

FRAMEWORK AND ENFORCEMENT STRATEGY FOR HEALTH
PROFESSIONS REGULATION IN ETHIOPIA

by

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ABSTRACT

This thesis examines the best system for health professions regulation in Ethiopia with a view to sketch the roles of state and non-state actors in that system. It argues for statist regulation as self-regulation is worrisome for its tendency to promote private interest instead over public protection. A statist regulation is an efficient system that is more capable of establishing accountable and procedurally fair processes and strengthening public trust than a system of self-regulation. But the state lacks capacity, expertise, and legitimacy, and risks capture and corruption. These could be resolved through an enforcement strategy rooted in responsive regulation theory. That strategy should emphasize soft regulatory instruments, which requires utilization of the capacity and motivation of non-state actors, particularly health professional associations. A statist regulatory framework that harnesses the contribution of non-state actors in implementing soft regulatory strategies would effectively protect patients and improve the quality of health care services in Ethiopia.

LIST OF ABBREVIATIONS USED

AHPRA	Australian Health Practitioners Regulation Agency
AMA	American Medical Association
BIG Act	Individual Health Care Professions Act 1993
BMA	British Medical Association
BPR	Business Process Reengineering
CHRE	Council for Healthcare Regulatory Excellence
CIBG	Central Information Center for Professional Practitioners in Health Care
CPD	Continuing Professional Development
CPJ	Committee to Protect Journalists
CPSO	College of Physicians and Surgeons of Ontario
CSRP	Civil Service Reform Program
DACA	Drug Administration and Control Authority
EFMHACA	Ethiopian Food, Medicine and Health Care Administration and Control Authority
PSA	Pharmaceutical Supply Agency
EHNRI	Ethiopian Health and Nutrition Research Institute
EMA	Ethiopian Medical Association

ENA	Ethiopian Nurses Association
EPRDF	Ethiopian Peoples' Revolutionary Democratic Front
ESA	Ethiopian Standards Agency
EU EOM	European Union European Election Observation Mission
FDRE	Federal Democratic Republic of Ethiopia
FMA	Finnish Medical Association
FMOH	Federal Ministry of Health
GMC	General Medical Council
HCCC	Health Care Complaints Commission
HPCSA	Health Professions Council of South Africa
HPRAC	Health Professions Regulatory Advisory Council
HRW	Human Rights Watch
HSDP	Health Sector Development Program
KNMG	Royal Dutch Medical Association
MPTS	Medical Practitioners Tribunal Service
NGOs	Non-Governmental Organizations
NHS	National Health Services

NSW	New South Wales
<i>Pro Medico</i>	Association for Continuous Professional Medical Development in Finland
PSC	Professional Standards Committee
PSCAP	Public Sector Capacity Building Program
RHPA	Regulated Health Professions Act
SNNPR	Southern Nations and Nationalities and Peoples Region
UK	United Kingdom
USA	United States of America
USAID	United States Agency for International Development
<i>Valvira</i>	National Supervisory Authority for Welfare and Health
WHO	World Health Organization
WMA	World Medical Association

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CHAPTER 1

INTRODUCTION

This thesis seeks to address this question: “how should regulatory authority be allocated among different regulatory actors to ensure effective regulation of health professions in Ethiopia?” Until 2009, health professions regulation in Ethiopia had mainly been undertaken by the state bureaucracy. There have, however, always been strong elements of self-regulation in the regime, particularly in the form of contribution from representatives of health professional associations.

In 2009, the government started to reform that system as part of a national Civil Service Reform Program (CSRP) implementation in the health sector. The CSRP objective was to build the capacity of the civil service, and enhance its efficiency, responsiveness, transparency and accountability. Within this framework, the reform to health professions regulation was partly motivated by the finding the existing system of health professions regulation was dysfunctional, and unable to address the problem of malpractice, and improving quality of health care services. That system needed fundamental change, namely, a new design of health professions regulation.

The goal for the new design was to prescribe licensing and license renewal processes to ensure practice by competent and ethical health professionals. It would also identify legislation and standards necessary to establish an effective health professions regulatory system, and adopt the responsive regulation model as its enforcement strategy. The reform envisages that most health professionals would be regulated at the state level. Consequently, the Federal Government would continue to regulate a few professions, and

play a greater role in legislative and standards development. These reforms are currently being implemented.

The need for the reform and most of its components are not greatly debated. In contrast, the framework of the new health professions regulatory system, which takes a statist approach and reduces the strength of the elements of self-regulation and the roles of associations in regulation, has been a source of contention between the government and the professional associations. The health professional associations have wanted self-regulation even before the new statist approach to health professions regulation was adopted. Dissatisfied with previous regulatory systems in which they had influential roles, they argue that self-regulation is an effective regulatory system for health profession in Ethiopia. On the other hand, the government argues that it can ensure the effectiveness of the system through its statist approach.

During my two years of work in health care regulation reform in the country, I have met with representatives of health professionals associations in technical working groups, consultative workshops and trainings. In the dialogue I had with these professionals, I encountered their discontent over the state intervention in their professions regulation, and their professional associations' limited role. Unfortunately, the professional associations do not formally seek dialogue with the state over regulatory power allocation that can ensure the effectiveness of health professions regulation. The state also does not adequately consult with professional associations over this issue. This leaves the debate over regulatory power allocation unresolved.

I believe unless the state and the non-state actors, particularly professional associations, enter into a constructive dialogue over the issue, the health professionals will resent and resist the implementation of the new regulatory design. The resentment could create an obstacle for effectiveness of the new design. The examination of regulatory power allocation to different actors in health professions regulation in Ethiopia is important to inform the constructive dialogue between state and non-state actors on the respective responsibilities each should assume to ensure the effectiveness of the new design.

I believe the new health profession regulatory system's ability to deliver on its promise of protecting patients from harm, and improving the quality of health care, depends on developing better understanding and cooperation among the important actors on how to allocate regulatory power among them. No single actor can bring substantial change in a complex health care system without a better understanding of the capacity, underlying interests and indispensable contributions of other important actors.

This thesis provides context for and argues that the statist approach to health professions regulation is the proper reform choice for Ethiopia. It makes suggestion on how this approach can be made effective to improve quality of health care services in the country. The thesis is organized into four major Chapters. Chapter 2 discusses the development of health professions regulation in Ethiopia, and traces its historical evolution until the 2009 reform. It shows that before the reform, health professions regulation had been undertaken within the state bureaucracy, but with strong elements of self-regulation. The Chapter then presents a general overview of the reform and its current level of implementation. The decentralization and enforcement strategy of health professions

regulation envisaged in the reform are examined in detail. The discussion further highlights the main arguments and rationales behind the claim for self-regulation of the health professions, and behind the statist approach to doing so. The other three chapters examine the debate in detail.

Chapter 3 sets up the conceptual framework for understanding health professions regulation in Ethiopia. It argues that the concept and purpose of regulation envisaged in the reform is narrow and lacks clarity. As such, there must be a broader conception of regulation that involves multiple actors and enforcement strategies by which to achieve the broader objective of quality improvement and patient safety. The Chapter also presents comprehensive criteria for ‘good’ regulation to be used for evaluating the effectiveness of alternative health professions regulatory systems.

The main arguments of the thesis are presented in Chapters 4 and 5. Chapter 4 is organized in to three sections. The first Section examines the economic and sociological literature on health professions regulation and its application to a choice of regulatory framework for Ethiopia. It examines the claim for self-regulation in Ethiopia in light of private interest theories, and it argues that the tension between public protection and private interests inherent in self-regulation constitute enough concern for Ethiopia to adopt another model. In contrast, a statist approach is a better option for Ethiopia, as the state is a disinterested party, as compared to self-regulatory professional bodies, and is better committed to protecting public interest. Section two assesses the pros and cons of statist *vis-à-vis* self-regulation in Ethiopia in more detail. The assessment reinforces the theoretical preference for a statist approach by showing that it is a more efficient

regulatory system for Ethiopia than self-regulation. The state is also more capable than self-regulatory bodies to establish accountable and procedurally fair processes and to strengthen public trust. It is admitted that the effectiveness of the statist approach for health professions regulation would depend on its enforcement strategies. Section three argues that such enforcement within the parameters of responsive regulation theory should emphasise soft strategies, that is persuasion and broad-based dialogue with health professionals. As such, the expertise and capacity of health professional associations should be utilized, indeed maximized.

Chapter 5 reinforces the theoretical and conceptual arguments made for statist health professions regulation via soft regulatory strategies that engage multiple actors, particularly health professional associations. This reinforcement is done by presenting evidence on medical regulation in selected countries in two sections. The first Section presents the medical regulation framework and enforcement strategy in selected jurisdictions, namely, UK, New South Wales (Australia), Ontario (Canada) which practice self-regulation, and Finland and the Netherlands which rely on state-led arrangements.

The second Section analyzes the relevance of the country experiences and the broader global trend they set in health professions regulation, to the exigencies of health professions regulation Ethiopia. I argue that the global trend in health professions regulation shows greater state intervention and oversight over self-regulation. Among other things, this is promoted by the shortcomings of self-regulation in protecting the public interest, particularly in light of issues of accountability, due process and public

trust. This practical evidence reinforces the conceptual arguments that caution Ethiopia about the merits of self-regulation. It also demonstrates the state's role as the indispensable, ultimate guardian of the public interest in the delivery of quality health care services. The comparative study on enforcement strategies shows that the utilization of soft strategies in statist regulation of health professions necessitates proactive involvement of multiple actors, particularly professional organizations. For Ethiopia, this reinforces the argument that its statist approach should emphasize the implementation of soft regulatory strategies. This requires harnessing the motivations, expertise and capacity of professional associations to carry out soft regulatory strategies in the country's statist regulatory framework.

In conclusion, it is argued that a statist system for regulating health professions is the preferred option for Ethiopia. As such, the choice of statist approach is commendable. But this system needs to conceptualize regulation broadly enough to enable carrying out activities targeted to improve quality of health care services. It is also argued that the system should design effective enforcement strategy based on responsive regulation theory. That strategy must acknowledge the importance of various regulatory instruments that would improve health care practice. These activities should be carried out by multiple actors, particularly health professionals associations.

CHAPTER 2

DEVELOPMENT OF HEALTH PROFESSIONS REGULATION IN ETHIOPIA: A FOCUS ON RECENT DEVELOPMENTS

Since its beginning in the early 1940s, health professions regulation in Ethiopia has undergone many changes. Recently, in 2009, the health professions regulation system underwent an overhaul using Business Process Reengineering (BPR) as a public management tool. The new health professions regulatory system reduces the role of professional associations and elements of self-regulation evident in previous regulatory regimes. The thesis explores the implication of this regulatory power allocation in establishing effective regulatory system. This Chapter provides background information on the development of health professions regulation in Ethiopia that will inform the analytical discussion in subsequent chapters. It is organized in five sections.

The first section presents relevant background information about Ethiopia that helps to contextualize a policy discussion on health professions regulation. It provides an overview of the constitutional and political organization and the health care system of the country. Section two traces the evolution of health professions regulation in the country until the introduction of the reforms in 2009. It highlights major historical developments and presents the health professions regulatory system that the reform seeks to change.

Section three discusses the reform as introduced by the BPR. The BPR study, namely, a Health and Health Related Services and Products Quality Regulation Core Process, sets out a new health professions regulatory design. The decentralization and enforcement strategy of health professions regulation are the most important features of the new design relating to regulatory power allocation. As such, they will be a focus of the

discussion. Section four presents the legislative framework that codified the reform's blue-print. Section five argues that the new health professions regulatory system adopts a statist approach to allocation of regulatory responsibility. It asks also whether the statist approach of power allocation is a better option than alternative systems.

1. The Context: Country Profile

i. Demography and Health Status

According to the Central Intelligence Agency's World Fact Book, Ethiopia, Africa's second most populous nation, has a population of more than 93 million.¹ The population is growing at an annual rate of 2.7%, with 83% of the people living in rural areas, and 17% in urban settings. Of the total population of Ethiopia, 44% are under 15 years, 52% are between 15 to 65 years, and only 3% are over the age of 65 years.²

Despite the fact that there have been some improvements in their health status over the last fifteen years, the Ethiopian population still faces high morbidity and mortality from communicable and non-communicable diseases. In 2005, life expectancy at birth in Ethiopia was 54 years.³ While the under-five mortality rate fell significantly to 101/1000, the country's maternal mortality rate, at 590/100,000, is among the highest in the world.⁴

¹ Central Intelligence Agency, "The World Factbook- Ethiopia" (2012), online: CIA <<https://www.cia.gov>>.

² Federal Ministry of Health (FMOH), *Health Sector Development Program (HSDP) IV-2010/11-2014/15* (Addis Ababa: Federal Ministry of Health, 2010) at VIII [FMOH, *HSDP IV*].

³ *Ibid.*

⁴ *Ibid.*

ii. Government and Politics

In May 1991, the Ethiopian Peoples' Revolutionary Democratic Front (EPRDF) toppled the then socialist government after winning a long civil war.⁵ It promised to establish a federal democratic republic.⁶ Federalism was a newly introduced state structure in the highly centralized state structure throughout modern Ethiopian history. After a four year transitional period, the Federal Democratic Republic of Ethiopia Constitution was adopted in December 1994.⁷ Consequently, Ethiopia's first national and regional legislative elections were held in June 1995 and the government of the FDRE was established in August 1995. Ever since, elections have been held every five years, and each time thus far, the EPRDF has been the winner. It has been contended that all these elections have not met the minimum international standards of free and fair elections.⁸

⁵ Siegfried Pausewang *et al.*, "Democratization in Ethiopia: Some Notes on Theory and Methodology" in Siegfried Pausewang et al., eds, *Ethiopia Since the Derg: A Decade of Democratic Pretension and Performance* (London: Zed Books, 2002) 1 at 1.

⁶ Theodore M Vestal, *Ethiopia: A Post-Cold War African State* (Westport: Praeger Publishers, 1999) at 7; Andreas Eshete, "Implementing Human Rights and a Democratic Constitution in Ethiopia" (1993) 21:1-2 *A Journal of Opinion* 8 at 8.

⁷ *Constitution of the Federal Democratic Republic of Ethiopia Proclamation*, no 1 (Ethiopia), 1995.

⁸ For example, the European Union European Election Observation Mission (EU EOM) has observed two legislative elections in 2005 and 2010 and concluded that the elections fall short of the minimum international standards for free and fair elections. EU EOM, *Ethiopia Legislative Election– Final Report* (2005), online: EU EOM <<http://www.eueom.eu/files/dmfile/FinalReport.pdf>> at 1; EU EOM, *Final Report – Ethiopia House of Peoples' Representatives and State Council Elections* (May 2010), online: EU EOM <http://eueom.eu/files/pressreleases/english/final-report-eueom-ethiopia-08112010_en.pdf> at 1.

The Constitution establishes a federal parliamentary republic that consists of a Federal Government and State members (Article 50(1)). Both the Federal Government and states have legislative, executive and judicial powers (Article 50(2)). The powers the Federal Government and states are defined in the Constitution. The Federal Government shall respect the power of states. Likewise, states should respect the power of the Federal Government (Article 50 (8)). The Constitution does not contain adequate provisions for governing intergovernmental relations among states, and between states and the Federal Government. Currently, disputes over issues of intergovernmental relations are not common. Where such disputes arise, they are resolved politically. The fact that EPRDF and its affiliated parties almost totally control the federal and states governments may have contributed to, generally speaking, smooth intergovernmental relations.

Article 51 of the Constitution provides the power of the Federal Government while Article 52 provides that all powers not exclusively given to or concurrently held with the Federal Government shall be reserved for the states. The powers of the Federal Government are generally issues of national concern. These include overall economic and social development, national standards and basic policy criteria for health and education, federal police and defence, foreign policy, international commerce, copyright and patents, possession and bearing of arms, standards for measurement, declaration of a state of emergency and immigration and granting of passports. The Federal Government legislative power is vested in two chambers of parliament, the House of Peoples' Representatives, and the House of Federation (Article 53). The House of Peoples' Representatives is the highest authority of the Federal Government (Article 50 (3)), and it issues legislation on all issues falling under the Federal Government's jurisdiction

(Article 55 (1)). Its laws are called *Proclamations*. The House of Federation has the power to interpret the Constitution (Article 62). The highest executive power is vested in the Prime Minister and Council of Ministers, and both are accountable to the House of Peoples' Representatives (Article 71). The Prime Minister is the Chief Executive, the Chairman of the Council of Ministers and the Commander-in-Chief of the national armed forces (Article 74(1)). The Council of Ministers consist of the Prime Minister, the Deputy Prime Minister, Ministers and other members designated by law (Article 76(1)). It enacts laws, called *Regulation*, pursuant to powers vested by Proclamations (Article 77 (13)). Judicial power, at Federal and States level, rests in a judiciary that is independent of the legislative and the executive branches (Article 79).

There are nine autonomous states and two city administrations that constitute the federation (Article 46). The nine states are Tigray, Afar, Amhara, Oromia, Somali, Benishangul-Gumuz, the Southern Nations and Nationalities and Peoples Region (SNNPR), Gambella, and Harari State. The two city administrations are Addis Ababa, and Dire Dawa City Administration. State Council is the highest organ of authority in the State that is accountable to the people of the State (Article 50 (3)). The State Council can issue legislation on matters under State jurisdiction. It has the power to enact a State Constitution consistent with the Constitution of the Federal Democratic Republic of Ethiopia (Article 50(5)). Without prejudice to the residual power of states, Article 52 (2) provides states various powers including organizing their government; formulating and executing economic and social policies, strategies, and plans of the State; administering land and natural resources in accordance with Federal laws; imposing and collecting taxes and duties on revenue sources reserved for states; drawing and administering the

State budget; and establishing and administering State police force. The states and the two city administrations are further divided into administrative divisions called *Zones* and *Woredas* (districts). The latter is the grass root level administrative unit that is run by a council elected by the people.

The Constitution enumerates the power of taxation of the Federal and States governments, exercised exclusively or concurrently (Articles 94-100). Undesignated power of taxation will be determined by the two-third decision of the joint session of the House of Peoples' Representatives and House of Federation (Article 99).

It is in line with this Federalism that Ethiopia's national and state level health care system is administered. States have substantial autonomy and responsibilities in coordinating and implementing state government functions, including health care. Each regional state and city-administration has its own health department, otherwise called a Health Bureau. The bureaus are responsible for the implementation of health initiatives in their own state. In other words, they exercise public health powers and responsibilities that are not exclusively given to the Federal Government.

The Constitution gives power to the Federal Government to establish and implement national standards and basic policy criteria regarding public health (Article 51(3)). It also gives the Federal Government the power to formulate and implement overall policies, strategies and plan in respect of the country's overall social development (Article 51 (2)). As such, the federal government has adopted a national health policy and four consecutive national Health Sector Development Plans (HSDPs) to address the nation's health problems. The Federal Ministry of Health (FMOH) and various delegated agencies

under it, are the executing government organs that oversee the country's overall health care operation. Among others, FMOH is responsible to coordinate and direct the country's health sector development programs and to design and implement national health strategies.

In addition to the FMOH, there are various autonomous federal organs working on public health, including the Ethiopian Health and Nutrition Research Institute (EHNRI), the Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA), and the Pharmaceutical Supply Agency (PSA). EHNRI is the prime federal agency to conduct research on the public health problems of the country, to provide laboratory services and technical assistance in laboratory technology, and supervise regional public health laboratories.⁹ EFMHACA is a regulatory agency that is entrusted with the power and responsibilities, among others, to oversee the quality, safety and efficacy of medicine; quality and safety of food; regulation of scarcely available health professionals and specialized health service institutions; and environmental health services.¹⁰ PSA is responsible to ensure the availability of adequate supply of safe, effective and affordable medicine and medical supplies for the public and private sectors.¹¹

⁹ *Ethiopian Health and Nutrition Research Institute Establishment Council of Ministers Regulation*, no 4 (Ethiopia), 1996, art 5.

¹⁰ *Ethiopian Food, Medicine and Health Care Administration and Control Authority Establishment Council of Ministers Regulation*, no 189 (Ethiopia), 2010, art 6 [EFMHACA Regulation].

¹¹ *Drug Fund and Pharmaceuticals Supply Agency Establishment Proclamation*, no 553 (Ethiopia), 2007, art 9.

iii. Health Care Delivery System

Ethiopia's health care system is one of the least developed in the world. Compared to the health care systems of other countries, the World Health Organization (WHO) ranks the efficiency of Ethiopia's health care system efficiency at 180th out of 191 countries.¹² According to the draft national Human Resource for Health Strategy, the density of Ethiopia's health workforce is approximately 0.7 health professionals per 1,000 people, which is significantly below the 2.3 health care workers per 1,000 recommended by the WHO.¹³ Particularly, there is an extreme shortage of doctors in country. One doctor covers nearly 42,706 people.¹⁴

The federal and states governments are the major provider of health care service in Ethiopia. The public health sector has recently been re-organized into a three-tier delivery system. The Primary Health Care Unit, the first tier, comprises a primary hospital linked to health centers and health posts by referral system.¹⁵ While a primary hospital caters to 60,000-100,000 people, health centers are supposed to provide services to approximately 15,000-25,000 people at the district level. In addition, each health center accepts referrals from five satellite health posts, and each health post caters to 3,000-5,000 people.¹⁶ The

¹² Ajay Tandon *et al.*, "Measuring Overall Health System Performance for 191 Countries" (1997), GPE Discussion Paper Series: No. 30, online: WHO <<http://www.who.int/healthinfo/paper30.pdf>> at 21.

