemical form (is it a substance known to be toxic), (ii) the seriousness of the intended health claim (does it make a claim of curing a diseases), (iii) the conditions of use (does it require an intermediary), and (iv) the health

[1036] *Ibid.*
[1037] *Ibid.*
[1038] *Mod Claims, supra* note 1030.

implications of lower-than-expected performance (what is the impact if the NHP does not work).[1039] The final criterion becomes the most determinative; the seriousness of the health claim and the implications of lower-than-expected performance will be determinative of whether a claim is allowed. Safety and efficacy is now graded based on the harm of a product not working, not on whether the claim is valid. This suggests that products which makes claims that are not likely or serious enough to result in injury or harm can rely on a lower level of evidence. This upends the long-standing efficacy standard of other therapeutic products that no false or misleading health claims should be approved.

Evidence was now aligned to the claim.[1040] For **lower-risk claims** a much lower bar is in place, requiring a reputable book source, demonstrations as a food use, Phase I studies, and epidemiological studies. This allows for a very broad collection of claims for non-severe conditions (non-life threatening or where ineffectiveness does not impact health). **Medium-risk claims** also allow for a lower bar of evidence, including observational or narrative studies, Phase II clinical trials, and epidemiological studies. This opens the door to both qualitative and quantitative evidence demonstrating safety and efficacy. **High-risk claims** imply those products with a very severe implication of treatment failure and where the conditions of use have very low margins of error and may require a learned intermediary. For higher-risk claims, studies, evidence like that required for pharmaceutical drugs, in the form of clinical trials, is required to demonstrate efficacy and safety.

[1039] *Ibid.*
[1040] *Ibid.*

c. General Claims[1041]

This guidance also expanded the allowable number of general health claims. These go beyond the original four types of health claims envisioned by the standing committee or embedded in the wording defining NHPs. The new omnibus category of general health claim required a much lower bar of evidence as well as expanding the scope of the type of claims that would be allowed. It could be used for claims related to health maintenance, relief of minor symptoms, self-limiting conditions (i.e., those that will resolve with time) and those for which there is little to no harm if the treatment is ineffective. Evidence for these general claims is significantly reduced and includes "limited human evidence, textbooks that describe how constituents work within the body, and other evidence such as animal and in-vitro studies that suggest mechanism of action."[1042]

Health Canada laid out how to build a health claim.[1043] At the base are general claims which require lower amounts of evidence; as you move up, claims become more specific and higher risk and will require additional levels of evidence. Generally, the regulations seem to push applicants towards making more general and simplified claims. This does not mean that there will still not be a wide range of products, as many health claims for minor ailments (such as headaches or arthritis) apply to a wider market. The distinction between general and non-general claims is likely lost on the public.

[1041] *Ibid.*
[1042] *Ibid.*
[1043] *Ibid.*

By the time the *UPALR* regulations' 30-month exemption period ended in December 2013, NHPD had licensed an additional 38,835 NHPs, nearly 20,000 more products than expected.[1044] The majority of these products (81%) were non-traditional (63%) or food-like NHPs (18%) licensed under the new lower evidential standards for modern claims. Of these, 46% had been licensed by referring to pre-cleared information. The rest (54%) had taken advantage of being issued as low- or medium-risk products. In effect, the backlog of new product types, created by the broad definition of NHP, had been addressed by reducing the overall evidential standards for these products. It had also shifted the quantification of safety and risk for modern products away from a blanket prohibition without scientific evidence, to one quantifying harm related to the degree of the claim being harmful if not successful. NHPs whose failure it was predicted would not affect health outcomes, or which made general claims, were allowed with a low standard of proof. High-risk NHPs would be regulated as drugs, and medium- to low-risk products would require little to no evidence of safety or efficacy. The result was a proliferation of licensed NHPs that were sold to the public with very low levels of evidence.

In 2013, NHPD initiated consultations to update the guidance on the quality of NHPs and its site licensing approach.[1045] Under the updated system, when applying for a site license (SL), manufacturers would undergo an initial site inspection by Health Canada. Going forward, HPFBI would pilot on-site inspections to be conducted by third-party auditors to ensure good manufacturing practices (GMPs).[1046] This was an improvement on the existing system, which

---

[1044] Health Canada, *Final Status Submission Report Q2 - July 1, 2012 to September, 2012* (Health Canada: Ottawa, 2012).
[1045] Health Canada, *A New Risk-Based Approach to Site Licensing for Natural Health Products – Concept Paper* (Health Canada: Ottawa, 2013), hereinafter *RB-SL,* in anticipation NHPD also updated Health Canada, *Quality of Natural Health Product Guide Version 3.0* (Health Canada: Ottawa, 2013).
[1046] Health Canada, *A Revised Approach to NHP Site Licensing Proposal Document*, (Health Canada: Ottawa, 2013).

required only an attestation. While HPFB still had the authority to inspect sites, it would do so only on a "risk basis."[1047] (In 2019, Health Canada discontinued the on-site initial inspection program because it was deemed too burdensome on manufacturers).[1048] This left the SL system primarily a third-party validation regime with the potential for "risk-based" inspection by HPFB Inspectorate. In 2021 the Auditor General assessing these risk-based inspections found they were infrequent, not truly risk-based and seldom resulted in any compliance activity.[1049]

(vi) Self-Care (2014-2022)

In 2014, Health Canada introduced the *Consumer Health Products Framework* (CHPF)[1050] as part of the Food and *Consumer Safety Action Plan* (FCSAP).[1051] The goal was to bring products used by consumers without a prescription under a regime like that for NHPs. The expanded list of products to be included in the new regime were cosmetics, non-prescription drugs, disinfectants (a drug under the drug definition of the FAD), and NHPs. This meant that these products could make claims with the same limited evidential base and be subject to the reduced site licensing requirements, like those for NHPs. The NHP regulatory framework, originally established to deal with traditional medicines, vitamins, minerals, and homeopathies was now being expanded to include many more products. A system intended to create SEQ exceptions for traditional products, which was extended to non-traditional products making

[1047] *Ibid*.
[1048] Health Canada, *Evaluation of the Pilot Natural Health Products Good Manufacturing Practice Inspection Program*, (Health Canada: Ottawa, 2019).
[1049] *OAG, supra* note 29.
[1050] *CHPF, supra* note 905.
[1051] *FCSAP, supra* note 898.

spurious claims, was now being extended to reduce the evidential standards for products which were drugs.

This move would significantly reduce the safety, efficacy, and quality (SEQ) standards in place for non-prescription drugs, such as cough and cold remedies, emergency birth control, and disinfectants. This is questionable because the safety profiles of non-prescription drugs, disinfectants, NHPs, and cosmetics are not similar. Non-prescription drugs are drugs that require a full assessment of SEQ backed by clinical data; [1052] disinfectants also need to provide conclusive scientific information that they work. The consequences of these products not working could be severe, particularly in cases where infection or ongoing illness is being treated. Cosmetics have very little evidence to support any health claims, while NHPs have varied safety profiles.

On the one hand, this could be seen as rationalizing the different products that are sold in the same way and regulated under different regimes (*FDR*, *CR*, and *NHPR*) into one regime. However, on the other hand, it could also be viewed as an attempt to address the confusion that these products have created in the market, not by regulating or restricting the sale of products that make poorly proven claims, but by lowering the evidential standards across the board. It is an attempt to fill the gap created by the overly broad scope of the *NHPR* and the reduction of

[1052] NNHPD described non-prescription drugs on its website as "pharmaceutical drug products that are available to consumers without a prescription from a healthcare professional. In Canada, they are generally available to consumers at pharmacies or stores but could also require the assistance of a pharmacist.

- over-the-counter drugs: analgesics, cough and cold remedies, antacids, laxatives
- behind-the-counter drugs: emergency birth control drugs, certain heartburn drugs
- disinfectants: hard surface disinfectants, such as those for countertops."

See online at: https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/natural-non-prescription-health-products-directorate.html.

pre-market evidential standards to address non-traditional PLAs, to apply these standards more widely. In effect, it spreads the grey space between food and drugs to occupy much of the previous space regulated by food and drugs.

In announcing the planned new regulatory pathway, the Minister of Health noted that these "lower-risk products [needed] to be separated from prescription drugs."[1053] The new framework would "take into account the potential risk of the product in order to ensure that the right level of oversight" was applied. This would be in line with the government's "existing efforts to reduce unnecessary red tape."[1054] Health Canada was now equating risk with consumer choice and linking self-care with low risk. This is a risk categorization not based on science or ADR data but on a political assumption about the relative danger of these products. This is contrary to the early compliance approach of NHPD that had worked extensively to map natural health products based on a scientific quantification of potential risk.

The government planned to put forward a new set of regulations that would capture all of these products. In anticipation of this change in 2014, NHPD had its name changed to the Non-Prescription and Natural Health Product Directorate (NNHPD). NNHPD formally took over the regulatory process for non-prescription drugs and disinfectants which were still captured under the *FDR*. It also began the process for evaluating new cosmetics making health claims. At the

[1053] Health Canada, *Ministerial Notice to Stakeholders – Consultation on a Consumer Health Products Framework*, (Health Canada: Ottawa, June 9, 2014).
[1054] *Ibid*.

same time, Health Canada put forward guidance on the process for switching a drug from prescription to non-prescription status.[1055]

(vii) A New Risk-Based Compliance Approach

A large part of the CSAP was to also make compliance risk-based. In 2015 NHPD updated it's *Good Manufacturing Practice Guidance Document*[1056] to add a new risk-based compliance framework. Appendix 5 was added to the guidance to give a new graded response when regulatory non-compliance was detected during "site licensing, assessments (new application, amendments or renewal), inspection, or audit."[1057] This appendix was added based on complaints from industry and was part of NNHPD's *Revised Approach for Site Licensing*.[1058] The appendix creates a risk classification of breaches of GMP standards that relates compliance enforcement to "the nature of the deviation from GMP, as well as the number and extent of occurrences."[1059] The outcome is that NNHPD will allow for non-compliance in many cases where GMP standards are breached.

Under the new regime, at the time of licensing, GMP quality assurance reports (QARs) will be assigned a GMP compliance rating and given a designation of **compliant or non-compliant**. This takes the guidance from 2003 discussed earlier in the chapter (covering Type 1 risk, Type 2 risk, and Type 3 risk) and expands the categories of activities for which non-

---

[1055] Health Canada, *Data Requirements for Switching Medicinal Ingredients from Prescription to Non-Prescription status*, (Health Canada; Ottawa, 2014).
[1056] (Health Canada: Ottawa, 2015).
[1057] *Ibid*.
[1058] *Ibid*.
[1059] *Ibid*.

compliance will not lead to compliance action or a SL suspension. Non-compliant ratings would be divided into observations that are **critical, major, or other**. These are further sub-divided into observations around the categories of places, people, process, and products. [1060] **Critical** violations automatically receive a non-compliant designation, and an SL is not issued or suspended. **Major** violations require ongoing observances of non-compliance to invalidate the GMPs of the manufacturer, and an SL is generally still issued, with only minor compliance activities undertaken. Non-compliance in the **other** category leads to no compliance action and an automatic compliant designation or issuance of an SL. This system may be problematic as many "major" and "other" violations are not minor requirements for ensuring product quality and allowing them under SL could lead to impurities or adulteration of products. Many of these cases of non-compliance would not have been allowed for either drugs or foods. Sources of major violations could include insufficient processes to prevent cross-contamination; contamination with material from machinery (grease, oil, rust, leakage); and QAPs with no training or experience.[1061] The intent is likely to provide the regulator discretion in applying the full scope of GMP standards, but the effect is to reduce the quality assurance standards for NHPs and accept an even lower level of non-compliance. This is contrary to the primary recommendation of the standing committee that the first concern for NHPs should always be an assurance of quality.[1062]

The guidance refers to the *Health Canada Compliance Enforcement Policy* that was also updated in 2015 to give regulators greater flexibility in enforcing observation of non-compliance

[1060] *Ibid.*
[1061] *Ibid.*
[1062] *Supra*, note 894.

based on risk. It proposed a much more lenient collection of compliance actions to be applied to those found in contravention of the Act and regulations. The policy in turn refers to the Government of Canada *Compliance Enforcement Policy Framework*[1063] which creates a gradation of various activities the regulator can undertake to deal with non-compliance, from initiating communication to initiating litigation. However, it is worth noting that the new policy seems to acknowledge that in many cases where GMP violations are observed, the regulator is likely to take limited or no action against SL holders. This observation was confirmed by the OAG in 2021 which reviewed 71 cases of non-compliance and found most were not followed up by NHPD.

(viii) A New Old Self-Care Framework

I will discuss self-care in greater detail in the case studies. Briefly, with the change of government in 2015, the *Consumer Health Product Framework* fell by the wayside. Many of its concepts were reintroduced in 2016 by the new government as a *Self-Care Framework* (SCF).[1064] Much like the CHPF the SCF planned to bring similar low-risk products under one regulatory regime. It was conceived as a series of regulatory amendments that would arrive in phases. **Phase 1** would align the *NHPR* labelling standards with other products and introduce a disclaimer that these products were not approved using science. **Phase 2** would:

> …introduce expedited pathways for lower-risk non-prescription drug products, including a class-based licensing system, appropriate pharmacovigilance requirements and establishment of licensing that is commensurate with the risk of these products. These

[1063] *Compliance Framework, supra* note 892.
[1064] Health Canada, *Consulting Canadians on the Regulation of Self-Care Products in Canada*, online at: https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-care-products/consulting-canadians-regulation-self-care-products-canada.html, hereinafter *Consulting on SC*.

> changes are intended to decrease regulatory burden and costs to businesses, as well as introduce greater efficiencies for businesses.[1065]

Phase 3 would be a formal re-introduction of the NHP regime based on product classes with "simplified applications and enhanced premarket quality review."[1066]

When consulting on the issue,[1067] Health Canada received over 300 pages of comments submitted by 31 respondents, of which 75% were from industry, while only 20%, or 6 respondents, were from consumers or health professionals.[1068] In their consultation paper, Health Canada starts from the position that when observing products on the shelf (NHPs, OTCs, and cosmetics) "they're grouped together on store shelves based on the conditions for which they are intended to be used."[1069] For the consumer this leads to confusion because "they may make the same or similar claims about what they do and they may have packaging that all look alike."[1070] These similarities may lead a consumer to believe that these products are equally effective and have to follow the same rules and oversight to be allowed to be sold.

As will be noted in the case studies below, instead of suggesting that those products with a higher standard of SEQ should be labelled differently, the regulator instead suggests that the risk bar for all products needs to be reduced to the lowest denominator. This is not necessarily what a consumer would expect, as the regulator is lowering the bar for SEQ to meet the

---

[1065] Government of Canada, *Forward Regulatory Plan 2022-2024: Regulations Amending the Natural Health Products and the Food and Drug Regulations (Self-Care Framework)*, online at: https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/forward-regulatory-plan.
[1066] *Ibid.*
[1067] Health Canada, *Summary: What We Heard on Self-Care Products Regulation*, online at: https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-care-products.
[1068] *Ibid.*
[1069] *Ibid.*
[1070] *Consulting SC, supra* note 1064.

standards of the products with the least evidence demonstrating their effectiveness. Instead of raising the bar for NHPs, they drop the bar for OTCs. The public would likely ask that the standards for products be raised or that there be a clear distinction between products approved with no scientific validation versus those approved with some demonstration of effective use.

The consultation paper introducing the new framework provides a good summary of the issues which had developed for these products since 2004. Products were regulated under three separate sets of regulations, "each with different rules for how to bring a product to market, different evidence requirements for claims about what a product does, [and] different approaches to inspection of sites where companies make products."[1071] The permissiveness of the *NHPR* has meant that most combination products would choose to follow this pathway to market. As a result, many products, such as homeopathies, described in the case studies in the next chapter, were marketed under a regime with varying degrees of scientific certainty supporting their efficacy. In the case of NHPs, the regulator admits that it has increasingly been lowering the bar on safety and efficacy:

> [Increasingly] a wide range of supporting information is accepted for claims, ranging from scientific evidence to encyclopaedias of health and wellness philosophies based on premises other than science. Health Canada's practice of accepting other than non-scientific information to support claims for natural health products is based on an attempt to recognize that these products are not the same as conventional drugs, and often have a basis in philosophies that support the general health benefits of some ingredients through other means than scientific standards.[1072]

Non-scientific sources of evidence have increasingly been accepted to allow for the making of claims. Similarly, the consultation paper recognizes that there are inconsistent gaps in post-

[1071] *Ibid.*
[1072] *Ibid.*

market powers such that "at this time Health Canada does not have the authority to order a recall or a label change for a natural health product."[1073] Instead, when a case of non-compliance is detected, "Health Canada must work with a company to encourage it to remove a product from the market or change its label."[1074]

In summary, the changes brought in to address the backlog led to the licensing of over 100,000 products making dubious health claims in a very short time. Only about 10% of these were related to traditional health claims rooted in existing philosophies or belief systems. Instead, the majority were based on little to no evidence being provided to the regulator and self-attestation by manufacturers. This was creating confusion for the public about the efficacy of these products versus conventional medications and confusion around the merits of many NHPs.[1075] Rather than clarifying that NHPs were not based on science, the regulator was choosing to expand the number of products, including those with little basis in alternative philosophies, that could take advantage of lower evidential standards. Under the new regime, it was proposed that a classification based on "risk" would be developed that mirrored the existing regime for NHPs. Claims whose failure would be lower risk would be allowed without Health Canada's oversight, including for non-prescription drugs. Companies would merely be required to hold information that the claim was "truthful and accurate" based on information in their possession.

[1073] *Ibid.*
[1074] *Ibid.*
[1075] *Ibid.*

(ix) New Emerging Classes of Health Products

More recently Health Canada has begun to expand the "lessons" learned from the administration of the *NHPR* to a broader class of new therapeutic products. In 2019, the government amended the *FDA*[1076] to allow for the early-market access of a new class of Advanced Therapeutic Products (ATP) with limited pre-market clinical testing. The Minister was given the powers to define a product as an ATP by adding it to Schedule G of the *FDR*, and allowing for the "development of tailored [regulatory] requirements to allow access to the product or class of products in Canada."[1077] The original intent of the ATP provisions was to allow for new bespoke pathways for technologically advanced products that were so "complex or distinct" that they could not easily be assessed using traditional clinical trials.[1078]

COVID-19 has changed much, including the introduction of a new COVID vaccine approval provision of the *FDR* in 2021[1079] that allows for the approval of an NDS that does not include full clinical demonstrations of safety and efficacy[1080] where:

> **(b)** sufficient evidence to support the conclusion that the benefits associated with the designated COVID-19 drug outweigh the risks for the purpose and under the conditions of use recommended, with consideration given to the uncertainties relating to those benefits and risks as well as the public health need related to COVID-19.

These provisions are intended to be used exclusively for COVID-19 and are supplemented with additional requirements for post-market surveillance and risk-management practices.[1081] Where

---

[1076] *2019, C-97.*
[1077] *Ibid.*
[1078] *Ibid.*
[1079] *Ibid*, at *C.08.002.2.2.* Changes were made in 2021 in response to the urgent need for Covid Vaccines, see SOR?
[1080] *C.08.002(2)(g-h).*
[1081] *Ibid*, *s.2.3.*

clinical tests for a new drug -- in this case, a vaccine -- cannot be provided *a priori* to approval, the manufacturer is required to provide a plan to the regulator that "specifies how and when the manufacturer will provide to the Minister the missing information or material."[1082]

[1082] *Ibid*.

CHAPTER 6: CASE STUDIES – ENERGY DRINKS, HOMEOPATHIES AND SELF-CARE PRODUCTS

In the following chapter I will provide three case studies showing how the *NHPR* regime has dealt with specific classes of products: homeopathic remedies, energy drinks and self-care products (over-the-counter drugs [OTC] and cosmetics). This will largely be a policy analysis of how the status and regulatory/legal obligations of these products has evolved since the NHPR came into force in 2004. Each of these product classes was chosen because they illustrate a unique set of regulatory issues. Energy drinks, which exploded onto the market in the early 2000s, represent a class of products which had previously not been permitted to be marketed as foods, because of health claims and caffeine levels. The *NHPR* opened the door to their market access. Homeopathies (HM), while not based on a traditional belief system, have a history of widespread use with little safety concern, but little to no evidence demonstrating efficacy. The licensing of over-the-counter drugs and cosmetics as self-care products has pushed the NHP regime to change its focus from the licensing of complementary and alternative medicines to expanding the same regulatory norms to a new class of self-care products.

As part of the case studies, I will provide some background defining and contextualizing each product. I will then trace how they have been regulated over the course of the *NHPR's* existence since 2004. This will be followed by a description of what can be learned from each of these cases about the larger pattern of NHP regulation. I will note that based on my experience at the regulator, each of these classes of product occupied significant policy efforts because of the unique challenges they posed for NHPD.

(i) Case 1 – Energy Drinks: 'Red Bull Does not Give You Wings'

For the first case study, I will look at how NHPD dealt with a collection of products commonly called energy drinks (ED), or caffeinated energy drinks (CED) as they would come to be called by regulators. Energy drinks are a class of carbonated beverage which contain "a unique range of ingredients [including caffeine] and may feature health claims related to their capacity to restore energy and alertness."[1083] They are a relatively new product on the Canadian market since the early 2000s. They pose a series of still unresolved health risks. At the same time, their health benefit is questionable.

Originally, energy drinks were not licensable for sale in Canada because as a food (carbonated beverage with an additive) they exceeded maximum safe compositions standards for certain additives (notably caffeine, guanine, and taurine).[1084] Quickly recognizing the *NHPR* as a potential new pathway to market access, the manufacturers of energy drinks were some of the first applications for licensing that NHPD received in 2004. Manufacturers had realized that the permissiveness of the *NHPR* would allow them to market these products not based on composition but based on the fact they would make a health claim related to caffeine. Red Bull was one of the first products license applications received by NHPD and it was quickly followed by a flood of now ubiquitous energy drink products which would use this pathway to gain access to the Canadian market.

[1083] Health Canada, *Health Canada's Proposed Approach to Managing Caffeinated Energy Drinks*, (Health Canada: Ottawa, 2011), hereinafter *ED Approach*.
[1084] *FDR, supra* note 6 at *Part B*.

Throughout this process, the safety concerns and benefits of these products would remain highly contentious. Concerns were raised about the use of these products in vulnerable populations, such as pregnant women and children. Their use by adolescents, one of the markets that they were primarily targeting, would also increasingly be of concern. For many consumers, these products appeared indistinguishable from other carbonated beverages; they were marketed as part of an active lifestyle. Health risks were seldom made apparent, even though notionally they were a sub-class of drug. The levels of caffeine these products contained were linked to elevated heart rate and dehydration, as caffeine is a diuretic.[1085] Other substances, *guanine*, and *taurine*, are also associated with elevated heart rates and the potential for miscarriage.[1086] These products are highly dangerous when taken with alcohol, because they may lead to excessive drinking as the energy drink dampens the effect of the alcohol.[1087]

Energy drinks are big business. The worldwide market is estimated to be valued at $12 billion in the U.S. and somewhere in the range of $1 billion in Canada. The main manufacturers of these products represent some of the largest multinational corporations in the world, including Pepsi Co. and Coca Cola Ltd. In Canada they are also represented by a very powerful food lobbying group, the **Canadian Beverage Association** (CBA), previously called Refreshments Canada between 2001 and 2011. CBA represents over 60 brands of "juices, juice drinks, bottled water, sports drinks, ready to go iced teas and coffees, new-alternative beverages, carbonated soft drinks, energy drinks and other non-alcoholic beverages."[1088]

[1085] Burrows, T., Pursey, K., Neve, M., Stanwell., "What are the Health Implications Associated with the Consumption of Energy Drinks? A Systematic Review" (2013) *Nutrition Reviews* 71(3) at 135.
[1086] *Ibid.*
[1087] *Ibid.*
[1088] Canadian Beverage Association, online at: https://www.canadianbeverage.ca.

Stimulant-enhanced beverages are nothing new. As discussed in Chapter 2, many of the early formulations for tonics were sugar drinks laced with stimulants such as alcohol, cocaine, laudanum, etc. Coca Cola started as a carbonated tea laced with cocaine sold as a cure-all.

Figure 15: Early 20th Century Coca Cola Advertisement[1089]

Most of these products were outlawed early in the 20th century as adulterated products with unsafe additives. Many pivoted to become commercial carbonated drinks, such as Coca Cola, Pepsi, and Dr Pepper, with proprietary formulations containing high sugar content but no illegal stimulating substances (i.e. opium or cocaine).[1090]

[1089] Online at: https://i.pinimg.com/736x/a3/c2/df/a3c2df2657da3bda67199b3ef488f3fc--vintage-advertisements-vintage-ads.jpg

[1090] Bulson, N., "History of Things: The Origin and Evolution of Energy Drinks from Cocaine to Caffeine" (2020) *brobible*, online at: https://brobible.com/culture/article/origin-history-evolution-energy-drinks-cocaine-caffeine. See also Hitt, C., "Red Bull, Four Loko, and 5 Hour Energy Drinks: The History of Energy Drinks" (2021) *thrillist,* online at: https://www.thrillist.com/news/nation/history-of-energy-drinks.

The modern genesis of what we think of as energy drinks starts in Asia.[1091] In Japan, during the Second World War, soldiers were provided with drinks laced with amphetamines. In the post-war years Japan cracked down on amphetamine use, and into the vacuum the Tasho Company created a product called *Lipovitan*.[1092] *Lipovitan* looked and tasted like a cough syrup and included high concentrations of caffeine and taurine (an amino acid). In 1972, a similar product, *Krating Daeng* (Thai for Red Bull),[1093] was developed in Thailand as a quick one-shot alternative to coffee. Walk into any 7-Eleven in Thailand today and you will be greeted by a wall of similar energy drinks in small bottles all promising to boost energy and deal with fatigue.

The popular narrative is that an Austrian businessman looking to get over jet lag, Dietrich Mateschitz, drank some *Krating Daeng* and was so amazed that he decided to develop the product for the European market.[1094] The newer product was placed in cans with less sugar to appeal to Europeans, with the English name "Red Bull." Mateschitz had a strategy of linking the product to lifestyle, sporting events, extreme sports, and concerts designed to attract the 18- to 34-year-old market. The product was a huge success and by 2021, Red Bull had revenues of nearly 17 billion Euros globally.[1095] *Forbes* magazine estimated that in 2018 alone, nearly 6.8 billion cans of Red Bull were sold in over 171 countries worldwide.[1096]

Part of Red Bull International's strategy was removing regulatory barriers to market access across the world. As noted above, in 2004, Red Bull and similar energy drinks were prohibited

---

[1091] *Ibid*.
[1092] *Ibid*.
[1093] *Ibid*, the name comes from the often-repeated legend that taurine comes from bull semen, which it does not.
[1094] *Ibid*.
[1095] *Statista, online* at: https://www.statista.com/statistics/1225791/red-bull-brand-value.
[1096] Forbes, *Red Bull Profile*, online at: https://www.forbes.com/companies/red-bull/?sh=20e3f3cb61ce.

from being marketed in Canada as food products because of their formulations, which contained high concentrations of added caffeine, guanine, and taurine. In advance of the *NHPR* coming into force, Red Bull Canada was incorporated in 2004 to help transition and market the product in Canada. One of the very first applications received by NHPD for licensing of an NHP was for Red Bull. The manufacturer realized that the dosage and composition for these products was not a consideration under the *NHPR*; instead the submission could be judged based on the making of a claim and meeting the composition requirements of *Schedule 1*. Red Bull based its original claim on an existing NHPD monograph for caffeine that noted it could "help (temporarily) promote alertness and wakefulness and enhance cognitive performance."[1097] In marketing materials, this would be rendered into the slogan, "Red Bull gives you wings!"[1098] Seeing the potential of this pathway to market, a host of other energy drinks quickly followed Red Bull, seeking licensing as NHPs. By 2009 NHPD had received several hundred requests to license energy drinks from large industry players such as Pepsi Co, Rockstar Inc., and Coca Cola, mostly seeking to import these products from the United States.

Energy drinks posed a genuine conundrum for Canadian regulators. The *FDA* at the time lacked any provisions which allowed the regulator or Minister to deem a product as a certain class (food, medical device, drug, etc.). Yet, the refusal to license these products by the Food Directorate was now at odds with the legal requirement for NHPD to consider their application. There was also now a disparity in the safety standards which were being applied to these

[1097] NHPD, *Compendium of Monographs*, online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/product-licensing/compendium-monographs.html.
[1098] As of May 2023 a Red Bull can (250 ml) picked up in a drug store in Halifax, Nova Scotia, claims that it "vitalizes body and mind," and on the back of the can notes it is "Appreciated worldwide by top athletes, students, busy professionals and travellers on long journeys." Warnings include the statement that it is "not recommended for children, pregnant or breast feeding women, caffeine sensitive persons or to be mixed with alcohol. Usage: 2 (250 ml cans daily" The current formulation contains 80mg/250 ml of *caffeine* and 1000 mg/250 ml of *taurine*.

products by the *FDR Part B-Foods*[1099] and the *NHPR*. These products represented one of the first 'combination products' or 'food-NHPs' where each regulatory pathway notionally applied equally. These products also opened the door to a whole new class of 'fortified food' or NHPs with additives making health claims. Many of these had previously been blocked from becoming foods (including fortified drinks, vitamin waters, fortified juices, etc.). More pragmatic issues existed around how to ensure these products, if licensed, were distinguishable from foods and not consumed *ad libidum*. There were similar concerns about how these products might be advertised and sampled to the public.

At the same time, the NHPD's hands were tied. Technically, Red Bull met the requirements of the *NHPR* because none of its substances violated *Schedule 1*[1100] and *Schedule 2*[1101] and it was relying upon an NHPD-published monograph for caffeine to justify its claim. Similarly, Red Bull was manufactured in facilities which could meet the conditions for SL and GMPs required by the regulations. Red Bull argued that dosage requirements could be met by controlling the volume of each beverage, by making the dosage form a small 250 ml can. Labelling instructions could be included on the can, much as they were for other NHPs (Drink no more than two cans a day.). At the time, safety information about the risks of energy drinks was inconclusive. One could easily ask what criteria the regulator used to determine what the real benefits of energy drinks are, as they provide only limited innervation, with a host of potential unknown risks. Regardless, Red Bull was one of the first licenses issued by NHPD with NPN #800000012 (the 12th license issued), making the claim that it "enhanced mental or physical energy."[1102]

[1099] *Supra* note 6.
[1100] *NHPD, supra* note 2.
[1101] *Ibid*.
[1102] *LNHPD, supra* note 116.

Quickly, a host of additional energy drinks flooded the market (Monster Energy Drink, Rock Star Energy Drink, etc.). None of these products were licensed, but Health Canada was reticent to take direct compliance action against them as most had applications pending and were generally identical in composition to Red Bull. Health Canada justified this lack of enforcement action, citing the newly released compliance framework, which gave them the discretion to not impose direct regulatory action when risk was low.[1103]

It did not take long for media and academics to raise concerns around the safety of these products. In the U.S., where Red Bull had been on the market since 1997, a study came out which highlighted the potential dangers of energy drink consumption and abuse among adolescents, who seldom limited themselves to drinking one 250 ml can of the product.[1104] A similar study warned about the dangers of energy drink consumption when taken with alcohol, particularly among college-age students.[1105] Another study found that energy drinks were over-consumed and abused when used as study aides by adolescents and young adults.[1106]

As recounted in the introduction, in 2006, Health Canada received a report of a 15-year-old boy dying after drinking Red Bull samples at a sporting event. A coroner ruled that Brian Shepard had died of a cardiac arrest, and initially linked this event to his consumption of six to seven cans of Red Bull. Health Canada ruled it could not conclusively pronounce that Red Bull

---

[1103] *ED Approach., supra note 1083.*
[1104] Pomeranz, J. L., Munsell, C. R., and Harris, L. ,"Energy Drinks: An Emerging Public Health Hazard for Youth" (2013) *Journal of Public Health Policy* 34(2) at 254.
[1105] Leal, W. E., and Jackson, D. B., "Energy Drinks and Escalation in Drug Use Severity: Emergent Hazard to Adolescent Health" (2018) *Preventative Medicine* 111 at 391.
[1106] Alsunni, A. A., "Energy Drink Consumption: Beneficial and Adverse Health Effect" (2015) *International Journal of Health Sciences* 9(4).

had been the only factor that had led to Brian's heart attack.[1107] The Canadian Beverage Association commissioned its own "independent analysis" of the event and pronounced that Brian's death, and two other unrelated deaths observed in adolescents, could not conclusively be linked to energy drink consumption.[1108]

In 2009, a new class of energy drink began to enter the market. Alcoholic energy drinks mixed existing formulations with alcohol, often vodka or other grain alcohols. These products were still not approved by Health Canada, but became widely popular, especially with university-age students who used them to dull the effects of drinking with what one researcher called a "wide-awake" drunk.[1109] Unfortunately, alcoholic energy drinks were also associated with increased rates of alcohol poisoning, risk-taking behaviours, and in some cases, death.[1110] These products were also clearly violating the food provisions of the FDR, as alcohol was one of the most strictly regulated ingredient classes, and prohibited stimulant additives.[1111] A *Vancouver Sun* article, cited a letter obtained through an access-to-information request, which showed even inspectors at the Canadian Food Inspection Agency (CFIA) were asking Health Canada and HPFB for clarification about how these products were being allowed to remain on the market. The letter asked HPFB to spell out in a "transparent way its position on pre-mixed beverages marketed as alcoholic energy drinks."[1112] In 2010, Health Canada issued a letter to liquor control boards across the country clarifying that pre-mixed energy drinks were permitted

[1107] Toronto Star, "Energy drinks suspected to have caused deaths of 3 Canadians" (November 2012), online at: https://www.thestar.com/news/canada/2012/11/18/energy_drinks_suspected_to_have_caused_deaths_of_3_canadians.html.
[1108] CBA, *Energy Drinks: Safety*, online at: https://energydrinkinformation.ca/community-safety.
[1109] *Supra*, note 1105.
[1110] *Ibid*.
[1111] *FDR, supra* note 6 at Part B.
[1112] CBC, *Transparency supra* note 343.

under the current regulations "so long as the stimulant is derived from an ingredient that naturally contains caffeine."[1113]

In October 2010, under political pressure from Parliamentarians, the Health Minister convened a scientific panel to "provide recommendations on questions relating to the appropriate risk mitigation strategies for energy drink natural health products, as a result of potential safety concerns identified by HFPB."[1114] The committee membership included a collection of eminent regulators, academics, practitioners, and frontline health-care providers. These included the manager of pharmacovigilance for the WHO, a representative from the European Food Safety Authority (EFSA), a Canadian cardiologist, a Canadian pediatrician, a professor of pharmacy and a clinical nurse specialist. The committee was given a mandate to review several questions related to the "current medical and scientific evidence"[1115] about the safety of energy drinks and whether they "warrant additional risk management strategies further to Health Canada's current requirements."[1116]

The committee was further directed to look at the evidence around adolescents, cardiovascular events, and what needs to be in place to "allow Canadians to make informed choices with respect to these products (including address areas of uncertainty in the scientific data, ingredient interaction and educational activities)."[1117] The committee was to base its recommendation "on an assessment of the current available literature and evidence surrounding

---

[1113] *Ibid*.
[1114] MacDonald, N., Hamilton, R., Mallory, P., Moride, Y. and Shearer, J., *Report by the Expert Panel on Caffeinated Energy Drinks*, (Health Canada: Ottawa, 2010), hereinafter *ED Report*.
[1115] *Ibid*.
[1116] *Ibid*.
[1117] *Ibid*, at page 10.

the safety and efficacy of these products, as well as data from adverse reaction events."[1118] In conducting this review, the committee interviewed key witnesses at Health Canada, NHPD and HPFB, reviewed all domestic adverse drug reports (ADRs) associated with energy drinks, ADR data from cardiovascular events related to energy drinks, and other ADR documents related to energy drinks. The committee also had access to records of internal discussions at Health Canada, witnesses, and other evidence which was not available to the public.

The general finding of the committee was unequivocal: based on the potential risks, it felt that these products needed to be regulated as drugs. The committee further asked that "Health Canada desist from using the term 'energy drinks.' A more accurate designation to consider might be 'stimulant drug-containing energy drinks.'"[1119] They considered the name "energy drinks" to be "a marketing term and should not be used."[1120] If the products were not regulated as a conventional drug, the committee recommended that:

> Health Canada, at a minimum, maintain stimulant drug-containing drinks in the category of natural health product (NHP) and NOT move them to foods due to the significant drug effects of the caffeine added to these products.[1121]

The committee also expressed concerns that Health Canada had incorrectly framed the risk of these products by concentrating only on the few numbers of ADRs. Instead, they argued:

> due to the high volume of use, the risk of adverse events is considered to be a public health issue as these stimulant drug-containing drinks are not being medically prescribed for a health indication. In the absence of real therapeutic and medically indicated benefits, the Panel considers that the risks associated with the use of these drugs outweigh the benefits. Public health at the federal/provincial/territorial levels need to be apprised of the risks and efforts made to co-ordinate steps to mitigate risk.[1122]

[1118] *Ibid.*
[1119] *Ibid.*
[1120] *Ibid.*
[1121] *Ibid.*
[1122] *Ibid.*

In effect, the committee was suggesting Health Canada should not have allowed these products on the market for health and safety reasons. Now that they were allowed, they needed to be regulated with a higher level of scrutiny.

The committee also criticized Health Canada for failing to "mitigate the growing confusion for the general public"[1123] around these products. They went on to express concerns:

> at the number of stimulant drug-containing products on the Canadian market that do not have an NHP licence nor an exemption number. Some of these products do not meet NHP labelling guidelines. Many contain high levels of caffeine and could pose a hazard to consumers.

The committee noted that at the time, there were 190 products on the market without formal approval or with exemption numbers issued by the regulator. Exemptions numbers, issued under the *UPLAR* regulations, allowed products on the market with no formal approval as NHPD worked to clear the backlog. They noted Health Canada did not seem to engage in much compliance activity around these products. This was compounded because many of these products were on the market with incorrect labelling. The committee called on Health Canada to "ensure that all products meet strict labelling requirements and fully disclose the exact caffeine concentration (mg) prior to receiving an exemption number."[1124]

The committee also chastised Health Canada and HPFB for basing their risk assessment on little to no data, including data on benefits or risks. HPFB relied solely on limited ADR data and failed to undertake any proactive activities to assess existing clinical data. The committee recommended that Health Canada seek additional safety data from provincial Chief Coroners,

[1123] *Ibid.*
[1124] *Ibid.*

practitioners, and researchers to generate accurate safety data. ADR data should be expanded beyond the extremely few cases of death to include data on serious adverse events, drug interactions, and other co-factors. In the absence of additional data:

> Given the misperception by the general public that stimulant drug-containing drinks are foods, labelling for these products must be clear: that these are drugs, what the dose is per container, the maximum dose per ml, and the maximum daily dose for all caffeine sources.[1125]

The committee also recommended that only very fixed dosages of caffeine for these products be allowed, far below what most energy drinks on the market contained.

The report was again unequivocal in outlining the mitigation measures Health Canada needed to put in place for energy drinks. According to the report, "these products are drugs, therefore must be dealt with as a drug which includes meeting the requirements that other drugs must meet."[1126] The report drew the parallel with the National Association of Pharmaceutical Regulatory Authorities (NAPRA) National Drug Schedule (NDS) and recommended energy drinks should be treated as "over-the-counter drugs sold under the supervision of a pharmacist."[1127] The report also compared energy drinks to caffeine tablets with similar dosages (100-200 mg of caffeine) that could only be sold under the supervision of a pharmacist. Health Canada was chastised that it "must ensure that companies do not give out free samples as this is precluded for drugs."[1128] To clarify this confusion, greater oversight by a pharmacist would "signal to the public that these are drug products, not foods. Labelling information alone is unlikely to rectify this confusion."[1129]

[1125] *Ibid.*
[1126] *Ibid.*
[1127] *Ibid.*
[1128] *Ibid.*
[1129] *Ibid.*

The Minister of Health's reaction, likely under pressure from stakeholders, was to reject the findings of the committee and announce that Health Canada would be moving forward with regulating these products as foods.[1130] The Minister quickly requested that Health Canada conduct its own risk assessment, which contradicted the advice of the expert advisory committee by finding no direct link between energy drinks and health risks.[1131] However, the criteria used in this second review have not been released to the public. In the press releases, HPFB reported the "assessment had concluded that a number of information gaps need to be addressed to support the Department's efforts to regulate these products and enable their safe consumption."[1132] In the absence of clear, irrefutable evidence of harm, the regulator proposed these products should be on the market. A key reframing occurred here, as Health Canada worked only on the existing proven risk and was unwilling to pronounce on the potential risk, erring on the side of allowing the product when faced with uncertainty. In taking on this risk, one may question what benefits these products were conferring from a public health perspective, other than economic gain.

The Minister's decision is perplexing. Health Canada had received expert opinion that the risk profile of these products was high, and in the absence of wider additional evidence, that these products should be treated with caution and limited like other high-caffeine products as drugs. Yet, the Minister decided to place these products under a more permissive food regime which historically, prior to 2004, had limited these products from being on the market. In justifying this decision, the Minister, without any real data, cited that these products were low

[1130] *ED Approach, supra* note 1083.
[1131] Health Canada, *HPFB BCS Energy Drinks: An Assessment of the Potential Health Risks in the Canadian Context,* (Health Canada: Ottawa, 2011).
[1132] *Ibid*.

risk and should be regulated accordingly. Again, one could question: what public health benefit did these products have that justified taking on this risk? Or, what additional evidence existed that could justify taking on these risks?

The regulator promised to impose strict composition requirements on these new food products, including maximum caffeine levels, which were still higher than those allowed for OTC caffeine pills. The labelling requirements would include the language "high source of caffeine [and] do not mix with alcohol."[1133] Health Canada would also require manufacturers to begin self-reporting consumption incidents to collect "data on any consumption incidents associated with the product."[1134] This was a case of the public being used in an unregulated clinical trial to determine the long-term safety of marginally health-improving products.

To allow these products to enter the market, Health Canada asked the Food Directorate to issue rarely used Temporary Market Authorization (TMA) letters. The TMA process, under Sections B.01.054 and B.01.055 of the *FDR*,[1135] is designed to help regulators gather additional information to support a future amendment to the *FDR*. The TMA allows a food product to be licensed in Canada, even while it is not in compliance with food composition standards listed in the *FDR,* on a temporary basis. The TMA process had never been used to include this many new products at one time. TMA letters are not intended to be used for long periods of time and are generally issued after a long period of consultation with international bodies as a new food product or standard is about to enter the market.

[1133] *ED Approach, supra* note 1083.
[1134] *Ibid.*
[1135] *FDR, supra* note 6.

Going forward, existing energy drinks approved as NHPs or in queue would transition to foods with a TMA letter, and new energy drinks entering the market would apply for TMAs. As a condition of TMA letters being issued, energy drink manufacturer were required to issue a report every six months with any ADR and safety data that has come to their attention. Health Canada also promised to undertake additional research on the long-term health effects of energy drinks.

> Collaborate with Provincial, Territorial and international partners, in government and academia, to gather further data related to the long-term potential health effects associated with the consumption of caffeinated beverages such as Energy Drinks. Health Canada's initial focus will be on collecting up to date information on Canadians' consumption patterns for caffeinated beverages in order to better estimate exposure to caffeine and other ingredients, and the associated risks to support appropriate regulatory oversight[1136]

Health Canada committed to develop educational tools and materials for the public on the risks associated with caffeinated products. Neither of these commitments from Health Canada have been met. As will be discussed, several other levels of government have produced reports which call into question the safety of these products, but there has been no additional publicly available research produced by Health Canada. The only information on energy drinks that Health Canada has produced on the risks of these products are two web links to short pages, one on caffeine in foods[1137] and another about energy drinks.[1138] Health Canada also promised to "work closely with all interested stakeholders to develop and implement other appropriate risk management approaches such as marketing and advertising codes of practice." The CBA issued a voluntary

[1136] *ED Approach, supra* note 1083.
[1137] *Ibid.*
[1138] *Ibid*

code of labelling that mirrored the previously issued cautionary statement for pregnant women and mixing energy drinks with alcohol, but no other risks were included.[1139]

The eligibility criteria for qualifying for the TMA transfer were outlined in the guidance document *Category Specific Guidance for Temporary Market Authorization – Caffeinated Energy Drinks (2013)*.[1140] This guidance provides further clarification that energy drinks are not to be advertised to children, and:

> This condition, as well as a condition prohibiting providing samples to children, pregnant or breastfeeding women, is included as part of the Letter of Agreement associated with the TMAL[1141]

It also provided detailed instructions on labelling, which must include dosage form and clear risk information (not for children under 12 or pregnant women). It sets allowable levels of caffeine at 200 to 400 ppm (mg/L), but also allows for a 500 ml dosage form which would be the maximum daily allowable dose (2 x 250 ml cans). Between 2013 and 2022, Health Canada has issued over 400 TMA letters to energy drink manufacturers, most being issued to Red Bull (59), Monster Energy Drink (55) and Pepsi (50), allowing them to market new energy drink products in Canada.[1142]

Over the past decade, there has been a host of external sources which have increasingly questioned the safety data of energy drinks. In 2017, Toronto Public Health Department prepared a report on energy drinks, *Caffeinated Energy Drinks: Technical Report on Public Health*

[1139] (Health Canada: Ottawa, 2013).
[1140] *Ibid*.
[1141] *Ibid*.
[1142] Health Canada, *Lists of Foods that have Received Temporary Marketing Authorization Letters (TMALs)*, online at: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/acts-regulations/lists-foods-that-have-received-temporary-marketing-authorization-letters.html, accessed on July 14, 2022.

Concerns and Regulation in Canada, which summarized many of these concerns.[1143] While stopping short of criticizing the regulatory framework established by Health Canada, the report re-iterated the lack of safety information related to these products and that "public health should continue to monitor the evidence of CEDs and pursue policy measures and health promotion, as appropriate."[1144]

The U.S. *National Centre for Complementary and Integrative Health* (NCCIH) ruled that "a growing body of scientific evidence shows that energy drinks can have serious health effects, particularly in children, teenagers and young adults."[1145] It goes on to state that "large amounts of caffeine may cause serious heart and blood vessel problems…associated with anxiety, sleep problems, digestion and dehydration."[1146] The NCCIH was particularly concerned with their use with alcohol because of the potential that those who blend alcohol and these products may "not be able to tell how intoxicated they are."[1147]

Canada's Chief Health Officer was more direct, drawing definitive links between energy drinks and dangerous use of alcohol.[1148] The *Institut national de santé publique du Québec* produced a report, *Energy Drinks: Threatening or Commonplace*,[1149] where it concluded:

> The high caffeine and sugar content of energy drinks, along with their acidity, could have an effect on the health of children and teenagers: caffeine poisoning, sleep disorders, dental health problems, excess weight, etc. In addition, questions can be raised about the way in which the marketing strategies appeal to young audiences, present the frequent

---

[1143] Toronto Public Health, *Caffeinated Energy Drinks: Technical Report on Public Health Concerns and Regulation in Canada* (Toronto Public Health: Toronto, February 16, 2017).
[1144] *Ibid*.
[1145] NCCIH, *Energy Drinks*, online at: https://www.nccih.nih.gov/health/energy-drinks
[1146] *Ibid*.
[1147] *Ibid*.
[1148] Canada's Chief Public Health Officer, *The Chief Public Health Officer's Report on the State of Public Health in Canada, 2015: Alcohol Consumption in Canada*, (CPHO: Ottawa, 2016).
[1149] (Institut national de santé publique du Québec: Québec, 2013*)*.

> intake of large quantities of caffeine and sugar as normal, and make the use of stimulants for recreational or performance-related purposes appear common place.[1150]

The B.C. government also noted the dangers that can result from energy drink consumption, including "headaches, nausea, vomiting, upset stomach, electrolyte imbalance, nervousness, insomnia, tremors or seizures,"[1151] which can be more acute when they present in adolescents.

In 2017 Doctors Nova Scotia went so far as to ask for a ban on the products being sold to anyone under the age of 19. The president of Doctors Nova Scotia told media, "these are products which are very available to youth at the present time and there are significant medical concerns about their use and overuse."[1152] They were particularly concerned with the new 5-hour energy drink shots, which provide a concentrated dose of caffeine in a (59 ml) smaller-size bottle. New Brunswick's Chief Medical Officer similarly told media that these products should be limited from sale to adolescents, and clearly stated that "energy drinks contain moderate to high concentrations of stimulant drugs, including caffeine, which are associated with adverse health effects."[1153]

The lynchpin of the 2015 TMA process was that manufacturers would be allowed to market their products so long as they continued to provide safety information to Health Canada every six months. The logic was that, with time, this information would provide a clearer picture of the overall safety of these products. These reporting standards are dependent on the good faith and transparency of the ED manufacturers and are far less than the positive obligations for ADR

[1150] *Ibid*.
[1151] Health Link BC, *Caffeinated Energy Drinks*, (Government of British Columbia: Victoria: 2020).
[1152] CBC, *Energy Drink Ban for Teens Urged by N.S. Doctors*, (CBC News, November 2012).
[1153] New Brunswick – Office of the Chief Medical Officer of Health, *Position Statement: Energy Drinks*, (Chief Medical Officer, New Brunswick).

reporting established for drugs under *Vanessa's Law*. Still, manufacturers chafed at these requirements and complained to Health Canada that they were overly burdensome. As the regulator described it:

> industry stakeholders have raised concerns that marketing supplemented foods under the TMA requirements imposes a significant administrative burden on manufacturers; this includes the ongoing obligation imposed by the TMA to provide safety information.[1154]

Health Canada seems to agree with these calls from industry, announcing in its 2019 *Agri-Food and Health Canada's Regulatory Review Road Map*[1155] the need for a simplified regulatory pathway for these products because the current mechanism was "limiting flexibility and industry's ability to innovate."[1156] Nowhere was the relative health and safety of these products discussed.

In 2021, Health Canada introduced amendment to the *FDA* and *FDR*[1157] to create a distinct product class including energy drinks that would permanently make them a class of food with permitted high levels of additives that could make health claims.[1158] Health Canada cited a new risk assessment, internally completed at the department, which was still inconclusive about specific risks associated with these products. Hence, a new class of product called "supplemented foods" would be created that would allow for caffeinated beverages. One of the major changes would be to create an exemption for these products from the adulteration provisions of the *FDA*. Prior to the amendment, s 4(1) (a) and (d) of the *FDA* prohibited the sale of foods that contained poisonous or harmful substances. Under the amendment, these products

---

[1154] Canada Gazette, Part I, Volume 155, Number 26: *Regulations Amending the Food and Drug Regulations (Supplemented Foods),* herein after *Supplemented Food Regs.*
[1155] Online at: https://inspection.canada.ca/about-cfia/acts-and-regulations/forward-regulatory-plan/regulatory-roadmap/eng/1612197905956/1612197906166.
[1156] *Ibid*.
[1157] *P.C. 2022-707* June 20, 2022 and *SOR/2022-143* June 21, 2022
[1158] *Ibid*.

are now exempted from these provisions.[1159] These products would also be exempted from Sections 6.1(2) of the *FDA*[1160] and B.01.042 of the *FDR*[1161] which prohibited advertising and sampling of supplemented products. Finally, to prevent confusion, an amendment was made to Division 29, which prohibited the sale of foods which might be mistaken for supplemented foods. What could be added as a supplemented food was to be addressed as part of a proposed future set of regulations that includes "a list of permitted supplemental ingredients which could be updated regularly."[1162]

The pathway for energy drinks has gone full circle, from being prohibited, to becoming NHPs, to existing as a new class of products. This is despite the ongoing safety concerns around these products and despite no additional safety information being provided since 2004. It is likely pressure by the CBA and other industry players that pushed the Minister to go against the recommendations of their own advisory panel and allow these products on the market. Throughout this process, two points come to mind: (i) in making many of these decisions, the health and safety profile of these products, or their limited benefits, did not seem to be the deciding factor in decisions made. (ii) in the absence of irrefutable evidence of the products' harms, Health Canada has been unwilling to act on health concerns related to these products. Instead, Health Canada has tended to fall back on rhetoric around these products being low risk, with little evidence related to SEQ to justify this reasoning. In this case, the "innovation" or economic argument has likely been the main consideration.

[1159] *Ibid.*
[1160] *Ibid.*
[1161] *Ibid.*
[1162] *Ibid.*

(ii) Case 2- Homeopathies: *Similia similibus curentur* (Like Cures Like)

As discussed earlier, homeopathics represent a class of CAM products in which diluted substances, meant to elicit a negative response, are given to treat a specific disorder. They are based on the concept of "like cures like," according to which a "disease can be cured by a substance that produces similar symptoms in healthy people"[1163] and the "law of minimal dose" which presumes that "the lower the dose of the medication, the greater its effectiveness."[1164]Homeopathy is based upon the ministrations of Samuel Hahnemann (1755-1843) who outlined the process for producing homeopathies and how they could be used in treatment. The first homeopathic pharmacopeia, the *Organon,*[1165] provided a listing of which ailments each product in the pharmacopeia could be used to treat. Most homeopathics remedies are so diluted, greater than 1:100,000,000 parts per million, that any active ingredient is undetectable in the finished product. Hahnemann believed that this dilution was mitigated by violent shaking of or "potentization" at the time of compounding and professed a belief that "by his methods he could cure all or nearly all acute diseases."[1166] In this conception, the inoculating effect of homeopathics comes from the vital energy they convey, not any pharmacological effect.

Homeopathy has a long history of use, spanning at least 200 years, but it is not perfectly comparable to other traditional medicines in the sense that it is not part of a larger system of medicine or cultural belief. As Loudon notes, "while it can scarcely compare in antiquity with Chinese or Indian medicine, homeopathy is the longest established CAM to have arisen in

---

[1163] NCCIH, *Homeopathy: What You Need to Know*, online at: https://www.nccih.nih.gov/health/homeopathy. See also *Whorton, supra* note 472 at *Chapter 3: Delusion of Grandeur Homeopathy*.
[1164] *Ibid*
[1165] *Supra,* note 573.
[1166] *Whorton, supra* note 476.

Europe."[1167] It is represented by a sophisticated industry, particularly in Europe, which has been producing these products under highly developed manufacturing processes for almost a hundred years. Companies such as *Boiron Group* (France), *Doliosis* (Greece), *Biologishce Heilmittel Heel* (Germany), *Nelsons* (U.K.) and *Hahnemann Laboratories Inc.* (U.S.) are large industrial enterprises with worldwide distribution networks underpinning a $10-billion (USD) annual market.[1168] It has a long history of use in Canada,[1169] at least 100 years, and it is linked to a network of professional practitioners of homeopathic medicine. In Canada manufacturers are represented by the Canadian Homeopathics Association (CHA)[1170] and many provinces have regional self-governing homeopathics professional associations (the Alberta Homeopathics Association,[1171] the Ontario Homeopathic Medical Association,[1172] the Maritime Association of Homeopaths,[1173] etc.).

Homeopathics are composed mostly of sugar with some binding agents and trace (often undetectable) diluted substances. There is very little evidence demonstrating that homeopathics are effective. The most comprehensive study surveying the existing literature, conducted by the Australian government in 2015, looked at 225 research papers and stated that, "based on the assessment of the evidence of effectiveness of homeopathy, [we] conclude that there are no health conditions for which there is reliable evidence that homeopathy is effective."[1174] While

---

[1167] *Loudon, supra* note 368
[1168] *Homeopathy Product Market Size & Share Analysis*, online at: https://www.mordorintelligence.com/industry-reports/homeopathy-product-market
[1169] See Canadian Society of Homeopaths, *Background and History*, online at: https://www.csoh.ca /CSH_Background.htm. *Whorton, supra* note 472.
[1170] See online at: https://www.canadianhomeopathicassociation.ca
[1171] See online at: https://albertahomeopathicassociation.ca.
[1172] See online at: https://ohma.info.
[1173] See online at: http://maritimehomeopaths.org.
[1174] Government of Australia, *NHMRC Information Paper: Evidence on the Effectiveness of Homeopathy for Treating Health Conditions*, (NHMRC, Auckland: 2015), hereinafter *NHMRC.*

there is some research, largely European, which has shown some signs homeopathics may aid as a complementary treatment to conventional pharmaceuticals,[1175] these have been widely criticized for poor methodology (using open label trials, small samples, no blind procedures).[1176]

Conversely, homeopathics are not generally connected to ADRs if they are diluted as intended. Because of their benign nature, they tend to be inert and if prepared to specifications, unlikely to do any harm. ADRs can occur if homeopathics are incorrectly prepared and pathogens appear at rates higher that trace amounts. Such cases of poor-quality manufacturing tend to be rare in products from established companies. The greater risk from homeopathy tends to come when they are used to replace existing or needed therapies for acute illness.[1177] As will be discussed later, this may be particularly problematic when they are used in place of established treatments in children or in place of needed vaccinations. This harm of omission can occur because of an intentional desire to choose homeopathics over conventional medicines, or because they are marketed in a form that makes them hard to distinguish from other, proven, medications. Ernst strongly argues that that the regulator is complicit in allowing these confusions to persist.[1178] Still, for the most part, homeopathics have no greater clinically proven benefits or ills than a sugar pill.[1179]

[1175] Cucherat, M., Haugh, M. C., Gooch, M. and Boissel, J. P., "Evidence of clinical efficacy of homeopathy. A meta-analysis of clinical trials. HMRAG. Homeopathic Medicines Research Advisory Group" (2000) *Eur J Clin Pharmacology* 56(1) at 27.
[1176] *Ibid.*
[1177] Shaw, D. M., "Homeopathy is where the harm is: five unethical effects of funding unscientific 'remedies'" (2009) *Journal of Medical Ethics* 36(3). See also *Ernst Maze, supra* note 492.
[1178] *Ibid.*
[1179] *Supra*, note 175.

Despite the lack of clinical evidence demonstrating their effectiveness, homeopathics remain very popular. According to the WHO, homeopathics are the fourth-most-common form of CAM worldwide.[1180] In 2019 the WHO found that of 137 responding countries, 100 (72%) reported the common use of homeopathy. This is particularly true in Europe, where they are widely used in Germany, France, Switzerland, and Italy.[1181] In the EU, homeopathics are explicitly exempt from safety and efficacy requirements applied to drugs under *EU Directive 2001/83/EC*.[1182] Where these products are common in Northern Europe, they are taken as part of a larger preventative health regime, much like one might take a multivitamin. In 2014, Germans spent 650 million euros on homeopathy, and France 408 million euros. Figures are not available for the estimated size of the Canadian market, but it is estimated to be a $3-billion (USD) annual industry across the border in the United States.[1183]

Homeopathics pose specific challenges to regulators. In achieving the balanced goals of providing high-quality, safe, and effective NHPs while respecting consumer choice, regulators are faced with a product class which has little to no effectiveness or inherent risk, but for which there is a very high demand. At the time the regulations came into force in 2004, homeopathics were one of a few classes of CAM that had a long history of use in the Canadian market.[1184] Most homeopathics were taken as part of a prescribed regime of holistic medicines from practitioners but were sold under a variety of different conditions (over the counter, health food stores, some licensed as drugs). There was a wide range of homeopathic manufacturers. Many

[1180] *WHO 2019, supra* note 440.
[1181] *Ibid.*
[1182] *Ibid.*
[1183] *Ibid.*
[1184] *NHPR RIAS, supra* note 751.

homeopathics had been licensed in Canada as drugs early in the century and had valid drug identifying numbers (DINs). Others were sold as commercial products which had never been subject to any form of regulation.

Initial commentary from the homeopathic community about the proposed *NHPR* focused on a fear of over-regulation or that their freedom would be curtailed by the new regulations.[1185] This eventually morphed into a desire to have a specific inclusion of homeopathics in the definition of NHPs, or their express inclusion in the interpretation section of the regulations.[1186] The hope of the community was that this would ingrain the legal status of homeopathics as a class of drugs in the regulations. The definition as it appeared in the original *NHPR* intentionally referred to "substance set out *Schedule 1*, a **homeopathic medicine** or a traditional medicine,"[1187] but did not define homeopathic medicine in the regulations.

In 2004, all homeopathics on the market were required to be licensed under the *NHPR* or to be in the process of transitioning to be a licensed product. The guidance released in anticipation of the regulations coming into force, *Evidence for Homeopathic Medicines Guidance Document* (2003),[1188] defined homeopathics as "medicines that are manufactured from or contain as medicinal ingredients only those substances or sources referenced in the *Homeopathic Pharmacopeia of the United States* (HPUS) or the *Homöopathisches ArzneiBuch* (HAB), as amended from time to time."[1189] At the time, these represented the most accepted set

[1185] *Ibid.*
[1186] *Ibid.*
[1187] *Ibid.*
[1188] (Health Canada: Ottawa, 2003), herein after *E for Homeo 2003.*
[1189] *Ibid.*

of pharmacopeias. Quality and safety were assured by adhering to the ingredients at dosage levels (usually in the parts per million of any active ingredient) in these pharmacopeias. If these dosage standards were met, no finished product or manufacturing testing was required (i.e., at the time, the definition was purely ingredient based). Homeopathic products, when licensed, would receive a special drug identification number: a DIN-HM recognizing their status. (This is compared to the natural health product number (NPN) received by most NHPs).[1190]

The 2003 guidance allowed for one of three pathways for homeopathics to be licensed. The first pathway was for products which already had a DIN and were transitioning to the *NHPR* from their prior status of being licensed as a drug under the *FDA*. These products were on the market prior to the advent of modern SEQ standards and were grandfathered in as drugs when those standards were adopted. During the interim period, if a product had applied for transition, no compliance action would be taken until it received its DIN-HM.[1191] Products making this transition were not required to submit new safety or efficacy information, but going forward did need to comply with other requirements of the *NHPR*. Products produced in an establishment already licensed to produce a drug could use an existing drug establishment license (DEL) to apply for a transition to using the same establishment for an NHP site license (SL).

The second pathway to obtaining a DIN HM was for products which made an "unspecified (health) claim." These products were generally produced as part of a health plan developed by a homeopathic practitioner and were required "to be used on the advice of a health-

[1190] *Ibid.*
[1191] *Ibid.*

care provider."[1192] These products simply had to adhere to the composition and maximum concentrations for over-the-counter concentration of homeopathics identified in either the HPUS or the HAB.[1193] The intention for these products was that they would be compounded by a homeopathic practitioner. In this way, they were a form of compounded product prepared directly by homeopathic practitioners for their patients, with a limited market range.

The third pathway to product licensing was for new homeopathic products to be marketed with a specific health claim and indication for use. These products were also expected to comply with the ingredient and maximum concentration limits of the HPUS and HAB, but also had to ensure that the indication was supported by evidence. The evidential bar was like that being requested for new traditional indications, which included:

> photocopies of at least two independent homeopathic references for each homeopathic ingredient giving the name of the reference, the authorship, the edition, the year and place of publication (title page included). If one reference refers to and relies upon the other, then they are effectively one source. The intent is to establish evidence from more than one source.[1194]

This bar could be met by providing this evidence from the HPUS and HAS. New homeopathic indication also had to be "consistent with the principles of self-care,"[1195] i.e., not requiring the intervention of a health-care professional. The label had to "clearly describe the symptoms likely to be relieved [and] be specific, avoiding vague out-moded terms."[1196] This last criterion would prohibit general or unspecific claims.

[1192] *Ibid.*
[1193] *Ibid.*
[1194] *Ibid.*
[1195] *Ibid.*
[1196] *Ibid.*

To NHPD's surprise, many of the homeopathic applications they received post-2004 were for products making new and specific claims. As is noted above, Hahnemann, and the leading homeopathic pharmacopeias, had listings for treating almost any ailment. This meant new products could make treatment claims for almost any condition except those prohibited in *Schedule 1* of the *FDA.* The guidance also allowed for overlapping claims, i.e., combining X substance for treating colds and Y substance for treating fevers.[1197] The product only had to meet the composition standards of the pharmacopeias and meet the very low evidential bar to be marketed. These products were often packaged and labelled in a way that was indistinguishable from over-the-counter drugs and could be perceived by the public as being equally effective.

In response, in 2006 NHPD issued updated guidance, *Evidence for Homeopathic Medicine: Natural Health Product Directorate* (2006),[1198] which expanded the definition of homeopathics to include: (i) "manufactured from or containing as medicinal ingredients, those referred to in one of the acceptable pharmacopeias"[1199] and (ii) "**manufactured in accordance with the method** outlined in the acceptable pharmacopeias."[1200] The guidance also expanded the acceptable pharmacopeias to include the *Pharmacopée française* (PhF), the *European Pharmacopoeia* (Ph.Eur.) and the *Encyclopedia of Homeopathic Pharmacopoeia* (EHP).[1201] The changes meant that homeopathics were now licensed based on a dual condition of composition and manufacturing methods complying with existing pharmacopeias. Quality was further defined as the number of medicinal ingredient(s) per dosage unit being below limits in the designated

---

[1197] *Ibid.*
[1198] (Health Canada: Ottawa, 2006), hereinafter *E for Homeo 2006.*
[1199] *Ibid.*
[1200] *Ibid.*
[1201] *Ibid.*

pharmacopeias. This was intended to make quality directly aligned to traditionally safe limits and manufacturing processes.

The guidance went on to further define safety as "the ability of an NHP to produce a beneficial health outcome, outweighing the risk associated with using it, in humans, according to the recommended conditions of use."[1202] Efficacy was defined as "the extent to which a specific intervention, procedure, regimen or service produces a **beneficial result under ideal conditions."**[1203] Strangely, even though the guidance defined efficacy, it did not require evidence to prove efficacy. In fact, it was not being licensed based on efficiency standards at all.

Evidence to support a specific claim was expanded to include evidence for each condition and product. The regulations no longer exclusively required reference to pharmacopeias but asked for just two references, which could include additional sources. The guidance also now linked each medicinal ingredient to an indication:

> Sufficient evidence must be provided to demonstrate a clear rationale for the inclusion of each medicinal ingredient in the homeopathic medicine. For a homeopathic medicine with a specific recommended use or purpose (claim), evidence must link each medicinal ingredient to the symptom(s) of the claim it is intended to address. <u>It is not necessary to link each medicinal ingredient to every symptom included in the claim.</u> For example, if the claim is "For the fever, pain and irritability associated with teething," evidence might demonstrate that ingredient A treats fever and pain, ingredient B also helps reduce fever and ingredient C treats irritability.[1204]

In effect, the guidance now allowed for general maintenance claims if they were supported by homeopathic pharmacopeias. The appendix gave a listing of these new acceptable sources,

---

[1202] *Ibid.*
[1203] *Ibid.*
[1204] *Ibid.*

including references dating from 1834 through 2002. The guidance was also more specific, stating that applications needed to comply with other conditions in the *FDA* and *FDR,* including not making *Schedule A*[1205] claims or including substances in *Schedule F*.[1206]

One of the major additions in the guidance was the inclusion of a specific section on the labelling of HM products. Homeopathic products were now required to include an exclusive indicator that they were homeopathic products (homeopathic remedy, homeopathic drug, and homeopathic preparation). Labelling also must include a statement of recommended use and purpose, a statement with known risk information, and an explicit statement (at a minimum) to "consult a health-care practitioner if symptoms persist or worsen."[1207]

This guidance was an attempt to spell out more clearly the conditions that would be placed on the large number of new homeopathic products entering the market, to make them more distinct from conventional drugs. Yet, it had the opposite effect, expanding the allowable sources of evidence, claims, and types of treatment for which homeopathics could seek market authorization. This led to a proliferation of homeopathic products marketed for common conditions associated with OTC medications (such as cough cold, flu, allergies). They were packaged in a way that was indistinguishable from OTC drugs.

[1205] *Ibid.*
[1206] *Ibid.*
[1207] *Ibid.*

Figure 16: A homeopathic (left) beside an Over-the-Counter Drug (right)[1208]

While they did include a disclaimer, the text indicating they were a homeopathic medicine was small or hidden (see figure above). Of particular concern were a class of homeopathics called *nosodes* which were used as a substitute for flu vaccinations.[1209]

Over the following decade, there was a proliferation of new homeopathic products being sold which largely looked like over-the-counter drugs. There had long been published studies suggesting that homeopathics showed little to no efficacy,[1210] but starting in 2010, a number of governments around the world began exploring whether these products needed to be better regulated or prevented from making unproven health claims. In the U.K., a Parliamentary committee was asking whether the National Health Service should continue paying for homoeopathic therapies because their merit was increasingly being called into question.[1211] The report, published in February 2010 as *The House of Commons Science and Technology Committee – Evidence Check 2: Homeopathy*,[1212] was unequivocal: "in our view, the systematic

[1208] CBC - Marketplace, *Unproved Homeopathic Remedies for Kids Still Promising Relief Despite New Label Rules*, (CBC, May 2017) , online at: https://www.cbc.ca/news/health/homeopathic-labels-marketplace, herein after *Unproven Homeo.*
[1209] *Ibid.*
[1210] *Supra, note* 1179.
[1211] (UK House of Commons: London, 2010), online at: https://publications.parliament.uk.
[1212] *Ibid.*

reviews and meta-analysis conclusively demonstrate that homeopathics products perform no better than placebos."[1213]

The U.K. report went on to note that advocates of homeopathy had been highly selective with the evidence they brought forward, that patients who reported feeling better were likely subject to a placebo effect, and that doctors and pharmacists who prescribed homeopathy risked damaging the reputation of their professions. They also noted in relation to patient choice that:

> For patient choice to be real choice, patients must be adequately informed to understand the implications of treatments. For homeopathy this would certainly require an explanation that homeopathy is a placebo. When this is not done, patient choice is meaningless. When it is done, the effectiveness of the placebo—that is, homeopathy—may be diminished. We argue that the provision of homeopathy in the NHS, in effect, diminishes, not increases, informed patient choice.[1214]

They went further, chastising the NHS and the U.K. drug regulator for not using scientific evidence more aggressively to validate these products. In this regard, the committee commented that by funding these treatments the NHS was contributing to the perception that they were endorsed, or:

> When the NHS funds homeopathy, it endorses it. Since the NHS Constitution explicitly gives people the right to expect that decisions on the funding of drugs and treatments are made "following a proper consideration of the evidence," patients may reasonably form the view that homeopathy is an evidence-based treatment.[1215]

Allowing the products to pass what is supposed to be an evidence-based assessment would likely lead the public to believe that the products have been assessed based on evidence to be effective.

[1213] *Ibid*.

[1214] *Ibid*.
[1215] *Ibid*.

Health Canada was relatively silent on making any changes to how these products were licensed and labelled. That was until the 2015 CBC *Marketplace* article,[1216] described in the introduction, in which a reporter was able to obtain an NHP license for a children's cough and cold medication with quickly mocked-up packaging and two photocopied references from a hundred-year-old homeopathics textbook. Health Canada's response was to note these products "were low risk and designed to treat only minor, non-serious conditions."[1217] One *National Post* article, in assessing this response noted that this would be "a good recommendation for any medication. But Nighton is not a medication: it is a potion. By approving homeopathic remedies, Health Canada is complicit in peddling pseudoscience."[1218] In its conclusion, the article noted that:

> patients should be free to explore natural remedies for minor illnesses if they choose. But Health Canada should not be lending its credibility to medicines with no basis in science. "Safe and effective" should mean just that, if it can't be proven, it should not be approved.[1219]

The same article went on to be highly critical of nosodes, which Health Canada also continued to license, noting there is "zero evidence that these vaccines actually worked."[1220]

While Health Canada had previously been slow to react, its response to this media criticism was to hastily release a safety alert and update its guidance. The safety alert advised consumers and industry that "Health Canada is no longer allowing companies to make specific health claims… for cough, cold and flu for children under 12 and under, unless these claims are

---

[1216] *Nighton, supra* note 7.
[1217] *Ibid.*
[1218] National Post, *View: Health Canada is Complicit in Peddling Pseudoscience "Safe and effective" Should Mean Just That; If it can't be Proven, it Should not be Approved*. (National Post, March 2015), online at: https://nationalpost.com/opinion.
[1219] *Ibid.*
[1220] *Ibid.*

supported by scientific evidence."[1221] Several media articles pointed out that Health Canada had known about these issues with the scientific justification for homeopathics but had only reacted once they was raised by the media.[1222] We know from a letter obtained by the CBC under an access-to-information request that industry members were told in advance of the health warning by the Minister's office. The letter from the Canadian Health Products Association (CHPA) cited a meeting where they were told by the DG of NHPD that "the trigger for the intervention was the criticism of NNHPD's product evaluation and licensing process contained in a March 2015 episode of CBC's *Marketplace*."[1223] The letter then went on to criticize the proposed standards and to argue that the new proposed guidance violates the original spirit of the 52 recommendations of the standing committee. CHPA instead proposed a voluntary standard for homeopathics which would allow them to continue making claims but add additional labelling.

The letter represents a very rare view into the interplay between the regulator and manufacturing association. The letter cites four stakeholder engagements in which Health Canada and the industry representatives brokered updated guidance. The industry ultimately agreed to additional labelling standards and a limited restriction of claims related to cough and cold medications for children and nosodes. Nowhere in this space is there a discussion around SEQ standards and the appropriateness of other claims for these products. It is also interesting to note that many of these negotiations between NNHPD and industry were led by Phil Waddington, who was the original Director General and who set up the NHPD in 2004, now acting as a consultant.

[1221] *Ibid.*
[1222] *Ibid.*
[1223] *Ibid.*

In 2014 NNHPD issued new guidance on the *Evidence for Homeopathics Medicines (Version 2.2).*[1224] The new guidance was now clear that homeopathics could not "include direct or implied indications for the relief of cough, cold and flu symptoms for products indicated for children aged 12 years and under."[1225] Later that year NNHPD also updated the *Guidance Document: Labelling of Natural Health Products*[1226] to include a new Annex A on homeopathics that required front package labelling to include the statement, "this/these claims(s) are based on traditional homeopathic reference and not modern scientific evidence."[1227] Nosode products must clearly indicate on the label that the product is "neither a vaccine nor alternative to vaccination."[1228] Nosode products also needed to include a clear statement that "Health Canada does not recommend its use in children and advises that your child receive all routine vaccinations."[1229] Existing products were given until 2017 to fully comply with the new conditions. It took almost a decade and a half for the regulator to take any formal action to address the confusion around homeopathics. In addition, this action had only been initiated by criticism in the media.

Still, critics remained skeptical. A follow-up article by CBC *Marketplace*[1230] found that most homeopathics were still found beside OTC drugs for children in pharmacies. They observed that the new labelling, which was not very prominent, did little to make the products distinguishable from drugs.

[1224] Health Canada, *Evidence for Homeopathics Medicines (Version 2.2) (Health Canada: Ottawa, 2014).*
[1225] *Ibid.*
[1226] Health Canada, *Guidance Document: Labelling of Natural Health Products*, (Health Canada: Ottawa, 2013)
[1227] *Ibid.*
[1228] *Ibid.*
[1229] *Ibid.*
[1230] *Unproven Homeo, supra* note 1208.

Figure 17: New (right) Versus Old (left) Packaging for a Homeopathic[1231]

As is often the case, regulatory action in Canada was spurred by activities in the U.S. Starting in 2017, the FDA announced that it would be pursuing more aggressive regulatory action against homeopathics. Since 1988, the FDA had used "enforcement discretion" to allow homeopathic products to be manufactured and distributed without FDA approval. The FDA announced[1232] that they would ramping up enforcement against higher-risk (either by dose, population, or claim) homeopathic products. This new wave of enforcement followed the death of several toddlers who had consumed an adulterated homeopathic product, *Hylands Teething Tablets*.[1233] In this case, the noxious substance was not sufficiently diluted, and toddlers had suffered from belladonna toxicity. In announcing the new policy, the FDA commissioner Scott Gottlieb indicated:

> In many cases, people may be placing their trust and money in therapies that may bring little to no benefit in combating serious ailments, or worse – that may cause significant and even irreparable harm because the products are poorly manufactured or contain active ingredients that aren't adequately tested or disclosed to patients.[1234]

[1231] *Ibid*.
[1232] FDA, *Homeopathic Drug Products: Guidance for FDA Staff and Industry*, (FDA: Washington, 2022).
[1233] Ibid. See also online at: https://www.fda.gov/news-events/press-announcements/fda-warns-against-use-homeopathic-teething-tablets-and-gels and https://www.fda.gov/consumers/consumer-updates/hylands-homeopathic-teething-tablets-questions-and-answers.
[1234] See online at: https://www.fda.gov/news-events/press-announcements/fda-proposes-new-risk-based-enforcement-priorities-protect-consumers-potentially-harmful-unproven.

Going forward, the FDA was using a higher bar for products which might make claims with outcomes that were negative if they did not work, especially claims made in relation to children. In 2016, the U.S. Federal Trade Commission (FTC), responsible for product advertising and preventing fraud, also announced that they would be holding homeopathics to the same safety and efficacy standards as other products making similar claims, such as OTC drugs.[1235] In making their announcement they:

> recognize that an OTC homeopathic drug claim that is not substantiated by competent and reliable scientific evidence might **not be deceptive if the advertisement or label where it appears effectively communicates that**: 1) there is no scientific evidence that the product works; and 2) the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts.[1236]

This amounted to a pronouncement by the FDA that homeopathics had to list on their labels that they were not proven effective.

Health Canada proposed expanding the limitations on homeopathics to match those the U.S. had introduced half a decade earlier. In July 2022, Health Canada released new guidance on the *Evidence Required for Homeopathics*[1237] that would no longer allow claims for higher-risk homeopathics which were defined as "those for non-self-resolving or self-limiting conditions with potential for harm to health if product efficacy is underperforming."[1238] Under this guidance, if a condition is not likely to resolve itself on its own without intervention, a homeopathic product should not be used. In effect, this acknowledges that homeopathics should not be used unless their ineffectiveness would have no impact. It is also an admission that the

[1235] See online at: https://www.ftc.gov/news-events/news/press-releases/2016/11/ftc-issues-enforcement-policy-statement-regarding-marketing-claims-over-counter-homeopathic-drugs.
[1236] *Ibid*.
[1237] Health Canada, *Evidence Required for Homeopathic,* (Health Canada: Ottawa, 2022).
[1238] *Ibid*.

products do not confer a benefit. To be licensed to make higher-risk-type claims, homeopathics "must be supported by sufficient modern scientific evidence"[1239] (i.e., clinical data).

This is likely a positive development as it limits homeopathics from making many health claims and limits their use to minor health ailments. It is also a general admission, nearly two decades after the regulations were conceived and launched that these products are likely ineffective. Yet, one is left asking why it took almost two decades (19 years since 2004) for the regulator to effectively pronounce on the limits of these products. One is left wondering why the same labelling standards, indicating that the product was not approved using modern scientific evidence, was not required on all NHPs.

(iii) Case 3 – Cosmetics, Non-Prescription Drugs: Towards a Self-Care Framework

For the last case study, I will look at a more general class of products which has emerged over the course of the *NHPR*. A set of regulations that had originally been introduced to facilitate access to CAM products with lower evidential standards is increasingly being co-opted by OTC products and cosmetics. This includes the emergence of a conception of products for personal or self-care that should be made available with little oversight from Health Canada. This has long been called for by lobby groups which sought to expand the low standards set by the *NHPR* for SEQ to other product classes.

[1239] *Ibid*.

The goal was to make the point of sale (over the counter) the determining risk factor, not the inherent risk of the product. They would argue that, since the *NHPR* has expanded the criteria for making general claims for NHPs, why should this not be expanded to other product classes? There is particular interest in expanding the criteria to cosmetics (where few health claims have ever been validated), and non-prescription drugs or over-the-counter drugs (OTC) (which must meet all the requirements of a drug for SEQ under the *FDA*). Manufacturers were eager to take advantage of the more permissive nature of the *NHPR*. Cosmetics would be allowed to make claims with little to no evidence, traditional or otherwise, and OTC drugs could come to market without clinical trials and stay on the market with lower ADR monitoring burdens. In effect, this would allow for an expansion of the low SEQ criteria of the *NHPR* to a whole host of new products.

Both sets of products were represented by very active lobbying groups when the NHPR came into force in 2004. The *Canadian Cosmetic, Toiletry and Fragrance Association* (CCTFA), now the *Cosmetic Alliance of Canada* (CAC),[1240] represented over 150 cosmetics manufacturers operating in Canada. Their clients include large companies such as Amway, Estee Lauder, Christian Dior, Chanel, Yves Rocher as well as smaller manufacturers of alternative cosmetic products such as Natural Organic Matters, Laboratoire Native Canada Inc. among others. Their stated goal is to "shape legislation, regulation and policy to enhance the ability of member companies to conduct business effectively in Canada and to promote global competitiveness."[1241] OTC drugs at the time of the *NHPR* coming into force were represented by the Non-Prescription

[1240] See online at: https://www.cosmeticsalliance.ca.
[1241] *Ibid,* CAC - What we do, online at https://www.cosmeticsalliance.ca/about-us/.

Drug Manufacturers Association (NDMAC),[1242] which was established in 1896, and represents some of the largest drug manufacturers in Canada and the world, such as Bayer, GlaxoSmithKline, and Merck, as well as smaller manufacturers with the goal of "advancing Canadian self-care."[1243]

a. Cosmetics and Personal Care Products

Like the foods under the *FDR*, prior to 2004, cosmetics regulated under the *Cosmetic Regulations* (*CR*) were only allowed to make a very limited number of health claims. They were also subject to lower requirements for packaging and labelling. The effect of the *NHPR* was to allow for these products to make a broader range of health claims if they were NHPs, but they would be required to improve packaging (secure packaging) and improve labelling (including dosage forms and an NPN). CCTFA argued that a carve-out for the *NHPR* and *Cosmetic Regulations* should be created for a new class of personal care products (PCP).[1244] What the CCTFA was asking for was an exemption that would allow them to employ the more permissive regulatory requirements of the *NHPR*, but with certain exemptions around labelling and GMP standards. The number of products which would be captured under the PCP exemption were numerous, including most common toiletries (deodorants, sunscreens, toothpaste, lip glosses, etc.). The CCTFA was aware that pairing these products with health claims would allow for the creation of a very lucrative new market.

[1242] NDMAC is now part of Food, Health and Consumer Products Canada (FHCP), online at: https://www.fhcp.ca.
[1243] *Ibid*.
[1244] *Charting a Course, supra* note 23.

In 2009 Health Canada issued guidance on the classification of these cosmetics versus NHPs. The *Guidance Classification of Products at the Cosmetic Drug Interface*[1245] classifies these products as cosmetics or NHPs. The new guidance identified a personal care product "as a substance or mixture of substances which is generally recognized by the public for use in daily cleansing or grooming. Personal care products may fall into one of three regulatory categories in Canada: cosmetics, drugs or natural health products."[1246] Most cosmetic products that applied were classified as NHPs.

The result was a massive shift of existing products away from the *Cosmetics Regulations*, which prohibited all but a few health claims, to the NHP regime. Most were new cosmetics making a host of low-level health claims. This was despite the fact that no new information or evidence had been submitted showing the cosmetics could justify these claims. The health-based cosmetics industry, worth billions domestically and internationally, had begun carving out a regulatory niche for these new personal care products (PCPs). PCPs represent the first class of "combination product" that NHPD allowed. This was also the first example of blending the language of these products being labelled low risk with Health Canada's need to "improve the current legislation affecting these products so that they are regulated in a timelier, less onerous and consistent manner."[1247] This would be the root of the later self-care framework for NHPs, over-the-counter drugs, and cosmetics being regulated together.

[1245] *Supra note*, 922.
[1246] *Ibid*.
[1247] *Charting a Course, supra* note 23.

b. Over-the-Counter Drugs

Over-the-counter or non-prescription drugs are those that can be sold without a prescription, normally within a pharmacy. They are drugs under the *FDA*. At the time that the *NHPR* came into force, these products were reviewed for market authorization in a way that was indistinguishable from other drugs. They required clinical trials, toxicology testing, and a full demonstration of GMP standards being in place to satisfy a drug's establishment license (DEL). The point of sale of drugs, listing in formularies and where they can be sold is a provincial responsibility and regulated jointly by the pharmacy colleges and provincial governments in each province. Most provinces incorporated by reference the National Drug Schedule (NDS), created by the *National Association of Pharmaceutical Regulatory Authorities* (NAPRA),[1248] which had a committee process making recommendations around point of sale. This was facilitated by the *National Drug Schedule Advisory Committee* (NDSAC)[1249] which reviewed products to place them on one of three schedules:

When making decisions about the scheduling of a product, NDSAC applies a series of factors:

- First, whether it can **only be prescribed by a practitioner**; is it related to serious adverse effects; can serious interactions occur with other medicines; and does it have a narrow margin of safe use (*Schedule 1*).
- Second, does the drug **require intervention for correct choices**; is the product new to the market, with a significant potential for misuse; should self-assessments be confirmed by a pharmacist (*Schedule 2*).
- Third, does the product have **new ingredients; does it treat chronic or re-occurring conditions**, and does a pharmacist need to be near to expand or reinforce labelling information (*Schedule 3*).[1250]

[1248] NAPRA, see online at: www.napra.ca
[1249] *Ibid.*
[1250] *Ibid.*

Soon after the *NHPR* came into force, the *Non-Prescription Drug Manufacturers Association of Canada* (NDMAC) began raising concerns about the limited scope of the regulations. They began lobbying for clarification specifying that the regulations should apply to all products which are appropriate for "self-care."[1251] The main argument was that introducing more OTC products into the Canadian market could potentially save the health-care system millions of dollars each year. In their perspective, OTC drugs needed to be licensed using a simplified system equivalent to that of *NHPR*. In speaking to Parliamentarians, David Skinner, president of NDMAC, said:

> We believe that all products with health claims of similar risk should attract the same regulatory requirements, not just for post-market monitoring, but also for pre-market authorization to sell. This means there should be differing regulatory standards for products with differing levels of risk. Sadly, Canadian regulations are confusing, inefficient, and often arbitrary in the way they differentiate between health products of similar risk.[1252]

Skinner further argued that "lack of clarity has created a two-tiered market and reduced consumer choice."[1253] He went on to argue:

> NDMAC urges the committee to recommend that a simplified, consistent, and comprehensive system of regulation for self-care health products be created outside part C of the food and drug regulations. Within the self-care regulatory framework, post-market monitoring should be established based on well-known safety profiles of lower-risk products and the requirements be made proportionate to the risk.[1254]

Over the next decade NDMAC lobbied frequently for this simplified system for OTC drugs that would have the lower SEQ requirements of the *NHPR* but the greater patent and market exclusivity protections of drugs which existed under the *FDA*.

[1251] *Charting a Course, supra* note 23.
[1252] Parliament of Canada, Standing Committee on Health (HESA) meeting minutes, 2008, online at https://www.ourcommons.ca.
[1253] *Ibid.*
[1254] *Ibid.*

The *UPLAR Regulations* and the Stop C-51 Campaign, as discussed in the last chapter, slowed any specific attempts by regulators to modify the *NHPR*. While cosmetics were now being marketed as NHPs, most OTC drugs remained excluded from regulation under the *NHPR*. *Vanessa's Law*,[1255] which included provisions for placing therapeutic products into specific categories, excluded NHPs. *Vanessa's Law* did include the introduction of a *Prescription Drug List* (PDL) to which all new drugs were automatically added.[1256] The changes meant that Health Canada, or the Minister, under s.29.1[1257] could set out a "list of medicinal ingredients that when found in a drug require a prescription."[1258]

This change also meant that potentially, at the federal level, drugs could be removed from the PDL. These changes were supported by the guidance *Determining Prescription Status for Human and Veterinary Drugs (2013)*[1259] which outlined criteria for switching prescription drugs to non-prescription drugs. These changes were designed to create "simpler and quicker processes for making changes to the list of prescription drugs."[1260] Three broad principles were identified for removal of a prescription drug from the list associated with the level of oversight needed from a practitioner. These criteria included:

- **Supervision by a practitioner is necessary** for the diagnosis, treatment, mitigation or prevention or to monitor the disease;
- **The level of uncertainty** respecting the drug, its use or its effects justifies supervision by a practitioner; or

[1255] Vanessa's Law, supra note 240.
[1256] *Ibid*.
[1257] *Ibid*.
[1258] *Ibid*.
[1259] Heath Canada, *Determining Prescription Status for Human and Veterinary Drugs,* (Health Canada: Ottawa, 2013), online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/guidance-document.html.
[1260] *Ibid*.

- **Use of the drug can cause harm** to human or animal health or a risk to public health and the harm or risk can be mitigated by a practitioner's supervision.[1261]

Further subordinate criteria are outlined for each heading, including the inherent risk of taking a product incorrectly, potential ADRs, potential for masking other conditions, and limited experience with the drug. This created a pathway for more prescription drugs to become OTC drugs, but the process was still onerous and required OTC drugs to (1) go through the SEQ-based approval processes of other drugs, (2) be listed on the PDL, and (3) then seek exemption. An exemption was provided to expedite the PDL de-listing process "in cases where the health benefits of drug accessibility outweigh the benefits of the prescription requirements."[1262]

Drug manufacturers may have many reasons for wanting to switch a drug from prescription to OTC status. It may allow for a new drug, still holding a patent, to be sold directly to consumers. At the end period of patent exclusivity, it allows for a product to maintain market share based on brand recognition. It allows for the marketing of a drug to a much wider number of consumers. It allows for the application of much lower SEQ standards to be applied, particularly on an ongoing basis. It opens the door for expanding a class of drugs that are distinct from prescription drugs and can be marketed directly to consumers. It potentially could take scheduling decisions out of the control of NAPRA and provincial authorities to make it part of the licensing process. It also had the potential to expand the market for these drugs.

[1261] *Ibid.*
[1262] *Ibid.*

c. Self-Care

As noted earlier in the chapter, in 2014 the Harper government announced its intention as part of the *Food and Consumer Safety Action Plan* (FCSAP)[1263] to create a new formal class of consumer health products (CHPs). The *Framework for Consumer Health Products* (FCHP)[1264] was announced by the Health Minister in June of 2014 and "proposed that lower-risk products be separated from the framework for prescription drugs, and be moved under a new framework for consumer health products."[1265] As part of these regulations, a new class of product would be created because "Health Canada has determined that with enough supporting information and instruction, consumers can safely select and use these products to maintain and improve health."[1266]

The planned new regulations were to cover drugs, disinfectants, cosmetics and NHPs. The primary justification for the new framework was that the "product market is growing and changing,"[1267] and these products were "being sold in an increasingly wide range of locations from gas stations to pharmacies."[1268] This was a misnomer as only NHPs and cosmetics were allowed to be sold outside pharmacies at the time. Another driver was "the range of products increasing due to industry innovation."[1269] Again, most of this so-called innovation was to connect existing products with previously disallowed health claims. A final justification was the "evolution in how non-prescription drugs are scheduled," referring to the recent changes to the

---

[1263] *FCSAP, supra* note 902.
[1264] *Ibid.*
[1265] *Ibid.*
[1266] *Ibid.*
[1267] *Ibid.*
[1268] *Ibid.*
[1269] *Ibid.*

PDL. As a closing rationale, Health Canada mirrored the language of NDMAC that a new regime needed to be "flexible and responsive enough to adapt to rapid innovation… and the ever-increasing demand from the consumer for more self-care options and information on how to use these products safely and effectively."[1270]

There was no real consideration of the inherent safety or efficacy of these products, or a formal health risk assessment. Instead, pro-market lines about innovation and consumer choice were widely used to justify the new system.[1271] There is a great difference between the safety profile of a traditional NHP (likely benign if it does not work), a cosmetic (likely with no evidence or rationale justifying a health claim), a disinfectant (which should demonstrably disinfect based on efficacy information), and an OTC drug (which should be subject to the same safety and efficacy concerns of any drug). The government promised to develop a system that would align requirements based on the "benefits, harms and uncertainties by considering the nature, intended use and exposure of the product."[1272]

In designing the new regulations the regulators would "build on recent natural health product best practices to provide consistent oversight, to the extent possible, for all consumer health products." As is noted elsewhere, it is hard to argue that at this time the NHPD regime was a smashing success. NHPD had just completed the period following the *UPLAR* regulations where all products were marketed by virtue of just submitting an application, the backlog had only been addressed by reducing evidence standards, and a recent audit by Health Canada's own

[1270] *Ibid.*
[1271] *Ibid.*
[1272] *Ibid.*

auditors had found the approvals were based on little evidence and post-market safety was almost non-existent. In 2014 the portfolio for OTC drugs shifted to NHPD and it changed its name to the *Natural and Non-Prescription Drugs Directorate* (NNHPD).

In 2016 the new government introduced a new proposed *Self-Care Framework* which mirrored the previous government's proposal. Health Canada produced a consultation paper that outlined its proposal for a self-care framework, *Consulting Canadians on the Regulation of Self-Care Products in Canada*.[1273] In announcing the new framework, the government said:

> Health Canada's goal is a consistent approach to self-care products, to ensure consumers are protected while still providing access to a wide range of products, and to provide consumers with adequate information so that they can make informed choices about self-care products.[1274]

The new framework would be based on three principles: (1) "Products of similar risk profiles would be treated in a similar manner"[1275] by making rules to bring products to market more consistent and easier to understand; (2) the department "would review claims based on a new definition"[1276] placing the onus on companies to have scientific proof to support these claims if asked; and (3) a "risk-based approach to compliance and safety monitoring."[1277]

The new proposal would see non-prescription drugs, cosmetics, and NHPs regulated under a system like that in place for NHPs. These new products would be regulated under the new risk framework for NHPs, which generally prohibited "high-risk claims" but allowed

---

[1273] *Consulting SC, supra* note 1064.
[1274] *Ibid.*
[1275] *Ibid.*
[1276] *Ibid.*
[1277] *Ibid.*

moderate and "low-risk" claims with a lower bar of pre-market evidence. In the case of low-risk (or general) claims, little evidence would be provided to the regulator.[1278] ompanies become responsible for "having supporting information" to validate that claims were truthful and based on accurate information if asked later by the regulator. This would allow for the marketing of these drugs, including over-the-counter drugs, purely based on industry attestation that they had evidence proving these products worked. Paired with the attestation process for GMPs, this would put oversight of SEQ purely in the hands of industry.

For some classes of products which had floated between cosmetics, NHPs and OTC drugs as a regulatory class (toothpastes, mouthwashes, antiperspirants), this system made sense. For others, such as vitamins, minerals, cosmetics, pain relievers, anti-inflammatories, or other OTCs, it made less sense. For **lower-risk products** it would open the door to an ever-expanded number of licensed products with **no safety or efficacy information** at the time of approval. These products would not be allowed to make "diagnosis, treatment, prevention, cure or mitigation claims."[1279] **Higher-risk** claims would be reviewed in a system that would make them analogous to a drug (requiring clinical trials, full GMP, etc.). **Moderate-risk** products would be based on existing product monographs. It is important to note that monographs under the updated pre-cleared information policy reflect just approved product licenses. They include those based on lower evidence standards under the *UPLAR* regulations. The result would likely be a proliferation of low-risk (general) claims for new or existing cosmetics and OTC drugs to take advantage of the lower SEQ requirements.

[1278] *Ibid.*
[1279] *Ibid.*

Figure 18: The New Risk Based Categories under the NNHPR Self-Care Framework[1280]

The core of the planned proposal is that claims which "speak to the function of a product would no longer be considered health claims"[1281] because they were lower risk. How these criteria manifest in the difference between claims may be difficult for the consuming public to differentiate. Claims such as "improves the looks of scars, moisturizes or nourishes, cleans teeth, generally supports health maintenance, helps metabolize fat"[1282] would no longer require evidence to be licensed. For cosmetics, this means most of their unsubstantiated health claims would be allowed as long as they remained general. For OTC drugs it means that they could

[1280] *Ibid.*
[1281] *Ibid.*
[1282] *Ibid.*

make more general claims, (e.g., good for flu and colds) without being subject to the standards of approval for drugs.

Instead of suggesting that those OTC products with a higher standard of SEQ should be labelled differently, the regulator instead suggests that the risk bar for all products needs to be reduced to the lowest denominator. This is not necessarily what a consumer would expect, as the regulator is lowering the bar for SEQ to meet the standards of the products with the least evidence demonstrating their effectiveness. Instead of raising the SEQ bar for NHPs, they dropped the bar for OTCs. The public would likely ask that the standards for products be raised or that there be a clear distinction between products approved with no scientific validation versus those approved with some demonstration of effective use.

In anticipation, the Advertising Standards Council also created guidance, the *Guidelines for Non-prescription and Cosmetic Industry Regarding Non-Therapeutic Advertising and Labelling Claims*, [1283] to outline what advertising would be allowed. This guidance sought to clarify the difference between therapeutic (not allowed) and non-therapeutic claims, but again, much of the difference would likely be lost on the public. For instance, a claim for a skin salve that "repairs dry skin" would be allowed (non-therapeutic) while a claim to "repair (damaged) skin" would not be allowed (therapeutic). A claim for a cosmetic that "diminishes/reduces the look of the signs of aging" (non-therapeutic) would be allowed, but "prevents photo aging and/or related damage" (therapeutic) would not be allowed. A claim for oral care products that "remove stains" (non-therapeutic) would be allowed, but a claim to "remove permanent stains"

[1283] Online at: https://adstandards.ca/wp-content/uploads/2020/02/Guidelines-for-Nonprescription-and-Cosmetic-Industry-EN.pdf.