¹³ FMOH, *Human Resource for Health Strategic Plan: Ethiopia 2009-2020* (Draft Document for Consultation, 2010) at 2 [unpublished].

¹⁴ *Ibid.*

¹⁵ FMOH, *HSDP IV*, *supra* note 2 at 4.

¹⁶ *Ibid.*

second tier is a general hospital that covers 1-1.5 million people.¹⁷ Most of the first and second-tier health institutions are administered and financed by state health bureaus or a *woreda* health offices, the district level administrative unit of the state health bureaus.¹⁸ They are state level health care institutions. The last tier is a specialized hospital that covers between 3.5-5 million people.¹⁹ Most of these specialized hospitals are federal hospitals that are administered by a Board and financed by the federal government. They are overseen by the FMOH or Ministry of Education, if they are a university teaching hospital.²⁰

The private sector also operates hospitals, clinics and diagnostic centers.²¹ They are licensed and regulated by state health bureaus. By 2007/08, out of 149 hospitals in the country, 40 hospitals were private-for-profit and there were 9 hospitals operated by charitable organizations. The rest are directly operated by the federal and states governments. There were a total of 1,788 private clinics in the country.²² Private clinics mostly provide ambulatory health care services while private hospitals provide inpatient health care services. The private-for-profit hospitals and clinics are concentrated in urban

¹⁷ *Ibid.*

¹⁸ *Ibid.*

¹⁹ *Ibid.*

²⁰ *Federal Hospitals Administration Council of Ministers Regulation*, no 167 (Ethiopia), 2009.

²¹ *Licensing and Supervision of Health Institutions Council of Ministers Regulation*, no 174 (Ethiopia), 1994.

²² Planning and Programing Department, *Health and Health Related Indicators – 2007/08* (Addis Ababa: Federal Ministry of Health, 2008) at 19.

and semi-urban areas; particularly most of these hospitals are located in the capital city, Addis Ababa.²³

Neither the federal nor states governments provide financial assistance to the private sector. Patients pay out of their pocket for health care services from private hospitals and clinics except those few that are covered by insurance scheme purchased by their employers. Patients also pay to get service from public sector health facilities but the payment is very minimal in contrast to the fee in the private sector. Furthermore, the public sector provides health care services for free for patients that do not have the capacity to pay upon presenting proof of poverty from their district administration.

iv. Health Care Financing

Sustainable health financing has been identified as one of the major challenges in the Ethiopian health care system. Ethiopia's health care expenditure is financed by development partners, out of pocket payments and government budgets. The proportion of health expenditure is 40% from development partners, 37% from household, out-of-pocket payments, 21% from the government (both federal and states), and the rest by a combination of employer insurance schemes and other private sources.²⁴ To address health financing, the federal government adopted a law in 2010 mandating individuals

²³ Vilasini Devi Nair *et al.*, "Private Hospital Sector Development: An Explanatory Study on Providers Perspective in Addis Ababa, Ethiopia" (2011) 21: supp 1 Ethiopian Journal of Health Sciences 59 at 60.

²⁴ FMOH, *HSDP IV*, *supra* note 2 at 30.

employed in the formal economic sector to be covered under a health insurance scheme.²⁵ This scheme covers a little more than one million people. To expand health insurance across the nation, the government is piloting community-based health insurance schemes in some selected areas.

2. Health Professions Regulation: A Brief Historical Account

i. Early Developments

Health professions regulation in Ethiopia is an understudied area. The lack of adequate literature on the field accounts for the limited discussion that follows on the origin and development of health professions regulation in Ethiopia. The discussion is limited to a review of relevant legislation and broad themes in the country's social and political development over the years, as connected to health professions regulation.

In Ethiopia, modern health care services emerged in an organized manner in late 19th and early 20th centuries.²⁶ The regulation of health care practitioners through licensing and registration started later. Medicine and dentistry regulation began in accordance with the Medical Practitioners Registration Proclamation No 42/1942.²⁷ It limits the practice of medicine and dentistry to those practitioners licensed by the Director of Medical Services. At that time, the Directorate of Medical Services was a department in the

²⁵ *Social Health Insurance Proclamation*, no 690 (Ethiopia), 2010; *Ethiopian Health Insurance Agency Establishment Council of Ministers Regulation*, no 190 (Ethiopia), 2010.

²⁶ Yifru Berhan, "Medical Doctors Profile in Ethiopia: Production, Attrition and Retention –In Memory of 100-Years Ethiopian Modern Medicine & The New Ethiopian Millennium" (2008) 46:1 *Ethiopian Medical Journal* 1 at 5.

²⁷ *Medical Practitioners Registration Proclamation*, No. 42 (Ethiopia) 1942.

Ministry of Interior.²⁸ Article 7 of the Proclamation criminalized the practice of medicine, surgery and dentistry by a person without license from the state. Nonetheless, the prohibition did not curtail the practice of traditional medicine (Article 8). The law also provided disciplinary measures against “infamous conduct in any professional respect” that could result in the revocation of the practitioner’s license. The Director of Medical Services would nominate a Board to investigate an allegation of infamous conduct (Article 6).

The Board may have been composed of professionals. Article 2 of the Public Health Proclamation No 26/1942 hinted that the Director of Medical Services must be a medical practitioner. Thus, medical regulation was undertaken by professionals within the state bureaucracy. The influence of the British medical regulation system is evident in the use of the infamous conduct notion in disciplinary proceedings. At that time, the British played a key role in Ethiopian domestic affairs, including serving as advisors and judges in public administration.²⁹ This followed the joint military expedition between the exiled Ethiopian government and the British against Italian occupiers of Ethiopia. The occupation lasted for five years, and Ethiopia regained its sovereignty in 1941. For the British, the fight was part of the World War II effort to defeat Italy in its East African colonies. However, after the victory, the British remained in Ethiopia and exerted

²⁸ Eileen Stommes & Seleshi Sisaye, “The Development and Distribution of Health Care Services in Ethiopia: A Preliminary Review” (1980) 13:3 *Canadian Journal of African Studies* 487 at 487.

²⁹ Bahru Zewde, *A History of Modern Ethiopia 1855-1991* (Oxford: James Currey Publishers, 2001) at 179.

significant influence on Ethiopian public administration, finance, and issues of territorial integrity.³⁰

The Pharmacists and Druggists Proclamation No 43/1942 regulated both the professions and the facilities where they were practiced.³¹ The pharmacists and druggists practiced independently, in contrast to doctors and other health professionals whose practice emerged in employment relationships with a health care facility. The Pharmacists and Druggists Proclamation contained only four provisions. It provided that without a license from the Director of Medical Services, a person should not engage in the business or practice of a pharmacist or druggist. It also provided that the premises where the profession of pharmacist or druggist was practiced had to be licensed by the Director of Medical Services.

The Medical Practitioners Registration Proclamation No 42/1942, and the Pharmacists and Druggists Proclamation No 43/1942 were repealed by the Medical Practitioners Registration Proclamation No 100/1948.³² The new law regulated the practice of a physician, surgeon, dentist, pharmacist, midwife, nurse and any other person “who holds himself out to the public as being able or prepared to examine, diagnose, treat, prescribe for or dispense for, patients for gain” (Article 2). “Medical practitioner” is the generic phrase the new law used to refer to all these health professionals.

³⁰ *Ibid.*

³¹ *Pharmacists and Druggist Proclamation*, no 43 (Ethiopia), 1942.

³² *Medical Practitioners Registration Proclamation*, no 100 (Ethiopia), 1948, art 17.

The law was issued subsequent to the reorganization of the public health system under the Public Health Proclamation No 91/1947.³³ The system was administered by the Ministry of Public Health, a successor to the former Directorate of Medical Services. The General Advisory Board of Health was established by the Public Health Proclamation No 91/1947 to advise the Minister. The Board consisted of at least eleven members to be appointed by the Minister. It had the power to hire experts necessary for undertaking its activities (Article 4). In this way, unlike other advisory boards that relied on the staff of the public office they advise for technical assistance, it wielded some power beyond its mere advisory mandate.

The Board was given two main responsibilities by the Medical Practitioners Registration Proclamation No 100/1948. First, it was responsible to evaluate applications for professional license and to provide its recommendations to the Minister. The Ministry acted as secretariat of the Board in accepting and ensuring the completeness of an application for licenses to be referred to the Board (Article 4). On the other hand, the Minister was the final decision-maker on licensing applications upon the recommendations of the Board. Such recommendations had to assure that the applicant was of “good character” and an Ethiopian citizen or one legally residing in Ethiopia (Article 5).

Secondly, the Board was responsible for investigating and recommending the proper course of action to the Minister on disciplinary matters. To this end, the law expanded the notion of infamous conduct to include unprofessional conduct, incapacity, or “gross

³³ *Public Health Proclamation*, no 91 (Ethiopia), 1947.

negligence in the performance of [a] profession” (incompetence). Any criminal conviction of a health professional was also a ground for disciplinary action that could result in the revocation or suspension of a license. The Minister had the power, upon the recommendation of the Board, to revoke or suspend a license where the health professional was convicted in a criminal case, found lacking the capacity or competence to practice the profession, or to have committed an unprofessional or been guilty of infamous conduct (Article 8).

The 1948 Medical Practitioners Registration Proclamation also conferred on the Minister or his authorized representative the power of inspection. This allowed an inspector to enter, at any reasonable hour, the premises of a medical practitioner for the purpose of inspection (Article 12). The Minister was also given the power to set rules necessary for the implementation of the Proclamation (Article 14). Like its predecessor laws, the implementation of the health professions regulation was done mainly by professionals within the state bureaucracy.

In 1964, the Minister of Public Health issued the Pharmacy Regulation to strengthen the regulation of the practice of pharmacists, druggists and pharmacy technicians, and the manufacturing, distribution, and sale of medicine.³⁴ The Pharmacy Regulation established a Pharmacy and Laboratory Department in the Ministry of Public Health under the supervision of a Chief Pharmacist (a pharmacist in charge of the Department) (Article 4). The Pharmacy and Laboratory Department kept a separate registry for pharmacists, druggists, and pharmacist technicians (Article 5). The Department made the entry into the

³⁴ *Pharmacy Regulation Legal Notice*, no 288, (Ethiopia), 1964 [Pharmacy Regulation].

registry and issued professional licenses upon the recommendation of the General Advisory Board of Health. The Pharmacy Regulation created two departments in the Ministry of Public Health responsible for health professions regulation. By establishing a Pharmacy and Laboratory Department, it separated the regulation of pharmacists, druggists and pharmacy technicians from the registration and licensing of doctors, surgeons, dentists, midwives and nurses.

The Pharmacy Regulation laid out the requirements and procedures for obtaining permits to open pharmacies, drug shops, rural drug vendors, medicine manufacturers, importers of medical supplies, and wholesalers of medical supplies.³⁵ It also provided the standards of services expected from these institutions.³⁶ Provisions relating to regulation of medical products, such as labeling and advertising of drugs, were also incorporated into the Pharmacy Regulation.³⁷

The Medical Practitioners Registration Proclamation No 100/1948 had already established the Board's power to hear and made recommendation to the Minister on disciplinary matters relating to pharmacists, druggists and any other health professional dispensing drugs to patients. The Pharmacy Regulation extended the Board's power to hear and provide recommendations to the Minister on disciplinary matters over institutions having the Minister's permit to engage in manufacturing, import, wholesale and sale of drugs (Articles 72 *cum* 73). The Pharmacy and Laboratory Department was

³⁵ *Ibid* arts 13-24.

³⁶ *Ibid* arts 25-51.

³⁷ *Ibid* arts 52- 64.

responsible for referring a complaint, after investigating its merits, to be heard and decided by the Board (Article 73). The expansion of the Board's mandate indicated its growing influence.

The Drug Administration and Control Proclamation No 176/1999 repealed most parts of the Pharmacy Regulation Legal Notice No 288/1964.³⁸ The law transformed the Pharmacy and Laboratory Department into an autonomous regulatory organ called the Drug Administration and Control Authority (DACA), with the task to “ensure the safety, efficacy, quality and proper use of drugs” (Article 3). DACA was responsible for setting standards of competence for, and licensing institutions engaged in the drug trade, such as pharmacies, drug shops, importers and wholesalers.

The Medical Practitioners Registration Proclamation No 100/1948 was repealed by the Medical Practitioners Registration (Repealing) Proclamation No. 218/2000.³⁹ Later in 2002, the Ethiopian Health Professionals Council Establishment Regulation No 76⁴⁰ was issued for the regulation of all health professionals in Ethiopia, including pharmacists, druggists and pharmacy technicians.

³⁸ *Drug Administration and Control Proclamation*, no 176 (Ethiopia), 1999, art 40 (1) (b).

³⁹ *Medical Practitioners Registration (Repealing) Proclamation*, no 218 (Ethiopia), 2000, art 2.

⁴⁰ *Ethiopian Health Professionals Council Establishment Council of Ministers Regulation*, no 76 (Ethiopia), 2002.

ii. The Ethiopian Health Professionals Council

The establishment of the Ethiopian Health Professionals Council did away with the previous health professional registration, licensing and disciplining activities under the General Advisory Board of Health. The Council was given the power to advise the Minister of Health on regulation of health professionals. Its main mandate was to ensure the quality of health professionals' training in collaboration with relevant bodies, undertake registration and licensing, and ensure observance of professional ethics (Article 4). Practically, the Council acted with delegated authority as the decision-maker, particularly relating to professional registration and licensing, and professional ethics. The disciplining aspect of health professionals was conceived in terms of professional ethics that did not distinguish between the ethical and legal obligations of health professionals.

The law provided that the composition of the Council was to include one representative from each health bureau of the nine states and two city administrations, seven members from different departments and teams in the Ministry of Health (including two surgical and internal medicine specialists), thirteen members representative from professional associations, a representative from DACA, and two representatives from the Ministry of Education. The law also left room for adding members to the Council where appropriate, for example, to include a representative of new health professional associations (Article 5). The representatives from the different government offices were mostly health professionals. Generally, the Council was located in the bureaucracy and consisted of health professionals. Thus, there was strong element of self-regulation even though the authority for regulation was that of the Minister and state bureaucracy state bureaucracy.

The aspect of self-regulation was exercised by various health professionals regulating all health professions collectively.

The Council was required to meet four times per year, and its day to day activities were done by its different committees and Secretariat. The committees were the Executive Committee, Education and Training Sub-Committee, Registration and Professional License Sub-Committee, and Professional Ethics Sub-Committee (Article 9). The Chairman and Vice-Chairman of the Council, who were also member of the Executive Committee, were appointed by the Minister from its members. Other members of the Executive Committee were elected from the Council. The Executive Committee had the power to establish Sub-Committees, and coordinate and supervise their work. It ran the daily functions of the Council and executed the Council's mandate when the Council was not in session (Article 11).

Without prejudice to the Executive Committee's power to establish other sub-committees, the law provided for three statutory sub-committees whose members were elected from the Council. The Registration and Professional License Sub-Committee and Professional Ethics Sub-Committee were the most important and relatively active sub-committees. The Registration and Professional License Sub-Committee was responsible to set criteria for professional licenses and decide on professional license applications. The Professional Ethics Sub-Committee was responsible for investigating complaints about the ethical conduct of health professionals', and submits its finding and proposed punishment to the Executive Committee. The Executive Committee was given the

statutory role of approving the Sub-Committees' decisions and activities. Practically, the Executive Committee endorsed the decisions and activities of the Sub-Committees.

The Secretariat of the Council was run by a Registrar and Deputy Registrar appointed by the Minister from the staff of the Ministry (Article 18). The Secretariat was responsible for keeping the register of health professionals, received and submitted applications for professional licenses to the Registration and Professional License Sub-Committee, and received matters relating to health professional education and ethics and directed them for consideration by the appropriate sub-committee.

The Health Professional Council Establishment Regulation No 76/2002 introduced a professional license renewal requirement every five years. A professional was required to present documents from an employer as to his/her ethical practice. The law also stipulated that the Council could require the professional to sit for an examination when necessary. Practically, however, the Council did not require an examination for licensing and license renewal.

As the Council's mandate was to advise the Minister, the Minister had the final say on health professional regulatory matters. In particular, the Council was expected to submit, through the Executive Committee, proposed decisions submitted to it by the three sub-committees on examination and results, criteria for licensing, decisions of registration and licensing, investigation on disciplinary matters and punishment. The Minister could uphold a proposed decision of the Council or render a different decision. The Minister could also direct the matter for reconsideration by the proper Sub-Committee where he/she believed that the case had not been "examined properly" (Article 24 (1)). The

decision of the Minister on professional registration and license, and on disciplinary matters was final.⁴¹

The implementation of the Ethiopian Health Professionals Council Establishment Regulation No 176/2002 was not satisfactory. The Council did not regularly meet, as required by the law. The Education and Training Sub-Committee was inactive and failed to introduce examination for licensing and license renewal. The relatively active Registration and Professional License Sub-Committee held meetings regularly. Nonetheless, a professional license was not uniformly required to practice in private and public health facilities. Practically speaking, a professional license was only required for practice in the private sector. Employment in the public sector did not require professional license from the Council. A professional license renewal process was not seriously taken up. The Professional Ethics Sub-Committee only handled a handful of cases, and its proceedings and activities were not open and transparent.

The Council's regulatory activities, generally, were inadequate and reactive. There were no notable efforts to provide and promote ethical direction among the health professions. Indeed, the Ministry of Health, in collaboration with the Ethiopian Medical Association,

⁴¹ There is no law that clearly provides for judicial review of decisions made by administrative agencies in Ethiopia. However, Article 37 (1) of the Constitution guarantees right to access to justice that reads: “[e]veryone has the right to bring a justiciable matter to, and to obtain a decision or judgment by, a court of law or any other competent body with judicial power.” And, Article 79 (1) of the Constitution provides that “[j]udicial powers, both at Federal and State levels, are vested in the courts.” On the basis of these provisions, an appeal to the Federal Courts may be made on the final decision of the Minister. Aberham Yohannes & Desta G/Michael, *Administrative Law: Teaching Material* (Addis Ababa: Justice and Legal Research Institute, 2009) at 198 [unpublished].

issued a code of ethics booklet, *Medical Ethics for Physicians Practicing in Ethiopia*, in 1998.⁴² The latest edition of the booklet was published in 2000. The Ethiopian Pharmacists Association, Ethiopian Nurses Association, and recently the Ethiopian Midwives Association, have also issued codes of ethics guiding the practices of their respective professions.⁴³ However, the Council's influence in the production of these documents and, more importantly, promoting them among health professionals was poor. There was no formal teaching of ethics in medical schools. All in all, the health professions regulatory system under the Council was dysfunctional and ineffective to ensure the protection of patients from harm and for improving health care quality.

During the last decade, the media highlighted some cases of professionals who failed to observe their ethical obligations. The Council did not respond, nor acted properly to meet the public's expectation in regard to the cases and what they implied for ethical conduct in the health professions. Nor did the professional associations respond by effectively promoting professional ethics. A notable exception may be the establishment of Ethics Committee in the Ethiopian Medical Association. The need to reform the health professions' regulatory framework was already felt when the government launched its civil service reform program through the Business Process Re-engineering (BPR) initiative. This is considered next.

⁴² Massresha Abuhay, *Ethics and Legal-Medicine* (Addis Ababa: Mega Publishing and Distribution PLC, 2010) at 18.

⁴³ The Ethiopian Midwives Association Code of Ethics is available online. Ethiopian Midwives Association, *Professional Code of Ethics and Conduct for Midwives* (2011), online:<<http://www.ethiopianmidwives.org/EMA%20cod%20of%20ethics%20for%20we b.pdf>>.

3. Reforming the Regulation of the Health Professions: The BPR

In 2004, the federal government launched a national Public Sector Capacity Building Program (PSCAP) to improve the effectiveness and responsiveness of public service delivery, and to improve good governance and accountability.⁴⁴ One component of the PSCAP has been the Civil Service Reform Program (CSRP).⁴⁵ The CSRP aims to build the capacity of the civil service to ensure effective execution of government policies and strategies, delivery of efficient, fair, and impartial public service, and to improve the transparency and accountability of the civil service.⁴⁶ It started in 2005 with various initiatives to reform the civil service, including “quick win” reforms approach to improve the federal and state government institutions’ service delivery speed, efficiency and fairness.⁴⁷ While undertaking “quick win” reforms which sought to cut unnecessary processes and save service delivery time and cost, the BPR was used as a major

⁴⁴ Mesfin Tafesse, “The Ethiopian Civil Service Reform Program” in Taye Assefa, ed, *Digest of Ethiopian National Policies, Strategies and Programs* (Addis Ababa: Forum For Social Studies, 2008) 373 at 398; Ministry of Capacity Building, *Public Sector Capacity Building Program* (Addis Ababa, 2004) [Unpublished].