(therapeutic) would not. The key criteria would become: does the product inherently do a thing, versus is the product claiming to cause or have a therapeutic effect. Or more specifically, the difference was the use of the words "diagnose," "treat," "repair" or "prevents" as part of the claim. Some of these very fine distinctions might be lost on the public.

The proposed *Self-Care Framework*[1284] is intended to roll out in three phases: **Phase 1** is a simplification of the labelling intended to "improve the labelling of Natural Health Products." It was proposed this would include a new statement on the label for low-risk products, specifying that "these products have not been approved by Health Canada" as well as including clear ingredient information and allergy statements.[1285] **Phase 2** would be to create a new regulatory pathway for OTC products to come to market. Originally this was to be bundled with the labelling changes in Phase 1. **Phase 3** was to be a process undertaken to create mechanisms to gather more evidence on the safety of these products. (It is interesting to note the improved framework for gathering safety data was to be implemented following the other two phases and planned following amendments to the *NHPR*).

In June 2022, Health Canada launched Phase 1 with an amendment to the *Natural Health Products Regulations* [1286] which introduced new labelling standards. Labels are now to clearly list all ingredients, include clear contact information, list food allergens, and use plain language. The amendment did not include, as suggested in the consultation paper, a labelling requirement that low-risk products include a "not approved by Health Canada" label. The transition

[1284] *Consulting SC, supra* note 1064.
[1285] *Ibid.*
[1286] *SOR/2022-146*

provisions of these regulations *(s.24(1)-(3))*[1287] allowed for a three-year grace period before NHPs already on the market must fully comply with the new labelling requirements. In 2022 Health Canada also updated subsection *C.01.001 (1)*[1288] of the *FDR* to expand the list of non-prescription drugs which could be provided as samples.

The proposed self-care regulatory amendments (Phase 2) have been delayed by disagreements over the range of products to be covered by the new self-care framework.[1289] NHP producers are worried that it will be too restrictive, while those from the OTC industry and cosmetics industry want it to be broad enough to include their products. Small manufacturers are worried that large manufacturers will use the new framework to advance general claims for cosmetic and OTC products and that Health Canada will make standards too difficult to bring new products to market. The diversity of feedback between small manufacturers, large manufacturers, and health-care practitioners about the new proposal was captured in their consultation report where Health Canada noted:[1290]

> Many from the NHP sector feel the current approach to these products is already sufficiently risk-based and are concerned that the proposed approach represents an unnecessary change. However, others in the NHP sector indicate that similar products (e.g. sunscreens, toothpastes, medicated shampoos, acne creams) as presently regulated are subject to different rules and oversight and acknowledge that there is disparity in the current system. Other participants are concerned that the proposed risk-based approach when ultimately implemented may not be sufficiently rigorous to prevent or identify problems that could potentially emerge (e.g., with those self-care products that would warrant a lower level of oversight under the proposed approach).[1291]

[1287] *Ibid.*
[1288] *Ibid.*
[1289] *Consulting SC, supra* note 1064.
[1290] *Ibid.*
[1291] *Ibid.*

With regards to compliance and enforcement, some expressed "concerns about whether this approach would affect the availability, diversity and cost of NHPs,"[1292] while others said they would prefer:

> a more rigorous and restrictive approach, citing inconsistencies in Health Canada's current post-market powers, including differing or lack of powers for mandatory recalls and for compelling label changes and differing fines for similar products when a company fails to follow certain rules.[1293]

Regardless, the ultimate conclusion was that "moving forward, there is a need for more details on how products would be classified, how risk should be defined, and what types of evidence would be required to support claims."[1294] In effect before moving forward, the self-care framework needed to better scope the intended changes and planned outcomes of their proposed regulatory modernization.

Both the cosmetics lobby and NDMAC, now FHCP, have signalled to their members that they intend to continue to apply pressure regarding the creation of a self-care framework. The lobbying group Food, Health and Consumer Products Canada (FHCP),[1295] which has since been absorbed NDMAC, continues to make its proposed direction clear in a submission to the Competition Bureau on the digital transformation of self-care.[1296] In addition to arguing that direct-to-consumer sale of OTC drugs should be allowed online, and that all that is needed for informed consumer choice is "electronic tools and search engines to find information to support safety and effective self-care,"[1297] they also argued for a simplification of the pathway for

---

[1292] *Ibid.*
[1293] *Ibid.*
[1294] *Ibid.*
[1295] It is interesting to note that the name of this group, FHCP which was reconstituted just a few years ago, directly mirrors that of the Framework on Consumer Health Products (FCHP).
[1296] Online at: https://ised-isde.canada.ca/site/competition-bureau-canada/en/how-we-fostercompetition/consultations/submission-food-health-consumer-products-canada.
[1297] *Ibid*

prescription drugs to become OTC. As they put it, "switching innovative OTC drugs from prescription status can only generate health-care system savings, but economic benefits as well."[1298]

Health Canada seems to agree, and as part of its *2022-24 Forward Regulatory Plan*,[1299] proposed changes under Phase 2 of the plan that "are intended to decrease regulatory burden and cost to business, as well as introduce greater efficiencies for business."[1300] The Forward Regulatory Plan is associated with the *Health and Bioscience Sectoral Regulatory Review* run by a central agency, Treasury Board of Canada Secretariat, with the goal of introducing a new self-care framework to:

> address the unnecessarily burdensome requirements to bring low-risk products to market, the one-size-fits-all approach to fees for those products, the delays to market for new low-risk products…Canadians would benefit from the changes by having improved access to new products and being better able to make informed choices. Canadians will be able to have confidence that the self-care products they use will be safe, effective and of high quality.[1301]

As noted above, Health Canada has signaled in the Next Steps section of their website on the self-care products initiative[1302] its intention to "introduce a risk-based approach to regulatory oversight for all self-care products."[1303] The main thrust of this proposal going forward would be to "introduce expedited pathways for lower-risk non-prescription drugs and would align the oversight for non-prescription drugs with other self-care products of comparable level of

---

[1298] *Ibid*.
[1299] Online at: https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/forward-regulatory-plan/plan/self-care-framework.html
[1300] *Ibid*.
[1301] *Ibid*.
[1302] Online at: https://www.canada.ca/en/health-canada/services/self-care-framework.html
[1303] *Ibid*.

risk."[1304] We end up with a self-care framework, just as was asked for by NDMAC at the start of the NHPD regulatory program that seems to be based neither on addressing the unique characteristics of traditional CAM products nor focusing on the safety of Canadians, but rather on simplifying the process for industry.

The case of cosmetics and OTC drugs as they relate to NHPs is problematic for several reasons. The *NHPR,* which had originally been introduced to facilitate access to CAM products has been coopted by OTC products and cosmetics. Neither of these types of products have the unique historical or belief-based rationales that have justified the consideration of lowering the SEQ bar for NHPs. As noted elsewhere, NHPs, cosmetics, and OTC products do not share the same risk profiles. Similarly, the ability to prove or disprove claims with scientific evidence for OTC and cosmetics is not affected by long-established existing sources of alternative evidence or cultural practices.

As with energy drinks, instead of resolving the issue and pushing back on the application of a more permissive system and clearly defining the parameters of the *NHPR*, the regulator has instead sought to expand this product class to capture a host of products never conceived of by the original regulations or the directions given by the standing committee. Additionally, as noted in the previous case study, the *NHPR* have not been shown to be a burdensome set of regulations. OTC products are drugs, with active medicinal ingredients that make it problematic to regulate them like NHPs. Cosmetics and other personal hygiene products should not be allowed to make health claims that they cannot prove.

[1304] *Ibid*.

CHAPTER 7: EVALUATION OF THE *NATURAL HEALTH PRODUCTS REGULATIONS*

How Do We Assess Good and Bad Regulations?

In *Understanding Regulation: Theory, Strategies and Practice,*[1305] Baldwin, Cave and Hodge give some criteria by which regulations can be benchmarked: (i) meeting legislative mandates, (ii) accountability and control, (iii) due process, (iv) employing expertise, and (v) efficiency in implementing the regulatory mandate.[1306] I would add to these the criterion of (vi) **validity** for science-based regulations: does the regulation base its decisions on valid scientific data to do what it purports to do (i.e., achieve the original health policy intent which led to the creation of a regulatory program). **Legislative mandate** basically asks: does the regulatory activity and the regulatory body have an authority which originates in an elected legislature? Legislative mandate can cause tensions when the mandate is unclear or is set up with inherent "tensions or conflicts" between regulatory goals. **Accountability** requires that the "regulation is properly accountable and controlled so it is responsive."[1307] Accountability fails when regulators are not representative in their consultations, when they engage in activities without any recourse to assessment, or when the regulator acts in ways which stray from their original mandate. **Due process** occurs when procedures are sufficiently fair, accessible, and open to democratic and legal influence. Failures in due process occur when decision-making is not exercised efficiently, becomes biased, or unfairly limits its participants. **Expertise** relates to the fact that regulatory decisions must rely on judgement (often highly technical or requiring expertise) that calls upon the use of accurate

[1305] *Baldwin et al, supra* note 46.
[1306] *Ibid*, at 39.
[1307] *Ibid*.

and impartial information. Expertise can fail when it is not clear to the public how expertise is being employed, when regulatory processes become so technical that they are difficult to evaluate, or when expertise is not used in an unbiased or neutral manner. **Validity** relates to the regulations actually implementing their mandate effectively and producing measurable reproducible results. Making sure a set of science regulation has validity can create tensions with accountability and due process, and can fail if speed of process or poorly quantified outcomes are used in assessing regulatory success.

Baldwin et al. note that there are some common criteria that relate to regulatory failure:

> Regulators will 'fail' when they do not produce (at a reasonable cost) the outcomes that are stipulated in their mandates or when they do not serve procedural or representative values properly. Thus, regulators may be criticized, inter alia, because they gain results inefficiently, or produce unwanted side-effects or because they lack transparency and accountability or exhibit bias and unfairness.[1308]

Whether a set of regulations succeeds or fails will often be based on the tools and/or perspectives used in evaluating the regulation, or the "understandings regarding [the regulation's] objectives and problems [to be addressed]."[1309] Interpretation of a regulation's goals by regulators, politicians, and the public can be highly subjective. On the same facts, the regulated will tend to claim over-regulation, while civil society and the public may claim under-regulation.[1310] Few governments or regulators, in turn, are likely to point out their regulatory failures to the public. Instead, success or failure is often characterized by the policy objectives of the government of the day, or by the most politically active body lobbying on the regulations. Regulatory gaps, in particular in food and drug law, often only come to public attention after very public failures.[1311]

[1308] *Ibid* at 69.
[1309] *Ibid*.
[1310] *Ibid*.
[1311] *Taylor LLM, supra* note 16.

Baldwin et al. suggest that regulatory failure[1312] can fall into various categories: (i) **outcome failure** (not achieving that which the regulations were intended to do), (ii) **under-regulation** (regulating in a *deminimus* way that has minimal effect), (iii) **over-regulation** (stepping beyond a legislative mandate to create a too-high bar) or (iv) **creative compliance** (where regulators and regulated "side-step rules and negate regulations [so that they]become a form of box ticking rather than substantive"). It could be argued that the *NHPR* manifests many of these kinds of failures, being an example of creative compliance (with measures put in place but with a very low bar for compliance), under-regulation (with little oversight of GMPs or substantive review of efficacy), over-regulation (as the definition of NHPs is not sufficiently nuanced to include many products that should be regulated) and depending upon how the original intent of the regulations is emphasized, outcome failure (the *NHPR* is not ensuring that products on the market meet SEQ standards).

Bovens in his article *Two Concepts of Accountability: Accountability as a Virtue and as a Mechanism* (2010)[1313] raises a distinction between systems which generate activities that amount to accounting versus those that actually produce activities that are accountable. This includes those activities that are just the generation of information (records, audits, evaluation) versus those that actually lead to accountability (effecting change or holding decision-makers to account for their decisions). He notes that there has been a trend in regulation and governance over the past several decades to generate measures of efficiency that are decoupled from actual outcomes or accountability, and hence operate solely as a form of accounting.

[1312] *Baldwin et al.,* supra note 46 at 69.
[1313] *Bovens, supra* note 342.

> [In one case] accountability is used primarily as a normative concept, as a set of standards for the evaluation of the behaviour of public actors. Accountability or, more precisely, being accountable, is seen as a positive quality in organizations or officials. [In the other case] accountability is used in a narrower, descriptive sense. It is seen as an institutional relation or arrangement in which an actor can be held to account by a forum.[1314]

Regulators can often hide policy and implementation choices behind these forms of accounting. How NHPD has currently framed effectiveness, largely in terms of addressing a backlog of product registrations and providing targeted oversight of "higher-risk products," may be at odds with its original goal "that all Canadians have ready access to [NHPs] that are safe, effective, and of high quality."[1315]

A second criterion that Abraham[1316] has put forward when assessing drug regulatory regimes is consideration of the intended and unintended consequences that result over time from a regulatory program's administration. Do the administration and governance decisions around a set of regulations create external sets of rules that become the formal or informal system rules which ultimately dictate regulatory outcomes? As Abraham notes:

> the lowering of techno-scientific standards for drug safety testing across the EU, U.S. and Japan is not an inevitable price to be paid for faster development of therapeutically valuable medicines, but more plausibly a consequence of the internationalization of neo-liberal corporate bias in pharmaceutical regulation.[1317]

The formal and informal decisions made by regulators also have active effects in creating the larger rule sets of how regulations are applied, and thus their ultimate success or failure.

[1314] *Ibid*, at 946.
[1315] Health Canada, *The Approach to Natural Health Products*, (Health Canada: Ottawa, 2013), online at: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodnatur/nhp-psn-eng.pdf.
[1316] *Abraham, supra* note 39
[1317] *Ibid, at* 870.

While I have just laid out the regulatory and policy developments that occurred within Health Canada and the administration of the *NHPR*, there are other aspects of its functioning that, as research, is more difficult for me to evaluate. Health Canada does not make much of its internal decision-making or policy development process visible to the public. Nor do I have the reach to closely explore the internal operations of NHPD. It was also decided early on that as part of my thesis I would not be conducting structured interviews with officials at Health Canada or elsewhere in government. Yet, there are other sources that have done much of this work. The courts have been asked to take a limited look at the *NHPR* based on criteria of legitimacy and bias in its decision-making. Additionally, there have been several audits and evaluations of the *NHPR* that have looked very closely and in depth at the operations of the *NHPR* and its regulatory program. I will look to these to suplement the observations that I have made to date and to help provide a more in-depth evaluation of the *NHPR*.

Part 1: Case Law on the NHPR

There is not a large body of case law directly related to the *NHPR*. With the exception of a few cases, judicial reviews of the regulations have been few. Instead, the case law has tended to focus on weak claims to the illegitimacy of the regulations (often rooted in tort law), reviews of specific decisions in which the impartially NHPD has in applying the SEQ standard has been challenged, and a collection of class actions certified against the manufacturers of products making unproven claims. The case law does not provide a cohesive or particularly useful body of law to help frame the *NHPR's* administrative effectiveness. However, it does reassert that the regulations are legitimate, that the *NHPR* does contemplate a varied efficacy standard for

traditional products, and that the primary goal of the regulations should be to promote health and safety. While not taken to trial, the series of certified class action suits do hint that there may be future room for actions related to the fraudulent selling of products making erroneous health claims.

(i) The Legitimacy of the NHPR – Vitamins, Pigs, and Charter Rights

Only two cases have dealt with the overall validity of the *NHPR*. The first, tried at the Alberta court level, was *R v. The Synergy Group of Canada Inc. and Truehope Nutritional Support Ltd* (Truehope).[1318] This case dealt with a compliance action taken against a product before and immediately after the *NHPR* came into force. The case centred on a defence of necessity in relation to a specific case of non-compliance with a Health Canada order to seek licensing of a marketed product as a drug (later as an NHP). The second case, *Mancuso, the Results Company and Dahl v. R,*[1319] was a constitutional challenge launched against the validity of the *NHPR*. The case argued that the pre-market assessment and enforcement powers granted by the *NHPR* and executed by government agencies such as the Minister of Health, the RCMP, Minister of Public Safety and Emergency Preparedness, and Attorney General exceeded the authorities delegated by the Act. The plaintiffs claimed damages based on perceived breaches of the Charter.

[1318] *2006 ABPC 196, herein after Truehope.*
[1319] *2014 FC 708, hereinafter Mancuso.*

a. Truehope: Pigs, Children, and a Bipolar Drug

In 1996, Synergy Inc. was incorporated to produce and distribute a vitamin/mineral supplement mixture for the treatment of bipolar disorder. The product had been developed after an Alberta farmer created a "vitamin/mineral supplement that had been used successfully with pigs over the years to reduce their rage and aggressive behaviour."[1320] He reproduced the product and administered it to his children, who he was worried would develop bipolar disorder like their mother. He observed that their "behaviours had returned to normal without the drastic side effects associated with drugs used to treat depression or bipolar disorder."[1321] Based on this rather weak evidential basis, he developed a vitamin/mineral product called Truehope**,** which he began to market in Canada and the U.S. as part of a health program called Empower Plus to treat bipolar disorder.

In 2002, Truehope came to the attention of Health Canada. The department was concerned that the product was being marketed like a drug and lacked a drug identification number (DIN). Synergy argued that the process for testing the effects of vitamin and mineral regimens was not suitable for clinical trials and that Truehope should not be subject to the GMP standards for drugs. Additionally, it argued that Truehope should not be regulated under the new regime being proposed for NHPs. In support of its claim, it submitted letters from over 200[1322] products users providing testimonials. Truehope argued that removing the product from the market would cause over 3,000 patients using the Empower Plus regime to experience a relapse

[1320] *Truehope, supra* note 1318.
[1321] *Ibid.*
[1322] *Ibid.*

of their bipolar symptoms. In March 2003, Health Canada issued a directive to Canadian customs officials to stop the cross-border distribution of the product. In July of 2003, search warrants were issued for the seizure of Truehope product by Health Canada compliance officers. In May 2004, Health Canada issued six charges against Synergy for breaches of the *FDA*, of which five were eventually stayed, except for the selling of a drug without a DIN between January 2003 and December 2003.

Synergy Group of Canada Inc. (Synergy) and Truehope Nutritional Support Ltd. (Truehope) brought an appeal of the charges, arguing that they were required to breach the *FDA* and *FDR* because of necessity. Necessity in this case was equated with the urgent and continual need to treat bipolar patients. It claimed to have contacted Health Canada multiple times to complete their due diligence around the necessity of the product. It also argued that it was not a manufacturer under the definition of the Act since it imported Truehope from the U.S. It further claimed that Health Canada's actions were unreasonable and that "this prosecution should be seen as oppressive and vexatious thereby amounting to an abuse of process."[1323]

The court found the defendants were entitled to the defence of necessity. Although the court did find that a U.S. importer meets the definition of "manufacturer" under the *Food and Drug Act*, it accepted the argument that Truehope represented a necessary treatment for thousands of bipolar patients. This conclusion was not based on any clinical evidence but on the testimony of two Synergy-employed psychologists, one of whom is still used to advertise the product on Truehope's website,[1324] validating the claims made for the product. The court rejected

[1323] *Ibid.*
[1324] *Ibid.*

Health Canada's argument that the product made widespread health claims without valid scientific evidence. The court also accepted the lobbying of Synergy for a license exemption (granted while compliance was being resolved in 2004) as an example of due diligence on the company's behalf. In assessing the claims of Truehope to abuse of process, the Justice notes:

> While this Court is not prepared to find that the various instances of the conduct of the representatives of Health Canada amount to the "clearest of cases" of an abuse of process to warrant a stay of proceedings, this Court does find that some of this conduct would have influenced the Defendants' beliefs that there was no reasonable legal alternative other than to disobey the D.I.N. regulation and that they had taken all reasonable care in the circumstances to comply with the law.[1325]

Subsequently, Truehope was licensed as an NHP, issued a DIN by NHPD, and is currently on the market making many of the same claims for treating health and mental illness.[1326]

Truehope represents one of the first cases of compliance enforcement attempted by Health Canada against an unlicensed CAM product. However, the decision of the court is not a robust one in food and drug law. The evaluation of the scientific necessity to treat cases of bipolar disorder was based on limited evidence (two Truehope-linked psychologists and unscientific testing on pigs and the inventor's children). The court validated a violation of food and drug law, both the *FDA* and *NHPR*, for the sale of an unlicensed drug as an NHP. While the case is likely treated in isolation and has never been cited, it may have had an initial chilling effect on NHPD's willingness to enforce non-compliance too forcefully.

[1325] *Ibid at para 110.*
[1326] *Ibid.*

b. Mancuso, the Results Company and Dhal: NHPR as Unconstitutional

In 2004, several plaintiffs brought a proceeding to the Federal Court that the *NHPR* was outside of the constitutional authority of the federal government, that Parliament never intended the definition of "drug" to apply to NHPs, and that the enforcement of the *NHPR* violated their *Charter* rights under *Sections 2(a), 2(b), 7, 8, 9 and 15*.[1327]Their specific claims were very broad and included:

- The federal government does not have the constitutional authority to regulate natural health substances under the division of powers set out in the *Constitution Act, 1867* (UK), 30 & 31 Victoria, c 3, reprinted in RSC 1985, App II, No 5 [*Constitution Act 1867*];
- Parliament never intended the definition of "drug" in the Act to apply to natural health products and therefore the Regulations exceed the authority delegated by the Act; and
- The enactment and enforcement of the Regulations and the application of certain sections of the Act to natural health products have infringed their rights under ss. 2(a), 2(b), 7, 8, 9 and 15 of the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being *Schedule B* to the *Canada Act, 1982* (UK), 1982, c 11 [*Charter*].[1328]

The plaintiffs "alleged that they have suffered damages as a result of their alleged *Charter* breaches as well as heavy-handed and tortious conduct by government officials and RCMP in enforcing the Act and the Regulations."[1329] The plaintiff also argued that Parliamentary jurisdiction was limited to products which posed health risks and "Parliament cannot extend jurisdiction to products which pose no or a *deminimus* health risk, so that the Regulations are therefore *ultra veres* the jurisdiction of Parliament."[1330]

[1327] *Mancuso, supra* note 1319.
[1328] *Ibid.*
[1329] *Ibid.*
[1330] *Ibid.*

The plaintiffs in this case were diverse. Among them was Nick Mancuso, a Canadian actor who claimed to use NHPs as part of his "belief system in terms of how to maintain good health and in general with respect to bodily and psychology integrity."[1331] He argued that the "state should not arbitrarily and selectively dictate what dietary supplements or vitamins can be sold to him, and that restrictions in the sale of natural food products and the communication of health claims"[1332] violate his rights under the *Charter (Sections 2(a) and 2(b), 7 and 15)*.[1333] David Portland and the Results Company argued that the site licensing provisions of the *NHPR* were "oppressive and totally unnecessary"[1334] because the products are safe, and the regulations are "unconstitutional and *ultra vires* the Act."[1335] The Results Company manufactured their product without a licence and refused to submit a site license application or comply with site licensing requirements under the *NHPR*. They argued that the *NHPR* was a form of censorship because it "prevented [them] from telling their customers the truth about what their products do"[1336] and that the enforcement of the regulators has been "excessive and abusive employing para-military methods of enforcement."[1337] Eldon Dhal, the owner of a health food store in Vancouver, had been subject to search and seizures of unlicensed NHPs. The store had been charged for violating the *Customs Act,*[1338] and found guilty on 33 counts in 2009 and 11 counts in 2013. He alleged that these compliance actions were "false and maliciously [executed] and that these enforcement activities violated their rights under *Sections 7, 8* and *9* of the *Charter*."[1339]

[1331] *Ibid.*
[1332] *Ibid.*
[1333] *Ibid.*
[1334] *Ibid.*
[1335] *Ibid.*
[1336] *Ibid.*
[1337] *Ibid.*
[1338] *Ibid.*
[1339] *Ibid.*

This case echoes much of the litigation and arguments that have been put forward by the supplements industry in the U.S. One is reminded of the supplements commercial with Mel Gibson decrying the illegal seizure of his vitamins described earlier. The government's response was to request the claim be struck because it was a combination of three claims that were "unduly complex, prolix and convoluted pleading that is so undefined and broad in scope as to be judicially unmanageable."[1340] The government also argued that "it does not meet the basic rules of pleading in that it fails to set out a concise statement of the material facts relied upon, is replete with bald allegations and colourful rhetoric, and pleads evidence instead of material facts in many instances."[1341] The government further argued that these gaps included "re-litigating matters that were, or ought to have been, raised in earlier proceedings."[1342]

The Federal Court judge tended to agree with the government's position. He noted that Mr. Mancuso had not "identified any specific dietary food supplements and vitamins to which he had been denied access and failed to plead the constituent element of the *Charter* violation."[1343] The ruling also noted that the request to invalidate the regulations was "so sweeping and imprecise as to be entirely unworkable."[1344] Mr. Dahl's challenges represented a "collateral attack…to challenge judicial decision in previous proceedings" and were without merit. To relitigate previous convictions and searches would "undermine the principles of consistency, finality and integrity in the administration of justice."[1345] Overall, the ruling declared that what was being asked was beyond the power of the court and would involve bringing the court and

[1340] *Ibid.*
[1341] *Ibid.*
[1342] *Ibid.*
[1343] *Ibid.*
[1344] *Ibid.*
[1345] *Ibid.*

government into a "broad inquiry… and in a broad-ranging policy discussion as to how such products are best regulated."[1346] The court went on to note:

> the Plaintiffs are asking the Court to review the whole scheme for classification, inspection and enforcement of food, dietary food supplements and vitamins and declare how it should be regulated. I agree with the Defendants that this is far beyond what is required in the present case, or indeed the power of the Court.[1347]

The ruling went on to deconstruct the plaintiffs' pleadings, paragraph by paragraph, as being imprecise, vague, and without factual basis. The Justice assessed the pleadings as "having no connection whatsoever with the content of the Act or Regulations that are challenged in this proceeding."[1348] In conclusion, he struck the action, because the "plaintiffs have yet to disclose a serious issue to be tried."[1349]

On appeal, the Federal Court of Appeal[1350] was even more direct in reaffirming that "no material facts were pleaded supporting"[1351] the *Charter* claims. It was noted that courts cannot, without clear arguments about how law has caused overreach, "evaluate when Parliament has exceeded the ambit of its legislative competency."[1352] This was of particular concern since the "legislation at issue pertains to literally thousands of natural health supplements."[1353] The court reaffirmed that the action was an abuse of process and there were no substantive reasons to proceed with the case.

[1346] *Ibid.*
[1347] *2015 FCA 227.*
[1348] *Ibid.*
[1349] *Ibid.*
[1350] *Ibid.*
[1351] *Ibid.*
[1352] *Ibid.*
[1353] *Ibid.*

(ii) Administrative Review – Bias at NHPD and Approval Rights

The next set of cases relate more directly to specific decisions and products that have been reviewed by NHPD. In these cases, the criteria and impartiality of NHPD in providing a product review, as well as the application of the *NHPR* criteria as they relate to safety, efficacy, and quality (SEQ), were challenged. In *Winning Combo v. R,*[1354] it was ruled that NHPD's product review process was not systematic and was actively subject to bias. In *Canada RNA Biochemicals v. R,*[1355] it was argued that the *NHPR* had to equally consider access as much as public health when interpreting its obligation to proactively issue a license. In *Swarath v. R,*[1356] it was argued much the same: that the intent of the regulations to ensure access should invalidate the imposition of site licensing (SL) and good manufacturing practices (GMP) conditions on NHP manufacturers.

a. The Winning Combo and Systematic Bias at NHPD

The long saga of The Winning Combo began around 2004, at the same time as the initiation of the regulations. In that year, a product called Resolve, used as a smoking cessation aid, was initially submitted for approval as an NHP. In 2006, the rights to this product were purchased by The Winning Combo Inc. (TWC), which assumed the in-process product license for Resolve was still with NHPD. In 2006, Resolve entered the market, and representatives from Pfizer complained to NHPD about "allegations of non-compliance…with marketing and advertising

[1354] *2016 FC 381,* hereinafter *Winning Combo.*
[1355] *2020 FC 688,* hereinafter *RNA Biochemicals.*
[1356] *2014 FC 75,* hereinafter *Swarath.*

standards."[1357] NHPD completed a health hazard evaluation (HHE) that found Resolve "contained a substance allegedly obtained from passionflower and that there was a likelihood of at least temporary adverse health consequences associated with its use."[1358] TWC and NHPD went back and forth with a series of letters contesting whether Resolve contained residual passionflower.

In July 2007, NHPD released a public health warning and rejected Resolve's product licensing application. NHPD designated Resolve as a health hazard, "which required a higher bar for safety and efficacy before licensing."[1359] On July 17, another letter was issued to TWC to stop sale and begin recall of the product. TWC requested judicial review of the decision on July 26, 2007. On August 21, 2007, NHPD issued a second letter updating their earlier decision that upon further review, "the primary basis for the rejection of The Winning Combo had been adjusted – Resolve was not an NHP, but rather a drug and therefore subject to rejection under the *FDR*."[1360] TWC continued to submit materials to NHPD between April and January 2007 requesting a reconsideration of the decision.

In April 2008, NHPD issued a decision based on the additional information provided by TWC that "there was insufficient evidence to support that the active ingredient [in Resolve] is an NHP and advised that conclusions regarding Resolve's safety and efficacy could only be reached pursuant to a review of an application for market authorization"[1361] as a drug under the *FDA*. On

[1357] *Winning Combo, supra* note 1354.
[1358] *Ibid.*
[1359] *Ibid.*
[1360] *Ibid.*
[1361] *Ibid.*

September 18, 2008, NHPD advised TWC that the refusal of its PLA was now based on safety and upheld based on TWC having provided insufficient evidence to demonstrate safety. A second reconsideration in 2009 by NHPD gave a final notice that a license would not be issued, citing a study provided by TWC "deeming it insufficient to establish Resolve as an NHP."[1362] NHPD indicated no further reconsideration would be considered.

That NHPD vacillated on the issue of safety was problematic, but the Justice noted that the *NHPR* at the time only required evidence that a product could be efficacious. The language in Section 5(g) was that efficacy was demonstrated by "information that supports the safety and efficacy,"[1363] which was a demonstration of the intent of the regulations. Citing the obligation under s.7 that the Minister shall issue a license if the requirements of (a) through (g) are met, the Justice noted that "even if 5(g) can be interpreted as a threshold substantive test, it must be less onerous than the standards of proof required for safety."[1364] Instead, "the information required for efficacy does not have to prove that the product 'likely' is efficacious, and no minimum standard of scientific proof is required."[1365] It was enough that the product may help with smoking cessation. This sets a very low bar for NHP efficacy, where "any substantive test for efficacy must be very modest and information that falls short of establishing a likelihood that a product may help with smoking cessation should be considered sufficient."[1366] Health Canada updated the *NHPR* in 2018 to include a revision to Section 5(g) that applicants submit information that demonstrates safety and efficacy.

[1362] *Ibid.*
[1363] *Ibid.*
[1364] *Ibid.*
[1365] *Ibid.*
[1366] *Ibid.*

The Justice's ruling on bias was even more critical. He found that there were clear grounds to believe that NHPD reviewers did not adhere to a reasonable process and made decisions based on an *a priori* opinion that Resolve should not be licensed. He observed that NHPD scientists, upon discovering that the initial decision was in error because the product did not include passionflower, quickly decided to reclassify the product. NHPD intentionally removed the ingredients of Resolve from the NHP monograph before determining it was not an NHP and therefore a drug. The Justice noted this supported "allegations of a serious breach of procedural fairness and unreasonableness."[1367] In conclusion, the Justice ruled that NHPD "[made]mistakes of fact and process that rendered their [decision] unreasonable, they are lacking procedural fairness and, I find that at this point to have to conclude, they provide evidence of a reasonable apprehension of bias."[1368]

The Justice also found additional bias during the licensing process, with officials at the HPFB Inspectorate and NHPD openly discussing, in emails, ways to refuse the Resolve application. The health hazard evaluation was based on selective evidence and TWC was not given an opportunity to respond to the evidence in the HHE, which would later prove to be in error, before a decision was issued. Furthermore, there was a lack of clear guidance from NHPD regarding the types of evidence required to prove efficacy. Instead, the Justice concluded, "Health Canada was simply applying any standard that would deny TWC's PLA."[1369] The Justice ultimately directed that the products should be licensed, stating "to simply return the

[1367] *Ibid.*
[1368] *Ibid.*
[1369] *Ibid.*

matter for reconsideration to a system that has shown itself to be so dysfunctional might simply plunge TWC back into the quagmire and trigger more litigation."[1370]

On appeal[1371] much of this decision was reversed. The Justice noted that the earlier ruling should not have ordered the product licensed, but that it should have been subject to a new, impartial, product assessment. The appeal decision reconfirmed the need for the Minister "to give license holders both notice and an opportunity to be heard before a suspension takes effect." In his decision, the Justice notes what began as a judicial review "metamorphasized into a six-year inquiry into the merits of the licence application, with the applicant and respondent before him filing competing evidence, each vying to win a scientific debate before the applications judge."[1372] The whole process and "conduct of the parties were directed to put the judge in a position to decide the substantive question which, by regulation, was for the Minister to make. Both parties sought to shape the record with dueling and evolving reports and evidence." The Appeal Court Justice found that while scientists seemed to have actively engaged in acts of systematic bias which tainted the decision, he could not "in absence of further evidence, justify the conclusion that the Department as a whole was systematically incapable of making a fair assessment of TWC's application."[1373] Similarly, questions around the standards to be applied to classification of the products were not *prima facie* biased, but the product of legitimate scientific debate. As such the product was returned to NHPD for reconsideration. The Supreme Court of Canada refused to grant leave to appeal this decision in 2018.[1374]

[1370] *Truehope, supra* note 1318 at para 155.
[1371] *2017 FCA 101.*
[1372] *Ibid.*
[1373] *Ibid.*
[1374] *SCC denied 2018, No. 37697.*

The Winning Combo does not provide much enduring case law. The decision regarding the standard of efficacy being a low bar was upheld, but subsequently revised by amending the *NHPR*. The decision regarding systemic bias at Health Canada and the parameters of reclassification being a scientific decision undermines the claims of global bias. Yet, they show that the early approval process employed by NHPD seemed to be highly unscientific and that evidentiary decisions were not systematic. This created a high degree of uncertainty and confusion in the application of the *NHPR*.

b. Swarath: Erectile Dysfunction and the Obligation to License

In 2014, a similar claim was raised in *Swarath v. R,*[1375] which argued that Health Canada had an obligation under s.7 to issue a license for products. The plaintiff brought forward a claim for tort damages because their product was not able to be put on the market. *Libidus* was a product to increase blood flow to address erectile dysfunction. NHPD had issued a stop sale order in 2006 because they had detected "undisclosed *acetidenafil*, an analogue of *sildenafil* (Viagra)."[1376] The plaintiffs did comply with the stop sale order but continued correspondence with Health Canada to contradict the original finding. In 2012, the manufacturers filed a statement of claim asking for $77 million in damages and $25 million in punitive damages, as well as an order permitting the company to market and distribute Libidus. In their claim, the plaintiffs "alleged gross negligence, arbitrariness, bad faith and malice on the part of Health

[1375] *Swarath, supra* note 1356.
[1376] *Ibid*.

Canada employees, and a conspiracy between the defendants and the pharmaceutical industry to suppress the distribution of Libidus."[1377]

The Federal Court struck the statement of claim, noting there was no basis to the tort claim because manufacturers did have a duty to care owed to the public based on health and safety concerns. The duty of the regulator was not just to ensure product access, as plaintiffs claimed, but to more importantly ensure product safety. The Justice in this case noted:

> The clear purpose of the relevant legislation and regulatory scheme in this matter is to **protect the health of Canadians** by preventing the sale of contaminated NHPs in Canada.[1378]

Furthermore, the Court ruled that an expectation that Section 7 obligated NHPD to issue a product license "ignores the legislative and regulatory framework within which that provision operates...in particular s.17 that directs a license manufacturer, importer and distributer to stop sale"[1379] when violating the regulations.[1380]

c. RNA Biochemicals: An Unfettered Right to Access

The scope of the right to licensing, or access, under Section 7 of the *NHPR*, was addressed more clearly in the 2021 decision of *RNA Biochemicals v. R*.[1381] RNA was seeking to license *Lumbrokinase* as a natural blood thinner based on a claim related to traditional Chinese

---

[1377] *Ibid.*
[1378] *Ibid.*
[1379] *Ibid.*
[1380] It should be noted that although this mechanism under *section 17* of the *NHPR* did allow for the removal of products from the market, the bar for this required a high degree of intentional non-compliance with the regulations. This generally equates fraud. As will be described below, NHPD has a poor history of successfully enforcing compliance with removal of sale orders.
[1381] *RNA Biochemicals, supra* note 1355.

medicine. NHPD refused the license on the basis that the "fibrinolytic properties of lumbrokinase entailed a potential risk of intestinal bleeding."[1382] In order for Lumbrokinase to be issued a product license, NHPD was requesting safety testing in humans. RNA argued that NHPD had misinterpreted the *NHPR* by "reading in terms such as health, population and risk benefit not found in the regulations."[1383] They argued the classification of the product as high risk was outside the regulations. RNA also asserted that the original intent of the regulations, as noted in the *NHPR RIAS*, highlighted that the purpose of "respecting freedom of choice and philosophical and cultural diversity should be weighed equally with the goal of providing Canadians with ready access to [NHPs] that are safe, effective and of high quality."[1384]

The Federal Court did not agree. Instead, it reinforced that the regulations prioritize health and safety over access. Citing the standing committee report which led to the creation of the *NHPR*, the Justice noted "the health of Canadians must remain as the most vital criterion underlying any regulatory analysis."[1385] The Justice then was very clear:

> while the Minister is expressly required by the NHP Regulations to evaluate safety and prevent injury to health, the imperative of freedom of choice and philosophical and cultural diversity exists only as an underlying principle rather that an identified criteria for evaluation. "[1386]

This clarifies that of the three original criteria outlined as intent for the regulations, which included access, cultural sensitivity, and ensuring SEQ of products, health had the primacy. The Justice went on to rule that while the regulations are intended to treat NHPs under a process and

[1382] *Ibid.*
[1383] *Ibid.*
[1384] *Ibid.*
[1385] *Ibid.*
[1386] *Ibid.*

purpose distinct from those for other drugs, "they are not intended to do so at the expense of the health (broadly considered) or safety of Canadians."[1387]

In reconsidering the obligations under Section 5(g) to demonstrate efficacy and safety, the Justice ruled that s.7 (the obligation to issue a license) does not undermine this provision. Citing *The Winning Combination*,[1388] the ruling asserts that "this provision [s.7] does not create a substantive standard" but "only an administrative consideration related to safety and efficacy."[1389] In assessing the product, the Minister "must be satisfied that the product is **safe and effective**."[1390] To meet this requirement:

> the Minister must be satisfied not just that the applicant has filed information on safety and effectiveness, but that the information demonstrates that the NHP is safe and effective when used in accordance with the recommended conditions of use.[1391]

Safety will be demonstrated by showing an NHP is "not likely to result in injury to the health of a purchaser or consumer."[1392] The Minister can act if they believe the product is not safe but should ask for information to respond to the concern. In the case when there is potential for injury to health, the Minister can act right away.

The Court assessed both the 2006 guidance on evidence required for efficacy (*Evidence for Safety and Efficacy of Finished Natural Health Products – Version 2.0*)[1393] and the 2012 Guidance (*Pathway for Licensing Natural Health Products Making Modern Health Claims*)[1394]

[1387] *Ibid.*
[1388] *Winning Combo, supra* note 1354.
[1389] *RNA Biochemicals, supra* note 1355.
[1390] *Ibid.*
[1391] *Ibid.*
[1392] *Ibid.*
[1393] *Trad Claims v.2, supra* note 1029.
[1394] *Mod Claims, supra* note 1030.

and found them justified. Because these products are self-administered, it was reasonable to classify them based on how safe they could be under conditions of use. In this case, Libidum was high risk. The ruling further intertwined the concepts of safety and efficacy:

> [A]product might be very effective in bringing about a particular health result, and yet be unsafe because it poses health risks. Similarly, a product may be very safe, but have little or no efficacy in bringing about a particular health claim.[1395]

What is "acceptably safe for a health product may depend on the product's effectiveness."[1396]

For NHPs, "an ineffective product may impact health by not treating a condition in the manner expected, or causing a consumer to forego other treatment options."[1397] The Justice noted the normal conundrum for all therapeutic products:

> we might accept a somewhat greater safety risk in a product that works very well, or accept a lower health benefit in a product that is very safe. At the same time, a product that is dangerous may be unacceptable regardless of how effective it is.[1398]

In assessing these criteria, the Court ruled that NHPD was reasonable to establish assessment of this criteria on a risk-benefit basis. The Justice also found that the assessment of this product on this criteria was reasonable.

On appeal,[1399] the Court reaffirmed that the onus is on the product license applicant to satisfy the Minister that the product is both safe and effective. The Justice rejected the idea that evidence for efficacy was less for NHPs because the original term "support" in Section 5(g) created a lesser standard than the term "demonstrate" for proving efficacy. The subsequent

---

[1395] *RNA Biochemicals, supra* note 1355.
[1396] *Ibid.*
[1397] *Ibid.*
[1398] *Ibid.*
[1399] *2021 FCA 213,* hereinafter *RNA Appeal.*

amendment to Section 5(g)[1400] which replaced the term "support" with "demonstrate" in the Court's opinion confirmed this argument. The Judge also indicated:

> the decision whether to issue a product licence is contingent on the Minister being satisfied that the product is safe and efficacious when used in accordance with its intended conditions of use. Here, with respect to the appellant's product, the Minister was not satisfied that that was the case. That decision was grounded in an ample evidentiary record and the appellant has not identified any aspect of the regulatory review process that could be considered unreasonable.[1401]

This ruling was a reassertion of the Minister's authority to reject product licensing applications and the primacy of the regulations as a set of health and safety regulations distinct from that of drugs.

(iii) Class Action Suits

The other area of case law which references the *NHPR* is a series of class action suits which have sought damages against distributors of specific products for making false and misleading health claims. *Wilkinson v. Coca-Cola*,[1402] *Clark v. Energy Brands Inc.,*[1403] and *Adanna v. Boiron Canada Inc.* [1404] were all granted standing for a class action suit, but the cases were settled out of court. The common thread in these cases was a claim that these products were making false claims about the effectiveness of products and misleading consumers. In all cases, manufacturers were quick to settle the class actions suits once they were certified. It is unclear how these cases would have ruled on the validity of health claims being made by NHPs, but it

[1400] *Ibid.*
[1401] *Ibid*, at para 25.
[1402] *2014 QCCS 2631.*
[1403] *2014 BCSC 1981.*
[1404] *2015 QCCS 312.*

does hint that in the future the courts may entertain a case arguing that NHPs are sold fraudulently.

Overall, the case law for NHPs in Canada is relatively limited. With the exception of *The Winning Combination* and *RNA Biochemical* they do not provide much clarity on the legal status of the *NHPR*. These cases do reaffirm the validity of the regulations and reaffirm that they are primarily a set of health and safety regulations. In the case of *The Winning Combination,* NHPD seemed to apply its scientific assessment with a highly disordered set of criteria that were likely favouring public health protection, but demonstrated bias. In the case of *RNA Biochemical,* it was reaffirmed that NHPD was allowed to establish criteria for classification and assessment related to safety and efficacy. It took until 2021 for the Court to rule in *RNA Biochemical* that the goals of respecting cultural diversity and ensuring access were underlying principles, but should not guide policy and decision-making. Cases like *Mancuso* and *Truehope* were outliers that emphasized the legitimacy of the regulations in the face of extreme claims to liberty.

Part 2: Government Audits and Evaluations of the *NHPR*

Over the past seven years, there have been four formal evaluations of the NHP regulatory program: three conducted by Health Canada in 2010,[1405] 2015,[1406] and 2016,[1407] and one by the

[1405] Health Canada – Executive Committee Finance, Evaluation and Accountability (EC-FEA), *Natural Health Products Program Summative Evaluation*, (2010), online at: https://publications.gc.ca/site/eng/9.823775/publication.html, hereinafter *2010 Evaluation.*
[1406] Health Canada, *Audit of the Management of the Natural Health Program (2015)*, online at: https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/audit-reports/2015/final-report-audit-management-natural-health-products-program, hereinafter *2015 Audit.*
[1407] Health Canada, Office of Audit and Evaluation, *Evaluation of the Natural Health Products Program 2010-2011 to 2014-2015* (2016), online at: https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/evaluation, hereinafter *2016 Evaluation.*

Auditor General of Canada in 2021.[1408] All were critical of the effectiveness of the regulations in ensuring that NHP products on the market were high quality, safe, and effective. These assessments are all highly critical that the *NHPR* has largely become a post-market registration system with little to no follow-up on licensed products. In this section, I will review these assessments (two evaluations and two audits), each completed by audit officials in the Government of Canada.

Audits normally have two restrictions on their findings. The first is that they do not comment on policy or the policy directions of a government or programs directly; instead, they focus on operation or execution. This can include restricting comment on specific guidance or directives, or intent of policy, although they do identify deficiencies. The second restriction is adherence to a very specific scope and time period. While audits or evaluations may note or launch a separate audit on new findings, they tend to limit their analysis to the lines of inquiry identified at the start of an audit.

It should be noted that audits are distinct from evaluations. Evaluations, while technically a form of audit, are much more operationally focused and will often be related to establish performance measures for a program as outlined in the reporting instruments (Departmental Plan, Departmental Results Reports, etc.).[1409] Evaluations are often conducted of each program in HPFB's portfolio on a rotating basis. Audits are generally an investigation of an issue of broader concern with very fixed parameters, and may be scoped to look at specific areas similar

[1408] *OAG, supra* note 29.
[1409] See online at: https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/report-plans-priorities/2023-2024-departmental-plan.html.

to an evaluation, but can also look more broadly at matters of concern to decision-makers. In the case of the OAG this includes investigating matters that are considered of such national importance that they should be brought to the attention of Parliamentarians.[1410]

(i) The 2010 Evaluation of the Natural Health Products Program (1999-2008)

In 2010 Health Canada completed a summative evaluation of the NHP program.[1411] The evaluation looked at how NHPD and its partners were delivering the program from April 1, 1999 through March 31, 2008. This covered the period from the work on developing the regulations through the first few years of their operation. For a few observations (related to licensing), they looked at data up to 2010. The scope of the evaluation "included the activities and outputs of all HC organizations involved in program delivery (NHPD, MHPD and the NHPB Inspectorate) as well as cross-organizational governance and administrative support structures."[1412] The evaluation explicitly noted it would not be looking at the effectiveness of various NHPs but rather "the effectiveness of Health Canada's NHP Programme."[1413] The evaluation looked at three categories: (i) relevance of the program, (ii) effectiveness of the program; and (iii) organizational delivery, efficiency, and economy. The evaluation was "undertaken in response to a request from Health Canada (HC) to conduct an independent and objective summative evaluation of the relevance and performance of the NHP program."[1414]

[1410] See online at: https://www.oag-bvg.gc.ca.
[1411] *2010 Evaluation, supra* note 1405.
[1412] *Ibid.*
[1413] *Ibid.*
[1414] *Ibid.*

The evaluation made 21 observations and nine recommendations. Overall, they found the program was relevant, noting "a continued need to assure the safety, efficacy and quality of NHPs"[1415] and that Health Canada was the appropriate agency to administer the program. It was observed that the NHP program had brought some discipline to what had been, to date, a largely unregulated product area. Yet, it was noted that partners still needed to increase cooperation and NHPD's role as lead in the area at HPFB needed to be re-enforced. Evaluators noted that as NHP use increases and more products arrive on the market, there is a need for the regulator to play a more proactive role in health promotion and oversight for these products.