⁴⁵ Tafesse, *supra* note 44 at 398.

⁴⁶ Getachew H Mengesha & Richard Common, “Civil Service Reform in Ethiopia: A Tale of Success in Two Ministries” (2007) 27 *Public Administration and Development* 367 at 370.

⁴⁷ Tafesse, *supra* note 44 at 399-401; Ministry of Finance and Economic Development (MoFED), *Ethiopia: Building on Progress – A Plan for Accelerated and Sustained Development to End Poverty (PASDEP) 2005/06-2009/10*, vol 1 (Addis Ababa: MoFED, 2006) at 179.

management reform tool.⁴⁸ Earlier encouraging results in some organizations prompted the application of BPR to reform service delivery in all government institutions in 2007.⁴⁹

Michael Hammer and James Champy provide the classic definition of BPR as, “the fundamental rethinking and radical redesign of business processes in order to achieve dramatic improvement in critical contemporary measures of performance, such as cost, quality, service and speed.”⁵⁰ The concept was first formulated to be applicable as a management tool to redesign corporations. Arie Halachmi and Tony Bovaird identify five elements of the concept of BPR reflected in many literatures. First, BPR is a complete challenge to the existing situation by asking the relevance of process, whether it is needed or adds any value, and identifying other processes or application of better information technology that would produce the same result. Second, BPR calls for radical redesigning of the core process in the organization rather than making incremental and marginal changes. Third, BPR envisages that the new process should improve performance

⁴⁸ Adebabay A Gebrekidan, “Promoting and Strengthening Professionalism in the Civil Service: The Ethiopian Case” (Paper delivered at the Capacity Building Workshop organized by United Nations Department of Economic and Social Affairs, United Nations Economic Commission for Africa & the African Public Sector Human Resource Manager’s Network, Addis Ababa, 14 March 2011), online: United Nations Public Administration Network <<http://unpan1.un.org/intradoc/groups/public/documents/aapam/unpan044787.pdf>> at 9; Tafesse, *supra* note 44 at 402.

⁴⁹ *Ibid* at 403; Tesfaye Debela, “Business Process Reengineering in Ethiopian Public Organizations: The Relationship Between Theory and Practice” 2:1 *Journal of Business and Administrative Studies* 20-59.

⁵⁰ Michael Hammer & James Champy, *Reengineering the Corporation: A Manifesto for Business Revolution* (New York: Harper Collins, 1993) at 32. This book was translated in to the official language of the Federal Government, *i.e.*, *Amharic*, and was used as a ‘*Bible*’ in applying BPR to the public sector in Ethiopia.

drastically from one performance curve to a higher one. Fourth, the changes that the new process brings should be aligned a corporate strategy that must clearly state the corporate mission. Fifth, the new core process should create or increase value that would make the corporation stand out from others.⁵¹

BPR had been popular among corporations and academics in late 1980s and early 1990s. This was followed by reports of difficulties to improve performance drastically, and researches critical of BPR.⁵² It was criticized as a violent and offensive technique.⁵³ More importantly, it is criticized for its failure to produce radical improvement.⁵⁴ Champy and Hammer acknowledged that BPR was not implemented in the radical manner as they originally intended, and argued this was mainly due to the inability of organizations to generate and survive necessary cultural change.⁵⁵

Many features of BPR, including rapid and radical change and producing dramatic performance improvement, are appealing to public sector reformers.⁵⁶ There is a desire to

⁵¹ Arie Halachmi & Tony Bovaird, "Process Reengineering in the Public Sector: Learning Some Private Sector Lessons" (1997) 17:5 *Technovation* 227 at 228.

⁵² Robert MacIntosh, "BPR: Alive and Well in the Public Sector" (2003) 23:3 *International Journal of Operations & Production Management* 327 at 328.

⁵³ Keith Grint & Peter Case, "The Violent Rhetoric of Re-engineering: Management Consultancy on the Offensive" (1998) 35:5 *Journal of Management Studies* 557-577.

⁵⁴ MacIntosh, *supra* note 52 at 329.

⁵⁵ James Champy, *Re-engineering Management* (London: Harper Collins, 1995); Michael Hammer & Steven A Stanton, *The Reengineering Revolution: A Handbook* (New York: Harper Business, 1995).

⁵⁶ MacIntosh, *supra* note 52 at 340.

efficiently deliver services in the public sector, “where the normal expectation is to do more with less.”⁵⁷ However, there are differences between corporations and public sector organizations that should be considered when BPR is applied in the public sector.⁵⁸ More importantly, the meaning of “value” in the private and public sector is quite different.⁵⁹ To identify business processes in the private sector that can be changed to increase “value” can be easily done as “value” is mostly measured in terms of cost in that sector. But in the public sector “organizational functions and procedures that do not add to value when performed in the private sector may have an inherent legal or symbolic value in the public sector; for example, the concept of due process or the consistent application of decision rules.”⁶⁰ Halachmi and Bovaird advise that in determining value-added in the process reengineering effort in the public sector, the meaning of “value” should be interpreted broadly.⁶¹

In Ethiopia, the government’s rationale for adopting BPR was the recognition that public sector institutions indulge in time-consuming and costly delivery of public services, and that they are also non-responsive and stagnant in their attitude to serving the public. Thus, the public sector was believed to require radical redesigning with an eye on outcomes.

⁵⁷ *Ibid* at 341; Halachmi & Bovaird, *supra* note 51 at 229.

⁵⁸ *Ibid*; Debela, *supra* note 49 at 35-36; MacIntosh, *supra* note 52 at 341.

⁵⁹ William Lahey, “New Governance Regulation and Managerial Accountability for Performance in Canada’s Health Care Systems” in Robert P Kouri & Catherine Regis, eds, *Grand Challenges in Health Law and Policy* (Quebec: Thomson Reuters Canada, 2010) 243 at 256; Halachmi & Bovaird, *supra* note 51 at 230.

⁶⁰ *Ibid*. See MacIntosh, *supra* note 52 at 341.

⁶¹ Halachmi & Bovaird, *supra* note 51 at 234.

Consequently, the BPR was introduced in all sectors of government administration at the Federal and States levels.

In 2008, health sector reform through BPR was started under the leadership and coordination of the FMOH and state health bureaus.⁶² Accordingly, the FMOH adopted the Health and Health Related Services and Products Quality Regulation Core Process in 2009.⁶³ The core process involves all regulatory activities in the health sector that the government should undertake to ensure quality of health services and products. Health professions regulation is one of the regulatory activities redesigned by the core process.

The BPR studied the status of health professions regulation in Ethiopia. It concluded that the system of health professions regulation has been ineffective and inefficient, except for the regulation of pharmacy practice.⁶⁴ The study acknowledged that the ineffectiveness of health professions regulation accounted for the low quality of health care services. The

⁶² FMOH, *Annual Performance Report of HSDP III- 2007/08* (Addis Ababa: Planning and Program Directorate, 2008) at 13.

⁶³ FMOH, *Health and Health Related Services and Products Quality Regulation Core Process* (Addis Ababa, 2009)[unpublished][FMOH, *Regulatory Core Process*].

⁶⁴ *Ibid* at i. The BPR study does not provide why the regulation of pharmacy practice was considered better. It may be due to the existence of a separate institution, *i.e.*, DACA, which regulated drugs in Ethiopia and their manufacturing, importing, wholesaling, and dispensing. It may also be because the regulation of pharmacy was given attention as it has been practiced mostly in the private sector. Pharmacy regulation has been continuously undertaken since the adoption of the Pharmacy Regulation in 1964 that regulates the practitioners and institutions where they practiced. The establishment of DACA strengthen that legacy. In contrast, it is only since 1991 that the private sector has started to play notable role in health care services delivery following the opening of the market after the fall of the socialist government. The regulation of health institutions were introduced in 1994. Before that health professions regulation was confined to paper work of licensing, and the institutions where they practice was not regulated.

frustration and loss of confidence in the regulatory system by the public was noted.⁶⁵ The infrequent use of the available disciplinary process, and the poor awareness of the functions of the Professional Ethics Sub-Committee resulted in the loss of public confidence in the complaints handling system.

The study also noted that malpractice was a critical problem attributed to multiple causes.⁶⁶ These included the lack of an adequate legal framework and standards for professional practice, such as comprehensive licensing requirements, scope of practice, and standard of care; poor compliance with available standards; lack of monitoring and evaluation; erosion of the professionals' sense of accountability and responsibility; inadequacy of the complaint handling system; and weak participation and contribution of health professional associations.⁶⁷ Malpractice led to health risks to the public, and erosion of public trust in the health professionals and their services. It also resulted in unnecessary cost to the health care system through prolonging and complicating patients' health problems.⁶⁸

The study identified unwritten rules and assumptions that needed to be broken to fundamentally redesign the health professions' regulation system and to address the problem of malpractice.⁶⁹ It identified that equating long term experience with

⁶⁵ *Ibid* at 49.

⁶⁶ *Ibid* at 55.

⁶⁷ *Ibid*.

⁶⁸ *Ibid*.

⁶⁹ *Ibid* at 57.

qualification, and the tendency to protect health professionals were unwritten rules that contributed to malpractices. The assumptions identified as requiring change were: presuming the competence of all health professionals; assuming that seriously regulating health professionals may lead to turn-over; and the belief that professionals comply with ethical standards.⁷⁰

The BPR study provided ideas on how to break the old rules and assumptions. It suggested only competent health professionals who satisfy clear licensing requirements should be licensed to practice, and that a professional license would only be renewed upon the professional's fulfillment of the required continued professional competence program. It was also agreed that seriously regulating health professionals by taking appropriate measures would not result in turn-over and brain-drain. More importantly, the study provided that there should be an effective mechanism to enforce professional ethics in collaboration with professional associations.⁷¹

After understanding the 'as-is' of the health professions regulation system, the BPR led to brainstorming to generate creative ideas upon which the new system that fundamentally differs from the previous system on measures of performance - cost, quality, service and speed – was to be designed. There was a debate on the relevance of licensing. It was argued that the licensing of health professionals should be abandoned, as it is a non-value adding process. On the other hand, there was strong agreement that health professional licensing ensures practice by only competent and ethical professionals. Hence, it was

⁷⁰ *Ibid.*

⁷¹ *Ibid* at 83.

agreed that all health professionals, whether practicing in the private or public sector, must be licensed. It was also agreed to build a national health professionals database that included a professional's educational background, ethical and criminal record, and other important details. Decentralization of the regulation of the health professions and a responsive regulation model for enforcement strategy were emphasized to ensure effective regulation.⁷²

The brainstorming and redesign followed BPR principles. The most important BPR principles for redesigning the health professions regulation system was to assure customer satisfaction by a speedy, cost-efficient, and quality licensing process. Empowerment of the employees of the regulatory authority, and hence, adopting a flat, non-hierarchical management style were also given significant weight by the designing team. The BPR study identified that on average, health professional licensing took 30 days involving 47 steps under the auspices of the Council's Registration and Professional License Sub-Committee.⁷³ This process was re-designed by excluding non-value adding requirements, and by empowering the employees of the regulatory organ (in particular the Health Professionals and Institutions Licensing Team members) to issue professional licenses by evaluating the documents and profiles of an applicant health professional. Consequently, the professional license process has been redesigned to be accomplished in seven steps and within 30 minutes.⁷⁴ Thus, the Council licensing process was replaced by

⁷² These issues will be discussed after the overview of the BPR on health professions regulation.

⁷³ FMOH, *Regulatory Core Process*, *supra* note 63 at 137.

⁷⁴ *Ibid.*

a speedy, cost efficient and quality process that satisfies customers. Quality is attributed to the comprehensive licensing requirements that can filter applications and ensure that only qualified health professionals get professional licenses. The process ensures that the professionals get an expedient licensing service. It also assures the public of the competence of licensed health professionals as licenses are to only be issued for those professionals that fulfill requirements set to ensure practice by competent and ethical professionals.⁷⁵

The next two sub-sections discuss the two important aspects of the BPR study that relates to regulatory power allocation. These are decentralization and enforcement strategy in the new health professions regulation design.

⁷⁵ It should be noted that the BPR study analysis of systematic failure of health professions' regulation was made at a general level. Though the government insisted that the study was adequate to explain the problem, its causes and the way forward, the generality of the observations are seen in the study's lack of rigor, articulation and clarity. For example, it explains that there is prevalence of malpractice, but it did not provide any data on its prevalence rate, and failed to discriminate on individual responsibility, and systemic failures in assuring quality of health care. It acknowledged that there is erosion of public trust in health professionals, but it failed to substantiate this claim by evidence. It identified that there were inadequate laws and standards for regulating health professions, and this was partly the reason for ineffectiveness of that system of regulation. But it failed to show in adequate length how the inadequacy of those laws and standards were responsible for the system's failure.

The fact that all health regulatory activities were studied by a team of about twenty professionals may have been a barrier to rigorous and extensive study, specifically on health professions regulation. The expertise, time and cost that the government could spend on each health regulatory activity may also explain the generality of the study. Meanwhile, dynamism in the public sector institutions that the BPR sought to achieve holds a promise for further evaluation and improvement of the reform itself.

i. Decentralization of Health Professions Regulation

The Constitution limits the role of the Federal Government to national policy issues and national standards relating to health: all other powers are given to the states. This requires states to assume more responsibility in the health professions regulation. The Federal Government role is limited to setting national standards relating to health professions regulation. What constitutes “national standard” relating to health professions regulation is arguable. Can licensing requirements be national standards? Should scope of practice be considered national standard? Is code of conduct for health professionals considered a national standard? I think all these matters are not a matter of national standards and states should issue laws on these matters.

Nonetheless, currently, states may not have the capacity to legislate on all these matters. I believe this practical consideration underlies decentralization of health professions regulation in the BPR. This may be challenged to be unconstitutional as issues pertaining to health professions regulation are not national matters requiring national standards. But states have not contested the significant role of the Federal Government to legislate on scopes of practice and code of conduct. The states even await direction from the Federal Government on these matters as they believe the Federal Government is more capable to legislate on these matters and provide them with model laws on other related matters. This attitude may be attributed to the legacy of centralized health professions regulation system since 1940s. Also, practically speaking, though lack of financial and human resource capacity is the problem of both the federal and states governments, the former has relatively better capacity to legislate on “national standards” (with broader understanding of the phrase) or provide model laws states should adopt.

The decentralization of health professionals' regulation down to the state health bureaus was the core of the health professions regulation reform. The federal regulatory organ's role is limited to regulating foreign-trained health professionals and scarce health professionals (doctors, midwives and anesthetists⁷⁶). Shortly before the reform, the licensing of certificate and diploma level professionals was already decentralized to state health bureaus. The emphasis on decentralization in the BPR was strategic. It promised closer monitoring of the practice of health professionals. It should, however, be noted that the decentralization left a significant role to the Federal Government considering the relative capacity limitation of states to assume all those responsibilities. In this regard, the power of the Federal Government to determine scopes of practice and code of conduct for health professionals is notable.

Meanwhile, there was no consensus among the BPR designing team⁷⁷ on delegation of health professions regulation to an independent professional body. The debate involved two variants of regulation by professional bodies. These were regulation by professional

⁷⁶ In Ethiopia, anesthetists are professionals with Bachelor of Science degree and are different from anesthesiologists who are doctors that specialized in anesthesiology.

⁷⁷ The BPR Design Team was selected professionals from DACA and development partners to study health regulatory activities, *i.e.*, the 'As-Is', and design effective regulatory design, *i.e.*, the 'To-Be'. The Team frequently reported to the Steering Committee which was made-up of top officials of DACA. The Steering Committee supervised and provided guidance to the Design Team. Some issues the Steering Committee could not resolve were presented to the Executive Committee for direction. The Executive Committee consisted of the Minister of Health, Vice Ministers of Health, Director Generals of EHNRI, PSA, and DACA. It was the highest organ established by the order from the Office of the Prime Minister to oversee the reform in the health sector. It adopted all the reform documents including the Health and Health Related Services and Products Quality Regulation Core Process.

associations and professional bodies separate from the associations.⁷⁸ The later variant suggested redesigning the Ethiopian Health Professionals Council on the basis of the South African model of health professional regulation. On this model, the Council would have boards for major health professions to oversee the licensing, continued professional development, and discipline of their respective practitioners. Both variants relied on the fact that self-regulation has been the standard form of health professions regulation around the world. The issue was finally resolved by a high level decision under the leadership of the Minister of Health. The Minister rejected regulation by health professional associations by drawing attention to their limited capacity.⁷⁹ It is also said that the Minister rejected the South African model of regulation by professional body, arguing that licensing is a government function and must remain so.

The argument that professional licensing is a government function reflects the governing political thought of the state in Ethiopia. Revolutionary democracy is the political theory of the ruling party, the EPRDF. Having ruled the country for more than twenty-one (21) years under the leadership of one man, who is Head of Government and of the Party, the party's political theory has become state ideology too. Revolutionary democracy is firmly and deep-rooted in the communist political philosophy that reserves a predominant role for the state to lead in the country's social development. The central tenet of revolutionary democracy is captured in the oxymoronic phrase, "democratic

⁷⁸ FMOH, *Regulatory Core Process*, *supra* note 63 at 87.

⁷⁹ *Ibid* at 92.

centralism.”⁸⁰ A debate occurs among a few elites at the center and their decision is binding on all others. The elites consider themselves as having a formidable mission, that of transforming the nation politically, economically and socially. The elites’ leadership and influence is the only pathway for the country’s progress. Accordingly, independent social and professional organizations are not encouraged, and the party uses such organizations to ensure their compliance with, and support for, its interests and policies.⁸¹ EPRDF argues that the political stability and development of the country depends on its continued rule. To that end, it has been working to control every aspect of public life.

After about fourteen years of power consolidation, EPRDF promised free and fair election in May 2005. EPRDF has always claimed to have the support of the rural population for its land and agricultural policies. Thus, it calculated that the rural population (which is about 83 percent of the total population) would vote for it in free and fair election. However, the preliminary election results showed an overwhelming support for opposition parties, and EPRDF promptly took measures to ensure its success in winning the election. Eventually, the political tension over vote rigging turned violent and took the lives of more than 200 civilians, with many more injured and a lot of property destroyed.⁸²

Political commentators say the lesson the EPRDF took from the May 2005 election has been the fact that democracy is a threat to its sustainable and firm hold on power. Hence,

⁸⁰ Vestal, *supra* note at 6 at 185.

⁸¹ *Ibid.*

⁸² EU EOM, *Final Report (2005)*, *supra* note 8.

it has implemented an unprecedented shrinking of political sphere and focused on economic development while reducing the sphere of political participation.⁸³ The result is a transition from revolutionary democracy theory, to a developmental state rhetoric.⁸⁴ But there is great similarity between the revolutionary democracy and developmental state rhetoric. The main difference may be that revolutionary democracy had been a little

⁸³ Messay Kebede, “Meles’s Political Dilemma and the Developmental State: Dead-Ends and Exit ” *Abugida* (June 13, 2011), online: Abugida <<http://www.abugidainfo.com/index.php/18194/>>.

⁸⁴ EPRDF proponents may argue that the Ethiopian government is really following developmental state path. Medhane Tadesse, “Meles Zenawi and the Ethiopian State” *Aigaforum* (October 16, 2012), online: Aigaforum <<http://aigaforum.com/articles/medhaneye-on-meles-zenawi-and-power.pdf>>; Habtamu Alebachwe, “Tadesse Medhane and his ‘Post-Meles Reform Agenda:’ Quest for Logic and Relevance” *Aigaforum* (October 21, 2012), online: Aigaforum <<http://aigaforum.com/articles/Habtamu-response-to-post-meles-reform-agenda-by-tadese.pdf>>.

Others argue developmental state is rhetorical and serves political interest of EPRDF to remain in power indefinitely. For instance, Messay Kebede argues that the Ethiopian ruling elites are not developmental elites. He identifies four key characteristics of developmental state. These are market economy, bureaucratic autonomy, development-oriented elite, and nationalist and elite education. He argues that Ethiopian move to development state lacks these prerequisites or characteristics of the developmental state. The market economy operates in unfriendly environment, and takes skewed form. EPRDF uses the bureaucracy as its political machinery “undermining impartiality and professionalism.” The bureaucracy does not reward merit, and is contaminated with “disturbing favorable treatments on the basis of political patronage, ethnic affiliation, and bribes.” The ruling elites are organized along divisive ethnic lines, their political ideology promote ethnic division and lack nationalist agenda. Also, they are predators. The education system is not designed to produce competent human capital, and there is no system to reward merit. And, no incentive exists to prevent brain drain. Therefore, Kebede concludes that developmental state is just rhetoric that is introduced to ensure long-term rule of EPRDF by weakening opposition parties. Democratic pluralism is a liability for EPRDF as shown in the May 2005 election. Kebede, *supra* note 83.

tolerant of multiparty democracy, free civil society and media, than is the developmental state rhetoric. Some people count evidence that show EPRDF and its government have become intolerant of political dissent and have weakened the democratization process through legal and other means. For instance, the Political Parties Registration Proclamation has restricted financial assistance to legally operating opposition political parties from foreign sources, including Ethiopians living abroad.⁸⁵ This will significantly reduce the capacity of opposition parties to open offices, rent meeting halls and undertake election campaigns, as their domestic financial resource is meager. As well, this law has made it compulsory to disclose the identity of any person in Ethiopia who supports opposition parties (Article 52 (1) (h)). This may hinder people who may fear harassment and retribution by EPRDF to contribute to opposition parties.