In relation to the effectiveness of the regulatory program, evaluators were less kind. They noted that the program had been taking a "broad-based approach, which meant they may be over-regulating products and under-emphasizing post-market verification." In relation to over-regulating, they noted that:

> Canada maintains the broadest definition of NHPs in the world. As a result of this definition, the number and type of products that require approval from NHPD is higher than what is experienced by regulatory authorities in other countries.[1416]

This includes "certain unforeseen products (e.g., cosmetics, functional foods) [that] have entered the NHP regulator stream since the *NHPR* came into effect." Evaluators noted that in other jurisdictions, namely Australia and the EU, provisions had been included in their legislative or regulatory frameworks to explicitly exempt certain products or make the boundaries between foods, drugs, and regulated CAM products clear. Similarly, both the EU and Australia had explicitly limited the scope of their regulatory regimes to products with a claim to basis in

[1415] *Ibid.*
[1416] *Ibid.*

traditional practices, excluding products making non-traditional claims and lacking a history of safe use.

Evaluators observed that Canada had initially focused on pre-market screening and assessment of NHP applications for safety, efficacy, and quality, with the intention of increasing post-market surveillance for all products once all transition provisions had expired in 2010. It was noted that in the last two years of operation (2008-09) NHPD had approved over 10,000 products (10,244) compared to a little over 6,000 products in the first four years of operation. In assessing this activity, they noted that NHPD has "been focused on developing process improvement to address the NHP backlog [but] greater attention is required to the existing [standard] for efficacy and the programme's approach to issuing site licenses."[1417] They noted that "efficacy remained an outstanding issue and that it is difficult for [many] NHP applicants to provide evidence of effectiveness."[1418] Both industry and academic interviewees expressed a strong belief that some level of efficacy needed to be maintained, but it was unclear how NHPD was applying evidential criteria.

More problematic was the finding by evaluators that "compliance and enforcement activities are largely complaint driven and the degree of NHP sector compliance with the *NHPR* is not known."[1419] They observed that in the absence of a formal site inspection program or a process to actively collect compliance information, NHPD could not accurately determine if it was effective in ensuring product safety or quality. Evaluators further observed that:

[1417] *Ibid.*
[1418] *Ibid.*
[1419] *Ibid.*

> Overall, the Programme has done little to advance its approach to conducting compliance and enforcement activities at the manufacturing and retail levels since the regulations came into power in 2004.[1420]

As part of this observation they noted that:

> Documentary evidence confirming the ill effects associated with non-compliance (e.g., number of illnesses or deaths caused by NHPs) and the NHP sector level of compliance (e.g., with GMPs or advertising requirements) does not exist.[1421]

This was directly attributed to the "absence of a formal site inspection program, active compliance reporting, or a well-developed marketing and oversight function"[1422] which "jeopardized the Programme's ability to determine the level of compliance among product and site license holders."[1423]

Lacking this information, evaluators were skeptical that NHPD had an accurate risk profile of NHPs. They noted that "there is limited evidence to confirm that the Programme's surveillance assessment and monitoring activities inform regulatory decision-makers."[1424] This meant that, in evaluators' opinion, NHPD was likely unable to accurately assess or fully understand the risks associated with NHP use in Canada. As evaluators described:

> Without a substantive base of information to collect, analyze and verify the ill-effects and risks associated with NHP use, the NHPD is challenged in exercising its regulatory authority under the *NHPR* based on a thorough and comprehensive understanding of risks associated with NHP use.[1425]

To rectify this issue, evaluators suggested that NHPD should conduct a risk assessment of product safety and compliance risks that could be used to quantify needed levels of regulatory intervention. A risk assessment should include a scientifically generated set of criteria for how to

---

[1420] *Ibid.*
[1421] *Ibid.*
[1422] *Ibid.*
[1423] *Ibid.*
[1424] *Ibid.*
[1425] *Ibid.*

vary regulation based on products' inherent levels of risk. This could then allow for a varied approach to regulatory intervention based on lower- and higher-risk products.

Without this assessment, evaluators were unable to pronounce to "what extent health benefits [have] increased and NHP-related illness decreased among Canadians because of programme activities."[1426] This was largely because NHPD had only generated "a weak foundation for qualitatively evaluating how health benefits have increased or wellness decreased as a result of NHP Programme activities or the use of NHPs."[1427] Interviewees indicated this was because "there is no recognized method to assess the health risk/illness avoided due to programme activities."[1428]

The oft-touted reason for increasing NHP access relates to allowing informed consumer choice. The evaluation noted that the program had worked to relay information about the risks and benefits of NHPs, but "these activities have focused primarily on industry and the scientific community."[1429] As a result, evaluators found "insufficient evidence to assess if the NHP Programme has increased awareness and knowledge of the risks and benefits of NHPs."[1430] There was a lack of information being relayed to the public, consumers, and health professionals to enable them to make informed choices about NHPs. To remedy this issue, the evaluators recommended that NHPD:

[1426] *Ibid.*
[1427] *Ibid.*
[1428] *Ibid.*
[1429] *Ibid.*
[1430] *Ibid.*

> should develop a comprehensive education and outreach strategy to enhance and extend activities that target and provide information to consumers (i.e., regarding general awareness of the NHP programme, and the risks and benefits of NHPs).[1431]

This should include an online system that: "clearly outlined the risks and benefits of certain NHPs to consumers;"[1432] "provided information on issues of non-compliance;"[1433] and listed "reports on compliance investigations and regulatory warning letters."[1434] Evaluators recommended that all of this information should be "made available to the public to raise awareness of all of the compliance activities of the Branch."[1435] Without this information, the full scope of regulation and health and safety associated with NHPs would not be available to the public to help inform consumer choice around NHPs.

Overall, the evaluation recognized the value of the NHP program in providing some order and structure to a previously unregulated product area. However, after six years, it indicated that the operation of the NHP program had a very long way to go. Compliance and enforcement were weak, and NHPD could not demonstrate any positive impact on protecting the health of Canadians. NHPD's lack of site licensing inspections meant that quality of NHPs could not be assured. NHPD needed to quantify how it assessed efficacy or health benefits rather than just concentrating on operational improvements to address the backlog. This was paired with the fact that NHPD had gathered little post-market data and had not developed a method to baseline the health benefit or risk from NHPs. Similarly, in a system that was expediting approvals largely based on a rationale of allowing for more informed consumer choice, NHPD had done little to

[1431] *Ibid.*
[1432] *Ibid.*
[1433] *Ibid.*
[1434] *Ibid.*
[1435] *Ibid.*

actively educate the public on the actual risks and benefits of NHPs. To rectify this situation, NHPD was called upon to generate more accurate and independent risk data on NHPs which could inform the program's own priorities and be used to inform the public on the actual risks of NHPs.

HPFB's response to the evaluation was to indicate that it would develop a "risk-based approach"[1436] to surveillance and product licensing. They also indicated they would develop a stakeholder focus plan "to inform stakeholders (including industry and consumers, health-care practitioners and retailers) via workshops, webinars, distribution of information sheets, newspaper articles"[1437] as well as "augment NHP labelling and risk information"[1438] to improve public awareness of the risks and benefits associated with NHPs. HPFB also indicated that it would develop a "risk-based approach" to improve site licensing. However, it did not indicate it would conduct the requested risk assessment to baseline the health benefits and risks of NHPs that would inform an updated "risk-based" approach. As will be noted in the following audits, little would be done to improve the inspection of sites and products for compliance, few educational tools would be developed, and there would be only scant attention paid to ensuring the safety and quality of products post-market.

(ii) The Audit of the Management of the Natural Health Products Program (2013-2015)

In June 2015 the Office of Audit and Evaluation of Health Canada conducted an audit to "assess the effectiveness of the management control framework for regulating natural health

[1436] *Ibid.*
[1437] *Ibid.*
[1438] *Ibid.*

products."[1439] This audit covered the period from 2013-2015. To accomplish this goal, auditors reviewed the full lifecycle of NHP regulation, "including pre-market evaluation, post-market monitoring, and compliance, enforcement and risk-reduction activities."[1440] This was accomplished by a comprehensive "review of policies, standards, guidelines and frameworks, interviews and enquiries, site observations, field work, testing and analysis."[1441]

While auditors generally observed that NHPD had good management and risk forecasting and internal governance in place, they were critical that the program may not be achieving its objectives. Because the pre-market evaluation is low for most of these products, the audit suggested that:

> Given the design of the pre-market approach, it would be important to have effective post-market monitoring and compliance activities commensurate with the relative risk of the products.[1442]

It was noted that "it will be important to enhance all post-market activities in order to maintain the integrity of the regulatory system."[1443] The audit made three general recommendations: to (i) improve the monitoring of post-market mitigation activities,[1444] (ii) enhance verification of GMP practices,[1445] and (iii) begin cross-referencing site licenses and product licenses.[1446]

In making their recommendation that Health Canada and NHPD should "implement an enhanced verification of good manufacturing practices as part of the site licensing model for

---

[1439] *2015 Audit, supra* note 1406.
[1440] *Ibid.*
[1441] *Ibid.*
[1442] *Ibid.*
[1443] *Ibid.*
[1444] *Ibid.*
[1445] *Ibid.*
[1446] *Ibid.*

natural health products,"[1447] auditors noted that sites were seldom inspected and poorly connected with compliance activities. Auditors went so far as to observe that:

> on-site compliance verification of GMPs **may** occur following the paper GMP assessment. However, on-site verification of GMPs is not part of the current site licensing model. In the past, the on-site compliance verifications of NHP facilities were conducted infrequently and generally resulted from complaints.[1448]

In 2014 NHPD had introduced a risk-based system allowing industry to opt into a voluntary use of third-party inspectors to validate GMPs, but auditors found "there were questions raised through the pilot about the value and consistency of the audits (for example, depth/scope of audit, role of auditors and extent of training)."[1449] The auditors also noted that concerns were compounded around imported products as "audit interviews noted concerns about the validity and quality of evidence supplied to support GMPs for importation from [other] countries."[1450] When auditors did evaluate paper records manufacturers had generated, they found significant clerical errors such as "site address errors, product specification errors and cases of false or misleading information related to manufacturing processes."[1451] Health Canada's own regional inspectors, when interviewed, noted that "there are limitations to the current paper-based self-assessment site licencing model and the most effective means of assessing GMPs is through an on-site audit."[1452]

Health Canada's response was to agree with the recommendations and fall back upon the proposed new site licensing guidance.[1453] In addition, Health Canada noted that it was

---

[1447] *Ibid.*
[1448] *Ibid.*
[1449] *Ibid.*
[1450] *Ibid.*
[1451] *Ibid.*
[1452] *Ibid.*
[1453] *Ibid.*

developing a revised principles-based approach that would target the greatest observed risks for compliance action.[1454] Yet, as was observed in the last chapter, this guidance included an annex which exempts many practices from compliance action, including many that would be considered adulteration for either foods or drugs.[1455] This creates a large lacuna in the law for ensuring the quality of these products. The next two audits, which take this regulatory issue forward by several years, will observe little improvement in GMP and post-market compliance activity.

The audit also recognized that while PLs and SLs are required for a product to be on the market, they are not administratively linked or cross-referenced in any meaningful way. This led evaluators to make a recommendation that Health Canada "needed to enhance the cross-referencing of product licenses and site licenses."[1456] The lack of linked records meant that auditors were required to do their own calculations to estimate the number of products likely to have been produced at various licensed sites across Canada. In an independent review, the auditors found that 20% of labels were non-compliant "because labels are not required as part of the application"[1457] and were not cross-referenced. This was partially because NHPD and HPFB had 10 different digital systems which were not interoperable to handle product information (SL, PL, compliance, ADRs, etc.).[1458]

[1454] *Ibid.*
[1455] *Ibid.*
[1456] *Ibid.*
[1457] *Ibid.*
[1458] *Ibid.*

In assessing post-market surveillance, compliance, and enforcement of NHPs, the auditors recommended that NHPD needed to "strengthen the targeted approach for compliance promotion and monitoring"[1459] so that it was actually achieving results. The auditors noted that Health Canada had implemented a "risk-based approach" to compliance, but were told by staff that "compliance actions were seldom taken."[1460] Interviews went further to inform auditors that:

> [any requested] corrective actions may be insufficient because a site licence or a product licence is not usually suspended when adulterated products are found. They also note that despite ongoing correspondence and phone calls, corrective actions concerning problem NHPs are usually taken only when there is a threat of or an actual stop-sale notice.[1461]

The auditors also noted that it may not have been a good decision to exempt NHPs from the broader compliance and enforcement authorities that were provided by *Vanessa's Law*.[1462] The auditors went on to assert that "in a regime where product and site licensing is based on the assertions of producers and importers, there is a need for more post-market activity."[1463]

In conclusion, the auditors suggested that in order to assure the safety and quality of these products, "the NHP Program would benefit from deriving more meaningful performance information related to compliance and enforcement."[1464] While there was a large volume of information reported about the program's activities, the majority related to workload at NHPD (reports opened and closed PLAs, active workload, items returned or retained); there was little information on compliance activities or the compliance of marketed NHPs. In fact, despite the wide variety of data it was collecting, the only expected result the NHPD set for itself in 2013-14

[1459] *Ibid.*
[1460] *Ibid.*
[1461] *Ibid.*
[1462] *Ibid.*
[1463] *Ibid.*
[1464] *Ibid.*

as part of the departmental performance report (DPR) was that "the Natural Health Product Industry understands regulatory requirements,"[1465] measured as a percentage of applications meeting regulatory requirements. This was a performance indicator measured in terms of the number of products approved to address the backlog. In previous iterations of the DPR, auditors noted NHPD had included performance objectives that included "increased availability of safe, effective and high-quality NHPs, timely regulatory decisions for NHPs and a timely regulatory response for NHP-related risks."[1466]

(iii) Evaluation of the Natural Health Products Program (2010-2015)

In March 2016, Health Canada released the results of a five-year evaluation of the *NHPR* program, the *Evaluation of the Natural Health Products Program 2010-2015*.[1467] A program evaluation is a much more detailed and sweeping evaluation that explores the objectives of a regulatory program matched to its achieved results and activities.[1468] The evaluation looked at how HPFB and NHPD performed in developing and implementing the regulatory framework, conducting communications and outreach activities, conducting pre-market activities "such as benefit-risk assessments of applications for licensing and approval"[1469] (PL and SL), and conducting post-market "surveillance, benefit-risk assessments, safety monitoring, compliance and enforcement activities."[1470] The evaluation did not look at certain areas covered by the audit

[1465] *Ibid.*
[1466] *Ibid.*
[1467] *2016 Evaluation, supra* note 1407.
[1468] *Ibid.*
[1469] *Ibid.*
[1470] *Ibid.*

in the year before, including internal management at NHPD, governance, and performance measurement.[1471]

The evaluation's results were scathing. In assessing whether the program was achieving its expected outcomes, evaluators found that while NHPD had made some improvements in overall health protection, questions "remained about the efficacy and quality of some natural health products, and this could have an impact on safety."[1472] The evaluators go on to note:

> there is concern that some natural health products make claims that are not supported by scientific evidence and that the lack of an on-site inspection program in conjunction with the current attestation model do not do enough to verify the quality of products manufactured both domestically and outside of Canada, which could have an impact on safety.[1473]

In assessing post-market activities (surveillance, product recalls, and risk communication), they noted that there was "limited follow-up on recalled products"[1474] and activities tended to be reactive and not proactive.[1475] This was compounded by challenges that remained with "product classification issues"[1476] and "accessibility [interoperability] of technology systems."[1477] They also noted that while stakeholder outreach had been extensive with industry, there was little outreach to the Canadian public other than a few fact sheets posted on the NHPD website. This meant that "there is limited evidence to show that Canadians are well informed of the risks and benefits of using NHPs, as well as Health Canada's role and activities in regulating NHPs."[1478]

[1471] *Ibid.*
[1472] *Ibid.*
[1473] *Ibid.*
[1474] *Ibid.*
[1475] *Ibid.*
[1476] *Ibid.*
[1477] *Ibid.*
[1478] *Ibid.*

The evaluation made three recommendations relevant to the overall effectiveness of the regulations. The first recommendation was that Health Canada may wish to reconsider allowing specific health claims in the absence of any evidence of efficacy. The second recommendation suggested an expansion of post-market monitoring to support pre-market attestation. The third recommendation suggested tightening up the NHP definition to address product classification issues.

In testing the quality of a random sample of over 750 products, evaluators found that 43% were deficient because their licensing was based on inaccurate statements or because the quality of medicinal ingredients did not match specifications.[1479] NHPD's assessment of products using their "risk-based" compliance method had found only 9% of these products to be adulterated. This finding raises the question of how effective Health Canada's risk-based compliance approach actually really was. The evaluators also noted that for a system with a low pre-market bar to market entry (limited evidence and attestation to GMP), there was limited proactive post-market product reviews, compliance monitoring, or regulatory action taken against non-compliant manufacturers, when compared to other international regimes, in particular the U.S. and Australia.[1480]

In assessing quality, key interviewees told evaluators that for NHPs, "verifying the quality of health products is a key aspect of regulatory activity given that most health issues are due to the improper manufacturing of products."[1481] Evaluators observed that:

[1479] *Ibid.*
[1480] *Ibid.*
[1481] *Ibid.*

> Both internal and external key informants were unsure if NHPD-conducted activities were sufficient enough to verify the quality of natural health products. Further, key informants pointed out that the quality of natural health products is currently based on attestation through a paper-based exercise which is not verified by an on-site inspection program.[1482]

While manufacturers do attest to the quality of manufacturing facilities and practices, interviewees went on to indicate "on-site inspection is typically a key component"[1483] of any regulatory system looking to ensure standards for GMPs. Evaluators also noted that NHPD was still unable to match or cross-reference product applications to site licence applications which in turn "limit the evaluation's ability to confirm that NHPD can attest to the quality of products."[1484] They cited a 2013 study by Newscaster et al.[1485] that found, of 44 NHPs randomly tested, over 60% were adulterated with ingredients not listed on the label. Yet by the time of the audit in 2016, NHPD had failed to develop a consistent system of GMP inspection, other than the rather ill-received risk-based self-inspection program criticized in the 2015 audit.

The evaluators noted that there were "various factors impacting whether health risk is minimized."[1486] NHPD lacked a clear IT structure such that the *Licensed Natural Health Products Database*,[1487] *Natural Health Products Ingredients Database*,[1488] and the *Compendium of Monographs*[1489] were not linked. Additionally there were no databases that linked approved products to the site that manufacturers made/imported/packaged/labeled products. Evaluators noted that:

[1482] *Ibid.*
[1483] *Ibid.*
[1484] *Ibid.*
[1485] *Ibid.*
[1486] *Ibid.*
[1487] *LNHPD, supra* note 116.
[1488] *NHPID, supra* note 115.
[1489] *Compendium of Monographs, supra* note 1097.

> This could be of concern in the event that issues are found with one particular manufacturing plant because the program would not be able to confirm, in a timely manner, how many licenced products may be affected.[1490]

Several interviewees also noted "there is limited follow-up action to verify that recalled products have been removed from the market."[1491] Witnesses (both in government and industry) also highlighted that the *NHPR* regulations are likely "not sufficiently strong … to persuade industry to address non-compliance."[1492] This is compounded by the fact that the *NHPR* was at the time still intentionally excluded from the expanded compliance powers of *Vanessa's Law*.[1493]

In assessing the measures that Health Canada has in place to ensure efficacy of products, evaluators noted that there had been improvement in the type of evidence required for different types of claims (traditional versus new) as a result of the 2012 guidance.[1494] Yet the type of evidence and relative merit of these products generated the most discussion amongst interviewees both internal and external to government. Several interviewees suggested that:

> the Department should be careful when it comes to allowing health claims on products that are regulated with less stringent standards of evidence, such as homeopathic products. Many internal key informants felt that the limited evidence required for products to receive an NPN was not clear, especially to the public, and is not aligned with Health Canada's science-based mandate.[1495]

It is particularly concerning that this was a sentiment expressed by those at the regulator who were setting the evidential standards for product approval. The evaluators were unequivocal in recommending:

[1490] *2016 Evaluation, supra* note 1407.
[1491] *Ibid.*
[1492] *Ibid.*
[1493] *Ibid.*
[1494] *Ibid.*
[1495] *Ibid.*

> As a science-based regulator, Health Canada may wish to reconsider its current practice of allowing specific health claims on natural health product labels that cannot be supported by scientific evidence.[1496]

Evaluators noted that while these products have generally been designated as lower risk, "risk is relative as long as individuals are not foregoing potentially needed medical treatment, and as long as products are manufactured properly."[1497]

The evaluation reinforced the need to link site licenses with product licenses, raised by the 2015 audit. It recommended that:

> Given the reliance on pre-market attestations for natural health products and the general reactive approach to post-market activities, the NHPD should consider expanding its post-market activities such as conducting on-site inspections, conducting more laboratory testing as part of compliance verification, and examining the need for stronger post-market powers in the area of natural health products.[1498]

Since product licenses and site licenses were reliant primarily upon attestations, NHPD needed to do more as part of post-market surveillance and should have expanded powers to enforce compliance. The evaluators noted that over the period of examination, 265 non-compliant products had been removed from the market, of which 128 had risks which could have caused death (Type I risk) and 67 could have caused temporary or non-lethal ADRs (Type II). Yet there were an additional 1,948 ADR incidents, the majority of which were closed without compliance action taken against PL or SL holders.

Another recommendation in the report related to the need to clarify the product classification mechanisms for NHP combination products. Evaluators specifically recommended

---

[1496] *Ibid.*
[1497] *Ibid.*
[1498] *Ibid.*

Health Canada should: "Clarify and tighten product classification definitions, specifically those related to natural health products, to help address product classification determination issues."[1499] Both industry and government officials expressed frustration with the lack of clarity around how classification decisions are made and how that has led to "regulatory shopping to find the least onerous and quickest pathway for their products to reach the market."[1500] Evaluators noted that this is a concern because "the requirements can be disproportionate to the level of risk, there are inconsistent requirements for evidence standards for efficacy, and the regulatory approach is not necessarily aligned with how the products are seen by consumers."[1501] This was particularly concerning because consumers "may not understand that different versions of the same product have had very different levels of review, especially with respect to efficacy."[1502]

In assessing how NHPD prioritized their communications and outreach activities, evaluators found that it engaged in extensive and frequent consultations with industry stakeholder groups.[1503] This included attendance at conferences and industry events, holding cross-country consultations, producing a newsletter largely directed at industry, and holding targeted sessions for industry when new guidance was issued. Health Canada even held a targeted event with industry run by a private lobbying firm, Develop Innovate Advance,[1504] on pharmacovigilance. This was seen by NHPD as leading to "a significant decrease in the number of [failed] submissions within the evaluation timeframes."[1505] Efforts to engage others tended to focus on "health-care professionals within the natural health community and not medical

[1499] *Ibid.*
[1500] *Ibid.*
[1501] *Ibid.*
[1502] *Ibid.*
[1503] *Ibid.*
[1504] *Ibid.*
[1505] *Ibid.*

professionals, such as family doctors, who regularly interact with Canadians who may be consuming natural health products."[1506]

At the same time, there was only limited communication to the public on a variety of topics. Key informants, both inside and outside government, were concerned that Health Canada was not explicit about what its role was and that NHPD was not adequately ensuring the SEQ of NHPs. Informants believed that it:

> could be clearer in communicating its[limited] role in regulating natural health products, particularly with regard to safety, efficacy and quality…[Health Canada] has not communicated effectively to the public and many Canadians do not appear to know what the presence of a Natural Product Number (NPN) on a product signifies.[1507]

What communication did exist was largely online and directed the public to a generic set of NHP information sheets. The evaluation noted that NHPD and Health Canada had not done any updated public opinion research since an often-cited 2010 Ipsos-Reid research poll on the Canadian public's opinions on NHPs. Interviewees were also critical that without updated information, NHPD was unaware of current public opinion and perception of these products. This gap led to an overreliance on consultations and communications from industry and an under-reliance on gauging the opinions of the NHP-consuming public. Ultimately, "without having baseline information on what consumers do and do not know about the products and regulations, it will be difficult for the program to identify and target any information gaps."[1508] NHPD lacked any formal communication plan and government witnesses stated that "they were unaware of the extent to which Canadians [were] aware of the risks and benefits of NHPs."[1509]

[1506] *Ibid.*
[1507] *Ibid.*
[1508] *Ibid.*
[1509] *Ibid.*

Even the oft-cited Ipsos-Reid study flagged that only 42% of respondents thought NHPs were safe.[1510]

Health Canada's response to the evaluation was to pledge to examine its approach to compliance, licensing, and communication based on an updated risk-based approach to licensing and post-market surveillance.[1511] They placed much weight on many of these issues being addressed in the implementation of the planned new *Consumer Health Product Framework*.[1512] This framework was replaced by a more principle-based "self-care framework" which, rather than increasing safeguards, arguably removed safety barriers and proactive regulatory activity, placing most SEQ assessment post-market, with an increasing burden on the consumer.

(iv) The 2021 Auditor General of Canada Audit of NHPs (2017-2019)

In April 2021 the Auditor General of Canada tabled with Parliament a report on *Natural Health Products – Health Canada*.[1513] An OAG report is generated for Parliamentarians, not just for the government of the day, and is meant to raise issues of such significant concern that they need to be brought forward to the public and directly to members of Parliament. The OAG has much greater investigatory powers, backed by Parliament, than normal governmental auditors and can review any materials that auditors deem necessary.[1514] The audit covered the period from

[1510] *Ibid.*
[1511] *Ibid.*
[1512] *Ibid.*
[1513] *OAG, supra* note 29.
[1514] *Ibid.*

2017 to 2019 and assessed whether Health Canada "ensured that natural health products offered to Canadians are safe and accurately represented on the basis of appropriate evidence."[1515]

The audit looked at "pre-market licensing for approving the sale of natural health products and post-market activities for monitoring industry compliance and product risks and issues."[1516] Specific criteria assessed included: (i) whether Health Canada approves NHPs that "are safe and free from false or misleading information, on the basis of appropriate information;"[1517] (ii) whether Health Canada assessed that manufacturers and foreign sites "comply with key good manufacturing practice before NHPs enter the Canadian market;" [1518](iii) whether oversight "is sufficient to conclude industry compliance;"[1519] (iv) whether Health Canada "monitors to identify unauthorized natural health products and false or misleading advertisement;"[1520] and (v) whether Health Canada "takes timely actions in response"[1521] to non-compliance.

The audit assessed much of the same systems as the 2015 audit and the 2016 evaluation and found little progress. The OAG was intentionally not critical of the evidence used at licensing,[1522] but found that because there was no assurance of quality or GMPs, safety and efficacy of these products was meaningless. As the OAG put it:

> Overall, Health Canada's oversight of natural health products available for sale in Canada fell short of ensuring that products were safe and effective…gaps in the oversight of manufacturing sites and in the monitoring of products once on the market left consumers

[1515] *Ibid.*
[1516] *Ibid.*
[1517] *Ibid.*
[1518] *Ibid.*
[1519] *Ibid.*
[1520] *Ibid.*
[1521] *Ibid.*
[1522] *Ibid.*

> exposed to potential health and safety risks because products were not always manufactured or marketed according to licence conditions.[1523]

NHPD and HPFB still seldom conducted post-market surveillance and the "absence of routine inspections did not allow Health Canada to ensure that manufacturing sites were following good manufacturing practices…and [Health Canada] did not monitor product label information."[1524] The auditors also noted that Health Canada did react to high-risk noncompliance, but its approach "was reactive and not always successful in having all products pulled from the shelves."[1525] The ultimate result was that product licensing and site licensing conditions were not followed and "products may not deliver the promised health benefits or may cause adverse reactions ranging from mild to severe."[1526]

The OAG assessed a sample of 25 active site licenses for manufacturers in Canada and found that only three had evidence of inspection for GMPs. Another 10 relied upon third-party inspection or other national authorities to validate GMPs for NHPD. For the other 12 sites, NHPD could not verify that SL holders had in place evidence demonstrating validation of QAP officials' credentials, SOPs for product testing, or test results showing product specifications had been met. In addition, they noted that NHPD was only in a position to assess GMP and SL once a product was on the market but "the department is not told when NHPs will be released, unlike for drugs."[1527] This means that no pre-market safety validation was possible. As a result, the OAG recommended that Health Canada should obtain sufficient evidence "to verify that licensed sites follow good manufacturing practices before products are released on the market and obtain

---

[1523] *Ibid.*
[1524] *Ibid.*
[1525] *Ibid.*
[1526] *Ibid.*
[1527] *Ibid.*

information about which natural health products are available on the market."[1528] Health Canada's response was that it had "limited regulatory authorities to compel companies to provide information on quality as part of the product-licence submission process."[1529] Additionally, Health Canada responded that it was again exploring an expanded risk-based compliance approach using paper-based practices, but more funding was needed to "explore mechanisms to obtain information about which products are available on the market."[1530]

The OAG also found that Health Canada "did little to prevent poor information from being given to consumers about licensed NHPs."[1531] The OAG investigated a sample of 75 licensed products to determine what was on product labels and the type of advertising on product websites. They found that 75% of product websites "were advertis[ing] with misleading product information,"[1532] and that 56% of products "were marketed with misleading label information."[1533] Some examples of the misleading information on labels included making health claims not authorized by Health Canada, false statements about a product being "recommended for children 3 and up"[1534] when it was approved only for use by adults, incomplete lists of risks, wrong dosage information, and a lack of clear safety information. A further 25% of these 75 products did not display the mandated NPN number. Based on these findings, the OAG recommended that Health Canada "monitor product label and advertising

[1528] *Ibid.*
[1529] *Ibid.*
[1530] *Ibid.*
[1531] *Ibid.*
[1532] *Ibid.*
[1533] *Ibid.*
[1534] *Ibid.*

information to ensure that they contain accurate and complete product information, consistent with their license conditions."[1535]

The OAG also assessed Health Canada's new principle/risk-based site inspection and compliance approach introduced following the 2016 evaluation.[1536] They found that the high-risk designation only included sites producing sterile products, and that other high-risk categories such as those making products for children, those making specific health claims, and those associated with a history of compliance failures were not part of the high-risk designation. This in effect limited the definition of high risk. The OAG also noted that only about 5% of PL holders submitted site licensing information to NHPD.[1537] This meant that for 95% of products, NHPD's risk-based approach still could not map a product's risk rating to site licenses and risk designations for inspections except for a fraction of products on the market.

Between 2017 and 2019, Health Canada only inspected 6% (46) of the 766 active domestic sites with site licenses. The OAG also found that even in cases where non-compliance was identified at sites, Health Canada lacked information on the corresponding product licenses for products being manufactured at these sites. Of the 46 sites inspected, Health Canada "found non-compliance with product quality at all [inspected] sites."[1538] This only led to the cancellation of 7 site licenses and 5 product licenses; 39 non-compliant sites did not have their licenses suspended. In those cases where follow-up was required, the OAG found at least 1 suspended product license was still selling its product online. In reviewing 7 of the 46 site inspections, the

[1535] *Ibid.*
[1536] *Ibid.*
[1537] *Ibid.*
[1538] *Ibid.*

OAG found that 5 of these sites were renewed "without verifying that the companies met other important good manufacturing practices, such as confirming the absence of chemical contaminants."[1539]

In reviewing a sample of 25 initial site-licence renewals by NHPD, the OAG noted that in 22 of the 25 renewals, Health Canada did not "verify that all sites followed good manufacturing practices."[1540] The OAG re-asserted that "without always verifying that product testing results meet specifications or that key documented procedures comply with good manufacturing practices, the department cannot be sure that products were safe and effective."[1541] Of the sampled 25 renewals, 9 companies had incomplete "standard operating procedures for product testing, sanitation, quality assurance, premises or equipment,"[1542] and 17 companies "did not provide product testing results that confirmed the identity and quantity of medicinal ingredients."[1543] In conclusion, the OAG suggested that its findings:

> Illustrate the risks of the department relying on manufacturers to attest that their sites follow good manufacturing practices when it approves site licences. Some of the department's findings could have been avoided if the department had performed more verification of good manufacturing practices when it issued and renewed site licences."[1544]

The OAG observed that Health Canada's own risk-based evaluation of 35 products in 2019 of recently released products found problems at all manufacturing sites, including "use of expired

[1539] *Ibid.*
[1540] *Ibid.*
[1541] *Ibid.*
[1542] *Ibid.*
[1543] *Ibid.*
[1544] *Ibid.*

raw materials, unacceptable amounts of contaminants, and product tests that did not confirm the product expiry date."[1545]

The OAG noted other deficiencies. In reviewing 48 products which made claims about cancer prevention online, only 4 were licensed, but they could find no compliance activity from Health Canada. They noted that when Health Canada was aware of a high-risk case of non-compliance they acted, but on average, it took three months to remove products from the market.[1546] In reviewing 40 cases of non-compliance, they found that Health Canada acted quickly on 36 cases of known high-risk non-compliance but in 4 cases companies ignored requests from Health Canada. In one of these cases a product was adulterated with a pharmaceutical ingredient. The OAG confirmed that as of October 2020, this product was still for sale on the Canadian market.

General Observations

If we take a step back and review the findings of the audits and evaluations discussed above, it becomes evident that the overall administration of regulations does not leave a positive impression. Many of the same issues have been raised repeatedly over the past 20 years, with little improvement observed. Regulators have failed to establish a baseline for the risks and benefits associated with these products. Consequently, the administration of regulations has never truly been aligned with the actual risks and benefits of these products. NHPD has not consistently implemented clear and effective measures to assess the safety, efficacy, or quality of

[1545] *Ibid.*
[1546] *Ibid.*

these products. Natural health products continue to face a high risk of adulteration, a problem that has persisted throughout the period covered by the audits and evaluations, from 2005-2021.

In terms of pre-market regulatory activities, several audits and evaluations have raised concerns about the value of a licensing system that does not evaluate the effectiveness of NHPs. Meanwhile, the courts have affirmed that Health Canada has the right to impose evidential criteria on licensees and that the primary objective of the regulations should be to promote health and safety. Access and respect for tradition are considered "underlying principles."[1547] The standards set for licensing NHPs have been criticized for being too low. Evaluators have even suggested that regulators should reconsider their practice of allowing specific health claims when there is no scientific evidence to support them. Instead of developing rigorous scientific, efficacy, and quality (SEQ) measures, regulators have focused their efforts on establishing a system that licenses the highest number of products, with ever-decreasing levels of pre-market evidence, as quickly as possible.

This issue is further exacerbated by a weak or almost non-existent post-market compliance system. The recent report from the Office of the Auditor General (OAG) highlights that without evidence of quality, any claims made regarding the safety or efficacy of a product are meaningless. The post-market surveillance system, which is supposed to be based on risk principles, has repeatedly been observed to be ineffective. Health Canada has conducted only limited on-site inspections and has consistently failed to ensure the accuracy of product composition and health claims on labels. Additionally, the process of site licensing relies solely

[1547] *RNA Biochemical, supra* note 1355.

on self-attestation, creating a separation between site licenses and product licenses. This gap makes it challenging to enforce compliance with post-market quality standards. In cases where enforcement measures are initiated, they are often ignored, allowing non-compliant products to continue being sold on the market.

The NHPD has primarily directed its engagements and consultation efforts towards industry stakeholders, neglecting to actively engage with the general public to gather opinions or assess understanding of the regulations. This includes conducting new public opinion research or gauging opinion about the need for access to these products. Instead, they focus their engagements on a very limited number of stakeholders, or are responsive to some of the more extreme voices as embodied by the response to C-51.

What we are left with are regulations employing a *deminimus* set of regulatory interventions (pre- and post-market) that do not do much. The regulations enable an initial registration of products with very low, self-attested criteria subject to very low levels of post-market oversight. There is no requirement for these products to demonstrate that they have a health benefit. Most of these products are not, in any way, required to scientifically demonstrate that they do what they purport to do. Instead, they are subject to a reverse risk criterion: what is the harm of the claims they are making being untrue? This seems to represent an acceptance of products on the market making untrue health claims by a health regulator. "Risk-based" has tended to mean *deminimus* regulation. Risk-based methods for compliance monitoring seem to be failing. Finally, even in cases of identified non-compliance, NHPD is either unlikely or unable to enforce compliance or compel product removal. The result is a set of regulations that, to the

public, have the appearance of providing surety for these products, but in fact do little to provide additional health and safety protections.

CHAPTER 8 - RISK REGULATION AND THE DEREGULATORY AGENDA

In its 2019 report on adverse event data, Health Canada lumps drugs and natural health products (NHPs) into one category. For that year there were 96, 559 domestic adverse drug reports (ADRs)[1548] for drugs and NHPs combined, a four-fold increase from just a decade earlier in 2010, when 20,211 ADRs were reported.[1549] As was described in the regulatory impact statement introducing amendments to the *NHPR* in June 2022, "from the introduction of the *NHPR* in 2004 until December 2021, Health Canada has received reports of over 8,000 adverse reactions in which NHP use had a suspected role, of which over 5,000 [62%] were serious."[1550] In the same statement Health Canada admits that "research has shown that the reporting of adverse reactions is low"[1551] in Canada for NHPs, somewhere in the range of 1% to 2%, compared to 1% to 10% for drugs.[1552]

If we take this as a multiplier, it is likely that there have been hundreds of thousands of unreported ADRs for NHPs. Regulators continually cite that NHPs are low-risk, but the truth is that we likely do not have an accurate picture of their risk profile. Regulators have consistently been unwilling to raise the bar related to safety, efficacy, and quality; instead they have continually reduced standards, and made post-market compliance and ADR reporting the

[1548] The joint term adverse drug reaction or report (ADR) is used to refer to both NHPs and pharmaceutical drugs which are both a class of drug. ADR reports are often an aggregate by product of drug reactions in specific patients hence there will be more individual cases of adverse events than are reported in the ADR report.
[1549] See Health Canada, *Adverse Reactions, Medical Device Incidents and Health Product Recall in Canada* (Health Canada: Ottawa, 2019), online at https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications.
[1550] *Ibid*.
[1551] *Ibid*.
[1552] *Ibid*, Charrois, T. L., Hill, R. L., Vu, D., Foster, B. C., Boon, H. S., Cramer, K., and Vohra, S., "Community Identification of Natural Health Product–Drug Interactions" (2007) *Annals of Pharmacotherapy*, 41(7-8), 1124.

priority. Yet, as the audits and evaluations in the last chapter noted, NHPD has a hodgepodge "risk-based" approach to product review, compliance, and enforcement, with little effect on safety, efficacy, or quality. But even without this data, regulators have forged ahead with plans to expand the evidential criteria applied to these products to other classes of "low-risk" products.

This trade-off is likely small, since most NHPs, unless they are adulterated, tend to be benign substances with little measurable effect, positive or negative, on health. The formula becomes marginal innovation and efficacy for increased market access, with a lower bar of safety and quality. This is all hidden under an assumption that these products deserve a low level of intervention because they are "low-risk." There are many unknowns and compromises in this formulation, and as was noted in the last chapter, it is a stretch to call these regulations effective. Despite this, Health Canada has deemed this product line a regulatory success that should be emulated for other classes of products (over-the-counter-drugs, cosmetics, disinfectants) whose ingredients and efficacy have much greater risks.

This is, in effect, a form of soft deregulation, which keeps the outward form of a regulatory regime, but abandons many of the requirements for SEQ associated with traditional food and drug regulation. It moves from a prescriptive pre-market regime to a permissive post-market regime, where many of the quality and safety measures for these products are even lower than those for foods. There is unlikely to be additional safety and efficacy data generated post-market. These changes may partially have been driven by some of the deficiencies in the initial drafting and operational conditions of the *NHPR* that were described earlier, but they also align with a larger policy drift that has sought to recast the goals and regulatory needs of food and drug

law as supporting access and innovation. Rather than being seen as a case of poor regulation, the *NHPR* has been held up as an example of soft regulatory action that should be emulated because it encourages market growth in the CAM industry. It is regulation with the appearance of regulation but with none of the enforcement or obligations for regulated parties. Lost in all of this is the original intent of the *NHPR* to achieve a public health goal.

The Slow March of Deregulation

It is not by accident that the *NHPR* are a potentially weak set of regulations with a low level of enforcement. It is in fact the result of a process set in place over the last two decades to reframe both the purpose and nature of health and food and drug regulation. As Baldwin et al. note, this is the product of an intentional process of regulatory liberalization, where:

> The past thirty years have witnessed a crystallisation of paradoxes in regulatory dynamics…a continued concern with the 'evils' of regulation, such as 'red tape', overload, and excessive bureaucratisation of economic and social life.[1553]

This trend has also been accompanied by what has been termed a "better regulatory agenda":

> The rise of a 'better regulation' agenda is arguably a rhetorical device designed to hold out the prospect of coherence and consistency between these 'red tape' and 'regulatory quality' developments.[1554]

The better regulatory agenda is characterized by proponents as being more responsive, smart, problem-centred, risk-based or purpose-based than existing compliance regulatory models.

A pillar of this new regulatory approach has been framing regulations as a function of managing risk. This has led to a concept of "risk regulation" that has much of its origin in the

[1553] *Baldwin et al, supra* note 46.
[1554] *Ibid.*

regulation of the financial industries and rests upon three principles.[1555] The first is the idea that regulation can be empirically varied based on designation of level of proportional risk (risk characterization). Second in this conception is the assumption that risk can be quantified and contained with "rational planning tools, bespoke institutional design and targeted enforcement"[1556] (making risk management proportional). Third is the expectation that the risk regulation can be supported by alternative accounting measures or self-governance tools (risk accountability). However, the 2008 financial failure has increasingly led to criticisms of these systems and their underlying assumptions.[1557] Critics suggest that these models are closed systems that frame risk with little genuine oversight or relationship to the real world. This has led to a realization of the "continued need for oversight and the addition of objectives [taken from the real world] to [counteract] the earlier primarily economic and social objectives"[1558] of risk regulation.

Key to risk conception in health product regulation is the idea that products should be marketed with little pre-market assessment and allow for the greatest freedom of choice and economic innovation. These goals were in the background at first in proposals put forward by the government and Health Canada, but with time, the regulatory agenda has increasingly wrapped itself in the language of modernization, regulatory efficiency, and risk. This language recast the core risks of food and drug regulation related to safety, efficacy, and quality as low when compared to the potential benefits for market innovation and consumer choice. This tilts the purpose of these regulations away from public health and towards economic benefit. For NHPs,

[1555] *Ibid.*
[1556] *Ibid.*
[1557] *Ibid.*
[1558] *Ibid.*

the outcome is a set of very hands-off regulation, but one that adds a sheen of regulatory approval which helps industry add legitimacy to claims. Implicit in these decisions and the framing around them is an institutional process by which decision-makers (both political and bureaucratic) have shifted the safety bar for these products. A goal of health protection has moved from, in 2001, helping "the people of Canada maintain and improve their health"[1559] to the most recent (2022-23) expressed goals of being "a regulator, a catalyst for innovation, a funder, and an information provider."[1560] The shift is hidden behind arguments rooted in the rhetoric of modernization, regulatory efficiency, and risk.

Part 1 - The Evolution of the Canadian Regulatory Agenda

A 2002 report by the OECD[1561] gave Canada a passing grade but suggested it could increase efficiency by adopting a set of smart regulatory principles in several specific areas, including health. The Liberal government of the day established an External Advisory Committee on Smart Regulation (EACSR). In 2004, the EACSR produced a report, *SMART Regulation: A Regulatory Strategy for Canada.*[1562] The report stated that, in making decisions:

> Canada has limited resources to achieve a growing range of public policy objectives;.. It is therefore critical for government to apply risk management when deciding how to allocate regulatory resources. Resources should be allocated to achieve the greatest social and environmental benefits in the most cost-effective way.[1563]

[1559] Health Canada, *Departmental Report on Performance and Priorities (1999)*, online at: https://web.archive.org/web/20030502031008/http://www.tbs-sct.gc.ca/rma/dpr/98-99/HCAN98dpre.pdf
[1560] Health Canada, *Departmental Plan 2022-23*, online at: https://www.canada.ca/en/health-canada.
[1561] OECD, *Country Studies: Canada – Updated Report* (OECD, 2004), online at: https://www.oecd.org/canada/34425393.pdf.
[1562] EACSR, *SMART Regulation – A Regulatory Strategy for Canada*, (EACSR: Ottawa, 2004), online at: https://publications.gc.ca, hereinafter *EACSR*.
[1563] *Ibid,* at 37.

The report opined fairly authoritatively that there had been a change in how Canadians perceived and desired to be regulated.[1564]

> Canadians' views on regulatory reform have evolved considerably since the late 1980s. Canadians are more pragmatic than ideological. Citizens' demands for protection have increased over time, particularly with respect to health, safety and the environment; however, their views go well beyond the notion that more regulation is better. Canadians now see social, environmental and economic goals as intertwined. They believe that there is an excessive compliance burden on business. They also accept that markets, trade and competition serve both public and private interests. This represents an important change. Canadians believe that the government is ultimately responsible for the health and safety of Canadians and protection of the environment, but they are prepared to be flexible in how these objectives are attained, as long as both industry and government are accountable and achieve results.[1565]

The report proposed "a regulatory strategy for the 21st century"[1566] that included the adoption of new regulatory tools such as increased regulatory cooperation, incorporation of new instruments for government action, and modernizing regulatory processes. The report also called for greater accountability by improving performance and measurement of Canada's regulatory outcomes, a focus on results, and a need for culture change.

The report made several recommendations, including the development of a new risk management framework, a federal risk assessment standard for regulation, and the adoption of new instruments for government action. The report also suggested that the government should "frame and establish processes for the application of precaution in specific situations, such as when the potential risks or benefits to society are high."[1567] The government should incorporate "a broad range of instruments or tools to help them achieve their policy objectives,"[1568]including

---

[1564] *Ibid.*
[1565] *Ibid.*
[1566] *Ibid.*
[1567] *Ibid,* at 41 and 139.
[1568] *Ibid.*

"performance-based regulations, economic instruments, information and education programs, voluntary initiatives and standards."[1569] To achieve these goals, governments needed to tackle how departments: "frame instrument decisions;"[1570] "increase awareness of other tools;"[1571] "remove legislative constraint"[1572] to using these tools; and "increase the profile and use of economic instruments"[1573] rather than regulations to meet objectives. Key to enacting these changes was to look at new ways to improve "the process for making rules that affect Canadians' lives and interests."[1574] The EASCR proposed that "reforming the process in accordance with the values and principles of SMART[1575] Regulation would strengthen the public trust in Canada's regulatory environment and make it an asset for citizens and business."[1576]

As a starting point, the EASCR identified five areas for the development of new smart regulation. These included processes associated with manufacturing and product approval, (including the drug review process), biotechnology, life sciences (in the development of new drugs), First Nations economic development, the environmental assessment process, and gas exploration and development. These areas were selected because "the sectors or areas offered economic opportunity."[1577] The EASCR cited pressure from stakeholders (industry, the public,

---

[1569] *Ibid.*
[1570] *Ibid*, at 44.
[1571] *Ibid*, at 45.
[1572] *Ibid*, at 46.
[1573] *Ibid,* at 47.
[1574] *Ibid*, at 49.
[1575] S-M-A-R-T stands for: S = specific, M = measurable, A = assignable, R = realistic and T = time-bound. Doran, G. T., "There's a S.M.A.R.T. way to write management's goals and objectives" (1981) *Management Review* 70(11) 35.
[1576] *EASR, supra* note 1560.
[1577] *Ibid.*

or other sources) to "demonstrate the enabling and potential attributes of SMART regulation," and reported that there was "potential momentum for a smart regulation strategy."[1578]

(i) The SMART Regulation Roadmap

The government's response was the launch of a *SMART Regulation Roadmap*[1579] adopting the majority of the recommendations of the EACSR. It was framed as a regulatory renewal to ensure the government was able to "keep pace with evolving needs"[1580] of Canadians. It was put forward that these improvements would lead to:

> better access for consumers to new, safe and effective therapeutic drugs and medical devices, greater understanding and support for the needs of large industries [and] fewer regulatory layers for small- and medium-sized enterprise.[1581]

Achieving these goals and the smart regulation plan called for greater regulatory corporation between provinces and international partners, strengthening regulatory management, including "improved analysis, review and rationalization of the existing stock of regulations"[1582] and building "consensus amongst stakeholders on priority initiatives."[1583] As discussed earlier, the regulatory policy changes that occurred at that time at Health Canada, under the *Roadmap*[1584] included the new *Therapeutic Access Strategy* (TAS) with the aim of "improving the timeliness, efficiency and transparency of the drug review process."[1585]

[1578] *Ibid*.
[1579] Government of Canada, *Smart Regulation: Report on Actions and Plans* (Government of Canada, Ottawa: 2005), hereinafter *Roadmap*.
[1580] *Ibid*.
[1581] *Ibid*.
[1582] *Ibid*, at 9.
[1583] *Ibid*.
[1584] *Ibid*.
[1585] *TAS, supra* note 857.

The broader objective of the *Roadmap*[1586] was a complete rewriting of the Canadian regulatory framework. This included greater regulatory integration, reviewing current regulatory systems, changing rule sets, and adopting new smart regulatory tools. The scale of this ambition can be seen in the following diagram.