Some argue that freedom of expression has also been restricted by the Freedom of the Media and Access to Information Proclamation which introduced censorship (Article 42 (2)), and limited the financial sources of independent media (Article 7), with draconian penalties for violating its provisions (Article 45).⁸⁶ The Charities and Societies Proclamation has paralyzed civil societies working on rule of law and human rights

⁸⁵ *Political Parties Registration Proclamation*, no 573 (Ethiopia), 2008, art 52 (1) (a).

⁸⁶ *Freedom of the Media and Access to Information Proclamation*, no 590, (Ethiopia), 2008. The Committee to Protect Journalists (CPJ) expressed these concerns and asked for revision of the law but nothing has changed. CPJ, Press Release, “Ethiopian Press Bill Flawed: Needs Revision” (July 11, 2008), online: CPJ < <http://cpj.org/2008/07/ethiopian-press-bill-flawed-needs-revision.php>>.

promotion by denying them access to foreign assistance.⁸⁷ Almost all of such societies had been operational by virtue of external assistance. Consequently, they have ceased operation after this law was passed, except for a few which do very limited work utilizing membership contributions. The Anti-Terrorism Proclamation has broadly and vaguely defined terrorism to stifle dissent.⁸⁸ For example, during 2011/2012, more than five journalists were convicted on terrorism charges for discussing the Revolutions in North

⁸⁷ *Charities and Societies Proclamation*, no 621 (Ethiopia), 2009, art 14(5)[*Charities Proclamation*]. Human Rights Watch (HRW) criticize the law saying it puts “severe restrictions on all human rights and governance-related work as to make most such work impossible, violating fundamental rights to freedom of association and expression provided for in the Ethiopian constitution and international human rights law.” HRW, News Release, “New Law: Ratchets Up Repression” (New York, January 8, 2009), online: HRW <<http://www.hrw.org/news/2009/01/08/ethiopia-new-law-ratchets-repression>>. The law is “part of a larger campaign by the government to ensure that there will be no independent organizations of any type that can potentially challenge the firm totalitarian grip it has established on the Ethiopian society since the 2005 electoral debacle.” Berhanu Nega & Carl Milofsky, “Ethiopia’s anti-NGO law and its consequences for economic development” (2011) 46:S2 *Community Development Journal* ii34 at ii44-ii45.

⁸⁸ *Anti-Terrorism Proclamation*, no 652, (Ethiopia), 2009, arts 3 & 6. Article 19 argues that the law “seriously undermines freedom of expression right.” It notes that the law “gives broad and vaguely defined powers to authorities to criminalize speech that is not directly inciting terrorism and undermines the media’s fundamental right to protection of sources.” Article 19, *Comment on Anti-Terrorism Proclamation, 2009, of Ethiopia* (March 2010), online: Article 19 <<http://www.article19.org/data/files/pdfs/analysis/ethiopia-comment-on-anti-terrorism-proclamation-2009.pdf>> at 10. See CPJ, Open Letter to the Prime Minister Meles Zenawi, “Anti-Terrorism Legislation Further Restricts Ethiopian Press”(Washington D.C., July 23, 2009), online, CPJ<<http://cpj.org/2009/07/anti-terrorism-legislation-further-restricts-ethio.php>>; HRW, *An Analysis of Ethiopia’s Draft Anti-Terrorism Law* (Updated June 30, 2009), online: HRW <http://www.hrw.org/sites/default/files/related_material/Ethiopia%20CT%20Law%20Analysis%20June%202009_2.pdf>.

Africa and the Middle East, and its implications for the democratization process in Ethiopia.

Meanwhile both the revolutionary democracy and developmental state concepts imply greater role for the state in the economic, social and political development of the country. The developmental state theory argues for a stronger state that actively leads the economic and social development of the country.⁸⁹ The models of developmental state practised in China and Botswana have been frequently cited as a model for Ethiopia. EPRDF maintains that it does not only pursue economic development, but also the democratization process for the sake of political stability in the country. However, there is strong opposition to the government's developmental state theory and this has practically resulted in a deteriorating political condition in the country. The opposition parties argue that the developmental state theory undermines Ethiopia's transition to democracy.

The argument that the licensing and discipline of health professionals is a state function that should not be delegated to professional associations, or independently constituted professional bodies, fits the prevailing state political theory, *i.e.*, the theory of the developmental state. The state's role in the health sector is high. The state provides and funds a significant portion of health care services, and also regulates the provision of health care. These functions constitute the main duties which the state asserts would lead

⁸⁹ Meles Zenawi, "States and Markets: Neoliberal Limitations and a Case for Developmental State" in Akbar Noman *et al.*, eds, *Good Growth and Governance in Africa: Rethinking Development Strategies* (New York: Oxford University Press, 2012) 140 at 168.

to social development. In liberal democracies where the private sector and civil society organizations play equal or comparable roles in the health sector, in contrast to the state's role, the option to delegate regulatory functions to independent and autonomous professional bodies with clear and formal accountability to the state may be considered more effective than state regulation. However, Ethiopia's refusal to delegate such functions to professional bodies appears to be prompted by the developmental state theory which envisages the creation of a massive state bureaucracy and involvement in the social sector, in this case, through health professions regulation. As will be explained in the last section of this chapter, this thesis will explore a proper system of health professions regulation for Ethiopia in terms of role that state and non-state actors should play beyond political ideology.

ii. Enforcement Strategy for Health Professions Regulation

The BPR study provides that enforcement measures in health professions regulation should follow a pyramidal model of responsive regulation.⁹⁰ It prioritizes persuasion by which to shape the conduct of the health professional. Where persuasion fails, the study stipulates that measures against the health professional will escalate to civil penalty, criminal penalty, license suspension, and revocation in an ascending order.

As well, the BPR provides for strict regulation of health professionals as a fundamental way to assure practice by competent and ethical health professionals. The BPR stipulates that the mandate of the regulatory authority should exclusively be regulation.⁹¹ This does

⁹⁰ FMOH, *Regulatory Core Process*, *supra* note 63 at 92.

⁹¹ *Ibid.*

not clearly convey what regulation means.⁹² However, it indicates that regulation is about setting standards, licensing, inspection and disciplining. This overlooks the persuasive and educational roles of the regulatory authority. The BPR identifies the absence of adequate laws and standards governing the practice of health professions, and calls for more legalization. It highlights the need to ensure accountability of health professionals for malpractice by breaking the old assumption that doing so would result in health professionals' turn-over, and frustrate their colleagues. The BPR underscores the motto "no compromise on quality", but it does not elaborate on its meaning. These are indications that health professions regulation may take command-and-control approach.

The BPR does not elaborate adequately on enforcement strategies for health professions regulation. It has incorporated persuasion as an enforcement strategy. But it also seems to incline to a command-and-control approach of regulation that equates effective regulation with a punitive approach. Of course, practically, the seriousness envisaged in the BPR may not be realized. Nonetheless, it appears that the BPR's command-and-control approach contradicts the reference to persuasive enforcement measures.

This tension is also apparent in the developmental state theory and an enforcement strategy that relies on persuasion. This is because the developmental state concept envisages a strong and active state that is highly interventionist in social development. The state dictates most aspects of public life, leaving little space for individual freedom.

⁹² The conception of regulation in the BPR as relating to health professions regulation is apparently narrow in contrast to a broader notion of regulation that envisages involvement of multiple actors that deploy multiple enforcement strategies. This issue is fully discussed in Chapter 3 Section 1 below.

In contrast, persuasion is built on the recognition that individuals, particularly health professionals, positively respond to respectful dialogue and minimal guidance.

4. The New Legislative Framework for Health Professions Regulation

The BPR study is a blueprint for health professions regulation. It required a series of legislative measures to replace the existing system with the newly redesigned one. Consequently, the Food, Medicine and Health Care Administration and Control Proclamation No 661/2010 was issued.⁹³ The Proclamation is an umbrella law for all health care regulatory activities undertaken at the federal and states levels. It devotes a chapter each to regulation of the following thematic issues in health care: food safety and quality; medicine safety, quality and efficacy; narcotic drugs, psychotropic substances and precursor chemicals; hygiene, environmental health and control of communicable diseases; health professionals; health and health related institutions; and traditional and complementary or alternative medical practice. Each chapter sets out the most important regulatory principles and standards on each theme. The Proclamation is primary legislation that requires detailed standards and procedures for its full implementation.

The decentralization of health regulatory activities is the hallmark of the Proclamation. Again, the consistency of the decentralization with the Constitution's power allocation between the Federal Government and states may be arguable. But decentralization is reflected in the institutional and functional design of the Proclamation. Generally, it provides that the Federal Government is responsible for standard setting, and regulatory

⁹³ *Food, Medicine and Health Care Administration and Control Proclamation*, no 661 (Ethiopia), 2010 [*FMHACA Proclamation*].

activities “with respect to trans-regional food, medicine, health and controllable health related services and institutions.” States are given general residual health regulatory power (Article 3). The Proclamation envisages the establishment of a regulatory organ to implement regulatory functions at the federal and state levels (Article 2 (42) *cum* (43)). Accordingly, DACA is re-established as a new organ, named the Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA).⁹⁴ The Proclamation provides the regulatory functions to be accomplished by the EFMHACA.

These functions are:

- a) setting standards in relation to food, medicine, environmental health, health professionals, health and controllable health related institutions;
- b) licensing and regulating trans-regional food and medicine production, import, export, distribution, promotion and storage of food and medicine and quality control laboratory;
- c) registering and licensing insufficiently available health professionals;
- d) registering and licensing health professionals coming from abroad to deliver health service;
- e) licensing and regulating specialized health institutions;
- f) monitoring and regulating trans-regional environmental health services;
- g) undertaking quarantine services with concerned bodies at entry and exit ports; and
- h) other regulatory activities with respect to trans-regional food, medicine, health and controllable health related services and institutions.⁹⁵

⁹⁴ *EFMHACA Regulation, supra* note 10 art 3.

⁹⁵ *FMHACA Proclamation, supra* note 93 art 3(2) [emphasis added].

Some of the standards to be stipulated by the EFMHACA will need the approval of the national standard setting organ, *i.e.*, Ethiopian Standards Agency (ESA) (Article 4(1)).⁹⁶

The broad responsibilities that EFMHACA assumes were previously fragmented and given to DACA and different department of the Ministry of Health.

EFMHACA operates as an autonomous executive organ accountable to the Ministry of Health. The decision to make it accountable to the Ministry was debated at length. Most employees of EFMHACA preferred being accountable to the Prime Minister, as was DACA. They argued that service providers and the regulatory authority in the health sector should be two separate entities with no lines of accountability between them.

The Ministry of Health is a major service provider. Its direction and supervision of regulatory activities involves a conflict of interest that could undermine EFMHACA's effectiveness. However, the Prime Minister's Office decided to reduce the number of government agencies accountable to it due to the burden of work this involves. Accordingly, many government agencies and authorities were made accountable to the

⁹⁶ ESA is an autonomous statutory governmental agency accountable to the Ministry of Science and Technology. It is the sole National Standards Body in Ethiopia. It has the National Standardization Council that examines and approves standards submitted its technical committees. This Council is composed of appropriate government and other bodies designated by the government, and the Director General of ESA serves as its secretary. *Ethiopian Standards Agency Establishment Council of Ministers Regulation*, no 193 (Ethiopia), 2010.

related Ministerial offices. Thus, the accountability of EFMACA was assigned to the Ministry of Health.⁹⁷

A Director-General and two Deputy Directors-General run EFMHACA. There is also an Advisory Board that advises the Authority on policy and strategic matters (Article 9 of the Council of Ministers Regulation No.189/2010). The members of the Advisory Board consist of representatives from professional associations, higher education institutions, consumer associations, and other appropriate associations, institutions and professionals. The Minister of Health designates the members upon nomination by the Director General (Article 8(1) of the Regulation). The Advisory Board's role in the daily functions of EFMHACA is limited to the policy and strategic matters that arise infrequently.

Each state government is also required by the Proclamation to establish or designate a regulatory organ to implement the health regulatory mandates of the state. Except for the SNNPR State, no other state has established an autonomous regulatory authority in its region. Rather, each has designated a department in their respective health bureaus as a regulatory organ. Article 3(3) of the Proclamation provides that all residual regulatory powers that are not given to the federal government shall be the responsibility of the state

⁹⁷ In Canadian health care system, the institutional independence of regulators depends on the extent of managerial control the ministries of health exercise over them. Lahey, *supra* note 59 at 251. I also believe that the managerial control that the Ministry of Health would practically exercise over EFMHACA is more important to determine the independence of EFMHACA, and the effectiveness of regulation in Ethiopian health care system. If the legal accountability is practically interpreted to consider EFMHACA as a Department/Directorate of the Ministry of Health, then EFMHACA can hardly function as an effective regulator in the health sector. For similar debate in UK, see also C Hood, *et al.*, *Regulation Inside Government: Waste Watchers, Quality Police, and Sleaze Busters* (Oxford: Oxford University Press, 2000).

regulatory organ. With respect to health professions regulation, this means most health professionals will be regulated at the state level. Article 3 (2) only provides for the direct regulation of scarce and foreign-trained health professionals by EFMHACA. However, in the later part of the Proclamation as shown below, EFMHACA is given more roles in setting scope of practice, standard of practice and code of conduct laws that would be applicable to all health professions. These powers are given to EFMHACA considering the limited capacity of states to legislate on these matters. Practically, this would leave states to legislate on comprehensive licensing requirements, and fitness to practice processes. Thus, health professions regulation in Ethiopia may be considered a partly decentralized system. But compared to the system before the reform, the system of health professions regulation is highly decentralized, and once states capacity is strengthened, it will be decentralized fully.

Chapter Seven of the Proclamation contains the foundational principles and major activities in health professions regulation. Article 33(1) prohibits the practice of a health profession by a person without a professional license issued by EFMHACA or a state regulatory organ. The term of the professional license may not exceed five years. States may prescribe more stringent standards and require, for example, professional license renewal every three or four years. License renewal shall only be made upon the satisfaction of an “ethical and competence evaluation” (Article 33 (2)). The details of this requirement are yet to be sorted out. However, there is a plan to establish a professional profile accessible to all regulatory organs and which includes the professional’s ethical record. Competence is believed to be assured through successful attendance and completion of stipulated Continued Professional Development (CPD) programs.

Article 34 provides that the practice of any health professional shall comply with the standard of care and scope of practice to be issued by the EFMHACA. One of the major deficiencies in the previous health professions regulatory system was inadequate rules that clearly provided scope of practice to the diversified health professions. There is an ongoing effort in EFMHACA to develop a comprehensive and clear scope of practice for regulated health professions.

It is not clear what “standard of care” in Article 34 may refer to, as the phrase is not defined in the law. It may refer to ethical and policy guidance for health professionals, including regular update and guidance on controversial issues. It may also be broadly understood to refer to clinical guidelines. Currently, there is no work on developing standards of care *per se*, other than as included in health facilities’ standards. This is due to the presence of other priorities, particularly the need to build the infrastructure of health professions regulation. EFMHACA is expected to engage, in the near future, in clarifying and developing the standard of care required of health professionals. I believe that EFMHACA’s mandate to determine the scope of practice and the standard of care is justified as it has better capacity than states’ regulatory organs to set standards that require the mobilization of significant expertise.

Article 35 (1) provides that it is a legal obligation for health professionals to comply with “relevant code[s] of ethics.” This provision arguably renders ethical codes adopted by professional associations binding on the practitioners. Its broader interpretation may consider codes of ethics issued by health professional associations as laws. At least, these codes of ethics may establish the standard of practice in the profession that could

otherwise be established by expert witnesses in litigation. Specifically, Article 35 (2) provides that there shall be a Regulation issued by the Council of Ministers that will determine the code of conduct for health professionals. This provision is being implemented via the drafting of a comprehensive code of conduct to apply to all health professionals. It contains cross cutting ethical rules, such as on fees and commissions, confidentiality, research ethics, advertisement, obligation to serve despite the professional's belief, and retention of human organs. It was drafted to be issued as the Code of Conduct Regulation. Eventually, it was decided to make it a Chapter in the draft Food, Medicine and Health Care Administration and Control Council of Ministers Regulation.⁹⁸ The reason was to reduce the number of separate laws and fragmentation in the sector.

Professions-specific ethical rules will be published for each regulated profession by an EFMHACA Directive. A Directive is subsidiary legislation issued by administrative agencies pursuant to delegation by parliament or the Council of Ministers. The comprehensive and profession-specific code of conduct laws are intended to form clear guidance for health professionals' practice. They will be legally enforceable instruments that establish the accountability of health professionals. These legal instruments will fill one of the legislative gaps identified by the BPR.

Chapter Seven of the Proclamation also contains some provision that highlight some major obligations of health professionals. It obliges all health professional to report

⁹⁸ Ethiopia, *Food, Medicine and Health Care Administration and Control Council of Ministers Regulation* (2012) (first reading by the Council of Ministers in June 2012).

malpractices to the EFMHACA or state regulatory organ, and reportable communicable diseases to the proper public health emergency management organ (Article 36). A health professional must also keep, and report proper health information, and maintain its confidentiality (Article 37).

In the last three years, EFMHACA has been working to develop legislation and standards for the full implementation of the Proclamation. The draft Food, Medicine and Health Care Administration and Control Council of Ministers Regulation constitutes the major legislative work. It contains detailed provisions elaborating on most provisions of the Proclamation. The draft is in the final stage of promulgation after three years of development, discussion and review within the health sector. The Council of Ministers has discussed the draft, and directed second review and approval. It is expected to be adopted before the end of 2012. It contains two Chapters on health professions regulation. One of them deals with licensing requirements and the other is devoted to the comprehensive code of conduct for health professionals.

The above two sections presented the new health professions regulatory system brought by the reform. The next Section summarizes the regulatory power allocation in the new design and sets the research question for the thesis.

5. Research Question

The health professions regulation reform concentrated regulatory activities in the hands of EFMHACA and State regulatory organs. The role of the Education and Training Sub-Committee, and the Registration and Professional License Sub-Committee of the Ethiopian Health Professionals Council are in abeyance. Only the Council's Professional

Ethics Sub-Committee is still functioning. However, its operational procedure has not changed and its effectiveness has not been improved. Neither the BPR nor its implementing laws clarify the disciplinary process for health professionals. This gap allows the continuation of the functions of the Professional Ethics Sub-Committee. However, since its legacy is not commendable, a directive that clarifies its fitness to practice procedure may propose quite a different system.

The role of health professional associations in EFMHACA's standard setting activities is commendable. However, their role in the Council has diminished, like the Council's own authority. With the approval of the Food, Medicine and Health Care Administration and Control Council of Ministers Regulation No... /2012, the Council's establishment law will be repealed. This will end the Council's legacy of having promoted health professional associations and elements of self-regulation. In the new design of health professions regulation, the professional associations have no role in the licensing and license renewal processes. Their role in the standard setting will remain an ad-hoc arrangement, as it exists currently. Their role in the fitness to practice process is unlikely to be maintained.

The reform brought about a statist health professions regulatory design. The health professionals' desire for self-regulation was not accepted by the government for political reasons. The government's developmental state rhetoric does not allow independent professional bodies that proactively influence social development outside the state's bureaucracy or ruling party's control.

The professionals have been expressing their concern about the effectiveness of the state bureaucracy dominated regulatory regime that reduced the role of professional associations. The professional associations have been advocating for more fundamental paradigm shift in health professions regulation, *i.e.*, to self-regulation. There is a lack of literature on professional self-regulation in Ethiopia. As well, the professional associations barely have a policy statement on the issue. Despite this, my view is that the Ethiopian health professional associations demand self-regulation because of the pervasive nature of the claim, available literature elsewhere, and personal experience.

The World Medical Association (WMA) issued a declaration that urged national medical associations and doctors to strive for self-regulation in their respective jurisdictions.⁹⁹ This shows that the claim for self-regulation is widely made by professionals and their representative associations. Dr. Yifru Berhan, in his exhaustive account of the development of modern medicine in Ethiopia, argued for a greater role by the Ethiopian Medical Association (EMA) in medical education, licensing and disciplining. He presented the popular comparative argument that self-regulation is the norm in other countries as follows:

In other countries, medical associations/societies are so powerful providing many services including; given authority to accredit or reject medical doctors' credentials; given authority to cancel professional license in conditions where major professional breaches were encountered; and prepare and administer annual board examinations.¹⁰⁰

⁹⁹ WMA, *Declaration of Madrid on Professionally-led Regulation* (New Delhi, 2009, 60th WMA General Assembly), online: WMA <<http://www.wma.net/en>>.