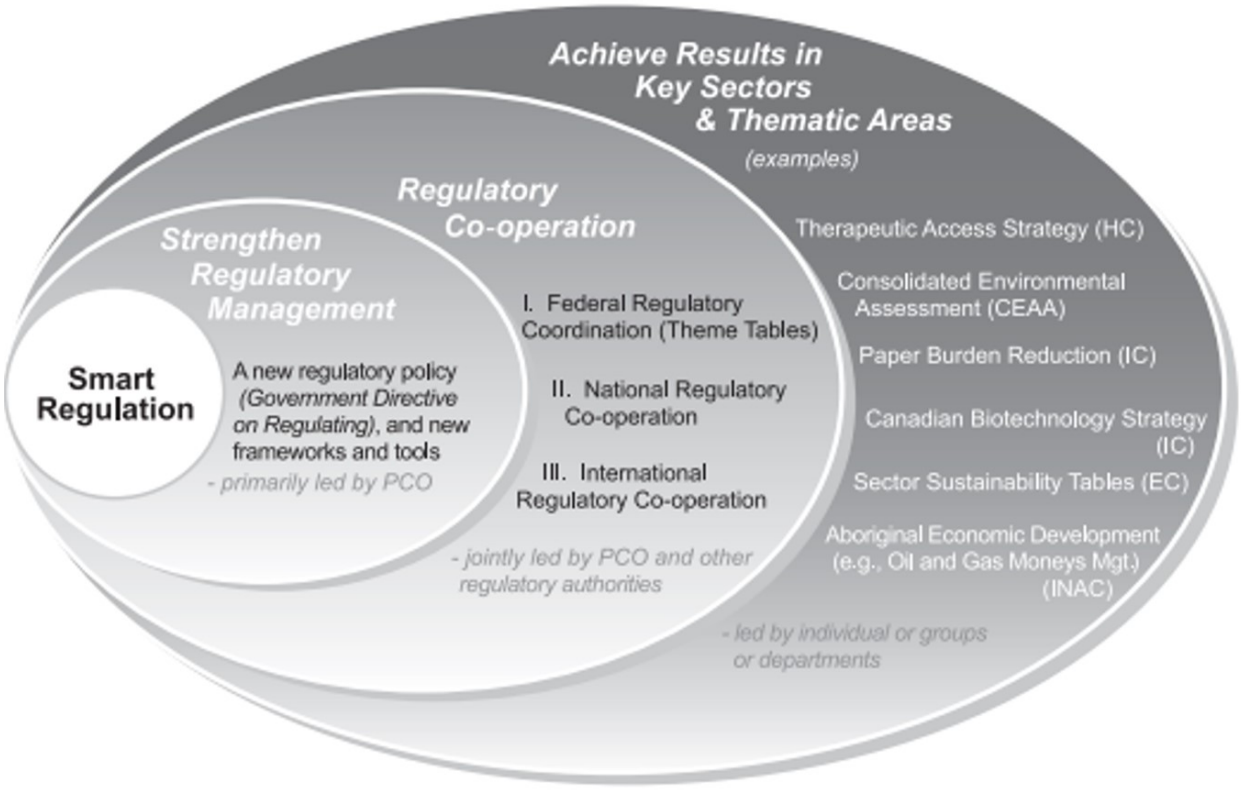

Figure 19: The SMART Regulatory Roadmap – Areas of Concurrent Work[1587]

In the first progress report on implementing the *Roadmap* in 2005,[1588] the government reported on several themes, including a healthier Canada, which included six specific activities or initiatives directed at reducing the regulatory burden related to food and drugs.[1589]

[1586] *Roadmap, supra note* 1579.
[1586] *Ibid*.
[1587] *Ibid*.
[1588] Government of Canada, *Smart Regulation: Report on Actions and Plans – Fall 2005*(Government of Canada; Ottawa, 2005), hereinafter *Roadmap Report.*
[1589] *Ibid*.

Core to the *Roadmap* were two additional planned initiatives. The first was the initiation of a *Paperwork Burden Reduction Initiative* (PBRI)[1590] to focus on reducing the burden of regulation on small business. It is common for regulatory modernization initiatives to frame their broader regulatory changes through a lens of reducing burden on small to medium business.[1591] A second initiative was the development of a new set of policy tools and processes overseeing the regulatory development process. Guidance was planned on instrument choice, which would reflect Braithwaite's pyramid of responsive regulation.[1592] A new triage template was developed for the assessment of regulatory submissions.[1593] Guidance was also developed, which was to come into force in 2006, to vary the regulatory considerations in advance of developing any new regulatory proposal.[1594]

(ii) Red Tape Reduction (2006)[1595]

In 2006, the Government of Canada changed, and the *Roadmap* was formally abandoned. The new Conservative government believed that the regulatory agenda of the previous government had not been ambitious enough. The new government was going to pursue an overt deregulation agenda. A second issue facing the new government was that they were a minority government, and they were looking for ways to implement their agenda using as many non-

[1590] Government of Canada, *Paper Work Reduction Initiative (PBRI)*, (Government of Canada: Ottawa), online at: https://ised-isde.canada.ca/site/paperwork-burden-reduction-initiative/en/resource-centre/government-canada/governments-20-paper-burden-reduction-exercise.
[1591] *Ibid.*
[1592] *Ibid.*
[1593] *Ibid.*
[1594] *Ibid.*
[1595] Government of Canada, *Red Tape Reduction Plan*, (Treasury Board of Canada Secretariat; Ottawa, 2012).

legislative tools as possible.[1596] It was quickly realized that the regulatory activity undertaken by the previous government under the *Roadmap* could be accelerated.

In 2006 the government issued the *Cabinet Directive on Streamlining Regulation* (CDSR).[1597] The CDSR sought to rationalize the regulatory development process by assessing the benefits of regulations to Canadians. It narrowed the goals of federal regular activity to: (i) protecting and advancing the public interest, which equated to "health, safety and security, the quality of the environment, and the social and economic well-being of Canadians;"[1598] (ii) promoting a fair and competitive market economy by "encouraging entrepreneurship, investment, and innovation;"[1599] (iii) advancing efficiency and effectiveness by "ascertaining that the benefits of any regulation justify the costs";[1600] and (iv) reducing timelines, increasing policy cohesion and minimizing duplication by cooperation "across the federal government, with other governments in Canada and with business."[1601] The guidance also made a concession that, in those cases where there was irreversible harm from regulatory failure, "precaution may be necessary when there is an absence of full scientific certainty."[1602]

A key component of the CDSR was the introduction of a more comprehensive set of criteria to be used in assessing the benefit and cost of regulations. The CDSR represented a shift in approach from considering alternative ways to meet regulatory goals to instead giving non-

---

[1596] *Ibid.*
[1597] Online at: https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/requirements-developing-managing-reviewing-regulations/guidelines-tools/cabinet-directive-regulatory-management, hereinafter *CDSR*.
[1598] *Ibid.*
[1599] *Ibid.*
[1600] *Ibid.*
[1601] *Ibid.*
[1602] *Ibid.*

regulatory goals equal weight with regulatory ones. Positive and negative outcomes were to include "economic, environmental and social impacts on Canadians and business."[1603] The guidance reiterated the need to "limit the cumulative administrative burden imposed on small business"[1604] and included the following goals:

- Limit the cumulative administrative burden and impose the least possible cost on Canadians and business that is necessary to achieve the intended policy objectives;
- Consider the specific needs of small business and identify the least burdensome but most effective approach to addressing these needs;
- Ensure that regulatory restrictions on competition is fair, limited, and proportionate to what is necessary to achieve the intended policy objectives;
- Prevent or mitigate the impacts and enhance the positive impacts of regulation on the environment, the health and safety of Canadians, and competitiveness, trade and investment.[1605]

These changes were more overt than those introduced by the *Roadmap* and refocused regulatory considerations away from compliance and their specific goals to more economic and business-based impacts. Not only were the principles of new regulation, responsive regulation, and smart regulation being adopted but the guidance set the "burden on businesses" as the key criteria in framing current or planned regulation.

Through several omnibus budget bills the Conservative government implemented changes to many acts using this business lens. They also began to modify departmental functions and regulatory activities to adhere to this lens. The Health Canada *Blueprint for Renewal*[1606] was the manifestation of these changes in policy direction at Health Canada. The Conservative government increasingly adopted third-party inspections regimes, most evident in transportation,

[1603] *Ibid.*
[1604] *Ibid.*
[1605] *Ibid.*
[1606] *Blueprint, supra* note 24.

food inspection, and environmental assessments, as well as a host of other smart regulatory tools.[1607]

In 2011, the Conservative government announced a much more proactive deregulatory agenda by commissioning a *Red Tape Reduction Commission* (RTRC).[1608] The commission was given the mandate to "identify irritants to business stemming from federal regulatory requirements … irritants that have clear detrimental effects on growth, competitiveness and innovation."[1609] The commission was made up of Conservative members of Parliament, representatives from large Canadian corporations, and the Canadian Federation of Independent Business. It was supported directly by a special unit established within the TBS and led by then Treasury Board Minister Tony Clement. Minister Clement identified the goals of the commission as "freeing business from unnecessary and frustrating red tape."[1610]

In 2011, the commission published a *What We Heard* report,[1611] which outlined specific "irritants" across all federal departments. This meant the government was no longer just introducing new regulatory tools, but instead, regulation was being cast as a negative force that had to be reduced. The resulting *Red Tape Reduction Plan*[1612] had three objectives: (i) reducing burden on business by "streamlining regulatory approval processes, reducing reporting requirements and information demands, and improving coordination of compliance and

---

[1607] *Ibid*.
[1608] RTRC, online at: https://www.canada.ca/en/news/archive/2011/01/red-tape-reduction-commission.html, hereinafter *RTRC*.
[1609] *Ibid*.
[1610] *Ibid*.
[1611] *Ibid*.
[1612] *RTRAP*, (Government of Canada, Ottawa: 2012), online at: https://www.canada.ca/content/dam/canada/tbs-sct/migration/hgw-cgf/priorities-priorites/rtrap-parfa/rtrapr-rparfa-eng.pdf, hereinafter *RTRAP*.

enforcement activities;"[1613] (ii) making it easier to do business with regulators through "41 individual proposals across departments focused on simplifying complex government processes and making it easier for business to do business;"[1614] (iii) improving service and predictability including establishing service standards.

A major part of the *Red Tape Reduction Plan*[1615] was the introduction of departmental and sectoral regulatory action plans as well as yearly forward regulatory plans that would spell out activities departments were undertaking to reduce the overall levels of regulatory activity. TBS was overseeing the sectoral reviews and centralizing the challenge function of departmental submissions. Health Canada, and in particular drug regulation, was identified as one of the sectoral areas requiring a regulatory review. [1616]

As a result of the *Red Tape Reduction Plan*, the Conservative government introduced two new tools. The first was a Cabinet directive on the adoption of the contentious "One-for-One" rule.[1617] The second was to introduce a small business lens to assess the value of any previously existing regulation. Under the One-for-One rule:

> when a new or amended regulation increases the administrative burden on business, regulators are required to offset from their existing regulation an equal amount of administrative burden cost on business.[1618]

In effect, it meant that regulators would "remove a regulation each time they introduced a new regulation."[1619] The small business lens meant departments were required to analyze all existing

---

[1613] *Ibid*.
[1614] *Ibid*.
[1615] *Ibid*.
[1616] *Ibid*.
[1617] *Cabinet Directive on Regulatory Management*, (2012), online at: https://www.canada.ca, hereinafter *CDRM*.
[1618] *Ibid*.
[1619] *Ibid*

and new regulations to reduce their impact. The small business lens introduced a host of new requirements on departments. Early in the stage of the development of a regulation, departments were required to complete a checklist that required "consultation with small businesses to understand their realities."[1620] For new regulatory proposals, departments were required to demonstrate to Ministers that "due consideration was given to reducing the burden imposed on small business."[1621] As part of fulfilling these obligations, a baseline of regulatory impact by each department was to be generated in an annual scorecard report linked to an Annual Forward Regulatory Plan. The goal was to ensure that this overall baseline of administrative burdens on business was being reduced every year.

In 2012, the government also introduced the new *Cabinet Directive on Regulatory Management*.[1622] It formally introduced the One-for-One rule at an administrative level, as well as the small business lens as components of regulatory management. The small business lens was framed to:

> ensure regulators take into account the impact regulations have on small business. This assessment will include the publication of a 20-point checklist that drives efforts to minimize burden on small business, avoidance of bureaucratic duplication and the communication of regulatory requirements in clear, plain language.[1623]

The directive also introduced several performance standards for departments that required them "at a minimum [to] address the timeliness of decision-making."[1624] TBS-RAS was given an expanded role in challenging departments to establish regulatory burden baselines, overseeing

[1620] *Ibid*
[1621] *Ibid*
[1622] *Ibid*.
[1623] *Ibid*, at 2.
[1624] *Ibid*

the submission of annual regulatory plans, pushing for the development of Annual Forward Regulatory Plans, and overall policing to ensure that departments were working to reduce their regulatory burden on small businesses.

The new directive also expanded the scope of what should be considered in a regulatory impact analysis statement (RIAS). Previously, the RIAS had focused on the intent and implications of new regulations; now they were to focus on the "health, safety, security, the environment and the social and economic well-being of Canadians."[1625] Additionally, the RIAS had to note "cost or savings to government, business or Canadians and the potential impact on the Canadian economy and its international competitiveness."[1626] Another new component included the "degree of interest, contention, and support among affected parties (industry)."[1627] An impact rating of low, medium, or high was developed in collaboration with TBS-RAS for each new regulatory proposal. It was likely that going forward, regulatory proposals would heavily favour economically weighted criteria.

The result was an even greater shift in the focus of regulatory activity towards deregulation and the effect of regulation on economic interests. The small business lens,[1628] while structured to limit the negative regulatory impact on small business, had a distributive effect on much larger enterprises and sectoral areas dominated by large enterprise (rail transport and resource development). This was a step beyond simply the adoption of smart regulatory principles, extending to the introduction of a general neoliberal program of deregulation. In the

[1625] *Ibid*
[1626] *Ibid*
[1627] *Ibid*
[1628] *Ibid*

case of health regulation, it has generally meant the adoption of smart and responsive regulatory tools, but also a reluctance to impose new regulatory conditions or guidance that could be seen as imposing a burden on industry.

In 2015, the government formalized these requirements by introducing the *Red Tape Reduction Act* (*RTRA*).[1629] The Act aimed to address concerns that "Canadians and business have expressed about how the increased administrative burden imposed by regulation has affected the cost of doing business."[1630] The Act formally defined administrative burden as "anything that is necessary to demonstrate compliance with a regulation, including the collection processing, reporting and retaining of information and the completion of forms."[1631] The main thrust of this bill was to formalize the One-for-One rule.[1632] Under Section 9 the Act also imposed an obligation for TBS to publish each year a report on the annual regulatory reductions in each department. Ironically, the *RTRA* was supported by a new set of regulations, the *Red Tape Reduction Regulations*,[1633] that set up a very prescriptive formula for how to calculate administrative burden ($\mathbf{C \times D \times E \div 1.07^{F \div G}}$)[1634] and activity costs ($\mathbf{A \times 0.142378 \div 1.07^{B-2012}}$). This formula is explained that:

[1629] *S.C. 2015, c.12.,* hereinafter *RTRA.*
[1630] *Ibid.*
[1631] *Ibid.*
[1632] *Ibid*, under *s.5.1* "If a regulation is made that imposes a new administrative burden on a business, ***one or more regulations must be amended or repealed*** to offset the cost of that new burden against the cost of an existing administrative burden on a business."
[1633] *SOR/2015-202*, hereinafter *RTRR.*
[1634] **A =** is the activity cost that is the sum of the cost for each activity for each period, and is calculated in accordance with the following formula: **C** = is the estimated hourly cost of labour, adjusted to 2012 price levels using the Consumer Price Index set out by Statistics Canada in CANSIM Table 326-0021, as amended from time to time, that is required in a period so that a business is able to complete the activity within that period; **D** = is the estimated number of hours required in a period so that the business is able to complete the activity within that period; **E** = is the estimated number of businesses that are required in a period to complete the activity within that period; **F** = is the specific period, out of the total number of periods determined in accordance with subsection (2), for which the calculation is being made; and **G** =is the number of times per year that the activity is required to be completed; and **B** = the year the regulation is registered.

> the cost of the administrative burden imposed by a regulation is the sum of the cost of each activity that is expected to be completed during the first 10 years after the regulation is registered.[1635]

While having an empirical basis, the formula is also based largely on a number of qualitative estimates, including "extrapolating how to complete various activities"[1636] and various estimates of hourly cost to implement, making the formula still largely subjective. The new Act also allowed for an exemption to the application of administrative burden in "emergencies, unique or exceptional circumstances including if compliance with that section would compromise public health, public safety or the Canadian economy."[1637]

Regulatory Competitiveness (2016-2023)

In 2016, the Government of Canada changed hands once again with the election of a new Liberal majority. The Liberal government continued the regulatory trend established by the previous government, announcing in the 2018 budget a new round of regulatory reviews, the establishment of a new *External Advisory Committee on Regulatory Competitiveness* (EACRC), and a new process intended to lead to an *Annual Regulatory Modernization Bill*.[1638] The EACRC was tasked with providing "advice on how to improve regulatory competitiveness in Canada and help identify opportunities to improve regulatory frameworks."[1639] It was composed mainly of representatives drawn from industry and was to work with TBS-RAS to provide recommendations for areas to focus on for the next phase of targeted regulatory reviews. The

[1635] *Ibid, at s.3*.
[1636] *Ibid*.
[1637] *Ibid*.
[1638] *ARMB*, see online at: https://www.gazette.gc.ca/rp-pr/p1/2021/2021-06-26/html/reg4-eng.html, hereinafter *ARMB*.
[1639] *Ibid*.

committee also provided advice to TBS in general about the removal of regulatory barriers that, in their opinion, impede competitiveness in several structural areas. One of the areas identified for initial action had been the regulatory system around drugs, which, as described in Chapter 1, has long been seen by industry as impeding innovation and the growth of international competitiveness.

The government has begun to move forward very quickly in adopting this new regulatory agenda. As part of the *Budget Implementation Act in 2019, No 1*,[1640] the first *Annual Regulatory Modernization Bill* (ARMB) was introduced, which included:

> 12 pieces of legislation to make common-sense changes that, for example: digitalized paper-based processes; promoted innovation by allowing exemptions from certain regulatory requirements to test new products.[1641]

On March 31, 2022, the second *ARMB, Bill S-6, An Act Respecting Regulatory Modernization*,[1642] was introduced to Parliament, which sought "to repeal or amend provisions that have, over time, become barriers to innovation and economic growth or to add certain provisions with a view to support innovation and economic growth."[1643] As part of Budget 2023, the government has announced its intention to introduce the third *ARMB*.[1644] The main thrust of the updated *ARMB* will be to further implement the digitization of regulation including the adoption of new way of doing business and looking at the proposed self-care framework.

[1640] *Ibid*.
[1641] TBS Regulatory Affairs Sector, *Lets' Talk Regulation*, online at: https://letstalkfederalregulations.ca/annual-regulatory-modernization-bill.
[1642] *Bill S-6 (44-1)* is currently before the Parliament having completed second reading on May 3, 2022.
[1643] *Ibid*.
[1644] Budget 2023, online at: https://www.budget.canada.ca/2023/pdf/budget-2023-en.pdf, hereinafter *Budget 2023*.

In 2020, a new *Cabinet Directive on Regulation*[1645] reframed the goals of regulatory rule-making around the themes: (i) advancing the public interest and supporting good government; (ii) openness and transparency; (iii) evidence-based; and (iv) regulations supporting a fair and competitive economy. Under this last criterion, "regulations should aim to support and promote inclusive growth, entrepreneurship, and innovation for the benefit of Canadian business."[1646]

The new directive moved away from the One-for-One rule, instead reinforcing the older idea of a lifecycle approach to regulatory development. The new direction, while maintaining a business lens, also brought in new lenses assessing impact on the environment, gender-based analysis, second official language, and the effect on Indigenous peoples, which reflected the Liberal government's agenda. The new directive also places more emphasis on the need for annual regulatory reviews of regulatory programs based on a new set of criteria:

- removing obsolete or spent regulations from the stock as soon as practical
- determining the effectiveness of the regulations in achieving their stated objectives
- mitigating unintended impacts, such as barriers to trade or innovation
- ensuring that references to technical standards are accurate and, where appropriate, incorporate the latest version
- demonstrating that the regulatory objectives have been achieved in a cost-effective manner
- identifying new opportunities to reduce regulatory burdens on stakeholders, including through the identification of regulatory cooperation opportunities
- minimizing impacts on small business
- instituting other changes, as appropriate, to strengthen policy objectives and performance
- amending regulations to resolve enforcement issues identified through implementation[1647]

[1645] Government of Canada, *Cabinet Directive on Regulation*, (Government of Canada: Ottawa, 2020), online at: https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/requirements-developing-managing-reviewing-regulations/guidelines-tools/cabinet-directive-regulation.
[1646] *Ibid.*
[1647] *Ibid.*

This represents a more balanced regulatory reduction agenda than that of the Conservative government, but it is still very focused on removing regulations and the impact of regulations on industry. It also still places a premium on regulatory interventions being reduced to a minimum so as not to negatively influence innovation and industrial competition.

This was paralleled with a renewed announcement of funding to continue to support the *External Advisory Committee on Regulatory Competitiveness* (EACR).[1648] Since 2018 the committee had been driving regulatory reform, and was now further mandated to:

- provide advice on how to promote regulatory excellence by supporting innovation, competitiveness and economic growth while ensuring health, safety, security, and environmental outcomes;
- bring together representatives from across the country to provide an independent perspective on improving Canada's regulatory system; and
- support the modernization of Canada's regulatory system, seeking to make the system more flexible, adaptable, and sustainable for the future.[1649]

The committee provided its advice directly to Treasury Board through a series of Recommendation Letters (May 2019, July 2019, January 2021, and March 2021) that had the same general themes of focusing on regulatory competitiveness, measuring cumulative burdens and recommending areas for regulatory reviews.[1650]

In its January 2021 letter, the EACR reinforced that the Canadian regulatory agenda should be focused on competitiveness by addressing the twin goals of "reducing unnecessary

[1648] *External Advisory Committee on Regulatory Competitiveness,* online at: https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/modernizing-regulations/external-advisory-committee-regulatory-competitiveness.html,hereinafter *EACR.*
[1649] *Ibid.*
[1650] *Ibid.*

burdens and accelerating innovation." [1651] As part of this letter the EACR acknowledged the new Center for Regulatory Innovation (a part of TBS-RAS) that was designed to "to encourage experimentation, empower the exploration of non-traditional solutions, and encourage a culture of innovation among regulators."[1652] As part of the same letter, they supported the idea of developing a regulatory competitiveness lens that would include considerations of "economic growth and trade, competition, cumulative effect and innovation," [1653] but they objected to the inclusion of criteria related to "investment attractiveness" (i.e., the worth of the investment offsetting reduced regulation). In their most recent letter the EACR recommend, rather crassly, that TBS "seize the opportunities presented by the COVID-19 pandemic to make the regulatory system more flexible and responsive."[1654] One of their most emphatic recommendations was a "doubling-down on digital innovation"[1655] in the regulatory space.

In 2020, TBS produced a report on reducing internal red tape within government.[1656] Many of the findings echoed the earlier deregulatory reports which called for simplifying rules and reducing burden on those dealing with internal rule sets. One of the key elements of the report was the introduction of principles from the technology sector related to design thinking. Design thinking and user experience (UX) principles used widely in the development of tech products aim to assess the direct needs of users, tailor specific solutions to address issues, and

[1651] Online at: https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/modernizing-regulations/external-advisory-committee-regulatory-competitiveness-advice-treasury-board/external-advisory-january-2021.html.
[1652] Online at: https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/modernizing-regulations/who-we-are.html.
[1653] *Ibid*.
[1654] *Ibid*.
[1655] *Ibid*.
[1656] *Blueprint 2020 Internal Red Tape Reduction Report: Cutting Internal Red Tape – Building a Service Culture*, see online at: https://internal-red-tape-reduction-report.github.io/chapter-1.

test them in the real world. Impediments to this type of process are seen in government as stifling innovation and use language which closely mirrors the language of deregulation. Solutions to these problems generally involve working around rule sets to make them agile.

Much of the new regulatory language has started to adopt these concepts. It includes wording which suggests that the complexity of modern regulatory solutions require bespoke regulations based on real-world observations of how users are affected. Post-COVID, the recommendations of the EACR and TBS have begun to incorporate much of this language. Although it is beyond the scope of this thesis, several Health Canada initiatives have also begun to adopt this language, including the new Agile Licensing Program and Real-World Evidence Program. While we cannot be sure what the next regulatory direction of the government will be, it is likely moving in the direction of these technology sector management principles.

(iv) Health Canada's Regulatory Review of Drugs and Devices Initiative (2017)

In 2017 as part of the *Regulatory Review of Drugs and Devices Initiative* (R2D2)[1657] initiative, TBS mandated overall regulatory reviews of most programs. Health Canada also initiated a new program to address "existing regulatory burdens."[1658] This was directly in response to the bioscience sectoral review initiated under the *Red Tape Reduction Act*.[1659] Led by TBS, these initiatives drove even further to incorporate a wide set of new regulatory designs focused on reduction of burden to sponsor innovation and bring needed products to market. As

[1657] Health Canada, Regulatory Review of Drugs and Devices Initiative (R2D2), (Health Canada: Ottawa, 2017) online at: https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices.html l, hereinafter *R2D2*.
[1658] *Ibid*.
[1659] *Ibid*.

the R2D2 initiative indicated, they were modifying the regulatory system to "make it more efficient, support timely access to products, and build linkages."[1660]

The R2D2 initiative also sought to expand the "use of real-world evidence to support a regulatory decision across a product's life cycle."[1661] Real-world evidence is data collected outside the strictly controlled environment of clinical trials and includes investigative testing once a product is marketed.[1662] Again, the *R2D2* initiative would offset these increases in access by "releasing information so Canadians know more about the products Health Canada authorizes."[1663] In effect, the *R2D2* initiative is offering a further decrease in the pre-market evaluation of drugs and an expansion of the expedited review of products based on a consideration of non-clinical data. In this initiative, Health Canada is moving very far away from the traditional SEQ standard. As has been noted by many authors,[1664] this arguably increases the risk taken on by the public and expands their responsibility for being informed consumers of products. This change came with little improvement in the innovative therapeutic quality of products other than their novelty.

(v) Health Canada's Bioscience Sector Review Roadmaps (2019)

As part of the Government of Canada's *Annual Regulatory Modernization Bill* review[1665] process, described earlier one of the first areas for targeted review was the bioscience sector. In

[1660] *Ibid.*
[1661] *Ibid.*
[1662] *Ibid.*
[1663] *Ibid.*
[1664] *Ibid.*
[1665] *ARMB, supra* note 1638.

Health Bioscience Sector Review (BSR) Roadmap,[1666] published in 2019, the department outlined planned activities to further reduce regulatory burden on the drug review process. The three pillars of the BSR roadmap are: (i) integrating management for new overlapping product categories (like NHP combination products); (ii) global health integration; (iii) and moving towards more agile and dynamic systems of drug approvals.

In Health Canada's own words, changes were needed because of the current pace of innovation, which was placing "challenges to existing oversight mechanisms and scientific approaches."[1667] More specifically, the road map notes that new technologies mean that:

> Pre-market evidence will become less possible as relevant technologies test the idea of sale and manufacture in food and drug [law] and the very concept of products in product regulation. These evolutions in manufacturing and markets create uncertainty about how to identify and manage quality and safety issues through modern regulatory frameworks and approaches.[1668]

This is a clear articulation by the regulator that they are moving away from the existing SEQ standard. It is a clear shift from regulations designed for health and safety to ones designed to sponsor economic and technical innovation. Much of this language draws on concepts found in project management and innovative disruption literature from the tech sector.

Framing the new goals of product regulation, Health Canada has leaned heavily on the advice of the *Economic Strategy Table* (EST)[1669] and their report *Canada's Economic Standing*

[1666] HSBSR, (Health Canada: Ottawa, 2019) online at: https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/targeted-regulatory-reviews.html, herein after *HSBSR*.
[1667] *Ibid*.
[1668] *Ibid*.
[1669] EST, see: https://ised-isde.canada.ca/site/economic-strategy-tables/en.

Roundtable: Health and Bioscience.[1670] This report's primary focus is on the expansion of the bioscience sector to "double the size of the health and bioscience sector in Canada."[1671] The barriers that this report suggests addressing include immediately dealing with complex regulations, risk-adverse procurement, disconnected digital health systems and a lack of executive level talent that impeded the adoption of innovations. The EST puts forward the same argument, that "denial of access to needed drugs"[1672] has its roots in "processes that stifle innovation and hinder the adoption of promising innovations."[1673] The report sees the goals of economic expansion and health protection as mutually supportive, going so far as to propose that Health Canada should pivot to be an "organization to be given a joint health and economic mandate,"[1674] acting as a "health procurement and innovation agency."[1675]

The BSR roadmap also leaned heavily on a report by the Canadian Chamber of Commerce from 2018, entitled *Death by 130,000 Cuts: Improving Canada's Regulatory Competitiveness.*[1676] This report cites the peril of overregulation in the food and drug sector and also highlights the need to "produce more modern and efficient regulatory frameworks, which in turn will promote greater economic growth and prosperity while providing necessary protections."[1677] This report highlighted the need for "non-prescriptive regulatory approaches, including the use of risk- and outcome-based regulations... while reducing compliance

[1670] EST, online at: https://ised-isde.canada.ca/site/economic-strategy-tables/en/tables/economic-strategy-table-healthbio-sciences
[1671] *Ibid.*
[1672] *Ibid.*
[1673] *Ibid.*
[1674] *Ibid.*
[1675] *Ibid.*
[1676] (Canadian Chamber of Commerce, 2018) , https://chamber.ca/publications/death-by-130000-cuts-improving-canadas-regulatory-competitiveness.
[1677] *Ibid.*

burden."[1678] The thrust of the BSR and the Chamber of Commerce reports is that the primary objective of food and drug regulators should be the removal of barriers, because the benefits in terms of innovation and economic growth of these products should be the primary goal of the regulatory system.

This is the full swing of the pendulum of drug regulation back to the innovation and access side. We can see how Health Canada has slowly, over the past two decades, moved from a precautionary model with a high degree of pre-market assessment in the early 2000s to one in which access and economic criteria serve as the key policy drivers. In 2021, Health Canada issued a new guidance on instrument choice, *Instrument Choice Framework for the Canada Consumers Products Safety Act*,[1679] which establishes oversight of new and existing products. The guidance acknowledges the need to, where possible, adopt the use of standards in placing oversight on industry but focuses on the fact that regulation should be the last option in regulating across the products. When assessing the implementation of various regulatory instruments, Health Canada will examine "the potential impacts on economic growth, entrepreneurship and innovation for the benefit of Canadians and businesses."[1680] This guidance highlights that this is specifically to be the case when regulating low-risk products.

[1678] *Ibid,* at 37-38.
[1679] Online at: https://www.canada.ca/en/health-canada/services/consumer-product-safety/legislation-guidelines/guidelines-policies/instrument-choice-framework/summary.html.
[1680] *Ibid.*.

(v) Non-Prescription Drug Action Plan (2022-Present)

In late 2022, Health Canada introduced its *Non-Prescription Drug Action Plan*[1681] to simplify access for non-prescription drugs. The goal of this new program is to advance the concepts of the self-care framework "to reduce burden where possible and align the level of oversight of non-prescription drugs based on their level of risk."[1682] As a starting point, the plan "introduces policy and operational solutions to remove barriers for getting non-prescription drugs to market." This will be followed by a planned amendment to the *FDA* "simplifying market access for non-prescription drug products."[1683] The goals are to "expedite market access for non-prescription drugs"[1684] in order to remove "repetitious and onerous requirements"[1685] and "introduce flexibilities for industry."[1686] The action plan proposes to produce a series of short-term solutions (starting in December 2022), medium-term solutions (targeting end of 2023) and long-term solutions (targeting end of 2024) to implement the changes. Short-term solutions primarily relate to updating labelling and patient information leaflets, while Health Canada has not, as of June 2023, released any details on medium- to long-term solutions. Instead, the website merely states that "we will publish notices about this work once it is completed."[1687] The goal is to "introduce a risk-based approach to regulatory oversight for all self-care products."[1688]

[1681] Online at: https://www.canada.ca/en/health-canada/services/self-care-framework/non-prescription-drug-action-plan.html#policy_and_operational.
[1682] *Ibid.*
[1683] *Ibid.*
[1684] *Ibid.*
[1685] *Ibid.*
[1686] *Ibid.*
[1687] *Ibid.*
[1688] *Consulting SC, supra* note 1064.

Access, innovation, and risk have therefore become inexorably linked to drug regulation in this slow program of deregulation. This has come about, first, by using risk methodologies to quantify the variables to be considered in food and drug regulation. Secondly, it has come about by identifying those priorities associated with benefits as linked to access and innovation. Thirdly, it has developed by defining the risk of many of these products to be low, based on policy considerations about the products' regulatory outcomes rather than scientific data. Finally, the definition and execution of risk-based regulation has sought to remove regulation for many of these products, linking the policy-defined relative level of regulatory oversight to the level of product risk. The ultimate outcome is that a distortion of risk regulation, or regulation proportional to risk, has eroded many of the health standards associated with these products. Holding the *NHPR* regulatory regime up as a triumph also is highly problematic because these products are being regulated with an increasingly pervasive regime designation as low risk, which has generally resulted in little to no actual or effective health protection. This raises the question: what is risk regulation, and how has this framing come about to dominate the policy debate around food and drug regulation in Canada?

Part 2 – Risk Regulation

Linked to all of the models and changes in regulatory practice described in the previous sections is the concept of risk; or rather, the conception that regulatory activity can be rationalized and calibrated based on risk. Braithwaite's compliance model is based on segmentation of compliance enforcement based on the highest and lower risk practices. Responsive regulation focuses its attention on those areas of highest risk to maximize outcomes.

In this conception, to apply more coercion than is necessary to accomplish a public good is a kind of injustice. Smart regulation allows for self and third-party regulation in those areas where the government, notionally, is not best placed to assess or manage risk. Both of these regulatory approaches are often misconceived as being purely about regulatory management techniques. Done poorly, these techniques can be recast as mechanisms for deregulation.

As the government and Health Canada move forward with their transformation agendas, they have increasingly framed regulation as less of a compliance activity and more of a risk mitigation activity. As the government has come to rely more on a concept of "risk regulation," it has become difficult to fully understand what it means by this often-used term. Good risk regulation should involve increased regulatory activity where there is a high degree of uncertainty, as well as reducing regulation when risks are known. Instead, Health Canada has used risk regulation as justification for reduced oversight of compliance for certain products and as a frame for reduced activity and increased permissiveness under regulatory regimes across all self-care products.

In the next section, I will try to unpack the term risk regulation and illustrate the impact it has had on health and safety through regulatory policy. Health Canada has used a variety of terms such as "risk-based," "low-risk," "regulation proportional to risk" and "risk regulation" rather interchangeably. I would argue that Health Canada frequently overlaps these terms and is not clear at setting the parameters around them or clarifying their meaning. I will unpack the term "risk regulation" in greater detail below, but I propose that Health Canada uses the term to describe: (i) the micro-level risks associated with specific products or product classes, such as

the risks and benefits to consumers; and (ii) the macro level at which resource decisions are made in specific areas. At the **micro level,** the regulator must look at clinical science, conduct a risk assessment, assess compliance activities, assess health and safety concerns and make licensing decisions about individual products or product classes. At **the macro level,** regulators, based on data aggregated from the micro level, must make decisions about where to focus regulatory efforts. The micro level can best be thought of as the science underlying the actual safety and benefit of a product. The macro level is the political area of policy-based decisions about government priorities around where to place regulatory efforts.

Calculations at the micro level for therapeutic products and foods are done by calibrating the SEQ standards and making individual approvals or compliance decisions on products. In the case of NHPs, a risk-based approach to licensing and compliance decisions for individual products was discussed in previous chapters. Calculations for the macro level should be based on the evidence gleaned from the micro level, but can also consider a wider set of political concerns as well as other forms of policy considerations. Should HPFB devote more of its scarce resources to NHPD, TPD, or the Veterinary Drugs Directorate? The concept of risk regulation gives the impression that a scientific methodology is being applied to what are policy decisions and that they are based on health concerns, but as demonstrated in the previous section, the concerns are increasingly being dictated by economic policy considerations.

A wealth of literature has been produced about the use of risk in decision making.[1689] In modern political thinking, risk plays a role in "constituting, framing, and structuring regulation

[1689] Blanchmanche, S., Marette, S., Roose, J. and Verger, P., "Do Not Eat Fish More than Twice a Week – Rational Choice Regulation and Risk Communication: Uncertainty Transfer from Risk Assessment to Public" (2010) 12

and regulatory processes."[1690] I will try to stay clear of most of these larger epistemological arguments around the nature and meaning of risk. Fully unpacking the issue of risk in decision-making in modern Western governance frameworks is beyond the scope of this thesis. Instead, I will focus on the concept of risk regulation. This played a key role in framing and normalizing many of the changes we observed in the *NHPR* regulatory regime. Those interested in reading a more detailed discussion about the full role of risk overlaid with regulation I would direct to Julia Black's excellent chapter on *The Role of Risk in Regulatory Process* in *The Oxford Handbook of Regulation*.[1691]

(i) Risk: Some General Concepts

"Risk" has different contextual meanings, and I will delve into those in greater detail when describing tensions between the micro and macro conceptions of risk regulation. However, for simplicity's sake, I will use the definition of risk put forward by Black as "the probability of [an] adverse event occurring multiplied by the impact of that event."[1692] This appears to be a straightforward and uncontroversial statement, yet determining what is considered an adverse event and the criteria to be applied around its impact are a highly subjective exercise.[1693] As Black also notes:

> Using the criteria of the appropriate management of risk as the justification for government intervention into society places a significant premium on finding a consensus

---

Heath, Risk & Society 271 at 272. Taylor, G., "The Reconfiguration of Risk in the British State" (2009) 24 *Public policy and Administration* 379, at 379, hereinafter *Taylor*. Rothstein, H., "The Institutional Origins of Risk: A New Agenda for Risk Research" (2006) 8(3) Health, Risk & Society 215.

[1690] Ibid at 303.

[1691] *Baldwin et al*, supra note 46 at 302.

[1692] *Ibid* at 310.

[1693] *Ibid*.

> as to which risks are selected and how severe (in terms either of probability or impact, or both) they are seen to be.[1694]

Although risks and the criteria which are applied to them can be systematized, their framing is often also a subjective exercise. As a starting point, Black argues that risk regulation is "best seen not as a free standing and technical guide to regulatory intervention but as a particular way to construct the regulatory agenda."[1695] With this in mind, we can see the changes by the government and Health Canada described above as an evolution framed as part of a regulatory agenda related to mitigating risk. How these risks are defined then becomes increasingly important in establishing policy drivers.

In his paper on the reconfiguration of risk in the British state, Taylor discusses how concepts from the "new right"[1696] "argued that risk is not to be feared, but embraced, that it should be viewed in a positive light [as it] stimulates both innovation and creativity."[1697] This change in perception led to a shift in responsibilities for dealing with risks to include "individual citizens as consumers of both products and their attendant risks."[1698] Dodds, in describing the trajectory of these concepts under the Blair government's *Better Regulatory Agenda*[1699] observed that regulating was reconfigured to no longer be about risk avoidance, but instead accepting risk and building greater risk tolerance in society. In this conception, "deregulation is seen as a corrective to regulators' [historic] overreaction to perceived risks, which are stifling economic

---

[1694] *Ibid.*
[1695] *Ibid.*
[1696] *Ibid.*
[1697] *Taylor, supra* note 16.
[1698] *Ibid.*
[1699] Dodds, A., "The Core Executive's Approach to Regulation: From 'Better Regulation' to 'Risk-Tolerant Deregulation" (2006) 40(5) *Social Policy and Administration* at 526.

and scientific progress."[1700] In this concept, accepting increased health risks is the cost of sponsoring greater innovation in health care.

Part of this reconfiguration involved reframing the public's and media's conception of risk as unfounded. Instead, proponents of new regulatory models:

> Stressed the dangers flowing from the public's irrational overestimation of risks, the impossibility and undesirability of a risk-free society, and the need to regulate so as to allow business to take and create risk in a way that allows economic progress to be made.[1701]

The public's risk tolerance needed to be expanded, and the public needed to be willing to take on more risk in exchange for economic progress. As Black concludes, this led to "a new risk-tolerance policy approach and an emphasis, not on better regulation as functionally improved regulation, but better regulation as less regulation."[1702]

In his article *Revolution Blues: The Reconstruction of Health and Safety Law as 'Common-Sense' Regulation*,[1703] Almond argues that the adoption of common conceptions of risk in regulatory settings is part of a larger program to "reframe the debate about the form that regulations ought to take"[1704] in health contexts. He observes that risk regulation is actually the product of a process of liberalization that:

> Creates a new orthodoxy of 'common sense' regulation which sets parameters around what is possible and permissible in terms of future policy, and which excludes alternatives that do not confirm to this model.[1705]

[1700] *Ibid*.
[1701] *Baldwin et al*, supra note 46 at 268.
[1702] *Ibid*.
[1703] (2015) *Journal of Law and Society,* 42(2).
[1704] *Ibid*.
[1705] *Ibid*.

A common sense conception of health regulation, much like the conception that the public are not good custodians of the conception of their own risk, espouses deregulation and risk-taking as desirable. Almond sees the recasting of the common sense health deregulation as a series of intentional steps by policymakers: (i) casting the scope of health regulation as unreasonable (health and safety gone mad), (ii) a financial rationalization of the regulatory area that pulls funding out of the health system and then ask regulators to do more with less (the financial rationalization of health resources) (iii) a selective process of consultations, often with industry, that re-affirm the need to curb regulatory over-reach (a red tape reduction agenda), and (iv) finally, a process of implementing a reduced regulator agenda (deregulation). The ultimate goal is to move "health and safety policy-making from political debate about the relative merits of regulation and towards the acceptance of taken-for-granted truth-claims [around normative risk] which exist beyond politics."[1706]

In 2008, Mary Wiktorowicz[1707] examined the start of the risk agenda being proposed by HPFB and was similarly skeptical. Wiktorowicz believed it represented a:

> shift from a comprehensive approach to public health protection to one based on strategic risk management, with responsibilities dispersed among government, industry, academia and consumers. The rebalancing of goals in the redesign of the regulatory process suggests a change in the role of the state in the context of public-health protection and highlights issues of concern to the public interest.[1708]

Like Abraham, she noted that the introduction of a new regulatory agenda starts with the 1994 program review of the then Liberal government, which removed 50% of the Health Protection Branch's (HPB) budget. The HPFB went from running product review programs with $249

[1706] *Ibid*
[1707] *Shifting Priorities, supra* note 848.
[1708] *Ibid*.

million in 1993-94 to $153 million in 1999-2000. HPFB went from proactively managing scientific programs which generated data on new drugs to rationalizing drug reviews and having to "rely on industry and external experts as a source of knowledge and expertise" [1709] to generate health and safety data. This scarcity required the introduction of cost recovery, billing product applicants for reviews, and the reframing of drug reviews as projects delivered for clients with performance standards. Delays became a backlog or red tape to the paying customer, not prudent analysis.

Wiktorowicz observed a "common sense shift" as another feature of the new risk agenda, where "[how] drug reviews are conducted … shifted from an anticipatory approach based on full-scale analysis to a reactionary one in which a product is considered safe until proven dangerous."[1710] As noted elsewhere, this is a shift from products being considered potentially harmful until proven safe (a Type I error) to products being considered safe until proven otherwise (Type II error). It was better to approve a product than to not approve a product. Utility should be assumed until it is proven otherwise. Again, this shifts the locus of risk from precautionary to one based on verifiable risk. Wiktorowicz expressed concern that accountability and responsiveness were being "re-defined from a focus on public health to the promotion of industrial competitiveness and responsiveness to the imperatives of industry."[1711] The risk was now how health and drug regulation would affect industry. She concludes by speculating that the public is likely "uninformed of [these] significant policy reforms,"[1712] that risk trade-offs are being made in food and drug regulation and that the public would "largely [be] unwilling to

[1709] *Ibid.*
[1710] *Ibid.*
[1711] *Ibid.*
[1712] *Ibid.*

accept the compromises to public-health protection that make the regulatory framework more responsive to industrial competitiveness."[1713]

(ii) **Risk Regulation: The Micro Level**

As was noted earlier, risk regulation has generally had two distinct meanings which are often conflated. The first is how the general societal risks of any activity are quantified and regulated. I am calling this the micro-level risk regulation, which includes specific risk decisions that regulators must take concerning therapeutic products or food. This includes the framework and methodology which is used by a regulator in making risk versus benefit judgements, as well as the individual decisions that are made by product reviewers in determining whether to approve a product. These two decision-making processes, one to standardize decisions and the other the actual decision, are intertwined and should guide each other. Methodologies for risk assessment by reviewers are found in policy and common practices, while the information gleaned from these individual risk assessments should inform institutional standards.

As noted by several authors (Avorn),[1714]the regulation of any drug is inherently a risky endeavour. Osimani observes that "there are cases where risk cannot be avoided or uncertainty reduced; for example the side effects associated with pharmaceutical products or when a decision about drug approval or withdrawal has to be made on the basis of available evidence."[1715]

[1713] *Ibid.*
[1714] *Avorn, supra* note 44.
[1715] Osimani, B., "Pharmaceutical Risk Communication: Sources of Uncertainty and Legal Tools of Uncertainty Management" (2010) *Health, Risk & Society* 12(5) 453 at 454, online at: http://www.tandfonline.com /doi/abs/10.1080/13698575.2010.509493, hereinafter *Osimani.*

Osimani outlines the nature of risks and their attendant uncertainties that must be addressed in pharmaceutical decision making. As a starting point, she notes that therapeutics are "credence products" which are "purchased [by the public] with little or no direct appraisal of their quality."[1716] Consumers rely upon the regulator to provide an evaluation of the product's utility, and in exchange, the state maintains a monopoly on the legal mechanisms which permit the entry to the market.

Osimani identifies three points, or sources of risk, associated with any medicines. The first is product opacity because products at the point of sale reveal little about "the effect they will have in the human body."[1717] In order to resolve this **opacity**, regulators gather "insights about drug effects indirectly acquired through theoretical knowledge and empirical investigations of various evidential [information] through (phase I–IV [clinical] studies)."[1718] The second is product **ambiguity** in that any drug can "both promote and endanger health."[1719] Drugs, including NHPs, are selective agonists that should target an illness but can also have effects on the other systems in the body. Finally, there are uncertainties related to the **effects** that any drug may have on an individual because "both drug efficacy and risk are strongly dependent on the individual's [unique] susceptibility to the drug."[1720]

Historically, these risk issues are resolved for drugs by the use of fairly robust systems of clinical testing and the SEQ norm, a risk assessment at the regulator and the intervention of

[1716] *Ibid.*
[1717] *Ibid.*
[1718] *Ibid.*
[1719] *Ibid.*
[1720] *Ibid.*

health-care practitioners (doctors and pharmacists) in prescribing the product. Assessing utility and exposure in a large population through clinical testing allows for the regulator to pronounce on opacity. Assessment by experts at the regulator, who use standardized methods for evaluating the scientific evidence, should adjust for the product ambiguity to be resolved. As Osimani has argued:

> the complexity and contradictoriness of data documenting drug efficacy and risks, the conflict of interest affecting the principal investigators of chemical entities and information deliverers (pharmaceutical sponsors), as well as time constraints, can be considered as the origin of much discontent about how pharmaceutical decisions are taken both by responsible authorities and the pharmaceutical industry.[1721]

Ongoing safety monitoring should help with the potential for unforeseen risks. These are not perfect measures, and they are subject to distortion by industry data and political considerations. The result is that these products always will carry a degree of **residual, or unsolvable, risk**. A large part of the risk decisions about these products is deciding who will bear this residual, unknown, risk: industry, the regulator, or the consumer.

Aligned with the concept of residual risk is the relative risk tolerance of regulators, politicians, and the public. Mitigating the tensions in the system between industry interests in having products on the market as fast as possible and the potential health and safety risk to consumers of the products is one of the major roles of the regulator. As Daemmrich[1722] notes, this leads to "risk versus risk trade-offs." The result is that drug "regulation requires risk-taking by regulatory agencies because both too rapid and too slow approvals are criticized as

[1721] *Ibid*.