¹⁰⁰ Berhan, *supra* note 26 at 73.

This argument presents a common misconception about self-regulation in Ethiopia. The self-regulation claim is often associated with legislative empowerment of existing professional associations to regulate their respective professions. But a distinction is not made between the role of professional associations as *de facto* trade unions, and their role in protecting the public interest as regulators. The reference to other countries' experience where the professions are self-regulatory overlooks the fact that in most of those countries, the self-regulatory organ whose purpose is the protection of the public interest is different from the professional association whose primary purpose is promoting the members' self-interest.

Berhan mixed the role of the association to protect its members, and the integrity of the profession with his claim for self-regulation. He wrote:

It is a well-known fact that Ethiopian physicians were facing numerous physical and psychological trauma. In particular, the mass media (newspapers, radio, television, and periodicals), theatre and movies have been harassing physicians unreservedly. It appears that a manuscript for any purpose has to humiliate physicians to get accepted by censors and the audience. It is not uncommon for a physician to be imprisoned for medically unjustifiable reasons.¹⁰¹

Berhan criticized EMA for its “silence for all these and other countless and unsubstantiated breaches to the medical profession.”¹⁰² Furthermore, he emphatically linked Ethiopian doctors' migration to foreign countries to the absence of protection for

¹⁰¹ *Ibid* at 74.

¹⁰² *Ibid*.

the profession's integrity.¹⁰³ This presentation of the threat to the profession's integrity seems an overstatement. However, the appeal to EMA to discharge its responsibility to protect its members and the profession contradicts its claim to gain regulatory authority for the same organ. Berhan suggested that EMA should be empowered to deal with "professional and ethical issues, standardizing physician's training and service", without which it cannot achieve the protection of the public from malpractice, or the doctors from professional violation.¹⁰⁴ Thus, he advised EMA as follows:

Therefore, the first step [should focus on getting] legal recognition....to monitor and evaluate professional teaching and training, and take appropriate measures when there is incoherence/breach of medical ethics with the standard medical practice. This legislative recognition is also an instrument to appeal to the legal body when physicians or the profession is unjustifiably under attack. It is also an opportunity for the association to bring all medical professionals under its umbrella for the sake of recognition as well as protection. If EMA gets empowered, it will be so easy for other health professional associations/societies to follow its footsteps for the benefit of the public and their members.¹⁰⁵

Berhan's claim is basically that the legislature should sanction a self-regulatory status for medical practice for dual purpose of protecting the public and the profession. The conflict of interest presented in this claim is clear, as these dual purposes cannot be pursued by the same organ at the same time. The conflict of interest is pervasive in the debate around self-regulation in Ethiopia. This is also evident in the professional associations' strong

¹⁰³ *Ibid.*

¹⁰⁴ *Ibid.*

¹⁰⁵ *Ibid.*

public benefit claim, expressed in their constitution and project activities, and which gives them the nature of a charity though they are registered as societies under the law. The Ethiopian law of charities and societies defines a charity as an institution established exclusively for the public interest, while a society is an institution established for promoting its voluntary members' interests and "to undertake other similar lawful purposes."¹⁰⁶ Nonetheless, the health professionals' associations have strong public benefit claims under a broader interpretation of the phrase "other similar lawful purposes" contained in the definition of "society."

Abdurahman Ali, Chief Executive Officer of the Ethiopian Nurses Association (ENA), says that lack of self-regulation is one of the challenges for his association.¹⁰⁷ Regulation by the association is seen as a mechanism for empowerment, mainly from the financial boost offered by compulsory membership fees. As such, Ali's claim for self-regulation is also not free from a conflict of interest.

During my two years of work in health care regulation reform in Ethiopia, I gained some insight into the health professional associations' demands for self-regulation. Their argument for self-regulation was based on comparative perspective, efficiency and expertise. For instance, in one of the most important consultative workshops organized by

¹⁰⁶ *Charities Proclamation, supra* note 87, art 55 (1) defines society as "an association of persons organized on non-profit making and voluntary basis for the promotion of the rights and interests of its members and to undertake other similar lawful purposes as well as to coordinate with institutions of similar objectives." Article 14 (1) of this law defines a charity as "an institution, which is established exclusively for charitable purposes and gives benefit to the public."

¹⁰⁷ Abdurahman Ali, "The History of Nursing in Ethiopia" (2011) 19 *Nursing History Review* 158 at 160.

DACA, Professor Asrat Demissie, President of the Ethiopian Nurses Association, remarked that though the draft health facilities standards are important to ensure quality of health care services, the value of self-regulation in health care should not be overlooked. In particular, he emphasised that the role of the professional association in self-regulation should be seriously considered.¹⁰⁸ Yehulu Denekew, Director General of the late DACA, acknowledged the great contribution of the professional associations in the development of health facilities standards. However, he did not further discuss the issue of self-regulation other than merely reflecting on consultative democracy ideals.¹⁰⁹

It is easy to reach the conclusion that granting regulatory power to the associations is not appropriate for reasons of conflict of interest. However, the issue is to determine whether self-regulation carried out by a new regulatory organ primarily constituted from the professions is the proper choice for Ethiopia. For a constructive debate over self-regulation in Ethiopia, it is appropriate to modify Berhan's, Ali's and Demissie's arguments that the demand for self-regulation is based on efficiency, expertise and is justified as a matter of comparison with other jurisdictions. If the debate is restructured this way, then I can safely say that the professional associations demand self-regulation over the statist approach.

The forgoing discussion shows that the professionals argue that self-regulation is an effective regulatory system, while the government holds that regulation can only be effectively accomplished by its bureaucracy. There is a general agreement about the

¹⁰⁸ DACA, *Proceedings of the National Consultative Workshop on Health Facilities Regulatory Standards* (Addis Ababa, February 2010) at 102 [unpublished].

¹⁰⁹ *Ibid* at 104.

outcome of health profession regulation. The difference lies in the proper regulatory power allocation that is best suited to achieve that objective of health professions regulation. The health professionals' aspiration for self-regulation cannot be ignored, as they may resent the legitimacy of state regulatory organ. Their resentment may be manifested in various ways such as by non-cooperation to the state's regulatory efforts, less respect for its direction and order, and low level of motivation and innovation in quality improvement and patient safety. These would challenge the effectiveness of statist regulation. On the other hand, simply because health professionals ask for self-regulation should not mean that they receive it. There is a need to critically examine the claims for self-regulation or statist approach, and their implication in assuring effective health professions regulation system. I believe such examination is an important step to create constructive dialogue and understanding among the major actors, *i.e.*, the state and health professional associations, and to ensure the legitimacy of the new health professions regulatory system.

Thus, the important question for the research is this: how should regulatory authority be allocated among different regulatory actors to ensure effective regulation of health professions in Ethiopia? Subsidiary questions are: Is self-regulation the best option for Ethiopia by which to regulate its health professionals? Or, can a statist approach to health professions regulation be an effective one? Or, can these approaches be reconciled to design an effective health professions regulatory system? These are the questions this thesis will address in the following chapters.

CHAPTER 3

THE CONCEPT AND RATIONALES FOR HEALTH PROFESSIONS REGULATION

The question posed in Chapter 1, namely, how the authority to regulate health professions in Ethiopia should be allocated between state and non-state actors, requires analysis within three important conceptual frameworks. First, the notion of regulation envisaged in the discussion of the regulation of Ethiopian health professions should be clarified. Second, the purpose of health professions regulation should be identified. Third, the choice of effective or a ‘good’ regulatory system requires agreed criteria against which alternative systems can be evaluated. The following sections discuss these issues by reviewing the general literature on health professions regulation and relating it to the Ethiopian context.

1. Regulation Defined

Regulation has no specific and agreed definition. The seminal definition says regulation is a “sustained and focused control exercised by a public agency over activities that are valued by a community.”¹¹⁰ Recently, a broad view of regulation is being adopted by academics.¹¹¹ Selznick’s definition is considered under-inclusive for its focus on a state

¹¹⁰ Philip Selznick, “Focusing Organizational Research on Regulation” in R Noll, ed, *Regulatory Policy and the Social Sciences* (Berkeley, CA, 1985) at 363 cited in Anthony I Ogus, *Regulation: Legal Form and Economic Theory* (New York: Oxford University Press, 1994) at 1.

¹¹¹ Robert Baldwin *et al.*, and Judith Healy adopted this approach, specifically in health care regulation. Robert Baldwin *et al.*, “Introduction: Regulation- the Field and the Developing Agenda” in Robert Baldwin *et al.*, eds, *The Oxford Handbook of Regulation* (New York: Oxford University Press, 2010) 3 at 12[Baldwin *et al.*, *Handbook of Regulation*]; Judith Healy, *Improving Health Care Safety and Quality: Reluctant Regulators* (Surrey: Ashgate Publishing Ltd., 2011) at 3.

and delegated self-regulatory bodies referred to as “a public agencies.” It is argued that regulation is being increasingly undertaken by non-state actors, such as committees, civil societies, epistemic communities, and firms.¹¹² Regulation is also being undertaken by supranational bodies. These developments make Selznick’s definition too narrow.¹¹³

Julia Black’s decentered understanding of regulation provides the influential broader notion of regulation. She defines it as:

the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behavior-modification.¹¹⁴

Black’s definition limits the broader notion of regulation used by Neil Gunningham and Peter Grabovsky. The latter view regulation as inclusive of all forms of social and economic influence that deliberately or incidentally contribute to address a problem.¹¹⁵ This makes the notion of regulation too broad and difficult to be subjected for systematic study. Black’s notion is limited by her association of regulation with the *intentional*

¹¹² Julia Black, “Decentering Regulation: Understanding the Role of Regulation and Self-Regulation in a ‘Post-Regulatory’ World” (2001) *Curr Legal Probs* 103 at 132 [Black, “Decentering Regulation”]; Healy, *supra* note 111 at 3.

¹¹³ Baldwin *et al.*, *Handbook of Regulation*, *supra* note 111 at 12.

¹¹⁴ Julia Black, “Critical Reflections on Regulation” (2002) 27 *Australian Journal of Legal Philosophy* 1 at 26 [Black, “Critical Reflections”].

¹¹⁵ Neil Gunningham & Peter Grabovsky, *Smart Regulation: Designing Environmental Policy* (Oxford: Oxford University Press, 1998) at 4.

attempt to produce an identified outcome.¹¹⁶ Her definition provides a broad understanding of regulation that rectifies Selznick’s under-inclusive state-centered definition with an inclusive notion of regulation that includes all intentional forms of social control activities. Healy argues that this broad understanding of regulation is particularly applicable in a health care setting for the following reasons.

The first reason ... is the absence in most health sectors of a sole external public agency regulator with powers of enforcement. Second, health sector regulation is carried out, not only by external public agencies, but also by a variety of other regulatory actors, such as professional associations. Third, health systems depend heavily on health professionals who exert considerable formal and informal power and apply mostly soft regulatory strategies. Finally, conventional regulatory mechanisms do not necessarily work in health care organizations in terms of their highly professional staff and the complex nature of their work.¹¹⁷

The notion of regulation is not clearly defined in the Ethiopian health care setting. Indeed, the term “regulation” does not have an equivalent word in the Ethiopian Federal Government official language, Amharic. It is translated directly to mean “control.” Black notes this absence of a parallel word for “regulation” outside English-speaking countries.¹¹⁸ However, the activities done as regulation in countries that work in English are also being undertaken under the label of “control” activities in Ethiopia. The major activities relating to health professions regulation include standard setting, licensing and

¹¹⁶ Black, “Critical Reflections”, *supra* note 114 at 25; Black, “Decentering Regulation”, *supra* note 112 at 142.

¹¹⁷ Healy, *supra* note at 111 at 3.

¹¹⁸ Black, “Critical Reflections,” *supra* note at 114 at 2.

license renewal, and fitness to practice process. In Ethiopia, all of these are primarily undertaken by EFMHACA, a public agency, and state level regulatory organs. Thus, apparently, even Selznick's definition of regulation encompasses the content of health professions regulatory activities in Ethiopia.

The major focus of the analysis in this thesis relates to the allocation of regulatory authority between state and non-state actors with the goal to ensure effective health professions regulation in Ethiopia. Black notes that the conception of regulation depends on the issue the writer is addressing.¹¹⁹ I argue that Healy's contention for the adoption of a broader conception of regulation should be applicable to health professions regulation in Ethiopia. The main argument of this thesis is that the enforcement strategies of health professions regulation in Ethiopia should be designed based on responsive regulation theory. I argue that effective regulation should primarily rely on the use of soft regulatory strategies backed by the readiness of the state to take coercive measures where the persuasive and educative measures are inadequate. The enforcement capacity of EFMHACA and the state regulatory organs is not sufficient enough to effectively design and implement soft regulatory strategies. These organs should use their limited regulatory resources for coercive measures. Meanwhile, non-state actors particularly health professional associations are interested in less interventionist regulation, and hence, will strive to ensure coercive regulatory strategies are used rarely. In contrast to the assets of the Ethiopian state, the professional associations have the expertise, flexibility, legitimacy, motivation, and capacity for innovation to effectively utilize soft regulatory

¹¹⁹ *Ibid* at 13.

strategies. Their current important role in standard setting can be enhanced to engage and mobilize their capacity and motivation to complement and support the state regulatory activity.

In the end, I argue that the health profession regulation in Ethiopia should involve multiple actors that deploy multiple strategies.¹²⁰ This means that the narrow conception of regulation, as apparently held by EFMHACA, may limit the effectiveness of health professions regulation by limiting plurality of actors and enforcement strategies. This thesis, therefore, relies on Black's notion of regulation to argue that, her notion should also inform the activities of EFHMACA and the state regulatory organs.

However, the adoption of Black's conception of regulation does not mean that the Ethiopian health care system is a highly complex one involving multiple actors with significant spheres of influence. Nor do I exaggerate the power and influence of non-state actors in Ethiopia, as compared to the state. Indeed, Black's conception of decentered regulation is based on regulatory studies from developed countries. It is also in developed countries that the study of regulation continues to develop. Healy's observation is also based on developed countries' context. Nonetheless, however weak the health care system of Ethiopia is, there has been a significant growth in the number of actors in health professions regulation, making the system more and more complex. The power and influence of the private sector, professional associations, charitable organizations, and newly emerging consumer associations have been growing. Thus, the relevance of Black's conception of regulation to the regulation of the health professions in Ethiopia

¹²⁰ These arguments are explored in detail in subsequent chapters.

can be established, given the emergence of multiple actors in the health care system with their growing power and influence. Next, the purpose of health professions regulation in Ethiopia is discussed.

2. Why Regulation?

The purpose of health professions regulation is to protect the public interest. The public interest requires regulatory protection for three main reasons. These are market failures, quality improvement, and distributive justice.

i. Market Failure

The market failure rationale argues that regulation is necessitated where the market fails to produce results that protect the public interest. In market-based system, individuals are left free to pursue their welfare goals in a market with the few restrictions of private law that govern such transactions. Regulation is viewed as the second-best option to market operation.¹²¹ The many reasons why the market fails to produce a collective good necessitates regulation in the public interest.

Regarding health professions regulation, information inadequacy is a reason why the market fails to protect the collective interest. The information asymmetry between a patient and his or her health professional poses difficulties to patients in terms of choosing a qualified and competent health professional, and as to understanding a

¹²¹ Ogus, *supra* note 110 at 1; Tony Prosser, “Regulation and Social Solidarity” 33:3 JL & Soc’y (2006) 364 at 366 [Prosser, “Regulation”].

proposed treatment.¹²² The intervention of the state to ensure that health care is provided by qualified, competent and ethical professionals is intended to fix this problem generated by the information deficit.

Anthony Ogus argues that information asymmetry cannot be fixed by private law for economic reasons.¹²³ Private law compensates actual injury but does not compensate the time, trouble and other costs the patient may incur as a result of the injury.¹²⁴ The transaction costs that include time, emotional distress and the likes, particularly discourage the pursuit of private law remedies for minor injuries suffered by patients. In general, economically, the resort of patients to private law is an inadequate pathway to remedy injury arising from information asymmetry.¹²⁵ In addition, there is an inherent private law limitation in a patient and health professional litigation. Private law remedies are reactive, as they are available after the occurrence of harm.¹²⁶ Therefore, Ogus submits that the combined effect of the market and private law failure to fix the

¹²² Tracey Epps, “Regulation of Health Care Professionals” in Jocelyn Downie *et al.*, eds, *Canadian Health Law and Policy*, 4th ed (Markham: LexisNexis: 2011) 75 at 76; Robert Baldwin *et al*, *Understanding Regulation: Theory, Strategy and Practice* (New York: Oxford University Press, 2012) at 16 [Baldwin, *Understanding Regulation*]; Ogus, *supra* note 110 at 4 & 121.

¹²³ *Ibid* at 27.

¹²⁴ *Ibid*.

¹²⁵ *Ibid* at 28.

¹²⁶ *Ibid*; Michelle M Mello *et al.*, “Fostering Rational Regulation of Patient Safety” (2005) 30:3 *J Health Pol* 375 at 387.

information asymmetry between a patient and a health professional justifies regulatory intervention in the public interest.¹²⁷

The market failure rationale is entrenched in health professions regulatory systems. Judith Allsop and Karthryn Jones note that patient protection is the objective of medical regulation in New South Wales (Australia), Ontario (Canada), Finland, New Zealand, and New York (the United States).¹²⁸ For example, the Ontario Regulated Health Professions Act provides that the object of the regulation is to ensure public access to “qualified, skilled, and competent...health professionals.”¹²⁹ Without state intervention, the public cannot know if a given health professional is “qualified, skilled and competent.” In Ethiopia too, the preamble of the Food, Medicine and Healthcare Administration and Control Proclamation provides that “it is found necessary to avert health problems due to incompetent and unethical health professionals.”¹³⁰ The preamble unfolds the underlying justification of the regulation as information asymmetry that constraints the capacity of the public to evaluate the competence of a health professional before undergoing treatment.

¹²⁷ *Ibid.*

¹²⁸ Judith Allsop & Karthryn Jones, *Quality Assurance in Medical Regulation in an International Context* (Final Report for the Chief Medical Officer, 27 October 2005) at 171.

¹²⁹ *Regulated Health Professions Act*, SO 1991, c 18, Schedule 2, s 2(1) [*RHPA*].

¹³⁰ *EFMHACA Proclamation*, *supra* note 93, Preamble, para3.

ii. Quality Improvement

The second rationale for public interest protection through health professions regulation is quality improvement. This rationale is based on broad social goals.¹³¹ Tony Prosser argues that social solidarity plays two important roles in regulation. First, social solidarity is vital in creating mutual trust between patients and health professionals.¹³² Trust is a necessary condition upon which the healthcare market operates. Second, the social solidarity rationale seeks to “prevent or limit the socially fragmenting role of markets.”¹³³ In the last two decades, quality improvement and patient safety has been incorporated and emphasised in health professions regulation internationally.¹³⁴ This development is explained by the social objective of regulation. It is a response to the deterioration of public trust in the health professions and the market’s inability to ensure patient safety by improving quality.¹³⁵

The traditional form of protecting the public via health professions regulation was through culling, that is, removing the incompetent, unqualified, and unethical professional from practice. This was basically undertaken by the licensing and

¹³¹ Tony Prosser, *The Regulatory Enterprise: Government, Regulation, and Legitimacy* (Oxford: Oxford University Press, 2010) at 14 [Prosser, *Regulatory Enterprise*]. See also, Prosser, “Regulation”, *supra* note 121 at 382.

¹³² *Ibid.*

¹³³ *Ibid.*

¹³⁴ Healy, *supra* note 111 at 7.

¹³⁵ *Ibid.*

disciplining process.¹³⁶ However, culling was found to be unsatisfactory in ensuring quality of care.¹³⁷ In addition, studies on patient safety and inquiries into medical scandals have exposed the inadequacy of the culling approach and led to demands for public protection through systematic intervention that reduces adverse events and improves clinical performance. European countries focus in regulation is on quality improvement in health care and even prefer the phrase “quality improvement” over “regulation”.¹³⁸ Allsop and Jones also note that ensuring patient safety has become the main objective of medical regulation in most jurisdictions.¹³⁹ For example, Ontario’s health professions regulation was reformed to ensure the development of “mechanisms to encourage the provision of high quality care.”¹⁴⁰ The primary objective of the Netherlands’ medical regulation is to “promote and monitor quality in [the] field of health care.”¹⁴¹ All in all, quality improvement has become a broader social rationale for health professions regulation.

Quality improvement also forms the core of health professions regulation reform in Ethiopia. EFMHACA’s mission has been reformulated to “promote and protect the public

¹³⁶ Troyen A Brennan, “The Role of Regulation in Quality Improvement” (1998) 76:4 The Milbank Quarterly 709 at 711.

¹³⁷ *Ibid* at 713.

¹³⁸ Healy, *supra* note 111 at 8.

¹³⁹ Allsop & Jones, *supra* note at 128 at 171.

¹⁴⁰ Health Professions Legislative Review, *Striking a New Balance: A Blueprint for the Regulation of Ontario’s Health Professions* (Toronto: Queen’s Print, 1989) at 9 [Legislative Review].

¹⁴¹ Allsop & Jones, *supra* note at 128 at 169.

health by ensuring safety and quality of ... health services through registration, licensing and inspection of health professionals.”¹⁴² The wording appears to restrict the regulatory instruments to registration, licensing and inspection, though the main objective remains ensuring patient safety and quality health care services. The BPR reform document titled “Health and Health related Services and Products Quality Regulation,” puts the reform’s emphasis on quality improvement. Thus, health professions regulation in Ethiopia pursues the social purpose of quality improvement, in addition to the protection of the public from the health care market failure.

iii. Distributive Justice

As a rationale for health professions regulation, distributive justice is the least discussed of all three in the literature, especially in contrast to the dominant market failure approach. However, distributive justice plays a role in determining the scope of practice for different health professions, and in task shifting among health professions. John Rawls influential conception of justice argues that if a person looks beyond the “veil of ignorance” from an “original position” where “no one knows his place in society, his class position or social status,” people would agree on some principles of fairness that constitute a theory of justice.¹⁴³ One of these principles, distributive justice, provides that the regulation of health professions should not affect disadvantaged groups’ access to

¹⁴² EFMHACA, ‘About Us’, online: EFMHACA <<http://www.fmhaca.gov.et>>.

¹⁴³ John Rawls, *A Theory of Justice: Revised Edition* (Cambridge: Harvard University Press, 1999) at 118.

health care services. Rather, regulation should ensure that disadvantaged groups' access to health care services is increased.¹⁴⁴

The distributive justice rationale is found in Prosser's human rights-based justification of regulation. Access to health care is recognized as a policy objective and, in the strongest sense, as a human right. The human rights approach differs from the consumerist perspective which views citizens in their capacity as consumers.¹⁴⁵ It acknowledges the inequality of citizens in accessing health care services.¹⁴⁶ As such, the distributional justice goal of regulation rectifies the discrimination and marginalization that the market could not address. In other words, distributional justice opens up a new market tailored to address systemic discrimination and marginalization.

For example, communities in remote rural areas may not have access to health care services where health care professionals and services are concentrated in urban areas. The limited supply of health care professionals and resources may hinder the communities' access to health care services. The private sector may not target the health care needs of these communities as it may require significant investment with non-commensurate return. In contrast, the government has policy and human rights obligations to ensure the communities access to health care services. Among other things, the government may decide to reorganize the health care system so as to address the health care needs of these

¹⁴⁴ Ogus acknowledged that distributional justice is a non-economic goal that social regulation pursues. Ogus, *supra* note 110 at 46-51.

¹⁴⁵ Prosser, *Regulatory Enterprise*, *supra* note 131 at 13.

¹⁴⁶ *Ibid.*

communities by efficient use of the available health workforce through task shifting.¹⁴⁷ Health professions regulation should be responsive to the reorganization of the health care delivery system through such task shifting. It should accommodate the health care workforce that would assume new responsibilities. The rationale for the task shifting, *i.e.*, distributive justice, must also underlie the responsiveness of the health professions regulatory regime.

The distributive justice goal of regulation addresses the special health care needs of the disadvantaged groups. There is no market that adequately addresses these special needs. The government should intervene to ensure the disadvantaged groups access to health care services. The intervention may involve task shifting. The task shifting may be opposed by market forces, and this requires regulatory response that justifies the government intervention. Distributive justice, normatively, justifies this regulatory response. In this sense, distributive justice addresses a special kind of market failure by reaching out to the needs of the disadvantaged groups.

Health professions regulation in Ethiopia envisages distributive justice goals. In particular, regulation is intended to increase accessibility to health care services by avoiding restriction on the scope of practices and facilitating task shifting. The Ethiopian

¹⁴⁷ Task shifting refers to “a process whereby specific tasks are moved, where appropriate, to health workers with shorter training and fewer qualifications.” By reorganizing health care delivery system through task shifting the existing health care workforce can be efficiently utilized and the accessibility of health care services can be enhanced. WHO, *Task Shifting: Rational Redistribution of Tasks among Health Workforce Teams – Global Recommendations and Guidelines* (2008), online: WHO <<http://www.who.int/healthsystems/TTR-TaskShifting.pdf>> at 7.

health policy prioritizes the attainment of universal primary health care coverage, and addressing maternal and child mortality. To that end, non-professional providers are trained to assume tasks that were previously performed by highly trained health practitioners. For example, health extension workers were trained as front-line public health workers with tasks to diagnose malaria, and to prescribe and dispense appropriate medications. The policy seeks to ensure accessibility of primary health care services to rural areas that are underserved by the mainstream health care system.¹⁴⁸ Health officers, who acquire 3-4 years of public health and clinical training, are given advanced training to undertake emergency lifesaving surgical interventions and caesarean section treatment. These procedures are normally undertaken by a medical doctor or a gynecologist and obstetrician. This initiative is tailored mainly to address women's health needs that the mainstream health care system has failed to satisfy.¹⁴⁹

iv. Interplay of the Three Rationales

The market failure, quality improvement and distributive justice rationales together justify and inform health professions regulation in Ethiopia. The market failure argument considers regulation as second best to the market. The issue of information asymmetry between the patient and the health professional requires regulation to ensure practice by competent and ethical health professionals. The market failure considers the necessity of regulation as a second best option next to free market. In contrast, the quality improvement rationale that is grounded on the social solidarity notion argues for

¹⁴⁸ FMOH, *Health Sector Strategic Plan HSDP III 2005/09-2009/10* (Planning and Programming Department: Addis Ababa, 2005) at 10.

¹⁴⁹ FMOH, *HSDP IV*, *supra* note 2 at 60.

regulation to ensure patient safety. The quality improvement rationale for health professions regulation calls for multiple strategies and actors to secure patient safety and quality improvement. This aligns with government's social obligation to ensure quality of health care services. The quality improvement rationale argues for regulation independently of market failure. The traditional regulatory activities of licensing, relicensing and fitness to practice practices are justified by the market failure argument. In contrast, regulatory activities that harness the different actors and strategies so as to ensure the delivery of quality health care services by the health professionals are justified by the concept of social solidarity.

There is therefore a tension between the market failure and quality improvement rationales. The market failure argument presents licensing and disciplining as a competence assuring mechanisms. However, the quality improvement rationale seeks to address more systemic problems that lead to medical errors and patient injury. It focuses on assuring competence of practicing professionals by different mechanisms like continuing professional development (CPD), peer-review, and clinical performance indicators. This resulted in expansion of the traditional mandate of health professions regulation.¹⁵⁰

Ethiopian health professions regulation consists of activities that seek to fix market failure and activities that seek to ensure social solidarity. Moreover, the distributive justice rationale justifies some regulatory decisions that respect policy intervention to

¹⁵⁰ Kiern Walshe, "Regulating Health Professionals" in Judith Healy & Paul Dugdale, eds, *Patient Safety First: Responsive Regulation in Health Care* (Crows Nest: Allen & Unwin, 2009) 144 at 154 [Walshe, "Regulating"].

address the special health care needs of disadvantaged people. It ensures that disadvantaged groups' health care needs are not left out due to the market's inability to reach them. Distributive justice compels responsiveness of regulatory decisions to the reorganization of the health care delivery system.

The foregoing discussion on the notion and rationales for regulation sets conceptual framework for evaluating the best regulatory design for Ethiopia. But this framework has to yield comprehensive criteria against which alternative designs will be evaluated. A system of regulation that is found to be more advantageous in contrast to other alternatives, or generally considered to be a 'good' regulatory system, will be suggested as the best choice for the country. The next section presents the most important criteria to choose a 'good' regulatory design among alternative systems.

3. 'Good' Regulation

There has to be criteria upon which any regulatory system is designed, reformed or evaluated. In determining how the regulatory power should be allocated to state and non-state actors, these criteria must be used to evaluate the different alternatives of power allocation and their ability to ensure protection of the public interest. However, there is no agreement on what these criteria are, or on value given to each.

In 1997, the UK Better Regulation Task Force issued five principles of good regulation applicable to evaluating and reforming a regulatory regime.¹⁵¹ The principles are

¹⁵¹ Better Regulation Task Force, *Principles of Good Regulation* (Crown: Leaflet, 2003), online:<<http://webarchive.nationalarchives.gov.uk/20100407162704/http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf>>.

proportionality, accountability, transparency, consistency and targeting.¹⁵² The Task Force explained that proportionality directs regulatory intervention to where it is necessary and commands commensurate enforcement measures with the regulated risk. Accountability requires that “regulators must be able to justify decisions and be subject to public scrutiny.” Consistency means “government rules and standards must be joined up and implemented fairly,” while transparency is about openness in the regulatory activity and coming up with a user-friendly regulatory design. Targeting ensures that regulation is problem focused and has minimum side effects. These principles remain influential in the UK government regulatory discourse.¹⁵³

The applicability of the Task Force’s principles in evaluating alternative forms of regulatory power allocation to different actors is limited. The principles generally appear to be more relevant to evaluating the effectiveness of a specific regulatory intervention, than to evaluating macro-level regulatory power allocation between different actors. For example, targeting is more relevant to guiding the decisions of a regulatory organ than it is to choosing the kind of regulatory power allocation that could establish an effective system. In addition, the Task Force’s principles appear to be motivated by the market failure rationale. For example, the principle of proportionality makes regulation second best to market. It overlooks positive role of regulation in improving quality in health care.

¹⁵² *Ibid.*

¹⁵³ These principles also guide the better regulation agenda of the Department for Business, Innovation & Skills . See <<http://www.bis.gov.uk/policies/bre/principles-of-regulation>>.

Healy enlists more than a dozen regulatory design principles applicable to the health care setting.¹⁵⁴ These include trust, transparency, accountability, coherency, proportionality, targeting, enforceability, responsiveness, harmony, clarity, equity, efficiency, participation, and solidarity. Among these principles, Healy argues that trust and transparency are the two most important principles that dominate the health care regulatory discourse.¹⁵⁵ Nonetheless, trust and transparency are not sufficient criteria against which the effectiveness of a given health professions regulation system can be evaluated against other alternative systems. The debate as to regulatory power allocation often involves arguments made on the basis of expertise and efficiency. The three rationales of regulation underlies Healy's list of regulatory design principles. For example, trust and responsiveness align with quality improvement objective of regulation while solidarity implies the value of distributive justice in regulatory decision-making. However, it is difficult to evaluate different regulatory power allocation systems on the basis of a dozen regulatory design principles. There must be few comprehensive and systematically organized criteria to evaluate alternative systems of regulatory power allocation.

The most inclusive and systematically organized criteria for evaluating a regulatory regime as to its worthiness of public support or legitimacy, or as to its effectiveness, are found in the works of Baldwin *et al.* The authors claim that there are five key criteria that dominate the discussion whether a given regulatory regime is effective or not. Firstly, the

¹⁵⁴ Healy, *supra* note 111 at 308.

¹⁵⁵ *Ibid* at 310.

legislative mandate should be determined as it is done in a democratic society where power has to be legitimately claimed from the elected law maker.¹⁵⁶ Secondly, the regulatory organ's accountability to and control by democratic institutions should be evaluated.¹⁵⁷ Thirdly, the fulfillment of due process requirements by the regulatory organ's procedures needs to be assessed.¹⁵⁸ This criterion includes a range of principles, including equality, fairness, accessibility, consistency, transparency and predictability. Fourth, the regulatory activity's need for expertise should be evaluated.¹⁵⁹ Fifth, the efficiency of the design in implementing its legislative mandate must be assessed.¹⁶⁰ The assessment of alternative regulatory designs on the bases of these criteria will identify the most effective regulatory regime. However, this does not mean that there would not be trade-offs in any in such assessment. A strong argument could be made under some criteria, for a specific design, while that design can hardly be justified on other criteria. A design can be taken as effective if, generally, strong arguments are made in its favor under all or most criteria.

In Ethiopia, it is hardly possible to come up with uniform regulatory design principles, like those of the UK Better Regulation Task Force, that are entrenched in government regulatory activities. However, the health regulatory blue-print provides a range of values

¹⁵⁶ Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 27.

¹⁵⁷ *Ibid* at 28.

¹⁵⁸ *Ibid* at 29.

¹⁵⁹ *Ibid*.

¹⁶⁰ *Ibid* at 30.

and beliefs that guide the regulatory organ's activity.¹⁶¹ These include customer satisfaction, openness (transparency), responsiveness, impartiality, consistency, and taking quality seriously. This list is not directly relevant to evaluate alternative forms of regulatory power allocation. These values and beliefs underlie the regulatory activities of any regulatory organ, whether a self-regulatory professional organ or a state organ. For example, consistency is a principle that any regulatory organ should follow in decision making. To assess whether a state or self-regulatory professional body would be consistent in its decision making would be highly speculative.

The aforementioned paragraphs show that there is no agreement on systematically organized and comprehensive criteria for evaluating a given regulatory design. Thus, a choice has to be made to identify key, comprehensive and analytical criteria relevant to coming up with an effective health professions regulation system. The five key criteria identified by Baldwin *et al.* are comprehensive analytical benchmarks by which to evaluate the potential effectiveness of a health professions' regulatory design. They capture the major arguments made for or against self-regulation and for the statist approach to regulation. Health professional associations in Ethiopia argue that self-regulation is the best system of regulation on the basis of expertise and efficiency. The state would argue it has better capacity to regulate the professions for its institutional and political ability to ensure accountability and due process. However, the legislative mandate criterion is not important as the mandate for different regulatory organs would be established after arguments for an effective regulatory design are made. As Healy

¹⁶¹ FMOH, *Regulatory Core Process*, *supra* note 63 at 197.

rightly argues, trust and transparency are important benchmarks in the professions regulatory design effectiveness debate. Baldwin *et al.*'s comprehensive analytical criteria espouse due process criteria to include transparency. But trust is a very important principle that appears frequently at the center of debate in systemic reform to health professions regulation. The ability of alternative systems of regulatory power allocation in restoring public trust in health professions regulation in Ethiopia should be evaluated. Therefore, accountability, trust, due process, expertise and efficiency are the criteria by which this thesis evaluates the effectiveness of alternative systems of power allocation in the Ethiopian health professions regulation enterprise.

This Chapter presented three important analytical frameworks for analysing the best regulatory design for health professions regulation in Ethiopia. To start with, regulation is understood as a sustained and focused attempt to alter the behavior of health professionals according to defined standards or purposes with the intention of public interest protection. It involves multiple actors and strategies. The public interest requires the practice of health professions only by competent and ethical professionals through licensing system. It also calls for quality improvement and patient safety while ensuring distributive justice by addressing the health care needs of disadvantaged people. To choose a 'good' regulatory design that effectively protects public interest, alternative designs should be evaluated based on expertise, efficiency, accountability, trust and due process criteria. In the following Chapters, alternative regulatory designs for health professions regulation in Ethiopia will be discussed based on these analytical foundations.

CHAPTER 4

HEALTH PROFESSIONS REGULATION BY THE STATE: CONCEPTUAL ANALYSIS

In Chapter 2, I argued that the health professions regulation reform adopted a statist approach, mainly due to the influence of the developmental state political theory. As such, the decision that chooses government regulation over self-regulation overlooked the significant insights that would have been gained from closer scrutiny of the pros and cons of each system. It is important to thoroughly explore the theoretical and practical reasons why state regulation is a better option over self-regulation in Ethiopian health professional regulation. Reflection on the enforcement strategies of the new regulatory framework is also required to implement the responsive regulation model envisaged in the reform. This chapter explains these points.

I argue that the tension between public protection and private interest inherent in self-regulation is a concern that cautions Ethiopia not to adopt self-regulation. State regulation would better serve the public interest than conferring the privilege of self-regulation on professional bodies. It is also a better option than self-regulation when these two are assessed against criteria for ‘good’ regulation. On the other hand, the enforcement strategy of a statist framework should emphasise persuasion and broad-based dialogue with professionals. In this regard, the expertise and legitimacy of professional associations should be effectively utilized. The next chapter reinforces these conceptual arguments with perspectives from global practice.

The next two sections examine the advantages and disadvantages of the statist approach to health professions regulation *vis-à-vis* self-regulation. The assessment is made at a theoretical level, and by applying the ‘good’ regulation criteria. The third section discusses the enforcement strategy for health professions regulation in Ethiopia.

1. Private Interest Theories

Private interest theories describe the origin and development of regulation as more fundamentally driven by private interest than for public protection.¹⁶² Among the different variants of the private interest theories, the economic theory of regulation and the Neo-Weberian theory regarding the sociology of professions provide relevant insights for a theoretical analysis of the claim of self-regulation in Ethiopia. These theories are analyzed in the rest of this Section as relating to the choice of regulatory framework for health professions in Ethiopia.

i. Economic Theory of Regulation

The economic theory of regulation, a dominant version of the private interest theories, assumes that all parties involved in regulation are “inherently self-regarding and orientated at maximizing their own (material) interest.”¹⁶³ Most importantly, the capture argument provides that “as a rule regulation is acquired by the industry and is designed and operated primarily for its benefit.”¹⁶⁴ The following extract elaborates this argument:

¹⁶² Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 43.

¹⁶³ *Ibid.*

¹⁶⁴ George Stigler, “Theory of Economic Regulation” (1971) 2 *Bell Journal of Economics and Management Science* 3 cited in *ibid.*

...where there is a failure of competition, or the existence of monopoly, there will be monopoly profit and the legislature will give the regulator the power to dispose of these economic monopoly rents. The regulated industry thus will have an incentive to influence the regulator so as to benefit from a 'regulatory rent', and there will be a market for regulation. This means that the regulator will be captured by the industry, since industry will have more to lose or gain than the regulator.¹⁶⁵

The capture argument is applicable to occupations which have an "incentive to seek regulation in order to raise barriers to entry and reduce competition."¹⁶⁶ Michael Moran and Bruce Wood, in their study of the development of doctors' regulation in the UK, USA and Germany, argue that doctors sought licensure to reduce supply and competition in order to secure higher income.¹⁶⁷ But they note that the rhetoric was not about the private interest of the doctors but the necessity of public protection from harm caused by the practice of bad doctors.¹⁶⁸ The doctors' quest for licensure was made before medicine became scientific and when doctors were solo practitioners transacting with patients without the involvement of the state or hospitals or modern day pharmaceutical companies.¹⁶⁹ However, the public protection claim has always been the overt rationale for health professions regulation, both at a time where it was sanctioned by the state

¹⁶⁵ *Ibid* at 44.

¹⁶⁶ Rob Baggott, "Regulatory Politics, Health Professionals, and the Public Interest" in Judith Allsop & Mike Saks, eds, *Regulating the Health Professions* (London: SAGE Publications, 2002) 31 at 37.

¹⁶⁷ Michael Moran & Bruce Wood, *States, Regulation and the Medical Profession* (Buckingham: Open University Press, 1993) at 35.

¹⁶⁸ *Ibid*.

¹⁶⁹ *Ibid*.

during the nineteenth century, and contemporarily where health professions regulation reform is debated.¹⁷⁰

The fact that health professions are largely self-regulatory is *prima facie* evidence for the regulatory capture notion that regulation primarily operates for the benefit of the professionals.¹⁷¹ As the following extract in an important Report preceding the implementation of health professions regulation reform in Ontario clearly illustrates, the traditional self-regulation model for health professions operated for the market interest of professionals.

The important principle...is that the sole purpose of professional regulation is to advance and protect the public interest. The public is the intended beneficiary of regulation, not the members of the profession. Thus *the purpose of granting self-regulation to a profession is not to enhance its status or to increase the earning power of its members by giving the profession a monopoly over the delivery of particular health services. Indeed, although these are common results of traditional regulatory models, they are undesirable results....*¹⁷²

The two common instances of self-interest driven action of organized health professionals are their action to restrict entry to the practice, and their “turf” battles over scope of practice.¹⁷³ In the USA, the doctors’ licensure was sought to restrict the practice of medicine by “unorthodox” medicine practitioners (homeopaths, osteopaths and

¹⁷⁰ Baggott, *supra* note 166 at 37.

¹⁷¹ *Ibid* at 38.

¹⁷² Legislative Review, *supra* note 140 at 9 [emphasis added].

¹⁷³ Epps, *supra* note 122 at 76-78.

chiropractors), graduates from substandard medical institutions, and untrained lay healers.¹⁷⁴ The orthodox doctors established the American Medical Association (AMA) in 1847 to control medical education and hence, restrict the supply of graduates.¹⁷⁵ It was at the first meeting of the AMA that a Committee on Medical Education was appointed.¹⁷⁶ AMA took longer time in controlling the supply of doctors which only became evident after 1900.¹⁷⁷ Its newly re-organized Council on Medical Education inspection rated about half of the medical schools as substandard.¹⁷⁸ This recommendation was supported by the subsequent Flexner Report (1910) that proposed a reduction in the number of medical schools.¹⁷⁹ As a result, after 1900, the supply of doctors was reduced. The reduction was also partly due to the inability of weaker medical schools to compete with the likes of Harvard and John Hopkins.¹⁸⁰ The AMA also succeeded in reducing the supply of medical doctors by opposing the federal government's funding to medical education until the 1960s.¹⁸¹ By the 1950s, the US had a chronic shortage of doctors and a government report in 1959 concluded that a 50

¹⁷⁴ *Ibid*; Moran & Wood, *supra* note 167 at 39.