[1722] Daemmrich A., and Krucken, G., "Risk versus Risk: Decision Making Dilemmas of Drug Regulation in the United States and Germany" (2010) 9(4) *Science as Culture* 505, online at: http://www.tandfonline.com/doi/abs/10.1080/713695270.

harmful."[1723] Regulatory agencies and governments will always bear "political risk of public criticism and legal challenge [which] cannot be avoided, since the consequences of each possible regulatory action – approval, delay, or non-approval – are only fully realized in retrospect."[1724]

To resolve this issue, regulators rely upon the technocratic process of risk-benefit assessment, which notionally is an impartial method for assessing available data. There are a host of different methodologies used in drug risk-benefit assessment. Many of these have proliferated in the last three decades as elements of new methods to quantify the decision-making process for drugs. Demortain argues that this was a result of regulators needing to rationalize their failure to identify drug safety issues (as unknowable risks) and demonstrate the constraints of what can prospectively be known about drug safety (the knowable unknowable risks). As Demortain further notes, this represents an:

> historical move from qualification to imputation, from safety evaluation to risk evaluation [where] law and practice [have] turned much less positivistic. It has embedded product evaluation in the idea that there is no definitive certainty concerning quality and safety of products, given their intrinsic uncertainty concerning quality and safety of products, given their intrinsic complexity, the ways they circulate, the conditions in which they are prepared and used and their interactions and accumulation in the environment.[1725]

As Demortain further notes, the adoption of risk methodologies is part of the general "rise of a political risk-management agenda [whose] objectives are inseparable from a form of blame-avoidance action."[1726]

[1723] *Ibid,* at 507.
[1724] *Ibid*.
[1725] Demortain, D, *Scientist and the Regulation of Risk – Standardizing Control* (Edward Elgar Publishing: Cheltenham, 2011).
[1726] *Ibid* at 96.

I will not fully explore the criticism of the inputs and output of this process for drugs, having briefly raised these concerns earlier, namely those related to the quality of clinical data, industry influence, and robustness of criteria considered. It is important to remember that many critics argue that much of the processes around risk categorization are portrayed as bringing a layer of objectivity to decision making, but often are subjective political or policy decisions around risk. As Rothstein notes, we are "no longer simply concerned with the governance of risk, we are now in an era of governance by risk."[1727] We have a "technocratic, decisionistic, and economic model of risk-assessment management"[1728] that makes assumptions about the implications and applications of risks. Modern risk-management practices are often self-referential and "miss the institutional 'irrationalities' that shape officials' perceptions of risk and associated behaviour."[1729] As Renn notes, what develops is a form of "collective understanding among all stakeholders and the concerned public on how to design procedures of justifying collectively binding decisions on acceptability and tolerability which are considered legitimate."[1730]

The methodologies for risk-benefit assessment for drugs are discussed extensively in the literature. Kurzinger[1731] does a good job of mapping out the various steps commonly employed in the quantitative benefit-risk assessment process commonly used by regulators around the world. It usually involves a quantification stage, gathering data, classifying evidence, identifying

[1727] *Rothstein,supra* note 1689.
[1728] Renn, O., Klinke, A. and Van Asselt, M., "Coping with Complexity, Uncertainty and Ambiguity in Risk Governance: A Synthesis" (2011) 40 *AMBIO* 231 at 234, online at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357789/, hereinafter *Renn.*
[1729] *Rothstein, supra* note 1727 at 85.
[1730] *Renn, supra* note 1728 at 242.
[1731] Kurzinger, M. L., "Structured Benefit-risk Evaluation for Medicinal Products: Review of Quantitative Benefit-Risk Assessment Findings in the Literature" (2020) *Ther Adv Drug Saf*. 8(11).

favourable and unfavourable outcomes, organizing or presenting this data, and then making a value judgment.[1732] The value judgement itself must assess the relative value of the specific risks and benefits to make a judgement. This judgement itself, although based on quantitative data, can often be considered qualitative. It is an imprecise science and very open to variance amongst specific reviewers, agencies, and even jurisdictions. At least in the case of drugs, there is a lot of risk data generated (good or bad) upon which to make these decisions. Much of the history described earlier around the development of the SEQ standard, often as a result of very public health disasters, is a result of regulators recalibrating the law and standards to control for unknown risks.

In the context of foods, risks are mitigated by reducing the overall unknowns associated with the product for consumers. Strict *ex ante* standards around composition and labelling make what is sold as a product, theoretically, free of adulteration or harmful content. This is backed by a robust system of *ex post* inspection and monitoring by the CFIA. Manufacturers are legally liable for the quality of their products. Product opacity and ambiguity are removed by providing assurance that the products have the mandated composition so that they are the food stuff they purport to be.

For other product classes, such as medical devices, a stratification based on known *ex ante* risks was developed. This classification system is based on (i) the intrinsic risk; (ii) the use to which the device will be put; and (iii) other criteria which may make a product more risky (puncturing the dermis, surgery being required, supporting a core bodily function – such as a

[1732] *Ibid*.

pacemaker).[1733] These criteria were developed after extensive consultations with external advisers and based on observable scientific criteria. Medical device regulators quantified the risk associated with opacity and ambiguity and used these to develop a varied licensing regime. Similarly, regulation for other product classes, such as radiopharmaceuticals and biologics, will have targeted risk procedures, procedures on handling of radioisotopes, and testing for each batch of biologics that are designed to address the specific risks of each type of product.

In the case of traditional NHPs, the safety and quality considerations of risk are adjusted to existing history of use and placing the product within an existing system of belief. In this case, the reputational risk for regulators associated with not respecting cultural and traditional belief likely outweigh any concerns related to health risk, except in the case of known carcinogens (e.g., St. John's Wort). The regulator is passing the credence risks for NHPs on to existing traditional information, and provides very little direct efficacy or safety oversight. This calculation will not always hold, as in the case of homeopathics, when the pressure from the public or media may push the regulator to vary licensing conditions. In this case, mitigation was additional labelling, but not increased evidence on efficacy.

For non-traditional NHPs, the SEQ standards used in risk-based assessment are already reduced when compared to the SEQ standard for drugs. Efficacy is generally lacking, safety is dependent upon a history of use, defined safe ingredients or tradition, and quality is based on self-attestation with little post-market inspection. This, in turn, means the various risks described by Osimani (opacity, ambiguity, and individual specific effects) are also hard to resolve. NHPD

[1733] *Ibid*.

does apply a similar risk-based methodology as TPD to product assessment, but meaningful questions of efficiency are removed from the risk criteria for most products. They are still credence products, as the public relies on regulators' review of risk to validate that the products have merit. Yet opacity (does the product work) and ambiguity (what are the benefits vs. risks in the body) are generally not considered. This leads to the question of what criteria are being used to validate the merit of NHPs. Additional labelling that indicates products are not scientifically reviewed by Health Canada would be clear indication these products are distinct from drugs.

For new NHPs, the intent was for NHPs to have an assessment that was based on available evidence of efficacy paired with known existing information gathered in NHPD monographs. The original description of a risk-based approach for NHPs related to their compliance strategy during the transition period, and the 2006 guidance, *Evidence for Safety and Efficacy of Finished Natural Health Products*,[1734] where they described a "risk-based approach" to enforcement by the HPFB Inspectorate. The guidance is very clear that a risk classification system will be

> **an evidence-based approach that classifies a product into a level of risk based on relevant information** from published and unpublished sources such as, but not limited to, journals, textbooks, reports from regulatory bodies, etc. The evidence will primarily be from experience of the product or ingredient in humans, but may also include relevant information, when necessary, from animal studies.[1735]

NHPD focused regulatory approvals on several categories of products for priority evaluation Similarly, HPFB compliance activity was to be based on those unlicensed NHPs which posed the greatest risk. These criteria were based on an ascending decision tree with the greatest health and

[1734] *Supra,* note 1393.
[1735] *Ibid.*

safety risk that could be posed by unlicensed NHPs.[1736] If HPFB Inspectorate identified a product for compliance activity and "the risk cannot be comprehensively determined by following the above assessment, NHPD will perform a health hazard evaluation/risk classification as requested by HPFB Inspectorate."[1737]

Due to the high volume of NHP applications, for new products there was pressure to shift the risk associated with these products. With the *UPLAR*[1738] regulations we see a shift in how the risk quantum around NHPs is framed. The greater risk is now associated with products not being licensed and addressing a "backlog." The *UPLAR* regulations were accompanied by process changes and new guidance designed to speed up approvals. The Parliamentary Secretary of Health at the time noted these changes would improve efficiencies and "allow industry to grow, while still assuring consumer safety and access to a wide range of authorized health products."[1739] The locus of risk shifts to the barriers stifling economic growth and consumer access. Product reviews would now be reviewed based on three new classes: (1) applications fully drawing on a monograph; (2) those drawing on a monograph with amended claims or additional information; and (3) and those requiring a full assessment of the product. The first two classes of products would only require a partial assessment. Around the same time, NHPD began to replace monographs with the term "pre-cleared information" (PCI) or existing approvals, meaning that any products (or component thereof) previously approved would *de facto* meet

[1736] *Ibid*. These criteria included: (i) does the product have an existing DIN (i.e. is it a drug that is now an NHP), (ii) is it being licensed under the Special Access Program as a drug, (iii) is the risk mitigated by the intervention of a practitioner, (iv) does the product have prohibited ingredients listed in Schedule F of the FDA, (v) does the product make a prohibited Schedule A claim, is the product intended for children or pregnant women, (vi) is the product a sterile dosage; or (vii) does the product have an ingredient that is prohibited by the *FDA* (Part a sections 8, 9, 10).
[1737] *Ibid*.
[1738] *UPLAR, supra* note 1016.
[1739] *Ibid*.

monograph criteria. During this time, NHPD also began to circulate a newsletter that focused on the rate at which it was addressing the "backlog," largely addressed to industry.[1740]

With the *UPLAR*[1741] regulation, there was new guidance issued for the *Pathway for Licensing Natural Health Products Making Modern Claims* (2012)[1742] that set out new risk criteria to be considered in applications. The new guidance sought to quantify risk by ensuring "the levels of evidence are rigorous enough to protect public health and maintain consumer confidence, while providing industry with a clearly defined pathway to bring products to market."[1743] The new guidance would measure safety and efficacy using a "risk-based approach" related to potential risks in : (i) ingredients' physical or chemical **form**, (ii) **seriousness of the health claim** and conditions of use implied, and (iii) the health **impact of lower than expected performance** of the product. This reframes the risk associated with NHPs towards the relative risk of the product not working.

As credence products, NHPD is accepting that there will be a certain amount of acceptable risk from false claims for NHPs, so long as they relate to conditions which would be expected to "naturally resolve in a timely manner or for which lower than expected performance of the product should not pose a major risk."[1744] The new guidance also accepts general health claims for NHPs with a similar level of evidence as that required for traditional medicines (two

[1740] *Ibid.*
[1741] *UPLAR, supra* note 1016.
[1742] *Supra* note 1046.
[1743] *Ibid.*
[1744] *Ibid.*

references). This also opens the door to products making a host of unproven general health claims.

There is an acceptance here by the regulator of products making low-level or general health claims which are misleading. The removal of a burden of proof for these products does not have the same cultural or belief-based risk associated with traditional medicines, yet they are being treated the same. This is hard to justify if your primary risk concerns are related to consumer interest and public health criteria. Instead, it is a fairly strong admission of or justification for completely ignoring Type 1 error (licensing products with no merit). This relocation of risk tolerance only works if there is a significant change in the primary criteria driving the risk calculus to access and innovation. Yet, we know from elsewhere in this thesis that the drive producing a "backlog" of products was an avalanche of new license applications for existing products (cosmetics, energy drinks, and fortified foods) taking advantage of the *NHPR* to make previously prohibited health claims. These health claims had previously not been allowed for new products because they were unfounded, unsafe, or explicitly prohibited under other regulations. This shift in risk locus was nowhere more evident than when the Minister of Health decided to ignore the risk recommendation of their own expert scientific panel on energy drinks and license them as food because they were "low-risk."

The *UPLAR*[1745] regulations were also aligned with a new "risk-based approach" to compliance and enforcement. Health Canada piloted a targeted compliance strategy to only a few manufacturers deemed high risk. However, as noted by both internal auditors in 2015 and the

[1745] *UPLAR, supra note 1016.*

OAG in 2021, the majority of sites reviewed by this risk-based approach failed to meet GMP requirements. This was compounded by an observation that the risk criteria used to determine "risk" were not mapped to probable cause of non-compliance, such as a history of non-compliance, products manufactured for high-risk populations, or making specific claims for high- or medium-risk products (e.g. treating COVID-19 or diabetes).

If Health Canada was implementing risk regulation, it was very poorly structured risk regulation. The result of the new risk-based compliance policy was the creation of a system that was purely reactive where "gaps in the oversight of manufacturing sites and in the monitoring of products once on the market left consumers exposed to potential health and safety risks."[1746] This was compounded by the fact that "Health Canada does not have the authority to order a change to a label or force a mandatory recall of a natural health product for any reason, including when a product presents a serious or imminent risk of injury to health."[1747] Even in those cases where risks were identified, compliance responses from manufacturers were low and generally involved an exchange of letters, with no change in behaviour from the manufacturers.[1748]

These enforcement measures were framed by Health Canada's new *Compliance and Enforcement Policy Framework,*[1749] which encouraged a variety of different actions to deal with non-compliance – most short of actual removal of products from the market. What results for NHPs is likely a shift of risk from *ex ante* to *ex post* market enforcement, with little justification for the products being on the market and making claims in the first place. This led to an updated

[1746] *OAG, supra* note 29.
[1747] *Ibid.*
[1748] *Ibid.*
[1749] *Compliance Framework, supra* note 1063.

Compliance and Enforcement Policy for Health Products[1750] (including NHPs) in 2018. The guide also claims to be risk-based and notes that expanded risk-based compliance actions include compliance promotion (raising awareness of obligations), compliance monitoring (monitoring compliance pre and post licensing), and enforcement. Both the updated Health Canada and HPFB compliance policy also conflate consumer choice, likely by assessing labelling, with the ability to assess opacity and ambiguity of products. Under compliance promotion, it is noted that "consumers also have a responsibility to educate themselves when buying health products."[1751] Consumers always have a high degree of asymmetry in knowledge, possessing less knowledge than regulators and product manufacturers about the risks of a product.

With the self-care framework, a new conception of risk is again introduced. Now, risk is quantified by how product choice is made (self-care), associated with a simplified criteria around claims being made. Self-selection is seen as a proxy for history of use and lower-level general claims are seen as low risk. The result is a proliferation of personal care products (cosmetics, hygiene products) making unproven health claims. I can walk into my bathroom and find a mouthwash that claims to "fight plaque, gingivitis, and bad breath," a shampoo that "refreshes and energizes," a toothpaste that is "gum detoxifying," disinfectant wipes that "kill 99% of viruses and bacteria," and a hand cream with a "plant-extract formula that immediately moisturizes skin." None of these claims have been proven *ex ante* of the product coming on the market, and most are unlikely to be based on science. In this case, it is an economic set of risks

[1750] *Health Canada, Compliance and Enforcement Policy for Health Products,* (Health Canada: Ottawa, 2018), online at: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement.
[1751] *Ibid*.

that drives the "risk-based" system which has evolved to allow these products on the market while making these claims for unsubstantiated health benefits.

The intrinsic nature of the product, the validity of the claims being made, and its conditions of use are secondary to whether it is making a structure function claim. As noted elsewhere, this new risk-based system is not based on scientifically observed risk, but on a conception that general function claims can be made with low impact of failure. These cease being credence products validated by the regulator, while they continue to have credence in the eyes of the public, but this is not warranted based on the level or regulatory assessment of SEQ. It is likely that the risks, aside from those related to confusion and fraud with the public, are low for many of these products. Yet regulators have removed much of the need for SEQ assessment of products for little public health gain. As the self-care system expands to include other product classes, notably OTC drugs, which are intrinsically (by chemistry and nature) risky, this risk-based approach starts to become more problematic. It also starts to place a much greater risk on the public and these products start to lose safety credence, as will the regulator if there is a significant increase in ADRs.

Health Canada asserts that the risk-based approach to NHPs is an example which should be reproduced, but what has happened is a shift to risk criteria based largely on abandoning parts of the SEQ assessment of these products. This does not make much sense unless we recognize the larger regulatory reframing that was described earlier in this chapter to recast the purpose of the risks and benefits of health regulation towards access. There is little additional information which justifies the explosion of new products making dubious health claims other than a desire

to sponsor economic growth. Yet this is hardly a framing of products based on ensuring that they are "safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity."[1752] It is a political decision to focus the risk goals of the NHPD towards access and economic goals.

(iii) Macro Risk-Based Regulation

At the macro level, regulators have increasingly relied upon the rationalization of regulatory activity based on directing resources towards those areas of regulatory activity which notionally have the greatest risk.[1753] At HPFB this has continually been an issue since it lost a high portion of its funding during strategic review. As discussed earlier, risk regulation as a concept is a product of a long history, beginning in the U.K., to rationalize regulatory activity. As Baldwin notes, "the essence of risk-based regulation is the prioritization of regulatory action in accordance with an assement of the risks that parties will present to the regulatory body's achieving its objectives."[1754] Because of economic rationalization, regulators' activities are limited by capacity and it is desirable to allow for other instruments to target activity of lesser need. In so doing, the focus is on achieving the control of the most relevant risk even if this means "not securing [full] compliance with a set of rules."[1755] Essential to this activity will be the measures put in place to frame what the priority risks are for compliance activity in any regulatory system. This leads to the question of what will be used to prioritize regulatory risk.

[1752] *Approach, supra* note 15.
[1753] *Shifting Priorities, supra note* 848.
[1754] Baldwin, R. and Black, J., "Driving Priorities in Risk-based Regulation: What's the Problem?" (2016) 43 *Journal of Law and Society* 565.
[1755] *Ibid*.

Baldwin defines a common set of criteria that will be used when regulators seek to implement risk-based regulation. The first is that a regulator must "clearly identify its objectives and the risks."[1756] Normally this would be articulated as a set of mandate or policy goals. In a science-based regulatory area such as food and drug law, this would also require gathering evidence on the actual risks through experimentation or valid compliance data. Secondly, a regulator should develop a system to quantify risks between regulatory programs. This usually involves creating some form of risk-scoring system or mechanism for quantifying risks and benefits associated with a product. Cost-benefit analysis has tended to be the micro-level tool used by regulators in making these decisions. Next, regulators must make decisions to quantify the various observed macro-level risks and benefits. (As discussed earlier in this section, this has tended to be a quantification in health regulation of public health versus economic risks).

Often risk-based decisions are quantified as a form of objective calculus where the degree of regulatory activity and resource allocation can only be "limited to the justifiable…supported on the basis of a systematic and transparent analysis."[1757] Yet, it is noted by Baldwin et al. that this is not an objective analysis; there is a high degree of rhetorical and political input:

> Experience, however, has revealed that risk-based frameworks are not neutral, technical instruments. Each aspect of a risk-based framework involved a complex set of choices and evaluations on such matters as the risk to be focused on and how such risks are to be defined. Risk-based regimes also demand that the regulator makes decisions on the risks that it will not prioritize… The result is that, in practice, a regulator's risk tolerance is often ultimately driven by political art than technical application.[1758]

[1756] *Ibid.*
[1757] *Ibid.*
[1758] *Baldwin et al, supra* note 46 at 282-283.

This political distortion can lead to distortions that can occur in poorly executed risk-based regulation. The first is how risk will be grouped or bundled in framing where to place efforts. More often than not this will require reference to past cases of non-compliance and focus on areas of political regulatory concern.

By significantly reducing compliance activities without increased information on harms, Health Canada's conception of risk-based regulation makes an assumption that risk, as currently defined, will remain static. As the collapse in the financial sector in 2008 showed, regulatory systems purely based on a few defined risks may ignore the larger systemic or emerging risks. A similar case could be made for the risk evaluations of opioids, which based on strict SEQ standards and risks only associated with product efficacy, ignored the much larger risk associated with additional social stress which followed. There is a danger when risks in a regulatory resource context, such as NHPD's, are based only on existing or known variables. Institutional bias will also distort the frame applied to risk in many given situations. Industry will generally seek to minimize the range of risks with regulators. Regulators may also limit these risks to simplify or manage the actual day-to-day activities of a resource-strapped regulator.

Baldwin et al. partially provide an answer to addressing these issues by raising the idea that any risk-based regulatory regime needs to be paired with a system of active generation of data on compliance and harms that exist "off-the-screen" when they propose a model of really responsive regulation.[1759] Any system of risk regulation where the "risks" are assumed *a priori* and not assessed on a regular basis is likely to underestimate unknown risks and rely on existing

[1759] *Baldwin et al*, *Really Responsive Regulation* at 269.

risks. This can lead to a systemic bias that does not seek out new sources of information and calibrate regulation accordingly. This is particularly problematic in cases like Health Canada, where risk regulation is defined based on a very weak empirical foundation of defining the risks and benefits of NHPs, and where compliance activity has consistently been seen as weak, ineffectual, and only responsive. As Baldwin et al. note:

> It is, after all, only through performance sensitivity -- by knowing the reliability of its detection (and, indeed, other [detection] procedures) – that it can form a view on such matters as levels of compliance and the balance between activities that are covered by regulation and those that escape the system.[1760]

Without this performance sensitivity, risk regulation can become simply a rhetorical exercise, or risks can become primarily related to criteria that are political. In the case of food and drug regulation this often means a swing towards emphasizing the risks and benefits derived from the economic goals of the regulated industry. This in turn may mean de-emphasizing the health risks and benefits associated with products, or in the case of NHPs, simply not effectively assessing them.

Politicians can be seduced by the promise that risk-based regulation is an objective way that the "complexities of regulation can be rationalized, managed and controlled."[1761] Risk-based regulation and its methods "suggest that the notoriously complex task of regulating can be rendered manageable, and that the contingencies of unpredictable events can be made controllable."[1762] In fact, risk-based regulation often involves political decisions about those areas which will not be regulated or at least under-regulated. Making these decisions, politicians and regulators are:

[1760] *Ibid*, at 272.
[1761] *Ibid*.
[1762] *Ibid*.

> Choosing which risk to focus on, [which] as noted above, [is] a political, not a technical issue, and judgements have to be made on such matters as: whether to target the largest risk or the places where the largest risk reductions can be effected for a given level of resource input; whether to focus on individual risk-creators or specific types of risks; the right balance between acting on systemic risks and controlling individual risks; and ultimately what is an acceptable level of risk.[1763]

Structuring decisions around risk requires "buying into a particular conception of the problem at hand. It leads to the framing of solutions in a particular way, and produces special challenges of justification and legitimacy."[1764] This includes creating implicit assumptions about the "limits of a regulator's responsibility and hence accountability."[1765] When regulatory failures occur, or the limits of regulatory oversight come to the public's attention, these rationalization decisions "can be difficult for regulatory managers to justify to the public and regulatees"[1766] if risk criteria were not enacted with enough transparency or were based purely on political motives.

For regulators employing risk in this way, there is a clever trick here. Risk can be used as a framing mechanism, but often without objective measures to scope and define a regulator's role. It is a process of political rationalization that may have the appearance of being a technical exercise of rationalization. In the case of drugs and NHPs, political decisions about the locus of control and purpose of food and drug regulation have been seen as shifting the axis of intervention from pre to post market. It has shifted from robust pre-market assessment of SEQ to reduced standards to ensure access and innovation. This is portrayed as part of a technical quantitative process of regulatory rationalization, but it is in fact a qualitative adoption of political assumptions about the purpose of food and drug regulation. In a study by Hood,

---

[1763] *Ibid.*
[1764] *Ibid.*
[1765] *Ibid.*
[1766] *Ibid.*

Rothstein and Baldwin,[1767] they found that the driver for most risk regulation across a variety of sectors was related directly to the "interest of the most powerful players"[1768] in the regulatory field. This was directly correlated with the fact that the "interest-driven explanation was the most accurate overall predictor of the content of a risk regulation regime."[1769] For NHPs it is likely that the conception of these products as low-risk is largely driven by the activities of large to medium NHP manufacturers.

As I noted in previous chapters, the main driver behind the evolution of the regulatory system for NHPD since 2010 has been introducing products to the market. Few NHPs are truly innovative therapies, but they do represent a huge market for Canadian manufacturers and importers. Designation of these products as low-risk allows for the introduction of a regulatory system with *deminimus* standards of SEQ. At the same time, it allows for the maintenance of a regulatory system that has the appearance of a set of health and safety regulations that gives credence to these products. It is credence that these products likely do not deserve if we base their merit on actual SEQ. In any case of risk-based regulation, the macro risk must be clearly defined and the risk-benefit trade-offs that regulators are making should be clear to the public. Similarly, any macro risk-based decision should be based on a strong foundation of micro risk data.

In the case of NHPs, we know that there is in fact little SEQ data generated for products pre or post market upon which to make valid risk allocation decisions. Instead, the government

[1767] Hood, C., Rothstein, H., and Baldwin, R., *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford University Press: Oxford, 2001).
[1768] *Ibid*.
[1769] *Ibid*.

has repeatedly merely decided to deem these products as low-risk. Or more likely, as demonstrated in the case of energy drinks and self-care products, the government decided to favour industry conceptions of risk over existing health goals or robust analysis of health risks and benefits.

CHAPTER 9 – CONCLUSION

In Budget 2023[1770] the Government of Canada announced its intention to introduce amendments to the *FDA* that would extend the legislative measures brought in by *Vanessa's Law* to cover the *NHPR*. As noted in the announcement, "these changes would protect the health of Canadians by enabling regulators to take stronger action when health or safety issues are identified with natural health products on the market."[1771] This likely means that the expanded powers to compel information, impose post-market conditions, and force products from the market that exist for drugs will be extended to NHPs. As noted in Chapter 1 and by Fierlbeck et al.[1772] the powers introduced by *Vanessa's Law* have been imperfect but it is progress that the government is finally extending these measures to include NHPs.

The proposed changes in the *Budget Implementation Act* (BIA)[1773] remove the exemption for NHPs from the definition of therapeutic product under s.2. The definition of therapeutic product now reads (with struck-out sections):

> therapeutic product means a drug or device or any combination of drugs and devices, ~~but does not include a natural health product within the meaning of the Natural Health Products Regulations~~[1774]

This change allows for the use of the provisions of *Vanessa's Law,* captured in Section 2.4(1)-(5) of that act, that give the Minister authority to deem a therapeutic product a drug, food, or

[1770] See *Budget 2023, supra* note 1644.
[1771] *Ibid*.
[1772] *Ibid*.
[1773] *BIA 2023, supra* note 242.
[1774] *Ibid*.

cosmetic for regulatory purposes. This means that applicants can no longer take advantage of employing the lower bar of the *NHPR* for combination products to seek licensing. Surprisingly, the *BIA* excludes NHPs from the application of Section 21.31, which is the Minister's power to compel the "holder of a therapeutic product authorization to conduct an assessment" and Section 21.32, the Minister's power to require additional tests or information to obtain additional information about a therapeutic product's effects on health or safety. The other provisions of *Vanessa's Law* are retroactively extended to cover all licenses that "were issued, before the day on which this section comes into force…[that authorize]… the import, sale, manufacture, packaging or labelling of a natural health product."[1775]

These proposed changes are a response to the 2021 OAG audit, and in particular its strong criticisms of the NHPD's extremely weak post-market compliance monitoring and enforcement regime. The fact that many non-compliant products and site licenses simply ignored the NHPD should be addressed by these amendments. On the other hand, the amendments do not address other issues raised by the OAG, along with earlier audits, related to how passive and ineffectual the NHP compliance monitoring and detection regime has been. It also does nothing to address the weaknesses in the licensing regime. While well intentioned, these changes may be arriving at a stage where much of the broader NHP regime needs reform if it is to achieve any effectual health outcomes. Additionally, it may be observed that the changes are, at a minimum, a decade late and do not address many of the structural or operational issues related to the *NHPR*.

[1775] *Ibid*.

If we step back and assess the regulations and their implementation, the overall picture is not favourable. A close examination of the *NHPR* suggests that as credence products, NHPs suffer from a credibility gap. Repeated audits have found that the quality of these products cannot be assumed. At its basis any health product regime should be able to ensure that adulteration is absent and that the product is what it purports to be. Many of these products were observed by auditors to be adulterated at rates that have not been seen in foods or consumer products since the early 1900s. In assessing the few sites chosen for inspection (only 6%) the OAG found that all 46 had issues with GMPs.[1776]

Intended to be a parallel to the drug regime with accommodations for traditional and cultural practices, these regulations have evolved into a system used largely to support non-traditional products with a very low bar of evidence. Efficacy is shown by an attestation that a license holder has proof supporting their claim. Quality is also an attestation process with no site inspection by Health Canada. This has led to a tidal wave of licensed NHPs that make spurious to unproven health claims on products as varied as expensive face creams to ubiquitous but also potentially dangerous energy drinks.

Returning to this dissertation's research question I believe that the ***NHPR* is a suboptimal framework**. A quick assessment finds that the *NHPR* and its attendant regime does not do much to advance public health goals or support the root justification of food and drug law in Canada. Section 9 of the *FDA* states that "no person shall label, package, treat, process, sell or advertise any drug (including NHPs) in a manner that is false, misleading or deceptive or is

[1776] *OAG, supra* note 29.

likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."[1777] It is hard to argue that NHPs are not creating an erroneous impression regarding their value, quality, merit or safety. Researchers such as Ernst[1778] would argue that instead of a set of health and safety regulations, what has been established is actually a very soft regulatory regime that provides credibility to these products, without providing much to advance their worthwhile use. My assessment would be much the same: what is in place by any other name is a very low-bar registration system, with some minor limits on the types of products and claims that can be put forward. If this is placed next to the very weak post-market system, it is very difficult to maintain the argument that the *NHPR* is doing much at all.

As was identified earlier in my thesis, the development of SEQ standards over the past century was a significant public health achievement. While imperfect, it serves as a bulwark against the spurious claims and poor quality of products that saturated the market prior to the introduction of greater safeguards in the late 19th century. The goal of this system is the promotion of health. The goal of the *NHPR*, as reinforced by the courts in 2021, should also be to serve as a set of public health promotion regulations where other goals are secondary:

> while the Minister is expressly required by the NHP Regulations to evaluate safety and prevent injury to health, the imperative of freedom of choice and philosophical and cultural diversity exist only as an underlying principle rather that an identified criteria for evaluation. [1779]

Health Canada also has the mandate to establish an impartial process for the review of safety and efficacy where "the Minister must be satisfied not just that the applicant has filed information on safety and effectiveness, but that the information demonstrates that the NHP is safe and

[1777] *FDA, supra* note 6 at s.9.
[1778] *Ernst, supra* note 418.
[1779] *RNA Biochemicals, supra* note 1355.

effective."[1780] Instead NHPD has spent most of the past two decades trying to address a self-created backlog, focusing on product access while creating a confusing set of guidance that increasingly lack rigour.

The government has the choice to set up a set of regulations that are sensitive to consumer choice, respect cultural practices, and allow for the sale of traditional and alternative medicines. This ultimately is a laudable goal. Yet this should be the intentional goal of such a set of regulations. As was noted in Chapter 3, there is legitimacy and value to many models of alternative medicine, even if they do not easily map to scientific methods. To many Canadians, alternative medicines have a very high, belief-based, personal value in how they pursue wellness. Yet, there must be a clear delineation that claims based on these systems are not tested using standard risk-benefit methods employed for other therapeutic products.

NHPs are not credence products assured by the rigorous assessment of regulators; they are faith-based products approved with very little oversight. Again, it is laudable to create a regulatory regime that brings some discipline to these types of products and claims, but it is very difficult to actively assess the merit or value of these products with any of the tools used for other therapeutic products. Respecting cultural diversity and philosophy of belief does not easily map to the systems used for product assessment in food and drug law. Ernst[1781] would argue that the *NHPR* has brought legitimacy to these products while the public is generally unaware of the limitations of regulatory oversight.

[1780] *Ibid.*
[1781] *Ernst, supra* note 418.

If we consider again the WHO *2014-2023 Traditional Medicine Strategy,*[1782] it defined three goals for regulation of alternative medicines. The first was that they develop "a greater knowledge base for active management of [CAMs]."[1783] Health Canada and NHPD seem to have gained operational experience in the regulation of these products, but I would argue that there is very little new knowledge about these products being generated. Particularly, there is a need for greater knowledge about the utility and safe use of these products, as well as the merit associated with non-traditional products. The second WHO goal is that regulatory regimes "strengthen the quality assurance, safety, proper use and effectiveness of [CAMs]."[1784] The *NHPR* regime has created a very weak quality assurance system and gives little guidance to consumers on the proper use and effectiveness of these products. Instead it cedes choice to a model of *caveat emptor*, where NHPs often mirror actual over-the counter-drugs, with little clarity on labels or packaging that they are belief-based products. The final WHO criteria asks that regimes work at "integrating [CAM] services into health-care service delivery and self-health care."[1785] Other than allowing access, NHPD and Health Canada have done little work on moulding how these products can be used or integrated into complementary health models. There has been a lack of sponsored research, clinical studies, or work of any kind to map these products and work to promote their utility in larger health models.

[1782] *WHO 2014-2023, supra* note 424.
[1783] *Ibid.*
[1784] *Ibid.*
[1785] *Ibid.*

(i) An Overly Broad Pathway

The gaps in these regulations can be linked to several sources. The first is the creation of an overly broad regulatory framework, or as was identified by Health Canada's own 2010 evaluation:

> Canada maintains the broadest definition of NHPs in the world. As a result of this definition, the number and type of products that require approval from NHPD is higher than what is experienced by regulatory authorities in other countries[1786]

Unlike most other comparator jurisdictions (the EU, Australia) Canada chose to adopt an expansive definition of NHPs. It also chose to not restrict this regime to purely traditional products. Both the EU and Australia are explicit that their regimes apply only to traditional and cultural products; otherwise products are treated as drugs. In these jurisdictions health claims for non-traditional products are subject to the same rigour as other drugs or health products to prove their safety, efficacy, and quality. In Canada, the overly broad definition of NHP allowed for virtually any product making a health claim or meeting the very inclusive composition requirement of Schedule 1 to claim to be an NHP. The result was a host of new and combination products that sought this licensing pathway. With time, these new or non-traditional products came to dominate the products seeking licensing.

To accommodate this swell of new applications, NHPD was required to adjust its regulatory process to fit these new classes of products. This meant extending exemptions around SEQ designed for traditional products to most of these new products. With time this eroded the initial attempts by NHPD to use the regulations to gather additional safety and efficacy data in

[1786] *2010 Evaluation, supra* note 1405.

monographs. What developed was a process that erred on the side of licensing. This culminated with the *UPLAR Regulations* which licensed almost 50,000 products under the presumption that the speed of licensing, not health and safety, was the primary regulatory risk. This was followed by guidance that sought to recast the efficacy requirement of these regulations as a reverse onus related to the likelihood of harm if a proposed claim was false. This indirectly becomes an acknowledgement that many claims are likely not accurate. At the same time, product review times were drastically reduced (to 10 days for most products). This was paired with new compliance guidance that further limited the types of violations that would result in enforcement.

The root of this confusion can be found at the inception of the regulations which tagged regulators with three competing goals to balance: "consumer freedom of choice and access while ensuring the quality and safety of such products."[1787] Baldwin et al. identified this as one of the key criteria that can lead to regulatory friction as "understandings regarding [the regulation's] objectives and problems [to be addressed]"[1788] are at odds. Ensuring quality, safety, and efficacy are not themselves in opposition to respecting cultural sensitivity and respecting access, but in the case of NHPs, there is very little capacity to demonstrate efficacy. For traditional medicines this is solved by demonstrating a history of use, and a linkage to an existing system of cultural knowledge. For newer products there is no such link to any form of evidence to demonstrate safety or efficacy. This means that to ensure access, NHPD has largely been required to abandon efficacy as a criteria, essentially removing the E from the SEQ formulation. In other cases, such as energy drinks, where safety was in question by a panel of experts, the regulator explicitly ignored external advice on safety largely driven by a push for market access from manufacturers.

[1787] *New Vision, supra* note 713.
[1788] *Baldwin et al, supra* note 46 at 69.

(ii) Structural Issues with the NHPR

Abandonment of the SEQ standards for NHPs is linked to structural issues with the *NHPR* as initially drafted. While attempting to mirror the *FDR*, it watered down or omitted many provisions that covered key areas of the SEQ formulation. The decoupling of site and product licensing and the introduction of only minimal GMP criteria led to compliance issues. The lack of advertising, sampling, and clear labelling requirements led to almost two decades of confusion and non-compliance by manufacturers, where in at least one potential case, energy drink samples may have led to the death of a teenage boy. The compliance provisions were likely overly broad and allowed too gradual an implementation timeline (rolling out through 2010). This gradual roll-out directly aligned with the need to implement the *UPLAR* regulations. While the *NHPR* included some of the most updated clinical trial provisions for any therapeutic product line, there was very little incentive for NHP manufacturers to complete clinical trials. Manufacturers who did complete clinical trials risked invalidating claims they could make without this evidence. A lack of clarity around the evidential standards required to demonstrate safety and efficacy, and ambiguity, led to several court cases that asserted NHPs had a reverse onus when refusing product licenses. The ambiguity was not resolved by the courts until 2021.

Not all of these structural issues could have been foreseen, but it took NHPD almost two decades before it proactively made any substantial regulatory amendment to address long-identified issues. The fact that a decade ago regulators intentionally excluded the regulations from the additional oversight powers provided by *Vanessa's Law* speaks to an unwillingness to improve the SEQ measures employed by the regulations. This likely was a partial response to

pressure from industry and the political reaction to the Stop C-51 campaign. Yet, NHPD was acutely aware that gaps in the regulations were causing regulatory and safety issues. In the case of homeopathics, which were causing confusion among consumers, regulators only reacted with new regulatory measures once there was extensive media attention following the CBC Nighton article. The new measures, which clearly required these products to be labelled as being based on traditional references and "not modern scientific evidence," should have been extended to all NHPs. The newest wave of regulatory activity is likely only in response to a very public and embarrassing audit by the OAG. The forward regulatory trajectory for NHPs is being driven by a push to characterize these products as self-care products. This regulatory agenda is commitment to innovation, modernization, reducing barriers, and improving drug access. It is hard to argue that, over the past two decades, NHPD has proactively sought to resolve many of the lacuna or gaps that existed in the regulations. Instead, it has cast these products as low risk and not warranting regulatory refinement.

(iii) A Focus on Access over Safety

These gaps in the regulations and administration mean that in the case of NHPs the SEQ standard has been so watered down as to become virtually meaningless. Since the regulations did not resolve or clearly articulate their approval criterial early in the process, the regulator chose to loosen the criteria for approvals. These new standards were often at odds with the criteria in place for foods (prescriptive) or for drugs (evidentially required risk assessment). The result was to begin to erode the SEQ standard for these other classes of products, particularly in the case of combination products. *Schedule A* (prohibiting certain claims) and *Schedule F* (prohibiting

certain ingredients) were both repealed because they limited the type and form of claims that were allowed for NHPs. These schedules represented the cornerstones of some of the earliest Canadian food and drug law intended to prohibit fraudulent claims and the use of harmful substances. The advertising and sampling rules for all therapeutic products were modified to allow for the advertising and sampling of NHPs. The prescription drug list under the FDA has been created to replace the scheduling process of provinces and the third-party review by NAPRA, to accommodate the creation of a self-care framework. The de-listing process from the prescription drug list is also currently being explored to allow for more drugs to move more easily from prescription to non-prescription status. In each of these cases the changes were not to make the food and drug legal regime in Canada more robust, but to accommodate the ability of NHPs to come to market.

(iv) Amplifying and Replicating Errors

These changes have far-reaching impacts. In effect they are moving the Canadian food and drug regime towards reduced levels of oversight. The 'grey' space between food and drugs that NHPs were originally intended to occupy has gradually been increasing until it has started to overtake the other regulatory regimes on this spectrum. With over 100,000 licensed NHPs, these products far outnumber all other therapeutic products on the market. The food regulations have open the door to allowing a larger number of unproven health claims. With time, one can see a point when increasingly, drug manufacturers seek to shift many of their products to non-prescription status at the moment that their period of market exclusivity f lapses.

The proposed self-care framework itself seems to be an awkward approach to resolving an issue largely created by poor NHP labelling and the permissiveness of the regime allowing products on the market which can easily be mistaken for over-the-counter drugs. This framework is being put forward instead of restricting other therapeutic products from making health claims or limiting the use of easily confused labels. Health Canada is taking the approach that more therapeutic products should be regulated in a manner that is similar to NHPs. In this perspective, instead of credence products being assured by the regulator to support accurate consumer choice, assurance should be removed from more products to allow consumers and the market to determine the value of products. Efficacy is being removed from the equation for these products with a very limited return in value to the consumer. As noted earlier, this is not without risks, particularly in the case of over-the-counter drugs, which are in no way products that should be subject to lower SEQ standards. For cosmetics, food-NHPs, and a host of other combination products, it opens the floodgates to making poor or little-assessed claims contrary to *Section 9* of the *FDA*.

Instead of recognizing the deficiencies of the NHPD regime, Health Canada seems to be pushing increasingly for this to become a model of regulatory oversight for other therapeutic product categories. The increasing use of agile methods of oversight, bespoke approval process, real-time evaluations, etc., are being reproduced across the whole food and drug regime. This is likely not by accident. The drive of the Canadian regulatory program over the past two decades has been to re-shift the agenda of drugs from a precautionary system focused on health promotion and prevention to one focussed on access in order to sponsor market growth.

If we use economic growth as the main goal for any health regulations, the *NHPR* have been a smashing success. Combination products, energy drinks, cosmetics making unproven health claims, and vitamin juices making unproven health claims were all prohibited by law for health and safety reasons before the *NHPR* came into force. Few of these products are producing improved health outcomes but they have been a boon to expanding the Canadian market. Taken with this lens in mind, the reduced safety standards, the removal of efficacy requirements and the poor quality control in place for these products has led to economic growth. Yet, the *NHPR* are presented as a set of health regulations administered by a department primarily concerned with health promotion.

(v) Whither the Standard for SEQ

In my master's thesis (2010) I asked whether, over time, the food and drug regulatory regime would lean towards a stronger system based on science, or whether it would lean towards market and access with lower scientific standards. At the time much of this fulcrum pivoted around the concepts of pharmacovigilance and progressive licensing which postulated that post-market surveillance was the better avenue for evaluation of drug safety, efficacy, and quality. Much of the push for this mode of regulation was driven by a call that drugs were over-regulated, and unnecessarily delayed from market and the argument that this over-regulation was stifling needed new drugs from making it to the market. My master's thesis demonstrated how few of these premises were actually correct; Canada has relatively low regulatory barriers and our approval times were comparable or faster than most other G8 countries. It seems that the *NHPR* have done much to erode this conversation in the direction of enabling products with unproved

health claims to be marketed with little to no oversight pre- or post-market. Yet rather than being seen as an erosion, they have been cast by Health Canada as a good example that relative access with little oversight is desirable.

Intentionally or unintentionally the *NHPR* have unspooled much of the gains brought about by the SEQ standards. NHPs are now rife with inaccurate claims and poor quality. They have led the regulator to an acceptance that efficacy should not be proven for a large class of new, non-traditional products. Spurious health claims are now allowed for these products. It is acknowledged that quality will be poor, and compliance will be low, because these products require exemption as a low-risk class of products. This represents a significant shift in the position of the regulator as it steps back from actively managing the SEQ of a significant product class in Canada. Justification around tradition, philosophy, and cultural practice are lost as this system now largely regulates new products without many of the claims to these belief criteria. Instead the regulatory system now largely validates new products. With this in mind, one can ask: whither the regulator for these products?

(vi) Lessons Learned for the Regulation of CAMs

My thesis highlights several observations that can be applied to any jurisdiction seeking to regulate complementary and alternative medicine products. As was noted earlier, these types of products pose very specific issues for any regulatory regime. Alternative medicines and the boundaries of these products are very difficult to define, which means that scoping the type and nature of products to be regulated will always be a challenge. The nature and evidential criteria

that alternative medicines used to justify their use are based on inferential reasoning, subjective observation, and the experience of the individual. This means that systems that seek to prove SEQ using scientific methods, like conventional drug regulation, will always be suspect to advocates of alternative medicines. For alternative medicine the individual's experience of their health is key, regardless of whether this can be reproduced using systematic methods. Belief in the validity of a treatment is given equal weight with any clinical proof of utility. Additionally, practitioners of alternative medicines often reject conventional medical principles outright. They generally align to a spectrum that asserts the supremacy of the individual in making choices and limiting the infringement of their rights to choose treatment. At the same time, there has been an assertion to set their practice on par with that of conventional medicine.

There is also a very distinct line between traditional or cultural practices and newer forms of alternative medicines, what one researcher called the hodgepodge of new, belief-based practices that have emerged in the West over the last few decades. Often taking bits and pieces of personal belief, supposition, and aspects of cultural practices, many very distinct from practices that have culturally or historically been used outside of the Western medical model with a history of established use. Placing Truehope (tested by one farmer on his pigs) in the same category as Ayurvedic or traditional Chinese medicine (with thousands of years of history of continual use) in the same category is problematic. In one case there is an argument that these modes of treatment have a proven history that justifies their continual use and investigation. Non-traditional products lack a justification rooted in long-standing traditions or beliefs. They are also part of a multi-billion-dollar wellness industry. Traditional medicine represents a legitimate set of cultural practices that should be accorded respect, and if not overtly harmful, allowed to

persist by regulators. Non-traditional practices lack much of this justification and should be required to demonstrate worth.

Any new regime that is developing a system for regulating alternative medicinal products must be clear about delineating the type of products and criteria for products included and excluded under the regime. This is achieved by being very specific in the product definition and setting boundaries around the types of products that will be allowed to seek licensing under the regime as well as the type of evidence required to justify licensing. By basing their inclusion criteria on claims and composition, the *NHPR* left the door open for products to selectively be treated like alternative medicines, when many were not. Even more effective is excluding products based on whether they are traditional or non-traditional products. In both the EU and Australia a product is either a traditional medicine or not. If not, products are required to seek licensing to make health claims just like any other drug. This excludes newer products from seeking licensing using exemptions or similar criteria. It also prevents combination products from seeking licensing. This distinction also allows for the accommodation that these products are not reviewed using criteria similar to that used for conventional pharmaceuticals.

At the initiation of any new regulatory regime for alternative medicine products, governments need to be clear about the objectives of the regulations. Developing a set of regulations that recognize cultural traditions and diversity of products is not necessarily compatible with regulations that seek to develop a knowledge base around the utility of products. Also expecting these products to manifest information that justifies their use is problematic, since it imposes a model of assessment that is at odds with many of the basic tenets of alternative

medicines. It is fair to have a system designed to respect belief, or one designed to assess utility, but it is difficult to blend the two in the same regime. The *NHPR* also layered on top of this a commitment to access. This meant that the regulations were subject to scope creep from the start. From the beginning, it would have been easier to acknowledge the limitation of the types of products being regulated and to remove any criteria related to efficacy from the equation. Alternatively, it would have been easier to structure a set of regulations that subjected all of these products to more rigour, developed more SEQ knowledge about NHPs, and used this process to help the public make validated health choices.

Before any regulatory regime for alternative medicines is developed, or as it is being developed, regulators should establish more comprehensive baselines of the risks and benefits of these products. Without the quantification of this information, regulators have no clear criteria against which to establish goals. Nor do they have any measures to determine whether the regulations are in effect working. NHPD has never truly baselined its safety or health objectives, and with time has come to equate licensing with regulatory success. This is completely de-coupled from a demonstration of improved health outcomes or any other regulatory objective. In the absence of a clearly stated objective, NHPD has used the rate of licensing as the demonstration of effectiveness. While it can be argued that this represents a measure for demonstrating that the regulations are capturing most products under the regime and making them subject to a form of limited oversight, this is a poor objective for a set of health regulations.

Quality should be a priority in all CAM regulation. It is likely that the greatest risk from NHPs, other than misinformation around claims, relates to quality. The repeated observation that

these products are often adulterated is an empirical demonstration that they are often of poor quality. Even more problematic is the likelihood that an NHP will be adulterated with a dangerous substance or contaminant because of poor manufacturing. If efficacy cannot really be assessed, regulatory efforts should concentrate on ensuring that products that come to market pose no risk. Regulators should concentrate on imposing strong manufacturing conditions to validate site licensing. This should be supplanted by a very robust and ongoing compliance monitoring (site inspection) regime. Penalties for non-compliance should be meaningful. For smaller manufacturers, clear accommodations can be made for compounding and small-batch distribution, but there should still be an emphasis on quality. This should be backed by a very robust requirement to document the manufacture and sale of these products (linking licensing, manufacturing, and sale) so that in the case of an ADR, products can easily be recalled and health measures taken.

The ultimate goal of any regulations developed for alternative medicines should be the promotion of health. This can be for the promotion of alternative health, it can be for the increased use of assessment to establish SEQ, or it can be for the integration of the two. It should not be for the advancement of economic interests. In the U.S., and to a limited extent in Australia and the EU, legislation has been used to advance the marketing of these products. *DSEA* in the U.S. has in fact limited the ability of U.S. regulators at the FDA to protect the public from fraudulent and even harmful products. This was done directly as a result of the lobbying of supplement manufacturers, not because it was the best health goal for Americans. The onus should be on manufacturers to establish that there is merit to their products based on some form of criteria that is designed to either justify their use based on cultural practices or SEQ standards.

Otherwise they should be regulated just like any other product making health claims, where the manufacturer should provide some justification for marketing their product.

(vii) Proposals for the Better Regulation of NHPs in Canada

I would argue that the *NHPR* and its attendant regime as they developed both overregulate some aspect of NHPs while under-regulating others. The pre-market approval of NHPs seems to spend a lot of time trying to assess safety and quality with measures that are very weak. Regulators should either decide that they will impose standards that require clear proof that the product has merit and no product which cannot demonstrate SEQ will be licensed, or they should remove the efficacy requirement completely. Clear distinctions should be made about the nature of these products, making clear that they are not approved by the regulator for efficacy. This is the process that was introduced for homeopathics, with increased labelling standards and a clear statement that products are not approved using scientific methods. Non-traditional NHPs should not be licensed using reduced SEQ data. The burden of proof for these products should be substantially higher than that of traditional products.

As part of its new self-care framework, Health Canada had indicated that it was intending to introduce new labelling standards for all NHPs that would identify them to the public as not having been approved using scientific methods; yet the most recent amendments to the *NHPR* only updated labelling standards to bring them more in line with allergy and composition descriptions on other therapeutic products. It is likely still unclear to the public that these products are not validated using a more rigorous framework. NHPD needs to use clear and

prominent labelling on these products to make them distinct from drugs. There should be no regulatory contribution to consumer confusion in between NHPs and drugs. Similarly, NHPD should engage in a more concerted educational campaign to inform the public about the risks and benefits of NHPs. This should be paired with increased funding of research into the risks and benefits of these products. Research could look into the SEQ of these products as well as mapping the etiology and cultural relevance of various NHPs and alternative medical practices.

NHPD needs to clean up its policy guidance; as it sits it is a very confusing. There should be explicit clarity around what evidence is required when making a product application. I would shift the onus back onto non-traditional products to provide some demonstration of their utility or criteria completely. Site licensing information should be required at the time of product licensing. This would mean compliance information is directly linked to licensing information. Non-compliant products could be directly linked to manufacturers, which would allow for other products manufactured at that site to be assessed for quality. Site licensees found to be non-complaint could then be linked back to all products licensed or in the process of being licensed at that facility.

Quality assurance should be the primary focus. Following the adoption of the post-market powers of *Vanessa's Law* in the *BIA 2023*, NHPD needs to adopt a stronger stance on post-market compliance and enforcement. This should involve an increased series of inspections and an expansion of the criteria that initiate inspections, beyond the weak risk-based model used today. Because of the high degree of adulteration and inappropriate labelling, NHPD needs to engage in product testing, sampling products on the market and chemically testing their

composition. This starts with inspecting products on market shelves to ensure that they are compliant. NHPD should produce a publicly available report on NHP adulteration. The compliance guide should be updated to clarify the categories of non-compliance that will lead to product removal; the current guidance allows for too high a degree of non-compliance. If the *NHPR* regime is moving towards a lower pre-market entry bar and expanding these criteria to other self-care products, then it cannot continue with a low post-market regime. NHPD should act decisively with its new powers to remove non-compliant products from the market.

There has to be a shift in perspective by regulators to implement more safety measures for these products. It has taken almost two decades for Health Canada to make any significant modifications to the regulations. Originally excluding NHPs from *Vanessa's Law* was an intentional choice, likely based on the stakeholder reaction to Bill C-51, which left a gap in the law for a decade. There is not a good health reason to have done so, as these new powers largely relate to post-market enforcement and compliance powers. Having these powers in place would also have limited the need to develop a self-care framework and combination products could simply have been deemed as belonging to a specific therapeutic class. Similarly, in those cases where NHPD has been willing to adjust or balance regulatory requirements to focus on access, such as for energy drinks, it should base decisions on accurate or systematic information. When there is positive information that products might be unsafe, the regulator should act.

There has been no systematic risk-benefit analysis of these products conducted by Health Canada. As one of the early evaluations notes, Health Canada has never created a baseline of the risks and benefits of these products. Instead, the rhetoric of risk has come to frame these products

as low risk. This speaks more to the political priorities of the government than it does to the actual risks of these products. As noted in the last chapter, this is a risk decision based on macro (political priorities about where to place regulatory efforts) more than one based on the micro (actually assessed SEQ via risk-benefit analysis) risk of these products. Similarly, making reference to a global low risk of self-care products makes an assumption that self-administration equates little or no risk. For many types of self-care products (combination products, cosmetics, hygiene devices), researchers have long argued that there is no systematic evaluation of their risk-to-benefit ratio. In the case of many hygiene products and cosmetics, it is only now being recognized that they often contain poorly understood chemicals and other additives that have potentially carcinogenic effects. In order to pronounce on risk, NHPD and Health Canada would need to complete much more extensive research and compliance monitoring.

I recommend that the movement of these and other products to a self-care framework be abandoned. As I have noted, it has long been a goal of NHP lobbyists to create a new regulatory class of products that removes most of the pre-market approval criteria from the regulation of NHPs. The expansion of this category is solving a problem created by the overly broad regulatory definition that allowed too many products to be put forward for licensing. Many of the products that are in the self-care category should never have been allowed to seek licensing as NHPs. The problem that similar products were subject to different regulatory regimes (drugs, foods, NHPs) is the result of a lack of clarity among these categories and scope creep, not that they inherently were all grouped by risk or common regulatory concerns. The confusion on the market among these types of products (labelling similarities) is likely a result of the regulator not

making labelling more explicit among various categories of products. The creation of a self-care regime legitimizes claims on products which are unproven.

It is crucial for the NHPD to enhance public awareness regarding the scope of their regulatory activities. To achieve this, the NHPD should implement the proposal outlined in their self-care framework plan to clearly label NHPs with a disclaimer stating that they have not been approved using scientific methods. Additionally, labelling requirements should be established to explicitly differentiate NHPs from conventional over-the-counter drugs. The public should have a clear understanding of the limited level of oversight applied to these products. NHPD should also develop an educational plan to effectively communicate to the public the risks and benefits associated with NHPs, as well as the scope and nature of their regulatory review. It is essential to make data sources on risks and evaluations (such as adverse drug reaction data, compliance data, product assessments, and evaluations) accessible to both the public and researchers. Furthermore, NHPD needs to increase its efforts to engage the public in consultations and policy-making processes. Updated research should be conducted to assess the usage patterns and opinions of the public regarding NHPs. The NHPD should explore methods to involve academics and external experts in the policy-making process, moving away from a limited circle of manufacturers and lobbyists, and seek their input on future regulatory directions.

My ultimate recommendation is that NHPD and Health Canada should move these regulations toward a system that registers products with ruthless compliance. Products which have not registered with NHPD should immediately be ordered removed from the market. The regulations should focus on traditional NHPs or products which can make a link to the principles

of traditional medicines. If it is not effectively being assessed, the efficacy standard should be abandoned in the regulations. Products which do not meet the definition of being traditional medicines should be forced to seek registration as either a food or drug. If there are to be provisions for non-traditional products then the regulator should complete a scientifically driven risk categorization process. This process should determine different levels of regulatory oversight based on the composition and utility of these products, similar to what has been done for medical devices. It should not be easy for non-traditional products with baseless claims to enter the market.

(iv) Proposals for the Better Development and Evaluation of Regulations

While beyond the specific scope of my thesis, in this section I will provide some general comment on Canadian regulatory theory. In my estimation the *NHPR* and its regime can be seen as an example of poor regulation. I would argue they are not an isolated example. The regulatory agenda and regulation-making process in Canada have leaned towards being *deminimus*. They have become overly focused on economic outcomes and adopted lenient compliance regimes. This is likely not a phenomenon unique to Canada. The push of a neoliberal regulatory agenda over the past four decades has sought to recast regulation as a burden, bureaucratic red tape, or an impediment to freedom of choice and market mechanisms. This neo liberal trend casts itself as a "common sense revolution" that sees the reduction of regulations as an acceptance of more risk in exchange for increased economic growth and freedom. This logic recasts the public as overly risk adverse and suggests that they should be willing to accept higher degrees of risk. This is paired with evolving models of oversight that have distorted the original model of

Braithwaite's compliance pyramid to rationalize less direct oversight of the regulated. In return, we are left with regulations that give the illusion of oversight but offer minimal direct regulation or accountability.

For health and safety regulation this is problematic. Effective heath regulation requires (i) a basis in empiricism and (ii) a prioritization of health outcomes to legitimize the value of the regulations. In certain types of regulation, such as environmental, health, and security, the outcomes of ineffective or inadequate regulation are often irreversible. When faced with unknowns, precautionary measures are warranted. Health Canada's original *Decision-Making Framework* (2002) appropriately recognized the importance of precaution and the potential health risks involved:

> Give health and safety precedence in making risk management decisions, over economic and other considerations. Balance Health Canada's mandate to protect the health and safety of Canadians, with the right of individuals to make personal choices. Where these two interests are at odds, decisions must always favour the former over the latter.[1789]

This has been one of the battlegrounds of regulatory policy over the past four decades, with one side advocating for the reduction of regulatory standards and the evaluation of risk in real-world settings (risk-based regulation), and the other arguing that precaution should be in place for unknown or irreversible harms (precautionary regulation). In the case of environmental and financial regulation, regulators have been hesitant to adopt precautionary approaches. However, events like the financial crisis and climate change demonstrate that this might have not been the wisest course of action. Similarly, in the realm of food and drug regulation, abandoning a stringent safety and efficacy (SEQ) standard will likely lead to a decrease in the value provided by therapeutic products.

[1789] *Decision Making Framework, supra* 849.

Canadian regulators should embrace more modern models of regulation. One suggested starting point is Baldwin's model of responsive regulation, which emphasizes adaptability and responsiveness. Regulation should not be viewed as a strict dichotomy between command and control versus permissiveness, economic goals versus health goals, or precautionary versus risk-based approaches. Instead, it should be pragmatically designed within a system of clearly defined objectives and continuous monitoring of its effectiveness in achieving regulatory goals. Regulation needs to be pragmatically framed in a system of clearly established objectives and ongoing monitoring of its effectiveness in achieving its regulatory goals. To enhance the regulatory process, it is crucial to accurately assess the risks and benefits associated with regulations, establish clear regulatory objectives, and consistently evaluate the outcomes of regulatory activities. This would be an ongoing form of regulatory outcome analysis. The current tool, the Regulatory Impact Analysis Statement (RIAS) is a point-in-time forward projection of the risks and benefits of regulatory activity. It seldom tests these assumptions in operation. The current system of regulatory monitoring and forward regulatory plans does not sufficiently address regulatory effectiveness, as it is primarily geared towards short-term political objectives of reducing regulatory burden.

Regulation needs to be seen and studied as a form of networked activity. It is not merely the regulations and legislative or judicial activities that are associated with a set of regulations. To truly understand the impact of regulations, we must consider the intended and unintended outcomes as they manifest in administration, the interconnected relationships and influences, and how regulations shape behaviour in the real world. Legal academics and researchers in the

humanities and social sciences should dedicate more time to examining how regulations are actually impacting systems. The *NHPR*, as an example, has a significant impact on the broader Canadian food and drug law regime, extending beyond its influence on alternative medicines. By normalizing weak regulatory oversight, it affects the whole framework of regulations pertaining to food and drug safety in Canada.

More pragmatically, the regulatory-making process in Canada should be refined. While beyond the observations of this thesis, I suggest it needs to be segregated as a function from economic goals. The Regulatory Affairs Secretariat (RAS) should be placed under the Privy Council Office (PCO), rather than the Treasury Board Secretariat (TBS), which is primarily focused on economic matters. Regulations should have clear and explicit intentions, and the sole intent should not always be reducing regulatory burden or promoting economic goals. The direction of the regulatory agenda should not solely be determined by the External Advisory Committee on Smart Regulation (EACSR), whose objective is to enhance economic competitiveness. This narrow focus is short-sighted. The suggestion to transform Health Canada into a department responsible for sponsoring innovation and health protection would create confusion between its mandate and goals. Similarly, the adoption of trendy management concepts like real-world product testing, agile product procurement, and exemptions for technically innovative products is short-sighted and likely to result in minimal health benefits while exposing consumers to unnecessary risks.

BIBLIOGRAPHY

CANADIAN LEGISLATION

Act to Impose License Duties on Compounds of Spirits; to amend the Act Respecting the Inland Revenue; and to Prevent the Adulteration of Food and Drink and Drugs Act (Inland Revenue Act), (1875) 37 Vict, c. 3.

Adulteration Act, (1860) 23 & 24 Vict, c. 84.

An Act to Amend and to Consolidate as Amended the Several Acts Respecting the Adulteration of Food and Drugs, S.C. 1884 c. 34.

*An Act to Amend the Law for the Prevention of Adulteration of Food and Drink and Drugs (*1872) 35 & 36 Vict., c. 74.

An Act to Amend the Food and Drug Act and to Make Consequential Amendments to Other Acts, 2008, Bill C-51, First Reading, April 8, 2008 (Canada, 39th Parl., 2nd sess.).

An Act to Amend the Food and Drug Act, Bill C-17, 2014, (Canada, 41st Parl., 2nd sess.).

An Act to Implement Certain Provisions of the Budget, Bill C-47, 2023, First Reading December 6, 2013 (Canada, 44th Parl., 1st sess.).

Budget Implementation Act, 2021, No. 1, R.S.C. 2021, c. 23.

Canadian Consumer Product Safety Act (*CCPSA*), R.S.C. 2010, c. 21.

Federal Food, Drug and Cosmetic Act of 1938, Pub. L. 75-717, 52 Stat. 1041, 12 U.SC. 301

Food and Drug Act, S.C. 1920 c. 27.

Food and Drug Act, (1985) R.S.C. c. F-27 s. 30.

Patent Act, R.S.C., 1985, c. P-4.

Protecting Canadians from Unsafe Drugs Act (*Vanessa's Law*) R.S.C. 2014, c. 24.

Red Tape Reduction Act (2015) R.S.C. c. 12

Sale of Food and Drug Act, (1875) 38 & 39 Vict., c. 63.

*Service Fees Act, R.*S.C. 2017, c. 20, s. 451.

Statutory Instruments Act (SIA) R.S.C., 1985, c. S-22.

User Fees Act, R.S.C. 2004, c. 6.

CANADIAN REGULATIONS

Cosmetic Regulations, C.R.C, c. 869.

Food and Drug Regulations, C.R.C. c. 870.

Medical Devices Regulations, SOR/98-282.

Natural Health Product Regulations, SOR/2003-196.

Natural Health Products (Unprocessed Product License Applications) Regulations (UPLAR), SOR/2010-171, s. 8.

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133.

Red Tape Reduction Regulations, SOR/2015-202.

CASES

Adanna v. Boiron Canada Inc., 2015 QCCS 312.

Canada RNA Biochemicals Inc. v. R, 2020 FC 668; 2012 FCA 213.

Clark v. Energy Brands Inc., 2014 BCSC 1981.

Jamieson & Co. (Dominion) Ltd v. Canada (Attorney General), [1987] F.C.J. No. 826

Mancuso, the Results Company and Dahl v. R, 2014 FC 708; 2015 FCA 227.

R v. The Synergy Group of Canada Inc., 2006 ABPC 196.

Standard Sausage Co. v. Lee, [1934] 1 D.L.R. 706

Swarath v. R, 2014 FC 75.

Wilkinson v. Coca-Cola, 2014 QCCS 2631.

Winning Combination v. R, 2016 FC 381; 2017 FCA 101; SCC denied 2018, No. 37697.

Wrigley Can. v. Can., (2000) 256 N.R. 387.

CANADIAN GOVERNMENT PUBLICATIONS, DIRECTIVES AND GUIDANCE

About the Canada Gazette, (Government of Canada: Ottawa).

Agri-Food and Health Canada's Regulatory Review Road Map (Health Canada: Ottawa, 2019).

A New Approach to Natural Health Products, (Health Canada: Ottawa, 2010).

A Revised Approach to NHP Site Licensing Proposal Document, (Health Canada: Ottawa, 2013).

A New Risk-Based Approach to Site Licensing for Natural Health Products – Concept Paper, (Health Canada: Ottawa, 2013).

Amendments to the Food and Drugs Act: Guide to New Authorities - power to require and disclose information, power to order a label change and power to order a recall, (Health Canada: Ottawa, 2014).

Auditor General of Canada Report 2 – Natural Health Products (OAG: Ottawa, 2021).

Bill C-51 Legislative Summary, (Library of Parliament: Ottawa, 2008).

Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food (Health Canada: Ottawa, 2006).

Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food (Health Canada: Ottawa, 2007).

Cabinet Directive on Streamlining Regulation (Government of Canada: Ottawa, 2007).

Cabinet Directive on Regulatory Management (Government of Canada: Ottawa, 2012).

Cabinet Directive on Regulations: Policies, Guidance and Tools (Government of Canada: Ottawa, 2016).

Caffeinated Energy Drinks: Technical Report on Public Health Concerns and Regulation in Canada (Toronto Public Health, 2017).

Canada's Chief Public Health Officer, *The Chief Public Health Officer's Report on the State of Public Health in Canada, 2015: Alcohol Consumption in Canada*, (CPHO: Ottawa, 2016).

Canada's Economic Standing Roundtable: Health and Bioscience (ISED, Ottawa: 2019).

Canadian Institute for Health Information, *Prescription Drug Spending in Canada – 2019* (CIHI: Ottawa, 2021).

Canada-US Regulatory Cooperation Council, *Work plan: Over-The Counter Products* (Government of Canada: Ottawa, 2016)

Charting a Course: Refining Canada's Approach to Regulating Natural Health Products (Health Canada: Ottawa, 2007).

Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats (Health Canada: Ottawa, 2017).

Clinical Trials for Natural Health Products (Health Canada: Ottawa, 2010).

Compendial Products Licence Applications, (Health Canada: Ottawa, 2008).

Compliance and Enforcement Policy – POL 0001 (Health Canada: Ottawa, 2003).

Compliance and Enforcement Policy Framework (Health Canada: Ottawa, 2018).

Compliance Policy for Natural Health Products (Health Canada: Ottawa, March 2004).

Consumer Health Products Framework (CHPF) (Health Canada: Ottawa, 2014).

Consulting Canadians on the Regulation of Self-Care Products in Canada (Health Canada: Ottawa, 2016).

Cost and Benefit Analysis: Natural Health Products (Unprocessed Product Licence Applications) Regulations (Health Canada: Ottawa, 2009).

Data Requirements for Switching Medicinal Ingredients from Prescription to Non-Prescription status (Health Canada; Ottawa, 2014).

Determining Prescription Status for Human and Veterinary Drugs (Health Canada: Ottawa, 2013).

Elements of Real World Data/Evidence Quality throughout the Prescription Drug Products Life Cycle (Health Canada: Ottawa, 2019).

Evaluation of the Natural Health Products Program 2010-2011 to 2014-2015 (Health Canada: Ottawa, 2016).

Evaluation of the Pilot Natural Health Products Good Manufacturing Practice Inspection Program (Health Canada: Ottawa, 2019).

Evidence for Homeopathic Medicine: Natural Health Product Directorate (Health Canada: Ottawa, 2006).

Evidence for Quality of Finished Natural Health Products (Health Canada: Ottawa, 2003).

Evidence for Safety and Efficacy of NHPs, version 2.0 (Health Canada: Ottawa, 2004).

Evidence for Safety and Efficacy of Finished Natural Health Products (Health Canada: Ottawa, 2006).

Final Report: Audit of the Management of the Natural Health Products Program (Health Canada: Ottawa, 2015).

Final Status Submission Report Q2 (July 1, 2012 to September, 2012), (Health Canada: Ottawa, 2012).

Food and Consumer Safety Action Plan (Health Canada: Ottawa, 2007).

Forward Regulatory Plan 2022-2024: Regulations Amending the Natural Health Products and the Food and Drug Regulations (Self-Care Framework) (Health Canada: Ottawa).

Foundational Framework for Treasury Board Polices (TBS: Ottawa).

Good Label and Package Practices Guide for Non-Prescription Drugs and Natural Health Products (Health Canada: Ottawa, 2018).

Good Manufacturing Practices Guidance Document (Health Canada: Ottawa, 2003).

Good Manufacturing Practices Guidance Document (NHPs) (Health Canada: Ottawa: 2010).

Good Manufacturing Practice Guidance Document (Health Canada: Ottawa, 2015).

Good Pharmacovigilance Practices (GVP) Guidelines (GUI-0102), (Health Canada: Ottawa, 2013).

*Guidance -Classification of Products at the Cosmetic Drug Interface (*Health Canada: Ottawa, 2009).

Guidance Document for Preparing a Submission for Food Health Claims (Health Canada: Ottawa, 2008).

Guidance Document - Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs) (Health Canada: Ottawa, 2015).

Guidance on Drug Establishment Licences (GUI-0002) (Health Canada: Ottawa, 2020).

Guidance Document: Labelling of Natural Health Products (Health Canada: Ottawa, 2013)

Guide to Making Federal Acts and Regulations (Privy Council Office: Ottawa).

HEAL Committee Report, *Natural Health Products: A New Vison* (Parliament of Canada: Ottawa, 1997).

Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks - August 1, 2000 (Health Canada: Ottawa, 2000).

Health Bioscience Sector Review (BSR) Roadmap (Health Canada: Ottawa, 2019).

Health and Biosciences: Target Regulatory Review (Health Canada: Ottawa, 2019).

Health Canada's Proposed Approach to Managing Caffeinated Energy Drinks (Health Canada: Ottawa, 2011).

Health Products and Food Branch Inspectorate, Natural Health Products Compliance Policy (POL-0044) (Health Canada: Ottawa, 2010).

HPFB BCS Energy Drinks: An Assessment of the Potential Health Risks in the Canadian Context (Health Canada: Ottawa, 2011).

Infographic: How New Laws and Regulations are Created (Department of Justice, Ottawa).

Inspection Tracker: Drug Manufacturing Establishments (Health Canada, Ottawa).

Instrument Choice Framework for the Canadian Consumer Product Safety Act (Health Canada, Ottawa).

Instrument Choice Framework for the Canada Consumers Products Safety Act (Health Canada: Ottawa, 2021).

Labelling Guidance Document (NHPs) (Health Canada: Ottawa, 2010).

Natural Health Products: 53 Recommendations of the Standing Committee on Health (Health Canada: Ottawa, 1997)

Natural Health Products – Over 43,000 Products Authorized for Sale and Growing (Health Canada: Ottawa, 2010).

Natural Health Products Compliance Guide (Health Canada: Ottawa, March 2004)

Natural Health Product Compendium of Monographs (Health Canada: Ottawa, 2003).

Natural Health Products Program Summative Evaluation (Health Canada: Ottawa, 2010).

Natural Health Products Program Advisory Committee, *Report 1 - Standards of Evidence for Non-Traditional Natural Health Product* (Health Canada: Ottawa, 2010).

Natural Health Product Tracking Survey – 2010 (Health Canada/Ipsos Reid: Ottawa, 2010).

Natural Health Product Tracking Survey 2010 Final Report (Prepared by Ipsos Reid: Ottawa, 2010).

Non-Prescription Drug Action Plan (Health Canada: Ottawa, 2022).

Management of Product License Applications (PLA) for Natural Health Products (Health Canada: Ottawa, 2010).

Ministerial Notice to Stakeholders – Consultation on a Consumer Health Products Framework (Health Canada: Ottawa, June 9, 2014).

Opportunities and Challenges Facing the Canadian Functional Foods and Natural Heath Products Sector (Agriculture and Agri-Food Canada: Ottawa, 2014).

Overview of the Natural Health Products Regulations Guidance Document (Health Canada: Ottawa, 2003).

Pathway for Licensing Natural Health Products Making Modern Claims (Health Canada: Ottawa, 2010).

Pathway for Licensing Natural Health Products Used as Traditional Medicines (Health Canada: Ottawa, 2010).

Policy on Regulatory Development (Government of Canada: Ottawa, 2018).

Preparing Submitting Reports for Marketed Drugs and Natural Health Products – Guidance Documents for Industry (Health Canada: Ottawa, 2018).

Products Licensing Guidance Document (Health Canada: Ottawa, 2003).

Product Licensing Document (version 2.0) (Health Canada: Ottawa, 2004).

Profile the Pharmaceutical Industry (ISED: Ottawa).

Quality of Natural Health Product Guide (Health Canada: Ottawa, 2015).

Quarterly Report (Spring/Summer 2005) (Health Canada: Ottawa, October 2005).

Red Tape Reduction Plan (Treasury Board of Canada Secretariat: Ottawa, 2012).

Report by the Expert Panel on Caffeinated Energy Drinks (Health Canada: Ottawa, 2010).

Regulation and Beyond: Progress on Health Canada's Therapeutic Access Strategy (Ottawa: Health Canada, 2005).

Regulatory Review of Drugs and Devices Initiative (R2D2) (Health Canada: Ottawa, 2017).

Site Licensing Guidance Document (Health Canada: Ottawa, 2003).

Site Licensing Guidance Document (NHPs) (Health Canada: Ottawa, 2015).

SMART Regulation – A Regulatory Strategy for Canada (EACSR: Ottawa, 2004).

Smart Regulation: Report on Actions and Plans (Government of Canada: Ottawa, 2005).

The Therapeutic Access Strategy (TAS) (Health Canada: Ottawa, 2003).

The Approach to Natural Health Products (Health Canada: Ottawa, 2013).

The Canadian Drug Inspection List (Health Canada: Ottawa, 2022).

The Food and Consumer Safety Action Plan (Health Canada: Ottawa, 2007).

Transition of Caffeinated Energy Drinks from NHPs to Food Using Temporary Market Authorization Letter (TMAL) (Health Canada: Ottawa, 2015).

INTERNATIONAL PUBLICATIONS, DIRECTIVES AND GUIDANCE

Government of Australia, *NHMRC Information Paper: Evidence on the Effectiveness of Homeopathy for Treating Health Conditions* (NHMRC: Auckland, 2015).

OECD*, Country Studies: Canada – Updated Report* (OECD: Paris, 2004).

TGA, *Assessed Listed Medicines: Assessed Listed Medicines Pathway for Complementary Medicines*, online at: https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-non-prescription-medicine/assessed-listed-medicines.

U.K. *The House of Commons Science and Technology Committee – Evidence Check 2: Homeopathy* (U.K. House of Commons: London, 2010).

U.S. Institutes of Medicine (IOM) – National Academies of Science, Engineering and Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (IOM: Washington, 2007).

U.S. House of Representatives - Committee on Oversight and Reform, *The Firm and the FDA: McKinsey & Company's Conflicts of Interest at the Heart of the Opioid Epidemic* (U.S. House of Representatives: Washington, April 2022).

U.S. Institutes of Medicine (IOM) – National Academies of Science, Engineering and Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (IOM: Washington, 2007).

U.S. National Centre for Complementary and Integrative Health (NCCIH), *Complementary, Alternative, or Integrative Health: What's In a Name?* (NCCIH: Washington).

U.S. Department of Health and Human Services, Food and Drug Administration, *Report to Congress: Changing the Future of Drug Safety: FDA Initiatives to Strengthen and Transform the Drug Safety System* (Washington: Department of Health and Human Services, 2009).

U.S. National Institutes of Health, Report *to the National Institutes of Health on Alternative Medical Systems and Practices in the United States: Alternative Medicines – Expanding Medical Horizons* (the Chantilly Report) (National Institutes of Heath: Washington, 1992).

U.S. Senate, Committee on Finance, *Report to Congressional Requesters: Drug Safety: Improvement Needed in FDA's Post market Decision-making and Oversight Process* (Washington: Government Accounting Office, 2007).

WHO, *Declaration of Astana*, (WHO: Astana, 2018).

WHO, *Codex Alimentarius: International Food Standards*, online at: https://www.fao.org/fao-who-codexalimentarius/en.

WHO, *WHO Global Report on Traditional and Complementary Medicine - 2019* (WHO: Geneva, 2019).

WHO, *International Standard Terminologies on Ayurveda* (WHO: Geneva, 2023).

WHO, *International Standard Terminologies on Chinese Medicine* (WHO: Geneva, 2022).

WHO, *Traditional Medicine Strategy 2002-2005* (WHO: Geneva, 2002).

WHO, *Traditional Medicines Strategy 2014-2023* (WHO: Geneva, 2014).

SECONDARY MATERIALS: BOOKS

J. Abramson, *Overdosed America* (New York: Harper Collins, 2004).

J. Abramson and C. Davis, *Uncertain Pharmaceutical Regulation: Innovation, Politics and Promissory Science* (Palgrave McMillan: U.K, 2013).

F. Accum, *A Treatise on Adulterations of Food and Culinary Poisons: Exhibiting the Fraudulent Sophistications of Bread, Beer, Wine, Spirituous Liquors, Tea, Coffee, Cream, Confectionery, Vinegar, Mustard, Pepper, Cheese, Olive Oil, Pickles, and Other Articles Employed in Domestic Economy, and Methods of Detecting Them* (Longman: London, 1820).

F. Ackerman, "Critique of Cost-Benefit Analysis, and Alternative Approaches to Decision-making: A Report to Friends of the Earth England, Wales and Northern Ireland" (Global Development and Environment Institute, Tufts University: Medford, Massachusetts, 2008).

S. H. Adams, *the Great American Fraud: Articles on the Nostrum Evil and Quacks, In Two Series, Reprinted from Colliers Weekly* (Colliers Weekly: 1906).

E. H. Ahrens, *The Crisis in Clinical Research: Overcoming Institutional Obstacles* (New York: Oxford University Press, 1992).

B. Anderson, B. *Methodological Errors in Medical Research* (Cambridge: Massachusetts: Blackwell Scientific Publications, 1990) at 72.

M. Angell, *The Truth About the Drug Companies: How They deceive us and What to do About it* (New York: Random House, 2004).

J. Avorn, *Powerful Medicines: The Benefits, Risks, and Cost of Prescription Drugs* (New York: Knopf, 2004).

P.L. Berger and T. Luckman, *The Social Construction of Reality* (Anchor: 1967), 33; 113.

J. B. Blake, ed., *Safeguarding the Public: Historical Aspects of Medicine Drug Control*, (Baltimore: Johns Hopkins Press, 1970).

R. Baldwin, M. Cave and M. Lodge, *Understanding Regulation: Theory, Strategy and Practice*, 3ed (Oxford University Press: Oxford, 2012).

R. Baldwin, M. Cave and M. Lodge, *The Oxford Handbook of Regulation* (Oxford University Press: Oxford, 2010).

U. Beck, *the Risk Society* (Sage: London, 1992).

I. Bedchuck, "The Politics of Risk Society," in Franklin (ed.), *The Politics of Risk Society* (Wiley: Cambridge, 1998).

R. Bivins, *Alternative Medicine* (Oxford University Pres: Oxford, 2007) Kindle Edition.

H. Boon, N. Kachan and A. Boecker, "Use of Natural Heath Products: How Does Being 'Natural' Affect Choice?" (Sage: Toronto, 2012).

J. Braithwaite, *Restorative Justice and Responsive Regulation* (Oxford University Press: Oxford, 2002).

W. Bynum, *The History of Medicine: A Very Short Induction* (Oxford University Press: Oxford, 2008).

R. J. Carlson, *The End of Medicine* (Wiley: New York, 1975).

T. Caulfield, *The Science of Celebrity* (Penguin: Toronto, 2015) Kindle Edition.

T. Caufield, *The Cure For Everything!: Untangling The Twisted Messages About Health Fitness And Happiness* (Penguin Group: Toronto, 2012).

T. Caulfield, ed., *Using and Abusing Evidence in Science and Health Policy: Article Collection* (BioMed Central: 2013).

M. H. Cohen, *Complementary* and *Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (The John Hopkins University Press: Baltimore, 1998).

R. Cooter, eds., *Studies in the History of Alternative Medicine* (Macmillan Press: Oxford, 1988).

Robert Cryer, Tamara Hervey and Bal Sokhi-Bulley, *Research Methodologies in EU and International Law* (Oxford and Portland: Hart Publishing, 2011).

R. E. Curran, *Canada's Food and Drug Laws* (Chicago: Commerce Clearing House, 1953).

C. Davis, and J. Abraham, *Unhealthy Pharmaceutical Regulation: Innovation, Politics and Promissory Science* (London and New York: Palgrave, 2012).

A. Daemmrich, *Pharmacopolitics: Drug Regulation in the United States and Germany* (University of North Carolina Press: North Carolina, 2004).

D. Demortain, *Scientist and the Regulation of Risk – Standardizing Control* (Edward Elgar Publishing: Cheltenham, 2011).

R. V. Ericson and A. Doyle, eds., *Risk and Morality* (Toronto: Toronto University Press, 2003).

E. Ernst and K. Smith, *More Harm than Good? The Moral Maze of Complementary and Alternative Medicine* (Springer International Publishing: Switzerland, 2018).

C. Fierlbeck, J. Graham and M. Herder, eds., *Transparency, Power, and Influence in the Pharmaceutical Industry: Policy Gain or Confidence Game?* (University of Toronto Press: Toronto, 2021).

M. Foucault, *The Birth of the Clinic: An Archeology of Medical Perception* (Vintage: Toronto, 1994).

S. Francia and A. Stobart, *Critical Approaches to the History of Western Herbal Medicine: From Classical Antiquity to the Early Modern Period* (Bloomsbury Academics: London, 2014).

B. Goldacre, *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients* (Random House: Toronto, 2014), Kindle edition.

M. Goozner, *The $800 Million Pill: The Truth Behind the Cost of New Drugs* (Los Angeles: University of California Press, 2004).

J. Graham, *A Lethal Guardian: The Canadian Government's Ban on Prescription Drugs* (Fraser Institute: Vancouver, 2005).

N. Gunningham and P. Grabosky, *Smart Regulation: Designing Environmental Policy* (Oxford: OUP, 1998).

S. Hahnemann, *Organon Der Rationellen Heilkunde* (Arnoldischen Buchhandlung : Dresden, 1810).

J. R. Harrison, *International Regulation of Natural Health Products* (Boca Raton: Universal Publishers, 2008).

A. Hartzem, H. Tilson and K. Chan, *Pharmacoepidemiology and Therapeutic Risk Management* (Harvey Whitney Books Company: Toronto, 2008).

C. Hood, H Rothstein and R Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford University Press: Oxford, 2001).

Institute of Medicine of the National Academics, Complementary and Alternative Medicine in the United States (The National Academic Press: Washington, 2004).

L. E. Jesson and S. A. Tovino, *Complementary and Alternative Medicine and the Law* (Carolina Academic Press: Carolina, 2010),

T. S. H. Kaan, "Traditional, Complementary and Alternative Medicine" in Y. Joly and B. M. Knoppers, eds., *Routledge Handbook of Medical Law and Ethics* (Routledge: New York, 2014) Kindle Edition.

L. Kang and N. Pedersen, *Quackery: A Brief History of the Worst Ways to Cure Everything* (Workman: New York, 2017).

Kesey, K., *One Few over the Cuckoo's Nest (Viking Press: New York, 1963)*.

L. Lacey, *Mi'Kmaq Medicines* (Nimbus Publishing: Halifax, 2012).

M. Lee and B. Campbell, *Putting Canadians at Risk: How the Federal Government's Deregulation Agenda Threatens Health and Environment Standards* (Candain Center for Policy Alternatives: Ottawa, 2006).

D. Levi-Faur, ed., *The Oxford Handbook of Governance* (Oxford University Press: Oxford, 2012).

J. Lenzer, *The Danger Within Us: America's Untested, Unregulated Medical Device Industry and One Man's Battle to Survive It* (Hatchette Book Group: New York, 2017)

J. Lexchin, *The Real Pushers: A Critical Analysis of the Canadian Drug Industry* (Vancouver: New Star Books, 1984).

_____*Transparency in Drug Regulation Mirage or Oasis?* (Ottawa: Canadian Centre for Policy Alternatives: Ottawa, 2004).

_____ *Drug Safety and Health Canada: Going, Going…Gone?* (Canadian Centre for Policy Alternatives: Ottawa, 2009).

_____ *Private profits vs public policy: the pharmaceutical industry and the Canadian state* (University of Toronto Press: Toronto, 2016).

G. Majno, *The Healing Hand: Man, and Wound in the Ancient World* (First Harvard Press: Cambridge, 1975).

M. S. Micozzi, *Fundamentals of Complementary and Alternative, and Integrative Medicine*, 6th Edition (Elsevier Canada: Toronto, 2018).

D. Millstine, *Types of Complementary and Alternative Medicine - Special Subjects*, (Merck Manuals Consumer Version: 2022).

M. G. Morgan, M. Henrion and M. Small, *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis* (Cambridge: Cambridge University Press, 1990).

T. Nesi, Poison *Pills: The Untold Story of the Vioxx Drug* Scandal (Thomas Dunne Books: New York, 2008).

J. Peel, *Science and Risk-Regulation in International Law* (Cambridge University Press: Cambridge, 2010).

K. Popper, *The Logic of Scientific Discovery* (New York: Rutledge, 2004).

R. Porter, *The Greatest Benefit to Mankind: A Medical History of Humanity* (W.W. Norton & Company: New York, 1999).

C. Price, *Vitamania: How Vitamins Revolutionized the Way We Think about Food* (Penguin: New York, 2015).

R. E. Purser, *McMindfulness: How Mindfulness Became New Capitalist Spirituality* (Repeater: 2019).

Reader Digest, *Magic and Medicine of Plants* (Readers Digest: New York, 1986).

L. S. Reed, *The Healing Cults; a Study of Sectarian Medical Practice: its Extent, Causes, and Control* (Committee on the Cost of Medical Care - University of Chicago Press: Chicago, 1932).

M. Revere, *Access Delayed, Access Denied: Waiting for New Medicines in Canada* (Fraser Institute: Vancouver: 2010).

R. A. W. Rhodes, *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability* (Open University Press: Buckingham/Philadelphia, 1997).

F. Roisin, *Who is Wellness For? An Examination of Wellness Culture and Who It Leaves Behind* (Harper Wave: New York, 2022).

J. R. Saul, *Voltaire's Bastards: The Dictatorship of Reason in the West* (New York: Vintage Books, 1992).

N. Shapiro, Hype: *A Doctor's Guide to Medical Myths, Exaggerated Claims and Bad Advice – How to Tell What's Real and What's Not* (St. Martin's Press: New York, 2018).

S. Shorthose, eds., *Guide to EU Pharmaceutical Regulatory Law*, 2nd ed. (Kluwer Law International: 2011).

S. Singh and E. Ernst, *Trick or Treatment?: Alternative Medicine on Trial* (Transworld Books: London, 2009).

T. Smith, K. Kawa, V. Eckl, C. Morton and R. Stredney, *Market Report by the American Botanical Council (ABC): Herbal Supplement Sales in US Increase 8.5% in 2018* (American Botanical Council: 2018).

A. Sokal and J. Bricmont, *Fashionable nonsense: postmodern intellectuals' abuse of science* (St Martin's Press: Boston, 1999).

E. W. Stieb, *Drug Adulteration: Detection and Control in Nineteenth-Century Britain* (University of Wisconsin Press: London, 1966)

M. Taylor, *A Bitter Pill to Swallow* - LLM Thesis (Dalhousie University: Halifax, 2010).

K. Thomas, *The Story of Thalidomide in the U.S.- Told through Documents* (New York Times: New York, 2020).

D. Watkins and M. Burton, *Research Methods in Law*, 2nd ed. (Routledge: London, 2018).

P. Waller, *An Introduction to Pharmacovigilance* (Wiley-Blackwell: Hoboken, 2010).

J. Whorton, *Nature Cures: The History of Alternative Medicine in America* (Oxford University Press: New York, 2002).

M. E. Wiktorowicz, J. Lexchin, et al, *Keeping an Eye on Prescription Drugs, Keeping Canadians Safe* (Health Council of Canada: Ottawa, 2010).

J. H. Young, The *Toadstool Millionaires: A Social History of Patent Medicines in America before Federal Regulation* (Princeton University Press: Princeton, 1962).

MONOGRAPHS AND WEB MATERIAL

J. Abramson, "Sociology of Pharmaceutical Development and Regulation: A Realist Empirical Research Program" (2008) 30 *Sociology of Health & Illness* 869.

_____ "Partial progress: governing the pharmaceutical industry and the NHS, 1948-2008" (2009) 34 *Journal of Health, Politics and Law* 931.

_____ "Evolving sociological analyses of pharmaceuticalization" (2011) 33 *Sociology of Health & Illness* 726.

_____ "Pharmaceuticalization of Society in Context: Theoretical, Empirical and Health Dimensions" (2012) 44 *Sociology* 603.

J. Abraham and C. Davis, "Risking public safety: Experts, the medical profession and 'acceptable' drug injury" (2005) 7 *Health, Risk & Society* 379.

_____"Interpellative Sociology of Pharmaceuticals: Problems and Challenges for Innovation and Regulation in the 21st Century" (2007) 19(3) *Technology Analysis & Strategic Management* 387.

_____"Sociology of Pharmaceutical Development and Regulation: A Realist Empirical Research Program" (2008) 30(6) *Sociology of Health & Illness* 869.

J. Abraham and R. Ballinger, "Power, expertise and the limits of representative democracy: genetics as scientific progress or political legitimation in carcinogenic risk assessment of pharmaceuticals?" (2012) 3 *Journal of Community Genetics* 91.

J. Abramson and T. Reed, "Trading Risks for Markets: The International Harmonization of Pharmaceutical Regulation" (2010) 3(1) *Health, Risk & Society* 113.

F. Ali, H. Rehman Z. Babayan, et al, "Energy drinks and their adverse health effects: A systematic review of the current evidence" (2015) 127(3) *Postgrad Med* 2015 308.

P. Almond, "The Dangers of Hanging Baskets: Regulatory Myths' and Media Representations of Health and Safety Regulation" (2009) 36 *Journal of Law and Society* 352.

_____ "Revolution Blues: The Reconstruction of Health and Safety Law as 'Common-Sense' Regulation" (2015) 42 *Journal of Law and Society* 202.

_____ "Regulatory Inspection and the Changing Legitimacy of Health and Safety" (2018) 12 *Regulatory Governance* 49.

A. Alumni, "Energy Drink Consumption: Beneficial and Adverse Health Effect" (2015) 9(4) *International Journal of Health Sciences*.

S. Ambee, M.A. Cohen, E. Stewart and P. Lanoie, "The Porter Hypothesis at 20: Can Environmental Regulation Enhance Innovation and Competitiveness?" (2011) 7 *Review of Environmental Economics and Policy* 2.

W. Arnott, "Cisapride and the Vanessa Young Inquest" (2001) 165(4) *CMAJ*.

A. R. Barry, A. R., "Patients' Perceptions and Use of Natural Health Products" (2018) 151 *Can Pharm J* 254.

R. Baldwin and J. Black, "Driving Priorities in Risk-based Regulation: What's the Problem?" (2016) 43 *Journal of Law and Society* 565.

L. E. Battaglia, "Drug reformulation regulatory gaming in Pharmaceuticals: Enforcement & Innovation Implications" (2011) 79(2) *European Competition Journal* 379.

J. Bauman, "The "Déjà Vu Effect:" Evaluation of United States Medical Device Legislation, Regulation, and the Food and Drug Administration's Contentious 510(k) Program" (2012) 67(3) *Food & Drug Law Journal* 337.

L. Bec, "What you Should know About High-Alcohol, High Sugar Drinks and Caffeinated Energy Drinks" (2018) Globe and Mail, march16, 2018.

G. M. Beghi and A.M. Morselli-Labate, "Does homeopathic medicine have a preventive effect on respiratory tract infections? A real life observational study" (2016) 11 *Multidiscip Respir Med*.

J. Beuth, B. Schneider, R. Van Leendert, et al, "Large-scale survey of the impact of complementary medicine on side-effects of adjuvant hormone therapy in patients with breast cancer" (2016) 30(1) *In Vivo* 191.

J. Black, "Risk-Based Regulation: Choices, Practices and Lessons Learnt" in *Risk and Regulatory Policy: Improving the Governance of Risk*, ed. OECD (2010).

_____ "The Emergence of Risk-based Regulation and the New Public Risk Management in the United Kingdom" (2005) *Public Law* 512.

_____ "Forms and Paradoxes of Principle-based Regulation" (2008) 3(4) *Capital Markets Law Journal* 425-58.

_____ "The Role of Risk in Regulatory Processes" in *The Oxford Handbook of Regulation*, eds., R. Baldwin, M. Cave, and M. Lodge (2010).

J. Black and R. Baldwin, "Really Responsive Risk-based Regulation" (2010) 32 *Law & Policy* 181.

_____ "When Risk-based Regulation Aims Low: Approaches and Challenges" (2012) 6 *Regulation & Governance* 2.

S. Blanchmanche, S. Marette, J. Roose and P. Verger, "Do not eat fish more than twice a week – Rational choice regulation and risk communication: Uncertainty transfer from risk assessment to public" (2010) 12 *Heath, Risk & Society* 271 at 272.

E. P. Bras, R. Lofstedt and O. Renn, "Improving the decision-making process for non-prescription drugs: a framework for benefit-risk assessment" (2011) 90(6) *Clin Pharmacol Ther* 791.

_____ "A decision-analysis tool for benefit-risk assessment of non-prescription drugs" (2013) 53(5) *J Clin Pharamcol* 475.

A. Bogdandy, P. Dann, and M. Goldman, "Developing the Publicness of Public International Law: Towards a Legal Framework for Global Governance Activities" (2008) 9(11) *German Law Journal* at 1376.

J. J. Borg, G. Aislaitner, M. Pirozynski and S. Mifsud, "Strengthening and rationalizing pharmacovigilance in the EU: where is Europe heading to? A review of the new EU legislation on pharmacovigilance" (2011) 34(3) *Drug Safety* 187.

R. A. Bouchard, "I'm Still Your Baby: Canada's Continuing Support for U.S. Linkage Regulations for Pharmaceuticals" (2011) 15(1) *Intellectual Property Law Review* 71.

R. A. Bouchard and M. Sawicka, "The Mud and the Blood and the Beer: Canada's New Progressive Licensing Framework for Drug Approval" (2009) 3(1) *McGill Journal of Law & Health* 50.

M. Bovens, "Analysing and Assessing Accountability: A Conceptual Framework" (2007) 13 *European Law Journal* 447.

M. Bovens, "Two Concepts of Accountability: Accountability as a Virtue and as a Mechanism" (2010) 33(5) *West European Politics* 951.

E. P. Brass, R. Lofstedt and O. Renn "Improving the decision-making process for nonprescription drugs: a framework for benefit-risk assessment" (2011) 90(6) *Clinical Pharmacology and Therapeutics* 791.

H. Bremmers, B. Meulen, W. Jo and K. Poppe, "A legal-economic Analysis of International Diversity in Food Safety Legislation: Content and Impact" (2011) 1 *European Food and Feed Law Review* 41.

D. Bruser, "Energy Drinks Suspected to Have Caused Deaths of 3 Canadians" (2012) *Toronto Star* November 18, 2012.

T. Bubela, H. Boon and T. Caulfield, "Herbal remedy clinical trials in the media: a comparison with the coverage of conventional pharmaceuticals" (2008) 6 *BMC Medicine*.

T. Bubela, T. Caulfield and M. Koper, "Media portrayal of herbal remedy versus pharmaceutical clinical trials: Impacts on decision makers" (2007) 26 *Medicine and Law Journal* 363-373.

L. T. Budnik, X. Baur, V. Harth and A. Hahn, "Alternative drugs go global: possible lead and/or mercury intoxication from imported natural health products and a need for scientifically evaluated poisoning monitoring from environmental exposures" (2016) 11 *J Occup Med Toxicol* 49.

N. Bulson, "History of Things: The Origin and Evolution of Energy Drinks from Cocaine to Caffeine" (2020) *brobible*, online at: https://brobible.com/culture/article/origin-history-evolution-energy-drinks-cocaine-caffeine.