¹⁷⁵ *Ibid* at 39.

¹⁷⁶ *Ibid*.

¹⁷⁷ *Ibid* at 39-40.

¹⁷⁸ Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, 1982) at 118.

¹⁷⁹ *Ibid* at 120.

¹⁸⁰ Moran & Wood, *supra* note 167 at 40.

¹⁸¹ *Ibid*.

percent enrollment increase in medical schools was needed.¹⁸² This led to the federal government's funding program for medical education from 1963.¹⁸³

The opposition of dentists to the claim by dental hygienists for independent practice in Ontario can be seen as an example of the “turf” battle over scope of practice.¹⁸⁴ The dental hygienist can only establish primary contact with the patient upon the permission of the dentist.¹⁸⁵ Dental hygienists, therefore, argued for a broader scope of practice and their ability to serve as the entry points for oral health care without the dentist's intermediary role.¹⁸⁶ This would ensure their autonomy and status, but at the expense of the dentists.¹⁸⁷ The dentists opposed the claim, arguing that dental hygienists are not equipped to serve as the entry point for oral health care so that their practice is not limited to receiving referral for cases requiring their speciality.¹⁸⁸ In 2007, dental hygienists were able to initiate to authorized acts based on their own clinical assessment without the order

¹⁸² *Ibid.*

¹⁸³ *Ibid.*

¹⁸⁴ Epps, *supra* note 122 at 77.

¹⁸⁵ Tracy L Adams, “Inter-professional Conflict and Professionalization: Dentistry and Dental Hygiene in Ontario” (2004) 58 *Social Science and Medicine* 2243 at 2250.

¹⁸⁶ *Ibid.*

¹⁸⁷ *Ibid* at 2251.

¹⁸⁸ *Ibid* at 2250.

of dentist.¹⁸⁹ This was designed to increase accessibility of oral health care and consumers' choice among alternate professionals.¹⁹⁰

Application of the Economic Theory of Regulation in Ethiopia

The economic theory of regulation, particularly the capture argument, has some relevance and also limitations in explaining health professions regulation in Ethiopia. Its limitation primarily rests on its inability to explain the origin of the regulation of modern medicine in Ethiopia. In the Ethiopian context, there is no evidence for the view that licensure was sought to limit both the supply of health professionals and competition. Given the available literature and general political economy of Ethiopia during the time when modern medicine emerged, the capture argument cannot explain the origin of health professions regulation in Ethiopia.

The practice of medicine and nursing emerged in the late nineteenth and early twentieth centuries, in the absence of market, as a charity and public good within the state structure. There was also no market competition in that regard. At the time, there were few health professionals, mostly foreigners, and a few foreign-trained Ethiopians. In addition, traditional healing practice was not affected by the licensure for the practice of modern health professions. Indeed, traditional healers could not pose a threat to modern medical practice, for reason of the latter's superiority in scientific knowledge, effectiveness and

¹⁸⁹ Health Professions Regulatory Advisory Council (HPRAC), *Critical Links: Transforming and Supporting Patient Care* (Toronto, January 2009) at 187.

¹⁹⁰ *Ibid.*

support from the state. Nursing and medical education were also started by state initiative and funding, with the assistance from other countries and international organizations.

But the capture argument provides relevant insights into the impact of self-regulation in restricting entry into the practice of health professions and the “turf” battles over scope of practice. The claim for self-regulation in Ethiopia includes the control of medical education to ensure its quality. The US experience has shown that AMA’s long lasting effort to control medical education finally resulted in a decline in the supply of doctors, necessitating the intervention of the federal government to fund more access to medical education.

The adoption of self-regulation in Ethiopia may create a barrier to entry into health professions practice. This is because such regulation would include maintaining or raising the standard of admission to medical and other health professions education. This may make it difficult to implement a human resource for health strategy that promotes turning out sufficient numbers of health professionals. The statist approach to health professions regulation is responsive to the implementation of such a strategy through flexible and innovative training curriculum that produces health professionals with adequate skills. The health science higher education system and human resource for health strategy are explained below in relation to their implication for a regulatory policy choice.

In Ethiopia, education to enter the medical and other health professions has been largely provided by public higher education institutions financed by the state. Admission to these institutions is controlled by the Ministry of Education. Until 2003, health professions education was fully funded by the government. After 2003, a cost sharing scheme was

introduced into the public higher education system to oblige a student to cover the full cost of living and 15 percent of tuition.¹⁹¹ Given the high tuition cost for training doctors and other health professionals, the public higher education system remains highly funded by the state. There is quality audit under the Ministry of Education, but criticism of the quality of medical and other health professions' education programs in the public universities abounds due to the dramatic increase in admission without a commensurate expansion of the teaching staff and facilities.

The involvement of the private sector in the training of health professionals is recent phenomenon- it has less than two decades of history. The sector's contribution to training doctors is minimal because it does not yet have the financial and institutional strength to engage in the expensive and lengthy exercise of training doctors. The private health programs are accredited by a specialized agency under the Ministry of Education (at the federal level), and under Education Bureaus (at the states level).¹⁹² There are criticisms about the quality of the private education and the competence of their graduates.

Parallel with efforts to improve the quality of education, the government focuses on turning out personnel for the health workforce. Nowadays, the shortage of professionals in nursing, pharmacy and laboratory technology seems to be stabilizing. The government wants to produce a high number of doctors, midwives and anesthesia professionals.

¹⁹¹ *Higher Education Cost-Sharing Council of Ministers Regulation*, no 91 (Ethiopia), 2003, art 4(1).

¹⁹² *Higher Education Proclamation*, no 650 (Ethiopia), 2009.

During the interview with the USAID magazine, *Frontlines*, the Minister of Health, Dr. Tedros Ghebreyesus, emphasised the “flooding strategy” of the government to handle the chronic shortage of doctors in Ethiopia. He responded to the question about the shortage of doctors as follows:

Yes, there is a serious shortage. We believe the root cause of the problem is a mismatch between supply and demand. Of course, brain drain contributes to the shortage, but we don't believe that brain drain is the main cause. The main cause is not training enough and not supplying enough, even though the demand is really high.

So our government designed two strategies: One is a flooding strategy, and the second is a retention strategy. In the flooding strategy, we're trying to really produce enough to satisfy the demand. And in the retention, we're introducing financial and nonfinancial incentives to keep them. Based on that strategy, our enrollment of medical students increased from 300 six years ago to 3,000 this year. The past three years, we have been enrolling an average of 1,400 per year. So we hope in the coming five, six years, the crisis will really start to abate significantly and stabilize.¹⁹³

As regards dealing with the shortage of midwives, Dr. Ghebreyesus responded:

Yes, we started acceleration training, and we enrolled more than 1,600 last year. And in the next two years, we will, I think, finish the accelerated training by training between 5,000 and 6,000 more. That is part of the flooding strategy.

We use the same strategy to train health officers, who manage our country's health centers. In just four, five years we trained over 5,000. We're training some of them on emergency lifesaving surgery

¹⁹³ Interview of Dr. Tedros Ghebreyesus by USAID Frontlines (May/June 2012), online: <http://www.usaid.gov/press/frontlines/fl_may12/FL_MAYJUN12.pdf>.

interventions, like Caesarean section, to save mothers, because we don't have enough surgeons or OB/GYN specialists in the country. So this is exactly the type of task shifting we were talking about: from surgeons or OB/GYN specialists to health officers or non-physician clinicians.¹⁹⁴

The interview explained the “flooding strategy”, accelerated training programs and task shifting as Ethiopia’s major strategies to improve shortage of skilled personnel in the health sector. But these strategies could compromise the quality of training and the competence of the trainees, unless comparable work is done on quality assurance. This strategy is criticized, particularly by health professionals, for lack of due consideration for quality. The evidence from other countries may cast doubt on the overt concern about quality. There may be underlying motives to protect the monopoly and market leverage created by the shortage of doctors. The policy objective to ensure accessibility to primary health care services by increasing the supply of doctors, midwives and anesthesia professionals outweighs the criticism as to the quality of their education and training. Self-regulation may pose a challenge to these strategic implementation efforts by raising admission and training standards. The state’s control over the education of the medical and other health professions is vital in Ethiopia to ensure the development of health workforce, and hence, to ensure accessibility to health care services for the population. Regulation by the state ensures harmonious implementation of the government policies and strategies. It will be responsive to the country’s health workforce strategy that seeks to achieve a distributive justice goal of ensuring accessibility of primary health care

¹⁹⁴ *Ibid.*

services to the public. Self-regulation may undermine distributive justice in health care for the economic interest of the profession.

Self-regulation may also be utilized for expanding or protecting the health profession's scope of practice in pursuit of greater autonomy, status and economic reward. Statist regulation is a better option for Ethiopia, as it would enable the state to handle the "turf" battle in which it is relatively disinterestedness. Given the poorly defined or ambiguous scope of practice and the recent diversification of health professions in Ethiopia, the statist approach to regulation becomes a more appropriate choice over self-regulation at this particular time.

Currently, Ethiopia does not have comprehensive and clear scopes of practice for its health professions. The most important guidance remains the conventional understanding of the professions' responsibilities gained during professional training. There are also scattered legal provisions generally setting out the health profession's scope of practice, or stipulating the level of a clinic or drug retail outlet a professional can run. Since 1942, the practice of doctors and pharmacists in Ethiopia has been distinguished respectively as prescribing and dispensing. There has not been any significant change in this distinction, which is now being challenged by the emergence of clinical pharmacy training. A small clinic is run by a nurse with 2 years of higher education training, or 3 years of vocational training. On the other hand, a medium clinic is run by a doctor or health officer (a Bachelor of Science holder with both clinical and public health training), while a specialist doctor is required to open a higher clinic. Similarly, a pharmacy is run by a pharmacist (a Bachelor of Pharmacy trained professional), while a druggist (a

professional with 2-3 years of pharmacy training) can only run a drug store with limited permission to dispense narcotic and psychotropic drugs. Generally, these are the major, scattered, legally stipulated areas of practice for the major health professions in Ethiopia. They need to be systematically organized and clarified.¹⁹⁵

There has been “turf” battle between druggists and pharmacists over the list of drugs that the former can dispense. The pharmacists argue that some lists of drugs should not be dispensed by druggists due to their limited training and, thus, incompetence in dispensing the drugs. They have been successful in this confrontation and so have monopoly over running pharmacies, a very profitable business in Ethiopia. This inter-professional conflict over scope of practice fits the capture argument that professionals utilize regulation for the pursuit of their economic interests in a manner that undermine protecting public interest.

The proliferation of new health professions training and advanced training in the conventional health professions have brought challenges to the practice of the traditional health professions in Ethiopia. For example, the scope of practice for dental professionals (a new 4 -5 years Bachelor of Science training program) has to be defined in relation to a dentist’s (a doctor with a speciality certificate) practice. The practice of ophthalmology has to be shared/reconfigured by defining the scope of practice for an ophthalmologist (a doctor with an ophthalmology speciality certificate), ophthalmic professionals (a new 4 - 5 years Bachelor of Science training program), and ophthalmic nurses (a nurse with

¹⁹⁵ This is recognized by the reform and the new regulatory framework legislation. And, there is an ongoing initiative for developing the scopes of practice for health professions in Ethiopia.

ophthalmic speciality). The advancement of nursing training to a university degree and to the masters level also occasioned a claim by the graduates to have equivalent status with health officers, along with the responsibility to prescribe some medications and to run medium clinics. There are also other areas of practice contested by different professions. The claim for greater role in the delivery of health care is essentially a quest for autonomy and status, and its subsequent economic rewards. The overt argument is that the authorization of the claimant profession ensures access to health care services by the public, while the opposition is based on the inadequacy of the profession's training and the incompetency of the professionals to deliver the services. Nonetheless, the debate on scope of practice is basically driven by self-interest.

Generally, there is evidence that the claim of the health professions for self-regulation has been driven by the self-interest of the professionals. In particular, self-regulation has been used as an effective mechanism to control the supply of the practitioners and, hence, to ensure monopoly over the practice. The Ethiopian experience also shows that the economic interest of the health professionals than public interest protection may drive regulatory decisions. The economic theory of regulation provides a relevant insight to Ethiopia by exposing the dangers of self-regulation. The state is a relatively disinterested arbiter to resolve "turf" battles between the professionals, and to protect public interest. Thus, the statist approach to health professions regulation in Ethiopia offers advantages over self-regulation in terms of the protection of the public interest.

ii. Sociological Theory of Professions

There is a developed literature on the sociology of medicine in the Anglo-American tradition of self-regulation. Generally, doctors in the Anglo-American tradition have been self-employed and interact directly with the market.¹⁹⁶ They have controlled the education, entry into practice, standard of practice, and discipline by their professional bodies.¹⁹⁷ In contrast, doctors' education and employment have largely been under the control of the state bureaucracies in European countries like Germany and France.¹⁹⁸ The state has been in charge of the licensure, standard setting and disciplining of the professions in these countries.¹⁹⁹ Despite these differences, the profession of medicine enjoys high social and economic status and autonomy in both traditions.²⁰⁰

Until the 1960s, the functionalist perspective dominated the literature on the sociology of professions.²⁰¹ Emile Durkheim, the founding father of functionalist sociology, argued that professionalism safeguards the stability of society through the transition from pre-industrial society to a modern society where previously shared values and norms have waned.²⁰² As society became more complex, functional interdependence among members

¹⁹⁶ John M Chamberlain, *Doctoring Medical Governance: Medical Self-Regulation in Transition* (New York: Nova Science Publishers Inc, 2009) at 48.

¹⁹⁷ *Ibid.*

¹⁹⁸ *Ibid.*

¹⁹⁹ *Ibid.*

²⁰⁰ *Ibid.*

²⁰¹ *Ibid* at 50.

²⁰² Emile Durkheim, *Professional Ethics and Civil Morals*, translated by Cornelia Brookfield (Glencoe: The Free Press, 1958) at 13.

of the profession necessitated cooperation among them.²⁰³ The practitioners of these professions have developed a collective selfless moral consciousness to replace the waning cohesive values and norms of the society.²⁰⁴ Accordingly, functional sociologists accepted the altruistic claim of the professions that they serve the public, and that this distinguishes them from other occupational groups.

However, the functional sociological analysis of medicine was found to be inadequate since the 1970s.²⁰⁵ The foundation of medicine's privilege on its altruistic claim has been criticized. Terence Johnson notes that "the professional rhetoric relating to community service and altruism may be in many cases a significant factor in moulding the practices of individual professionals, but it also clearly functions as a legitimation of professional privilege."²⁰⁶ Consequently, the neo-Weberian 'social closure' model has replaced the functionalist understanding of professionalism.²⁰⁷ It emerged from the reframing of the sociologists' question in understanding professionalism. Sociologists used to identify the traits of an occupation to be considered a profession.²⁰⁸ Everett Hughes introduced a critical question that sociologists should ask, namely: "what are the circumstances in

²⁰³ *Ibid* at 12.

²⁰⁴ *Ibid* at 13.

²⁰⁵ Chamberlain, *supra* note 196 at 51.

²⁰⁶ Terence James Johnson, *Professions and Power* (London: Macmillan Press Ltd, 1972) at 25.

²⁰⁷ Chamberlain, *supra* note 196 at 51.

²⁰⁸ *Ibid* at 50.

which people in an occupation attempt to turn it into a profession and themselves into professional people?”²⁰⁹

In addressing this question, the neo-Weberian social closure model relied on Max Weber’s theory of monopolization to understand professionalism.²¹⁰ Weber argued that occupational groups, such as medicine, sought to become privileged by collective mobilization so as to ensure “the closure of social and economic opportunities to outsiders.”²¹¹ Eliot Freidson’s influential work on the profession of medicine in America showed how medical professionalism ideologically operated to ensure exclusive control over the occupation. He argued that medical professionalism justified its autonomy on the basis of three arguments.

First, the claim is that there is such an unusual degree of skill and knowledge involved in professional work that non-professionals are not equipped to evaluate or regulate it. Second, it is claimed that professionals are responsible – that they may be trusted to work conscientiously without supervision. Third, the claim is that the profession itself may be trusted to undertake the proper regulatory action on those rare occasions when an individual does not perform his work competently or ethically.²¹²

²⁰⁹ Everett C Hughes, “Professions” (1963) 92 *Daedalus* 655 at 656 cited in Keith M Macdonald, *The Sociology of the Professions* (London: SAGE publications, 1995) at 6.

²¹⁰ Chamberlain, *supra* note 196 at 52.

²¹¹ Max Weber, *Economy and Society* (London: The University of California Press, 1978) at 342.

²¹² Eliot Friedson, *The Profession of Medicine: A Study of the Sociology of Applied Knowledge* (New York: Dodds Mead, 1970) at 137.

Magali Larson built on Friedson's critical work on medical professionalism as a social closure model by studying the historical development of medicine into a profession with market monopoly. She characterizes this development of an occupation into a profession as a 'professional project', a term that 'emphasizes the coherence and consistence' of the course of action the occupational group undertakes towards professionalization of the occupation.²¹³ Larson describes professionalization as "an attempt to translate one order of scarce resources – special knowledge and skills – into another – social and economic rewards. To maintain scarcity implies a tendency to monopoly: monopoly of expertise in the market, monopoly of status in the system of stratification."²¹⁴

Today, the critical studies of Freidson and Larson represent the popular sociologists' view that underscores "the role of professional self-interest, instead of alleged altruistic tendencies, in the initial formation and subsequent development of professions such as medicine."²¹⁵ Critics argue that the neo-Weberian argument undervalues the selfless service of most doctors who prioritize their patients' interest above their own.²¹⁶ The neo-Weberian social closure perspective acknowledges doctors' possession of "a distinctive mixture of cognitive and altruistic characteristics," but argues that these characteristics do

²¹³ Magali Larson, *The Rise of Professionalism: A Sociological Analysis* (Berkeley: University of California Press, 1977) at 6.

²¹⁴ *Ibid* at xvii.

²¹⁵ Chamberlain, *supra* note 196 at 56.

²¹⁶ *Ibid* at 58.

not “justify the extent to which they have traditionally been left alone to manage their own affairs.”²¹⁷

The other important criticism against the ‘professional project’ analysis of professionalism is its inapplicability to understanding knowledge- based occupations in statist countries. This is because it originates from the study of professions in America or Britain.²¹⁸ Keith Macdonald assessed the validity of this claim by studying the professional project pursued by medicine, mainly in Britain, USA, France and Germany. He noted that “[b]asically, the professional project seems best able to prosper where civil society penetrates the state, which in consequence is pluralistic or decentralized.”²¹⁹ The success of the professional project in the USA and Britain, where medicine was sanctioned by the state to regulate itself and thus established its status as a profession, is attributed to this pluralistic structure and liberalism’s conception of ‘little government’.²²⁰ In contrast, at the formative stage of the professions in France and Germany, these countries were centralized states that followed the statist approach of regulation for knowledge-based occupations such as medicine.²²¹ The professional project showed little success in France because at the time the professional bodies were established, French

²¹⁷ *Ibid.*

²¹⁸ Macdonald, *supra* note 209 at 95.

²¹⁹ Michael Burrage, “Beyond a sub-set: the professional aspirations of manual workers in France, the United States and Britain” in Michael Burrage & Rolf Torstendahl, eds, *Professions in Theory and History: Rethinking the Study of the Professions* (London: SAGE publications, 1990) 151 at 172-3; see also Macdonald, *supra* note 209 at 96.

²²⁰ *Ibid* at 96-7.

²²¹ *Ibid* at 97.

society was pluralistic but later an absolute monarch subordinated these bodies to state officials.²²² Despite this little difference, the professional project of medicine has not succeeded in France and Germany.²²³ Macdonald further remarks that:

The ways in which groups in these various societies achieve social closure is bound to have some fairly direct connection with the institutional and cultural features Thus, in Britain and the USA, status groups are free to form round their own activities and features, while in France and Germany the tendency is for members of society to use the state structures and its off-shoots such as the universities as the basis for status group formation and for social closure.... But it must be recalled that even in the strongly statist culture of Germany... evidence was adduced which shows the desire of members of knowledge-based occupations to achieve autonomy and to embark on a professional project.²²⁴

Therefore, Macdonald concluded that Larson's notion of the professional project is still relevant for Germany and France, since medicine as a profession existed and strove for professional autonomy, though its success was modest.²²⁵ Even in the former communist countries where medical service was provided and regulated entirely by the state, the concept of the 'project' is not irrelevant.²²⁶ Although these countries represent cases where "the actions of the professions are seriously circumscribed", they merely provide "one end of a range of freedom of action rather than an invalidation of the concept of the

²²² *Ibid* at 89.