T. Burrows, K. Pursey, M. Neve and M. Stanwell, "What are the Health Implications Associated with the Consumption of Energy Drinks? A Systematic Review" (2013) 71(3) Nutrition *Reviews* 135.

Canadian Chamber of Commerce, D*eath by 130,000 Cuts: Improving Canada's Regulatory Competitiveness, (Canadian Chamber of Commerce: 2018)*

D. Carpenter, D. Chattopadhyay, S. Moffit and C. Nall, "The Complication of Controlling Agency Time Discretion: FDA Review and Deadlines and Post market Drug Safety" (2011) 56(1) *American Journal of Political Science* 98.

P. I. Carter, "Federal Regulation of Pharmaceuticals in the United States and Canada" (1999) 21 *Loy L. A. Int & Comp L J* 215.

S. Cassese, "What is Global Administrative Law and why study it?" in *Global Administrative Law: An Italian Perspective*, J. Casses and S. Battini, eds., (Robert Schuman Centre for Advanced Studies –Global Governance Programme: RSCAS Policy Papers, 2012) 10.

T. Caulfield, "Vaccines work and "natural" alternatives are bunk!" (25 October 2016) *Policy Options*.

_____ "Time to stop legitimizing pseudoscientific health remedies" (April 2016) *Policy Options*.

_____ "The world is flat! Bring on reiki, homeopathy and all that other bunk!" (10 February 2016) *Policy Options*.

_____"Homeopathy and the ethics of researching magic" (February 2015) *Policy Options*.

_____ "The Law, Unproven CAM and the Two-Hat Fallacy" (2012) 17 *Focus on Alternative and Complementary Therapies* 4-8.

T. Caulfield and T. Bubela, "Popular Representations of Science, Research and Technology" in N. Ries and J. Shelley, eds., *Food, Health and Biotechnology: Consumer and Social Issues in Canada's New Food and Health Products Industries* (Advanced Food and Materials Network: 2007) 24.

T. Caulfield and S. Debow, "A systematic review of how homeopathy is represented in conventional and CAM peer reviewed journals" (2005) 5 *BMC Complementary and Alternative Medicine* 12.

T. Caulfield and C. Feasby, "Potions, Promises and Paradoxes: Complementary and Alternative Medicine and Malpractice Law in Canada" (2001) 9 *Health Law Journal* 183.

T. Caulfield and C. Rachul, "Supported by Science?: What Canadian Naturopaths Advertise to the Public" (2011) 7 *Allergy, Asthma & Clinical Immunology* 14.

T. Caufield and M. Toews, "Rare Diseases and Resource Allocation Policy: The Role of Canadian Legal Norms" (2017) 49 *UBC Law Review* 789.

T. Caulfield, U. Ogbogu and G. Robertson, "The Law, Unproven CAM, and the Referral Challenge" (2013) 18(1) *Focus on Alternative and Complementary Medicine* 1.

Canadian Broadcasting Corporation (CBC), "Bill C-51: Targeting Natural Health Products?" (June 2008), online at: https://www.cbc.ca/news/science/bill-c-51-targeting-natural-health-products-1.748783.

_____ "Criticism of Natural Health Bill C-51 Mounts" (May 2008), online at: https://www.cbc.ca/news/science/criticism-of-natural-health-products-bill-c-51-mounts-1.719529.

_____ "Energy Drink Ban for Teens Urged by N.S. Doctors" (November 2012).

Canadian Broadcasting Corporation – Market place, "License to Deceive – Nighton" (2015), online at: https://www.cbc.ca/player/play/2658659258.

_____ "*Unproved Homeopathic Remedies for Kids Still Promising Relief despite New Label Rules*" (May 2017), online at: https://www.cbc.ca/news/health/homeopathic-labels-marketplace.

Canadian Medical Association, "Editorial: Vioxx - Lessons for Health Canada and the FDA" (2005) 172(1) *CMAJ*

M. Charkhandeh, M. A. Talib and C. J. Hunt, "The clinical effectiveness of cognitive behavior therapy and an alternative medicine approach in reducing symptoms of depression in adolescents" (2016) 239 *Psychiatry* 325.

S. Chakraborty, "Ex-Post Pharmacovigilance and Trust: A Perspective" (2010) 2 *European Journal of Risk Regulation* 83.

D. R. Challoner and W.W. Vodra, "Medical Devices and Health – Creating a New Regulatory Framework for Moderate-Risk Devices" (2011) 365 *NEJM* 977.

N. Chappell, et al., "Conflict of Interest in Pharmaceutical Policy Research: an Example from Canada" (2016) 21(2) *International Journal of Health Governance* 66.

P. Claeson, "Requirement on Efficacy of Herbal Products" (2014) 158 *Journal of Ethnopharmacology* 463.

T. K. S. Christie and J. S. G. Montaner, "The Perverted Irony of Health Canada's Special Access Programme" (2006) 174(12) *CMAJ* 1746 (PUBMED).

M. H. Cohen and D. M. Eisenberg, "Potential Physician Malpractice Liability Associated with Complementary and Integrative Medical Therapies" (2002) 136 *Annals of Internal Medicine* 596.

L. Cosgrove, S. Annoy, B. Mintzes and A. Shaughnessy, "Under the Influence: The Interplay among Industry, Publishing, and Drug Regulation" (2016) 23(5) *Accountability in Research*, 23(5), 257.

E. F. Cook, "History of Pharmacopeias" (1946) 1(4) *Food, Drug and Cosmetic Law Quarterly* 518.

I. Crawford, "Moral Legitimacy: The Struggle of Homeopathy in the NHS" (2016) 30(2) Bioethics 85.

N. M. Cruz, J. H. Barahona and J. M. Sabate, "Steps towards Harmonization: A Look at Europe and the United States" (2006) 8(3) *Journal of Comparative Policy Analysis* 225.

K. C. Curran, "British Food and Drug Law-A History" (1952) 6(4) *Food Drug Cosmetic Law Journal* 247.

G. D. Curfman and R. F. Redberg, "Medical Devices – Balancing Regulation and Innovation" (2011) 365 *NEJM* 975.

C. Davis, "The Socio-Political Roots of Pharmaceutical Uncertainty in the Evaluation of "innovative" Diabetes Drugs in the European Union and the US" (2011) 72 *Social Science & Medicine* 1574.

C. Davis and J. Abraham, "Desperately seeking cancer drugs: explaining the emergence and outcomes of accelerated pharmaceutical regulation" (2011) 33 *Sociology of Health & Illness* 731.

_____ "Re-thinking innovation accounting in pharmaceutical regulation: a case study in the deconstruction of "therapeutic advance" and "therapeutic breakthrough" (2011) 36 *Science, Technology & Human Values* 791.

_____"A Comparative Analysis of Risk Management Strategies in European Union and United States Pharmaceutical Regulation" (2011) 13(5) *Health, Risk & Society* 413.

A. Daemmrich and G. Krucken, "Risk versus Risk: Decision making Dilemmas of Drug Regulation in the United States and Germany" (2010) 9(4) *Science as Culture* 505.

D. Demortain, "From Drug Crisis to Regulatory Change: The Mediation of Expertise" (2008) 10(1) *Health, Risk & Society* 37.

M. Deng and X. Wang, "Acupuncture for amnestic mild cognitive impairment: a meta-analysis of randomised controlled trials" (2016) 34(5) *Acupunct Med* 342.

R. DeVries, R. and T. Lemmens, "The Social and Cultural Shaping of Medical Evidence: Case Studies from Pharmaceutical Research and Obstetric Science" (2005) 62(11) *Social Science & Medicine* 2694.

C. Doehring and A. Sundrum, "Efficacy of homeopathy in livestock according to peer-reviewed publications from 1981 to 2014" (2016) 179(24) *Vet Rec* 628.

A. Dodds, "The Core Executive's Approach to Regulation: From 'Better Regulation' to 'Risk-Tolerant Deregulation" (2006) 40(5) *Social Policy and Administration* at 526.

B. Dong, Z. Chen and X. Yin, et al, "The efficacy of acupuncture for treating depression-related insomnia compared with a control group: a systematic review and meta-analysis" (2017) *Biomed Res Int.*

G. T. Doran, "There's a S.M.A.R.T. way to write management's goals and objectives" (1981) 70(11) *Management Review* 35.

J. Downie, P. Baird and J. Thompson, "Industry and the Academy: Conflicts of Interest in Contemporary Health Research" (2002) 10 *Health Law J.* 103.

N. S. Downing, et al, "Regulatory Review of Novel Therapeutics – Comparison of Three Regulatory Agencies" (2012) 366 *NEJM* 2284.

H. L. Dunn, "What High-Level Wellness Means" (1959) 50(11) *Canadian Journal of Public Health* at 447.

D. Dyzanhaus, "Accountability and the Concept of (Global) Administrative Law" (2008) Paper presented at the *Hauser Globalization Colloquium: Global Governance and Legal Theory*, Institute for Law and Justice – NYU School of Law, online at: http://www.iilj.org/publications/2008-7Dyzenhaus.asp.

H. G. Eichler, F. Pignatti, H. Leufkens and A. Breckenridge, "Balancing early market access to new drugs with the need for benefit/risk data: a mounting dilemma" (2008) 7 *Nat Rev Drug Discov* 818.

R. M. Entmann, "Framing: Toward Clarification of a Fractured Paradigm" (1993) 43 *Journal of Communication* 51.

K. Epstein, "US Congress considers new tracking system for medical devices after excessive recalls" (2012) April 23 *BMJ.*

E. Ernst and M. Pittler, "Alternative therapy bias" (1997) 385 *Nature* 480.

E. Ernst, "The current state of research into homeopathy" (2016), online at: http://edzardernst.com/2016/08/the-current-state-of-research-into-homeopathy/.

E. Ernst, "How the Public is Being Misled about Complementary/Alternative Medicine" (2008) 101(11) *J. R. Soc. Med*. 528.

L. B. Faden and K. I. Kaitin, "Assessing the performance of the EMEA's centralized procedure: a comparative analysis with the US FDA" (2007) 42 *Drug Inf J* 45.

L. B. Fade and C. P. Milne, "Pharmacovigilance Activities in the United States, European Union and Japan: Harmonic Convergence or Convergent Evolution?" (2008) 63(3) *Food and Drug Law Journal* 83.

R. Fears, G. Griffin, D. Larhammar, V. Meulen and J. W. M. Meer, "Assessing and regulating homeopathic products" (2017) **282**, 6 *Journal of Internal Medicine* 563.

B. C. Foster, K. Cvijovic, H. Boon, et al, "Melatonin interaction resulting in severe sedation" (2015) 18 *J Pharm Pharm Sci* 124.

B. Fox, "Closing the Information Gap: Informing better medical Decision Making through the Use of post-market safety and Comparative Effectiveness Information" (2012) 67 *Food & Drug Law Journal* 83.

M. A. Gagnon, "Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health," 41(3) *Journal of Law, Medicine and Ethics* 571.

J. Gardner and K. Dew, "The Eltronix Controversy: Risk and How Actors Construct their World" (2011) 13(5) *Health, Risk & Society* 397.

B. Garrett, S. Murphy, S. Jamal, M. MacPhee and et al, "Internet health scams—Developing a taxonomy and risk-of-deception assessment tool" (2018) *Health & Social Care in the Community*.

A. I. Geller, N. Shehab, H. J. Weidle, et al, "Emergency department visits for adverse events related to dietary supplements" (2015) 373 *N Engl J Med* 1531.

S. J. Genuis, G. Schwalfenberg, A. J. Siy et al., "Toxic element contamination of natural health products and pharmaceutical preparations" (2012) 7(11) *PLoS ONE*.

M. Gilhooley, "Vioxx's History and the Need for Better Testing" (2007) 37 *Seton Hall Law Review* 941.

D. Gingery, "Bill outlines FDA 'progressive' and 'exceptional' drug approval pathways" (2011) 8(11) *Community Oncology* 528.

Z. Gok Metin and L. Ozdemir, "The effects of aromatherapy massage and reflexology on pain and fatigue in patients with rheumatoid arthritis: a randomized controlled trial" (2016) 17(2) *Pain Manage Nurs* 140.

S. A. Goldman, "U. S. Postmarketing Pharmacovigilance Compliance in the Midst of Regulatory Uncertainty" (2007) 62(3) *Food and Drug Law Journal* 513.

S. Grabia and E. Ernst, "Homeopathic aggravations: a systematic review of randomised, placebo-controlled clinical trials" (2003) 92(2) *Homeopathy* 92.

J. Graham, "Smart Regulation: Will the Government's Strategy Work" (2005) 173(12) *CMAJ* 1469.

J. Graham and R. Nuttall, "Faster access to new drugs: Fault lines between Health Canada's regulatory intent and Industry innovation practices" (2013) *Ethics in Biology, Engineering & Medicine – An International Journal,* 4(3) 231-239.

L. A. Grossman, "The Origins of American Health Libertarianism" (2013) 13 *Yale J. Health Policy and Legal Ethics* 76.

J. A. Green and S. H. Podolsky, "Reform, Regulation and Pharmaceuticals – The Kefauver – Harris Amendments at 50" (2012) 367 *NEJM* 1481.

E. Gutierrez, J. Silbert-Flagg and S. Vohra, "Management of Natural Health Products in Pediatric: A Provider-Focused Quality Improvement Project" (2015) 29(2) *Journal of Pediatric Health Care* 137.

N. P. Guehlstorf and L. K. Hallstrom, "The Role of Culture in Risk Regulation: a Comparative Case Study of Genetically Modified Corn in the United States of America and European Union" (2005) 8(4) *Environmental Science & Policy* 327.

R. Habibi, L. Guenette, J. Lexchin, E. Reynolds, M. Wiktorowicz and B. Mintzes, "Regulating information or allowing deception? Pharmaceutical sales visits in Canada, France and the United States" (2016) 44(4) Journal *of Law, Medicine and Ethics* 602.

R. Habibi, J. Lexchin, B. Mintzes and A. Holbrook, "Unwarranted claims of drug efficacy in pharmaceutical sales visits: are drugs approved on the basis of surrogate outcomes promoted appropriately?" (2017) 83 *British Journal of Clinical Pharmacology* 2549.

R. Habibi and J. Lexchin, "Quality and quantity of information in Summary Basis of Decision documents issued by Health Canada" (2014) 9(3) *PLoS One*.

J. H. Hamence, "The 1860 Act and Its Influence on the Purity of the World's Food: Historical Introduction" (1960) 15(11) *Food Drug Cosmetic Law Journal* 711.

M. Hamrell, "Raising Suspicions with the Food and Drug Administration: Detecting Misconduct" (2010) 16(4) *Science and Engineering Ethics* 697.

W. Hammitt and et al, "Precautionary Regulation in Europe and the United States: A Quantitative Comparison" (2005) 25(5) *Risk Analysis* 1215.

C. Harlow, "Global Administrative Law: The Quest for Principles and Values" (2006) 17(1) *European Journal of International Law* 187 at 190.

J. A. Hattangadi, J. T. O'Reilly and A. Recht, "US Food and Drug Administration Regulation of Medical Devices and Radiation Oncology: Can Reform Improve Safety?" (2012) 8(1) *J Oncol Pract* 53.

A. Hayes, "The History of Snake Oil" (2015) 294 *The Pharmaceutical Journal*.

P. C. Hebert, "Editorial: Progressive Licensing Needs Progressive Open Debate" (2007) 176(13) *CMAJ* at 1801 (PUBMED).

M. Herder, E. Gibson, J. Graham, J. Lexchin and B. Mintzes, "Regulating Prescription Drugs for Patient Safety: Does Bill C-17 Go far Enough?" (2014) 186(8) *CMAJ* 287-E29.

M. Herder, "Toward a jurisprudence of drug regulation" (2014) 422 *Journal of Law and Medical Ethics* 244.

_____ "What Is the Purpose of the Orphan Drug Act?" (2017) 14(1) *PLoS Med*

M. Hirako, N. McAuslane, S. Salek, C. Anderson and S. Walker, "A comparison of the drug review process at five international regulatory agencies" (2007) 41 *Drug Inf J* 291.

C. Hitt, "Red Bull, Four Loko, and 5 Hour Energy Drinks: The History of Energy Drinks" (2021) *thrillist,* online at: https://www.thrillist.com/news/nation/history-of-energy-drinks.

A. Howerter, T. Hollenstein, H. Boon, et al, "State-space grid analysis: applications for clinical whole systems complementary and alternative medicine research" (2012) 19 *Forsch Komplementarmed* 30.

P. Hughes, S. Rees, S. B. Kalindjian and K. L. Philpott, "Principles of early Drug Discovery" (2011) 162(6) *British Journal of Pharmacology*.

F. Hulstaert and et al, "Pre-Market Clinical Evaluations of Innovative High-Risk Medical Devices in Europe" (2012) *International Journal of Technology Assessment in Health Care* 278.

P. Hutt, "A History of Government Regulation of Adulteration and Misbranding of Food" (1984) 39(2) *Food, Drug and Cosmetic Law Journal* 33.

B. M. Hutter, "Variations in Regulatory Enforcement Styles" (1989) 11 Law & Policy 153.

_____"The Attractions of Risk-based Regulation: Accounting for the Emergence of Risk Ideas in Regulation" (2005) *CARR Discussion Paper no. 33*, online at: http://www.lse.ac.uk /accounting/CARR/pdf/DPs/Disspaper33.pdf.

J. Jacobs, W. Jonas, M. Jimenez-Perez, et al, (2003) Homeopathy for childhood diarrhea: combined results and meta-analysis from three randomized, controlled clinical trials. (2003) 22(3) *Pediatr Infect Dis J* 229.

L. R. Jager and J. T. Leek, "An estimate of the science-wise false discovery rate and application to the top medical literature" (2014) 15(1) *Biostatistics* 1.

W. Jammal, C. Stewart and M. Parker, ""CAM Creep": Medical Practitioner Professional Discipline and Integrative Medicine" (2014) 22 *JLM* 221.

K. M. Job, T. K. Kiang, J. E. Constance, "Herbal Medicines: Challenges in the Modern World. Part 4. Canada and United States" (2016) 9(12) *Expert Rev Clin Pharmacology* 1597.

I. F. Jones, "Arsenic and the Bradford poisonings of 1858" (2000) 265 The Pharmaceutical Journal 938.

J. S. Kahan, "The evolution of FDA regulation of new medical device technology and product applications" (1986) 41 *Food Drug Cosmetic Law Journal* 207.

R. Kanusky, "Pharmaceutical Harmonization: Standardization Regulation among the United States, the European Economic Community and Japan" (1993) 16 *Hous J. Int. L* 665.

T. J. Kaptchuk, E. Friedlander, J. M. Kelley, et al, "Placebos without deception: a randomized controlled trial in irritable bowel syndrome" (2010) 5(12) *PLoS ONE.*

A. Kaur, H. Yousef, D. Ramgobin-Marshall and R. Jain, "Energy Drink Consumption: A Rising Public Health Issue" (2022) 23(3) *Pub Med* .

B. Kingsbury, "The Concept of "law" in Global Administrative Law" (2009) 20(1) *The European Journal of International Law*.

B. Kingsbury, N. Krisch and R. B. Stewart, "The Emergency of Global Administrative Law" (2005) 65(8) *Law and Contemporary Problems* 17.

N. E. Kirshbaum, "Role of state government in the regulation of food and drugs" (1983) 38 *Food Drug Cosmetic Law Journal* 1999.

A. M. Knoll, "The Reawakeniung of Complementary and Alternative Medicine at the Turn of the Twenty-First Century: Filling the Void in Conventional Biomedicine" (2004) 20 *J Contemp Health L & Policy* 329.

W. Kondro, "Health Canada Proposes New Regulatory Regime for Drugs" (2007) 176(9) *CMAJ*, (PUBMED).

E. A. Konik, R. C. Jungling and Bauer, "Herbs and dietary supplements in the European Union: a review of the regulations with special focus on Germany and Poland" (2011) 8(1) *J. Diet Suppl* 43.

D. B. Kramer and A. S. Kesselheim, "User Fees and Beyond – The FDA Safety and Innovation Act of 2012" 367 *NEJM* 1279.

D. B. Kramer, S. Xu and A. S. Kesselheim, "Regulation of Medical Devices in the United States and European Union" (2011) 366 *NEJM* 848.

B. Kroes, "The Legal Framework Governing the Quality of (Traditional) Herbal Medicinal Products in the European Union" (2014) 158 *Journal of Ethnopharmacology* 449.

H. M. Krumholz, J. S. Ross, A.H. Presler and D.S. Egilman, "What Have We Learned from Vioxx?" (2007) *BMJ* 20(334) *BMJ*.

M. L. Kurzinger, "Structured Benefit-risk Evaluation for Medicinal Products: Review of Quantitative Benefit-Risk Assessment Findings in the Literature" (2020) 8(11) *Ther Adv Drug Saf*.

M. Kwa, L. J. Welty and S. Xu, "Adverse Events Reported to the US Food and Drug Administration for Cosmetic and Personal Care Products" (2017) *JAMA* 177(8) 1202.

H. Laeeque, H. Boon, N. Kascha, J. C. Cohen and J. D. Cruz, "The Canadian Natural Health Products (NHP) Regulations: Industry Perceptions and Compliance Factors" (2006) 6 *BMC Health Serv Res* 63.

W. Lahey, "New Governance Regulation and Managerial Accountability for Performance in Canada's Health Care Systems" in R. P Kouri and C. Régis, eds., *Grand Challenges in Health Law and Policy* (Editions Yvon Blais: Cowansville, 2010).

P. La Rochelle, J. Lexchin, D. Simonyan, "Analysis of the drugs withdrawn from the US market from 1976 to 2010 for safety reasons" (2016) *Pharmaceutical Medicine*.

W. E. Leal and D. B. Jackson, "Energy Drinks and Escalation in Drug Use Severity: Emergent Hazard to Adolescent Health" (2018)111 *Preventative Medicine* 391.

D. B. Leiderman, "Risk Management of Drug Products and the U.S. Food and Drug Administration: Evolution and Context" (2009) 105(1) *Drug and Alcohol Dependence*.

M. Leitch, "ISO 31000:2009 – The New International Standard on Risk Management" (2010) 30(6) *Risk Analysis* 887.

T. Lemmens and R. A. Bouchard, "Regulation of Pharmaceuticals in Canada" in J. Downie, J., Caulfield, T. and Flood, C. M. eds., *Canadian Health Law and Policy*, 3rd ed. (Markham: LexisNexis Canada Inc., 2007).

T. Lemmens and S. Gibson, "Decreasing the Data Deficit: Improving Post-Market Surveillance in Pharmaceutical Regulation" (2015) 59(4) *McGill Law Journal* 943.

T. Lemmens and C. Tess Sheldon, "The Governance of the Safety and Efficacy of Psychopharmaceuticals: Challenges and Opportunities for Reform" in J. Chandler and Colleen Flood, eds., *Law and Mind: Mental Health Law and Policy in Canada* (LexisNexis 2016) 223.

A. Leonardo Alves, A. Mantel-Teeuwisse, A. Paschke, H. Leufkens, L. Puil, E. Poplavska, and B. Mintzes, "Unbranded advertising of prescription medicines to the public by pharmaceutical companies (Protocol)" (2017) 7 *Cochrane Database of Systematic Reviews*.

G. Lesi, G. Razzini, M. A. Musti, et al, "Acupuncture as an integrative approach for the treatment of hot flashes in women with breast cancer: a prospective multicenter randomized controlled trial" (2016) 34(15) *JCO* 1795.

J. Lexchin, "Progressive Licensing of Drugs: Music or Noise?" (2008) 3(4) *Health Care Policy* 11 (PUBMED).

_____ "Those Who Have the Gold Make the Evidence: How the Pharmaceutical Industry Biases the Outcomes of Clinical Trials of Medications" (2012) 18(2) *Science and Engineering Ethics* 247.

_____ "Harmonization in Drug Regulation, But Who's Calling the Tune? An Examination of Regulatory Harmonization in Health Canada" (2012) 42 *International Journal of Health Services* 119.

_____ "New Drugs and Safety What Happened to New Active Substances Approved in Canada between 1995 and 2010?" (2012) 172(21) *Arch Intern Med* 1680.

_____"The pharmaceutical industry in the context of contemporary capitalism" in H. Waitzkin ed. *Health care under the knife: moving beyond capitalism for our health* (New York: Monthly Review Press, 2018).

_____ "The pharmaceutical industry and Health Canada: values in conflict" in J. Germov and J. Hornosty eds., *Second opinion: an introduction to health sociology*, second Canadian edition. (Toronto: Oxford University Press, 2016).

_____ "Drug pricing in Canada" in Z. Babar ed. *Pharmaceutical prices in the 21st century*. (Springer International Publishing: Switzerland. 2015).

_____ "Quality of evidence considered by Health Canada in granting full market authorisation to new drugs with a conditional approval: a retrospective cohort study" (2018) 8 *BMJ Open* 20.

_____ "The pharmaceutical industry in contemporary capitalism" (2018) 69(10) *Monthly Review*.

J. Lexchin and B. Mintzes, "A compromise too far: a review of Canadian cases of direct-to consumer advertising regulation" (2014) 26 *International Journal of Risk* and *Safety in Medicine* 213.

X. Li, Q. Xiao, K. Ze et al, "External application of traditional Chinese medicine for venous ulcers: a systematic review and meta-analysis" (2015) *Evid Based Complement Altern Med*.

J. Li, S. Zhang, R. Zhou, et al, "Perspectives of traditional Chinese medicine in pancreas protection for acute pancreatitis" (2017) 23(20) *World J Gastroenterol* 3615.

S. Lloyd-Bostock and B. M. Hutter, "Reforming Regulation of the Medical Profession: The Risk of Risk-Based Approaches" (2008) 10(1) *Risk Regulation and Health* 69.

R. Lloyd, S. Wadhwa and W. Chambers, "Food and Drug Administration approval process for ophthalmic drugs in the US" (2008) 19(3) *Curr Opin Ophthalmo* 190.

O. Lobel, "The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought" (2004) 89 *Minnesota Law Review* 342.

J. London, "Tragedy, Transformation, and Triumph: Comparing the Factors and Forces That Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act in the United States" (2014) 69(2) *Food* and *Drug Law Journal* 315.

L. Long, A. Huntleyand E. Ernst, "Which complementary and alternative therapies benefit which conditions? A survey of the opinions of 223 professional organizations" (2001) 9(3) *Complement Ther Med* 178.

I. Loudon, "A Brief History of Homeopathy" (2006) 99(12) *J R Soc Med* 607.

K. Lowe and E. McLaughlin,"Caution! The Bread is Poisoned: The Hong Kong Mass Poisoning of January 1857" (2015) 43(2) *The Journal of Imperial and Commonwealth History* 189.

R. Ludtke and D. Hacke, "On the effectiveness of the homeopathic remedy *Arnica montana*" (2005) 155(21) *Wien Med Wochenschrift* 482.

A. Lundh, J. Lexchin, B. Mintzes, J. Schroll and L. Bero, "Industry sponsorship and research outcome: systematic review with meta-analysis" (2018) 44(10) *Intensive Care Medicine* 1603.

L. Ma, B. Wang, Y. Long, et al, "Effect of traditional Chinese medicine combined with Western therapy on primary hepatic carcinoma: a systematic review with meta-analysis" (2017) 11(2) *Front Med* 191.

H. MacPherson, E. Newbronner, R. Chamberlain, et al, "Patients' experiences and expectations of chiropractic care: a national cross-sectional survey" (2014) 23(3) *Chiropractic Manual Ther.*

C. MacDonald and S. Gavura, "Alternative Medicine and the Ethics of Commerce" (2016) 30(2) *Bioethics*, 77.

J. Maddox, J. Randi and W. W. Stewart, "High-dilution experiments a delusion" (1988) 334 *Nature* 287.

D. Malleck, "Pure Drugs and Professional Druggists: Food and Drug Laws in Canada, 1870s-1908" (2006) 48(3) *Pharmacy in History* 103.

P. J. May, "Regulatory Regimes and Accountability" (2007) 1 *Regulation & Governance* 8.

W. G. McBride, "Thalidomide and Congenital Abnormalities" (1962) 2 *Lancet* 1358.

A. R. McCabe, "A Precarious Balancing Act: The Role of the FDA as Protector of Public Health and Industry Wealth" (2003) 36 *Suffolk U. L. Rev.* 787 at 804 (WL).

N. McNeil, "The Food Safety Modernization Act: A Barrier to Trade? Only if the Science Says So." (2012) 67(2) *Food & Drug Law Journal* 177.

Z. Meghani, "The US' Food and Drug Administration, Normativity of Risk Assessment, GMOs, and American Democracy" (2009) 22(2) *Journal of Agriculture and Environmental Ethics.*

L Milgrom and K. Chatfield, "Is homeopathy really 'morally and ethically unacceptable'? a critique of pure scientism" (2012) 26(9) *Bioethics* 503.

B. Mintzes, "The tip of the iceberg of misleading online advertising: Comment on trouble spots in online direct-to-consumer prescription drug promotion: A content analysis of FDA warning letters" (2016) 5(5) *International Journal of Health Policy and Management* 329.

_____ "Medication safety: opening up the black box" (2013) 22(9) *BMJ Quality and Safety* 704.

_____ "Is patient information on prescribed drugs just another form of advertising?" (2011) 343 *BMJ* 1.

B. Mintzes, S. Morgan and J. Wright, "Twelve years' experience with direct-to-consumer advertising of prescription drugs in Canada: A cautionary tale" (2009) 4(5) *PloS One* 1.

B. Mintzes, J. Lexchin and A. Quintano, "Clinical trial transparency: Many gains but access to evidence for new medicines remains imperfect" (2015) 116(1) *British Medical Bulletin* 43.

C. Moller, "European Governance: Meaning and Value of a Concept" (2006) 43 *Common Market Law Review* 313-36.

C. J. L. Murray and A. D. Lopez, "On the Comparable Quantification of Health Risks: Lessons from the Global Burden of Disease Study" (1999) 10(5) *Epidemiology* 594 (PUBMED).

V. Musini, B. Mintzes, A. Tejani and J. Wright, "Review overemphasises benefits and downplays serious harms" (2012) 345 *BMJ* 1.

B. Murdoch, S. Carr and T. Caulfield, "Selling falsehoods? A cross- sectional study of Canadian naturopathy, homeopathy, chiropractic and acupuncture clinic website claims relating to allergy and asthma" (2016) 6 *BMJ Open*.

B. Murdoch, R. Hyde-Lay and T. Caulfield, "An Examination of the Public Justifications for the Expansion of Canadian Naturopaths' Scope of Practice" (2012) 19 *Health Law Journal* 215.

P. Nanz and J. Steffek, "Global Governance, Participation and the Public Sphere" (2004) 39(2) *Government and Opposition* 314.

National Post, View*: Health Canada is Complicit in Peddling Pseudoscience "Safe and effective" Should Mean Just That; If it can't be Proven, it should not be Approved*. (National Post: March 2015).

V. J. Navarro, H. Barnhart, H. L. Bonkovsky, et al, "Liver injury from herbals and dietary supplements in the U.S. Drug Induced Liver Injury Network" (2014) 60 *Hepatology* 1399.

C. Nayak, P. Oberai, R. Varanasi, et al, "A prospective multi-centric open clinical trial of homeopathy in diabetic distal symmetric polyneuropathy" (2013) 102(2) *Homeopathy*130.

C. Necyk, M. A. Ware, J. T. Arnason, et al, "Increased bruising with the combination of long-chain omega-3 fatty acids, flaxseed oil and clopidogrel" (2013) 146 *Can Pharm J (Ott)* 93.

J. Y. Ng and et al, "A Comprehensive Search String Informed by an Operational Definition of Complementary, Alternative, and Integrative Medicine for Systematic Bibliographic Database Search Strategies" (2022) 22 *BMC Complementary Medicine and Therapies*.

J. Y. Ng and M. Luong, "Evaluation of the Canadian Natural Health Product Regulatory Framework: A Scoping Review" (2020) *European Journal of Integrative Medicine* 37.

G. J. Nohynek, E. Antignac, T. Re and H. Toutain, "Safety assessment of personal care products/cosmetics and their ingredients" (2010) 243(2) *Toxicol Appl Pharmacol* 239.

S. Okie, "What Ails the FDA?" (2005) 352(1) *NEJM* 1063.

N. Obolensky, "The Food Safety Modernization Act of 2011: Too Little, Too Broad, Too Bad" (2012) 13(3) *Roger Williams University Law Review* 887.

E. B. Oberg, R. Bradley, K. Cooley, et al, "Estimated effects of whole-system naturopathic medicine in select chronic disease conditions: a systematic review" (2015) 4(2) *Altern Integr Med* 2192.

J. E. Oliver, T. Wood, "Medical conspiracy theories and health behaviors in the United States" (2014) 174(5) *JAMA Intern Med* 817.

B. Osimani, "Pharmaceutical Risk Communication: Sources of Uncertainty and Legal Tools of Uncertainty Management" (2010) 12(5) *Health, Risk & Society* 453.

C. Otter, "Milk and Victorians: The Problem of Adulteration" (2019) 45(2) *Victorian Review* 192.

M. Pandolfi, G. Carreras, "The faulty statistics of complementary alternative medicine (CAM)" (2014) 25(7) *Eur J Intern Med* 607.

E. Parasidis, "Patient over Politics: Addressing Legislative Failure in the Regulation of Medical Products" (2001) *Wis. L. Rev.* 929.

C. Paterson, C. Barts, L. Launso, et al, "Evaluating complex health interventions: a critical analysis of the 'outcomes' concept" (2009) 9 *BMC Complement Altern Med* 18.

D. Paul, "Comparison of the Drug Approval Process in the US, the EU and Canada" (2001) 1(3) *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing* 224.

G. Permanand and E. Mossialos, "Constitutional Asymmetry and Pharmaceutical Policy Making in the European Union" (2006) 12(4) *Journal of European Public Policy* 687.

C. Piana, E. Kliphuis and O. Della Pasqua, "Lack of compliance of European Public Assessment Reports to guidelines for pediatric drug development before the introduction of pediatric investigation plans" (2013) 11(1) *Clinical Trials*.

J. L. Pomeranz, C. R. Munsell and L. Harris, "Energy Drinks: An Emerging Public Health Hazard for Youth" (2013) 34(2) *Journal of Public Health Policy* 254.

A. Pugsley and M. J. Curtis, "Methodological Innovations Expand the Safety Pharmacological Horizon" (2012) 66(2) *Journal of Pharmacological and Toxicological Methods* 59.

C. Quintus and H. G. Schweim, "European Regulation of herbal medicinal products on the border area to the food sector" (2012) 19(3) *Phytomedicine* 378.

D.W. Ramey and W. Sampson, "Review of the evidence for the clinical efficacy of human acupuncture" (2001) 5(4) *Sci Rev Altern Med* 195.

N. Rao, H. A. Spiller, N. L. Hodges, et al, "An increase in dietary supplement exposures reported to US Poison Control Centers" (2017) 13 *J Med Toxicol* 227.

N. S. Rawson, "Time Required for Approval of New Drugs in Canada, Australia, Sweden the United Kingdom and the United States in 1996-1998" (2000) 162(4) *CMAJ* 501 (PUBMED).

A. S. Relman and M. Angell, "America's Other Drug Problem: How the Drug Industry Distorts Medicine and Politics" (2002) *The New Republic* 27.

O. Renn, A. Klinke and M. Van Asselt, "Coping with Complexity, Uncertainty and Ambiguity in Risk Governance: A Synthesis" (2011) 40 *AMBIO* 231 at 234.

S. Rioux, "Capitalist Food Production and the Rise of Legal Adulteration: Regulating Food Standards in 19th Century Britain" (2018) 19(1) *Journal of Agrarian Change* 64.

S. R. Rivas-Suarez, J. Aguila-Vazquez, B. Suarez-Rodriguez, et al, "Exploring the effectiveness of external use of batch flower remedies on carpal tunnel syndrome: a pilot study" (2017) 22(1) *J Evid Based Complement Altern Med*18.

S. A. Roberts, J. D. Allen and E.V. Sigal, "Despite Criticism of the FDA Review Process, New Cancer Drugs Reach Patients Sooner in the United States Than in Europe" (2011) 30(7) *Health Affairs* 1375.

C. C. Rosenbaum, "The History of Complementary and Alternative Medicine in the US" (2007) 41 *Annals of Pharmacotherapy*.

H. Rothstein, "The Institutional Origins of Risk: A New Agenda for Risk Research" (2006) 8(3) *Health, Risk & Society* 215.

H. Rothstein, P. Irving, T. Walden and R. Yearsley, "The Risks of Risk-based Regulation: Insights from the Environmental Policy Domain" (2006) 32 *Environment International* 1056.

H. Rothstein, O. Borraz and M. Huber, "Risk and the Limits of Governance: Exploring Varied Patterns of Risk-based Governance across Europe" (2013) 7 *Regulation & Governance* 215.

J. Rotstein, J. Barber, C. Strowbridge, et al, "Energy Drinks: An Assessment of the Potential Health Risks in the Canadian Context" (2013) 3(5) *International Food Risk Analysis Journal* 1.

M. Sade, "Complementary and Alternative Medicine: Foundations, Ethics and Law" (2003) 31 *J. Law, Medicine & Ethics* 183 at 184.

L. W. Salomon, "The New Governance and the Tools of Public Action: An Introduction" (2001) 28 *Fordham Urb. L.J.* 1611.

B. Saptarshi and J. C. Hassenplug, "Patient Access to Medical Devices - A Comparison of the US and European Review Processes" (2012) 367 *NEJM* 485.

M. Sawicka and R. A. Bouchard, "Empirical Analysis of Canadian Dug Approval Data 2001-2008: Are Canadian Pharmaceutical Players Doing More With Less" (2009) *McGill Journal of Law & Health*.

S. A. Schneider, "Notes on Food Law: An Overview of the Food Safety Modernization Act" (2011) *Arkansas Law Notes* 39.

J. Scott and S. P. Stum, "Court as a Catalysts: Rethinking the Judicial Role in New Governance" (2007) 13(3) *Columbia Journal of European Law.*

J. Scott and D. Trubek, "Mind the Gap: Law and New Approaches to Governance in the European Union' (2002) 8 *European Law Journal* (2002) 1-18.

M. Serafini, A. Stanzione, S. Foddai, R. Anton and L. Delmulle, "The European role on traditional herbal medicinal products and traditional plant food supplements" (2012) 46 *J. Clinical Gastroenterol*.

A. Schafer, "A bitter pill: consultations on drug safety appear to be stacked in favour of industry, which could be bad news for the public" (2011) Jan 19 *Ottawa Citizen* A:11.

A. Shahvisi, "No Understanding, No Consent: The Case against Alternative Medicine" (2016) 30(2) *Bioethics* 2016 69.

D. M. Shaw, "Homeopathy is where the harm is: five unethical effects of funding unscientific 'remedies'" (2009) 36(3) *Journal of Medical Ethics*.

K. Sheikh, *Many Personal Care Products Contain Harmful Chemicals. Here's What to Do About It*, (New York Times: February 15, 2023).

Z. Shi, T. Song,Y. Wan, et al, "A systematic review and meta-analysis of traditional insect Chinese medicines combined chemotherapy for non-surgical hepatocellular carcinoma therapy" (2017) 7(1) *Sci Rep*.

N. Silano, M. De Vincenzi, M and V. Silano, "The New European Legislation on traditional Herbal Medicines: Main Features and perspectives" (2004) 75 *Fitoterapia* 107.

S. G. Sreenivasmurthy, J.Y. Liu, J.X. Song, et al, "Neurogenic traditional Chinese medicine as a promising strategy for the treatment of Alzheimer's disease" (2017) 18(2) *Int J Mol Sci*.

A. W. Sloan, "Thomas Sydenham, 1624-1689" (1987) 72(4) S *Afr Med J* (PUBMED).

A. Smith, S. Jogalerka and A. Gibson, "Regulation of Natural Health Products in Canada" (2015) 158 *Journal of Ethnopharmacology* 507.

E. Soule, "The Precautionary Principle and the Regulation of U.S. Food and Drug Safety" (2004) 29(3) *Journal of Medicine and Philosophy* 333.

D. Sperling, "Food Law, Ethics, and Food Safety Regulation: Roles, Justifications, and Expected Limits" (2010) 23(3) *Journal of Agricultural and Environmental Ethics*.

U. Spiekermann, "Redefining Food: the Standardization of Products and Production in Europe and the United States, 1880-1914" (*2011)* 17(11) *History and Technology*.

P. T. Spiller, "A Positive Political Theory of Regulatory Instruments: Contracts, Administrative Law or Regulatory Specificity?" (1995) *69 S. CAL Rev 47*

N. Stafford, "William McBride: Alerted the World to the Dangers of Thalidomide in Fetal Development" (2018) 362 *BMJ*.

V. Stambolovic, "Medical Heresy – The View of a Heretic" (1996) 43 *Soc. Sci. Med* 60.

J. M. Stillman, "Paracelsus as A Reformer in Medicine" (1919) 29(2) *The Monist* 526.

E. W. Steib and E. J. Quance, "Drug Adulteration: Detection and Control in Canada" (1972) 14(1) *Pharmacy History* 18.

D. M. Strauss, "An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business" (2011) 66(3) *Food & Drug Law Journal* 353.

K. W. Swanson, "Food and drug law as intellectual property law: historical reflections" (2011) 2 *Wisconsin Law Review* 337.

J. Torfing, Jacob, "Governance networks" in *The Oxford Handbook of Governance* D. Levi-Faur. (Oxford University Press: Oxford, 2012).

S. A. Tabish, "Complementary and Alternative Healthcare: Is it Evidence-based?" (2008) *Int. J. Health Sci.*

S. Tai, "Comparing Approaches Towards Governing Scientific Advisory Bodies on Food Safety in the United States and the European Union" (2010) *Wisconsin Law Review* 627.

J. L. Tang, S. Y. Zhan and E. Ernst (1999) "Review of randomised controlled trials of traditional Chinese medicine" (1999) 319(7203) *BMJ* 160.

M. Tangkiatkumjai, "Potential Factors that Influence Usage of Complementary and Alternative Medicine Worlwide: A Systematic Review" (2020) *BMC Complemantary Medicine and Therapies* 20.

G. Taylor, "The reconfiguration of Risk in the British State" (2009) 24 *Public Policy and Administration* 379.

M. Taylor, "Chapter 2: A Background to Drug Regulation in Canada" in *A Bitter Pill to Swallow* - LLM Thesis (Halifax: Dalhousie University 2010).

K. E. Thomas, N. McAuslane, C. Parkinson, S. R. Walker and D. K. Luscombe, "A Study of Trends in Pharmaceutical Regulatory Approval Times for Nine Major Markets in the 1990s" (1998) 32 *Drug Information Journal* 787 (PUBMED).

S. Tombs and D. Whyte, "Transcending the Deregulation Debate? Regulation, Risk, and the Enforcement of Health and Safety Law in the UK" (2013) 7 *Regulation & Governance* 61.

Toronto Star, "Energy drinks suspected to have caused deaths of 3 Canadians" (November 2012).

D. Trubek and L. Trubek, "New governance and legal regulation: Complementarity, rivalry, or transformation" (2007) 13 *Columbia Journal of European Law* 542.

L. Trubek, "New Governance and Soft Law in Health Care Reform" (2006) 3 *Indiana Health Law Review* 139.

M. Vandergrift and P. Kanavos, "Health Policy versus Industrial Policy in the Pharmaceutical Sector: the Case of Canada" (1997) 41(3) *Health Policy* 241.

H. Vernon, C. Borody, G. Harris, et al, "A randomized pragmatic clinical trial of chiropractic care for headaches with and without a self-acupressure pillow" (2015) 38(9) *J Manipulative Physiol Ther* 637.

C. L. Ventola, "Current Issues Regarding Complementary and Alternative Medicine (CAM) in the United States (2010) *Pharmacy and Therapeutics* 35(8) at 461.

M. Verhoef, G. Lewith, C. Ritenbaugh, et al, "Complementary and alternative medicine whole systems research: beyond identification of inadequacies of the RCT" (2005) 13(3) *Complement Ther Med* 206.

A. Vitry and B. Mintzes, "Disease mongering and low testosterone in men: the tale of two regulatory failures" (2012) 196(10) *Medical Journal of Australia* 619.

D. Vogel, "The Globalization of Pharmaceutical Regulation" (1998) 11(1) *Governance* 1.

S. Vohra, K. Cvijovic, H. Boon, et al, "Study of Natural Health Product Adverse Reactions (SONAR): Active Surveillance of Adverse Events Following Concurrent Natural Health Product and Prescription Drug Use in Community Pharmacies" (2012) *Plos:One*.

I. E. Vural, M. Herder and J. E. Graham, "From Sandbox to Pandemic: Agile Reform of Canadian Drug Regulation" (2021) 125(9) *Health Policy* 1115.

R. Waliji and H. Boon, "Natural Health Product Regulations: Perceptions and Impact" (2008) 19(9) *Trends in Food Science & Technology* 494.

R. Waliji and M. Wiktorowicz, "Governance of Natural Health Products Regulation: An Iterative Process" (2013) 111(1) *Health Policy* 86.

J. Wardel, J. and J. Adams, "Indirect and Non-Indirect Risk Associated with Complementary and Alternative Medicine Use: An Integrative Review" (2014) 6 *European Journal of Integrative Medicine* 409.

P. M. Wax, "Elixirs, Diluents and the Passage of the 1938 Federal Food, Drug and Cosmetic Act" (1995) 122(6) *Ann Intern Med* 456.

H. A. Waxman, "A History of Adverse Drug Experiences: Congress has Ample Evidence to Support Restrictions on the Promotion of Prescription Drugs" (2003) 58 *Food & Drug L. J.* 299 (WL).

A. White, H. Boon, T. Alaraek, et al, "Reducing the Risk of Complementary and Alternative Medicine (CAM): Challengers and Priorities" (2014) 6(4) *European Journal of Integrative Medicine* 404.

S. Wiesner, A. Salamonsen and V. Fonnebo, "Which risk understandings can be derived from the current disharmonized regulation of complementary and alternative medicine in Europe?" (2018) 18(11) *BMC Complementary and Alternative Medicine*.

M. E. Wiktorowicz, "Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France" (2003) 28(4) *Journal of Health Politics, Policy and Law* 615.

M. E. Wiktorowicz, "Shifting Priorities at Health Protection Branch: Challenges to the Regulatory Process" (2008) 43(1) *Canadian Public Administration* 1.

M. E. Wiktorowicz, J. Lexchin and K. Moscou, "Pharmacovigilance in Europe and North America: divergent approaches" (2012) 75(1) *Soc Sci Med* 165.

S. J. Williams, P. Martin and J. Gabe, "The Pharmaceuticalization of society? A framework for Analysis" (2011) 33(5) *Sociology of Health & Illness* 710.

A. Wilson, and C. P Milne, "FDA's Risk Evaluation and Mitigation Strategies (REMS): Effective and Efficient Safety Tools or Process Poltergeist?" (2011) 66(4) *Food & Drug Law Journal* 569.

N. Yeates, D. K. Lee and M. Maher, "Health Canada's Progressive Licensing Framework" (2007) *CMAJ* 176(13), online at: https://www.cmaj.ca.

F. Zampieir, M. El Maghawry, A. Zanatta, and G. Thiene, "Andrea Vesalius: Celebrating 500 Years of Dissecting Nature" (2015) 66 *Global Cardiology Science Practice*.

L. Zeng, Y. Zou, L. Kong, et al, "Can Chinese herbal medicine adjunctive therapy improve outcomes of senile vascular dementia? Systematic review with meta-analysis of clinical trials" (2015) 29(12) *Phytother Res* 1843.

R. Zhang, D. Martin and C. D. Naylor, "Regulator or Regulatory Shield? The Case for Reforming Canada's Patented Medicine Prices Review Board" (2017) 189(14) *Canadian Medical Association Journal* E515.

G. Zhang, T. Higuchi, N. Shirai, H. Suzuki and E. Shimizu, "Effect of Erabu Sea Snake *(Laticauda semifasciata)* Lipids on the Swimming Endurance of Mice" (2007) 51(3) *Annals of Nutrition and Metabolism* 281.

C. Zollman and A. Vickers, "What is Complementary Medicine?" (1999) 319(7211) *BMJ* 693.

L. Zorzela, H. Boon, et al, "Serious adverse events associated with pediatric complementary and alternative medicine" (2014) 6(4) *European Journal of Integrative Medicine* 467.

M. Zurn, "Global Governance and Legitimacy Problems" (2004) 39(2) *Government and Opposition* 260.