²²³ *Ibid* at 97.

²²⁴ *Ibid* at 98.

²²⁵ *Ibid* at 98-9.

²²⁶ *Ibid* at 98.

professional project.”²²⁷ This defence of the professional project thesis, however, recognizes the need to elaborate the concept for application to these countries.²²⁸

The literature considered above shows that there is good reason to view with scepticism, the claim of professional associations for self-regulation in Ethiopia so as to serve the public interest. Rather, the associations’ claim may be understood as an attempt for greater autonomy for their respective professions, and consequently, for benefit in the form of economic and social reward. The claim of altruistic service on the part of the health professionals espoused by functionalist sociologists has been refuted. The neo-Weberian writers have shown that medicine’s professionalism has operated ideologically to ensure exclusive control over the practice in order to reap its economic and social benefits. The professional project notion showed how medicine gained greater autonomy and, consequently, consolidates its economic and social privilege through the political recognition of the state. In other words, neo-Weberian sociologists show that “the concept of professionalism is based more on professional self-interest than the collective interest.”²²⁹

A person who served as a lay member in the General Medical Council, the United Kingdom’s self-regulating professional body for medicine, noted this conflict of interest as inherently manifested in self-regulation when a choice had to be made between protecting the self-interest of the profession by protecting its reputation, and protecting

²²⁷ *Ibid* at 98 & 66.

²²⁸ *Ibid* at 34.

²²⁹ Judith Allsop & Mike Saks, “Introduction: The Regulation of Health Professions” in Allsop & Saks, *supra* note 166 at 7.

the public interest by exposing malpractice.²³⁰ Nonetheless, it should be noted that the pursuit of self-interest and the public interest by the professional bodies are not always incompatible; and indeed, in some cases, the two interests can coexist without contradiction.²³¹ For example, the British Medical Association campaign in the early twentieth century against rivals, who were purveying potentially harmful secret remedies, was both self-serving and protective of the public interest.²³²

In Ethiopia, like the statist Germany and former communist countries, the professional project was not pursued because the powerful centralized state was not penetrated by civil society when professional associations were formed and sought greater autonomy. The associations' claim for self-regulation is a manifestation of the collective solidarity of health professions to achieve greater autonomy. Once they secured autonomy, they would embark on professional projects to ultimately control the practice of their respective professions and to reap the economic and social benefits that accrue from control.

The insights offered by the relevant sociological literature fundamentally challenge the public interest arguments advanced by the health professional associations to call for self-regulation. It would be recalled also that the economic theory of regulation says that self-regulation may serve to promote the professions' interest rather than protect public interest. Inherent in self-regulation is a conflict between pursuing the professions' interest

²³⁰ *Ibid.*

²³¹ *Ibid.*

²³² *Ibid.*

and protecting the public. In contrast, the state is, relatively speaking, better situated as a disinterested party to protect the public. Therefore, theoretically, the statist approach to health professions regulation is a better option than self-regulation for Ethiopia. This, however, does not overlook the risk of capture and corruption of the state regulatory organs in Ethiopia. As will be argued later, this problem can be fixed with plurality of regulatory actors. The following section further contrasts the advantages and disadvantages of the statist framework for health professions *vis-à-vis* self-regulation based on the ‘good’ regulation criteria.

2. ‘Good’ Regulation

As discussed in Chapter Two, the most relevant criteria for ‘good’ regulation in the context of health professions regulation in Ethiopia are expertise, efficiency, accountability, trust and due process. Utilizing these criteria in what follows, I explore the debate on the preferred health professions regulatory framework for Ethiopia, namely, regulation by the state bureaucracy, or self-regulation.

i. Expertise

The regulation of health professions requires expertise with technical knowledge and skill on the part of the regulated profession. I explore the arguments for self-regulation based on expertise, and evaluate the extent to which they should influence the policy choice of the regulatory framework for Ethiopia.

Self-regulatory bodies have expertise needed to make regulatory decisions.²³³ The standard setting, evaluation and disciplining of health professionals require expertise. It may be said that expertise can be brought into the bureaucracy.²³⁴ However, the expertise of self-regulatory bodies is generally closer to the practice and the regulated professionals, and possesses updated information.²³⁵ In contrast, experts in the bureaucracy may be junior health professionals with limited clinical work experience, or they may be experienced clinicians detached from practice.

The expertise of self-regulatory organs are respected and trusted by the regulated professionals.²³⁶ The standards and decisions of self-regulatory organs are likely to be considered reasonable and acceptable to the professionals.²³⁷ Thus, expertise in self-regulatory bodies commands effective compliance more naturally than the compliance that the state can command.²³⁸ Self-regulatory bodies' scientific and technical excellence ascribes legitimacy to the direction they give for the regulation of their respective professions.

The aforementioned reasons are appealing for self-regulation in Ethiopia. However, I would argue that the claim to expertise should be given modest weight. The core regulatory functions of licensing and license renewal are basically routine activities that

²³³ Baggott, *supra* note 166 at 34.

²³⁴ Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 139.

²³⁵ *Ibid.*

²³⁶ Baggott, *supra* note 166 at 34.

²³⁷ *Ibid.*

²³⁸ Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 129.

do not require higher qualification of personnel than can be found in the bureaucracy. Other core regulatory functions that do require expertise, primarily standard setting and disciplining, are not routine activities. The expertise required for standard setting can be incorporated into the technical working group developing the standard. Disciplinary proceedings involving complicated cases which arise infrequently can benefit from expert witnesses. For example, in cases of unprofessional conduct by a gynecologist relating to sexual assault, the disciplinary committee may not necessarily require a gynecologist either in its membership or as an expert witness.

The expertise of self-regulatory bodies is not likely to be used in accordance with government health priorities, policies and strategies. But it may apply licensing requirements stringently to limit entry into the practice. As described above, this is what happened in other countries regarding the closure model of self-regulatory bodies. There is a risk that self-regulation in Ethiopia may create inconsistency and chaos in the health system.

The claim that self-regulation commands better compliance should also be qualified. It is not always that self-regulatory bodies are accepted by the regulated profession.²³⁹ In Ethiopia where the legitimacy of any institution is highly politicized and contested, the legitimacy of self-regulatory organs may not even be established. The internal hierarchy of a profession may constitute a major challenge to earning legitimacy for its self-

²³⁹ Baggott, *supra* note 166 at 35.

regulatory organ. This would reduce the compliance that self-regulatory bodies are assumed to command.²⁴⁰

The modest advantage that the presence of expertise is said to offer to the self-regulation claim is acknowledged. However, the statist regulatory mechanism has also the means to cope with the expertise deficit. Moreover, the qualified advantage that the self-regulatory system has over the statist approach on the basis of expertise, should be cumulatively assessed against other grounds of ‘good’ regulation.

ii. Efficiency

It is argued that self-regulation is efficient to regulate the health professions, mainly for the following three reasons. First, self-regulators have easy access to information on standards setting, monitoring and enforcement and hence, they incur low cost for these regulatory activities.²⁴¹ The high technical and leadership expertise of self-regulators ensure an expedient and inexpensive process of standard development. The regulated professionals are more likely to be cooperative and motivated to provide regulators with relevant information for monitoring and enforcement. The respect and reverence generally ascribed to self-regulators ensure easier compliance with their directions and orders by the regulated. The proximity of self-regulators to the activities of educational institutions and professional associations gives them a wider platform to communicate regulatory standards and good practices. By doing so, they can externalize the cost of

²⁴⁰ *Ibid.*

²⁴¹ Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 140.

enforcement by engaging and increasing stakeholders' interest and active involvement in soft regulatory implementation.

Second, the cost of regulation can be borne by the professions not the taxpayer.²⁴² Self-regulators generally collect revenue from licensing, relicensing and annual fees from the practitioners they regulate. But health professions regulation in Ethiopia has been financed by government revenue. The licensing and relicensing fee the state regulatory bodies collect is low and cannot be directly utilized for enhancing the regulatory system because of prohibition in the Ethiopian public finance laws. Raising the fee involves lengthy bureaucratic process. Even if there is fee adjustment, due to the public finance laws the revenue collected can hardly be directly utilized for the regulatory system improvement. As a result, state regulatory bodies have remained underfinanced.

On the other hand, the establishment of self-regulatory bodies could bring adequate finance and efficient regulatory system. The establishment of self-regulatory professional bodies creates an opportunity to introduce changes to public financing laws. Such laws could empower self-regulators to use revenue from licensing, relicensing and annual fees, and these usually suffice to finance their regulatory activities. This also creates opportunity to adjust, without prolonged government bureaucratic delay, the fees to cover the regulatory activities of self-regulatory bodies. The self-financing of self-regulatory bodies saves the taxpayers money to be redirected for other public services.

²⁴² *Ibid.*

Third, self-regulation can be an efficient system on account of its flexibility and responsiveness to address new regulatory challenges.²⁴³ The proximity of self-regulators to practice enables them to detect new challenges early. In addition, the smoother relations between the regulated and self-regulatory body encourages expedient and effective flow of information to facilitate timely detection of challenges. The expertise of self-regulators can ensure effective and prompt response to these challenges. The non-bureaucratic institutional culture of the self-regulatory bodies is also a positive asset. These bodies could more easily be flexible in making decisions that can be critical to regulatory effectiveness.

Nonetheless, on critical examination, these arguments for self-regulation have weaknesses. Self-regulation does not necessarily externalize the cost of regulation to the regulated, as the cost of approving standards and auditing the effectiveness of the system may be considerable.²⁴⁴ The high licensing and relicensing fees that self-regulatory bodies charge result in increases in the cost of health care services. Ultimately, society bears the cost of regulation, either by paying tax or higher prices for health care services. The smooth relationship between the self-regulators and the regulated professionals does not always show effectiveness of the regulatory system. Rather, a very smooth relationship may indicate the capture of the self-regulatory organ by the regulated.

²⁴³ Baggott, *supra* note 166 at 35.

²⁴⁴ *Ibid.*

Most importantly, self-regulation in Ethiopia would not be efficient due to the higher cost of the fragmentation that self-regulation could entail. This point is illustrated by taking the South African experience as an example. It would be recalled from in the discussion on the decentralization of health professions regulation reform in Ethiopia in Chapter 1 that the South African health professions regulation was the focus of the debate.

In South Africa, there are more than 37 regulated health professions. These professions are self-regulated by five councils. The South African Nursing Council, Pharmacy Council and Dental Technicians Council regulate their respective professions. The Health Professions Council of South Africa, which consists of 12 professional boards, regulates a range of health professions, including medicine and dentistry. The fifth self-regulatory organ is the Allied Health Professions Council of South Africa, which consists of four professional boards. There are five offices which host the regulatory activities of the five Councils, sixteen professional boards, and administrative staff who support the works of the Councils or/and the Boards. For example, the largest employer among the Councils, the Health Professions Council of South Africa, had 177 permanent and 13 temporary employees by the end of 2009/2010.²⁴⁵

²⁴⁵ Health Professions Council of South Africa (HPCSA), *Annual Report 2009/2010*, online: HPCSA <http://www.hpcsa.co.za/downloads/press_releases/annual_reports/hpcsa-annual-report-2009-2010.pdf> at 19.

Self-regulation in Ethiopia could similarly involve the creation of a significant institutional infrastructure. It requires the establishment of a regulatory body (Council, Board or College) for each health profession or cluster of health professions, office facility, and administrative staff to provide secretariat/registrar services to the governing organ of the regulatory body and its various committees.

In addition, the decentralization of health professions regulation in Ethiopia, mostly to the states, would imply plurality of the self-regulatory bodies in two ways. First, if the constitutional principle of decentralization of health professions regulation is adhered to, there would be a proliferation of self-regulatory bodies based mainly in the states. This would create a health professions regulation model similar to the Canadian system. In Canada, health professions regulation is the mandate of the provinces and territories, and the various self-regulating Colleges regulate their respective professions. For example, there are 21 health regulatory colleges regulating 23 health professions in Ontario, a province with a population of about 13 million. There are similar number of self-regulating health professions in the nine other provinces and three territories, some of which have a population of a few hundred thousand people and a number of which have populations of less than a million.

Alternatively, if the states agree to continuation of the regulation from the center, because of a high number of new graduates in health professions are coming out, at least, there would be a need to open branch offices in some parts of the country. Either way, the principle or the practical need for decentralization would require the pluralisation of self-regulatory bodies and, hence, an increase in the cost of establishing and running these

institutions. Even the modest plan to transform the previous Ethiopian Health Professions Council into an independent organ with its own office and staff is expensive option than transferring the Council's powers and responsibilities to the bureaucracy of the federal and states governments.

Fragmentation of health professions regulation may result in a complex and inconsistent regulatory regime. This problem will be particularly evident if a proliferation of self-regulatory bodies is allowed. Each self-regulatory body may develop legislations, standards and regulatory practices that allegedly reflect the peculiarity of the regulated profession and regional circumstance. These differences may create confusion for the professionals and the public. It may restrict easy movement of health professionals between states. As a result, there could be disparities in access, equity and quality of health care services among states. Thus, the fragmentation of health professions regulation through assigning it to self-regulatory bodies at the states level, entails far-reaching consequences than merely establishing an inefficient regulatory system. It could result in ineffective regulation. Eventually, harmonization, co-ordination and re-organization must be considered, imposing double cost on the society. At first, the society would cover the cost for establishing various self-regulatory bodies. Later on, the society would be burdened to sponsor the harmonization, re-organization and coordination of the fragmented, inconsistent and complex self-regulatory regime.

Canada and Australia provide good examples on the consequences of a fragmentation of health professions regulation, and the need to adopt a consistent, harmonious and simple approach through framework legislation. In Canada, the jurisdictions of Ontario, British

Colombia, Alberta, Manitoba, Quebec and the Yukon have introduced framework legislations that provide for a consistent approach to regulation by various regulatory Colleges in the respective province or territory.²⁴⁶ The harmonization reform in Australia has been made at the national level with the consent of the States and Territories. Since late 2010, almost all states and territories adopted the national scheme of health professions regulation within the framework of the Health Practitioner Regulation National Law Act 2009.²⁴⁷ These reforms have been undertaken with the resources and time of the government. Fragmentation in Ethiopia would eventually require similar harmonization reforms that would cost the government and, ultimately, burden the society.

The question of efficiency of self-regulation in Ethiopia ultimately calls for prioritization of the use of scarce health care resources. It also calls for the political commitment of the government to ensure the quality of health care services and patient safety. It is important to reflect on these issues as they relate to efficiency and the general question of self-regulation in health professions regulation.

Jean-Jacques Laffont, a father of modern theoretical research on the regulation of network industries such as telecommunication, electricity and water in least developed and developing countries, noted that institutional weaknesses in least developed and developing countries are major challenges that necessitate the development of peculiar

²⁴⁶ Epps, *supra* note 122 at 88.

²⁴⁷ Ian Freckelton, “Regulation of Health Practitioners: National Reform in Australia” (2010) 18 *Journal of Law & Medicine* 207 at 207.

regulatory theories other than theories applicable in developed countries.²⁴⁸ The institutional weaknesses he identified are categorized into four key problems: limited capacity, limited commitment, limited accountability and limited fiscal efficiency.²⁴⁹ Though this empirical and theoretical discussion arises from research on network industries regulation, some observations can be made as to their conceptual application to health professions regulation in Ethiopia.²⁵⁰ Particularly, the regulatory challenges of limited capacity and commitment are relevant in the discussion of the efficiency of self-regulation.

Limited capacity mainly refers to the regulatory organ's resource constraints.²⁵¹ The Ethiopian government budget allocated to the health regulatory organ is low even in view of the general health sector budget. This financial constraint undermines the human resources capacity of the regulator. The regulator pays for its professional staff according to the civil service pay scale. This scale is too low compared to the professionals'

²⁴⁸ Jean-Jacques Laffont, *Regulation and Development* (UK: Cambridge University Press, 2005) at 245; Antonio Estache & Liam Wren-Lewis, "Towards a Theory of Regulation for Developing Countries: Following Jean-Jacques Laffont's Lead" (2009) 47:3 *Journal of Economic Literature* 729 at 729; *See also* Antonio Estache & Liam Wren-Lewis, "On the Theory and Evidence on Regulation of Network Industries in Developing Countries" in Baldwin *et al.*, *Handbook of Regulation*, *supra* note 111 at 372 [Estache & Wren-Lewis, "Theory and Evidence"].

²⁴⁹ *Ibid* at 377; *See also* Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 414.

²⁵⁰ The limited regulatory capacities of developing countries have been acknowledged by John Braithwaite. Indeed, this understanding prompts his extension of responsive regulation theory to developing countries. He argued that developing countries can form a "regulatory society" model by networking governmental and non-governmental actors around capacity deficits. John Braithwaite, "Responsive Regulation and Developing Economies" (2006) 34:5 *World Development* 884 at 884 [Braithwaite, "Developing Economies"].

²⁵¹ Estache & Wren-Lewis, "Theory and Practice", *supra* note 248 at 377.

capacity to earn higher income in the private sector. Consequently, there is high staff turnover for better opportunities in the private sector. In contrast, self-regulatory professional bodies may attract and retain qualified personnel due to their revenue generation capacity, and financial and managerial flexibility. Nonetheless, the cost of starting up the fragmented self-regulatory bodies may be high for the government and society. In addition, as already pointed out, the cost of maintaining well-resourced self-regulatory bodies from licensing and relicensing fees may result in an increase in health care service costs. Thus, self-regulation is not an efficient system by which to overcome the limited capacity of the statist regulator because it imposes too high a cost on society. It is better to handle the challenge of the limited capacity of the state regulatory organ by other measures, like the provision of financial and non-financial incentives to the regulator's professional staff.

The government's level of political commitment to health professions regulation is not clear. Meanwhile, generally speaking, the low budget set aside for health professions regulation and other considerations²⁵² imply that the government is focused on ensuring the provision and accessibility of health care services. The government has a political commitment to ensure universal access to primary health care services, and to reduce maternal and child mortality and morbidity. Quality improvement through regulation of

²⁵² Particularly, the merger and consolidation of different health care regulatory activities in one regulatory organ, *i.e.*, EFMHACA, at the Federal level is said to weaken regulatory activities. The same organization of health care regulation is adopted at the States level too. Under this arrangement, the regulation of food, medicine, food establishments, health care facilities, health professionals, and environmental and hygienic control are to be undertaken by one authority at the Federal or States level. These broad mandates of the EFMHACA may undermine its effectiveness by divesting its focus with its limited financial and human resources.

the health professions is secondary to the government's other major commitments in the health sector. The scarce health care resources have to be targeted to those priorities. Thus, the resources allocated for health professions regulation is low. Practically, establishing various self-regulatory bodies to be supported with the limited resources available for health professions regulation is hardly possible. It would also be inefficient use of scarce health sector resources at the cost of health sector priorities. In a relatively limited commitment for health professions regulation, self-regulation would be inefficient use of scarce resources. It should be noted that this allocation of scarce resources is informed by distributive justice ideals. Distributive justice informs decisions of health care resources allocation in favor of increasing accessibility of primary health care services to the public. Spending significant amount of the limited health care resources, which should have been spent to other priorities in the health sector, to establish self-regulatory bodies can hardly be justified by distributive justice goals of regulation. Overall, state regulator could efficiently carry out the health professions regulatory activities with available limited resources.

iii. Accountability

Self-regulatory bodies are often criticized for lack of accountability and legitimacy in a democratic system.²⁵³ The global patient safety movement brought greater oversight and accountability to self-regulatory professional bodies.²⁵⁴ Nowadays, it is not uncommon that these bodies are required to report to the legislator, to submit their standards for government approval, involve lay representation in their governing organ, and publicize the results of their disciplinary proceedings.²⁵⁵ Reforms in countries where self-regulation was the norm have introduced different mechanisms of external control over self-regulatory bodies.²⁵⁶ It is an irony to argue for self-regulation in Ethiopia, given the unimpressive accountability record elsewhere of self-regulatory bodies. Nonetheless, the concern over accountability in the Ethiopian state bureaucracy also compels further scrutiny as to how self-regulation could contribute to improve it.

It has been noted above that the accountability of regulatory organs in developing countries is generally limited. In Ethiopia, accountability in the political system, and particularly, in health professions regulation, could hardly be considered satisfactory. The state regulatory organ is thus vulnerable to the risk of capture by the regulated

²⁵³ Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 142; Baggott, *supra* note 166 at 43; Carl-Ardy Dubois *et al.*, “Reshaping the Regulation of the Workforce in European Health Care System” in Carl-Ardy Dubois *et al.*, eds, *Human Resources for Health in Europe* (Berkshire: European Observatory on Health Systems and Policies, 2006) 173 at 185.

²⁵⁴ Healy, *supra* note 111 at 95.

²⁵⁵ *Ibid*; See also Baldwin *et al.*, *Understanding Regulation*, *supra* note 111 at 142-3.

²⁵⁶ Healy, *supra* note 111 at 63.

professionals.²⁵⁷ Capture is not a theoretical challenge, there is *prima facie* evidence that the state regulatory organ may be captured by the private sector.²⁵⁸

There is also evidence of corruption in the activities of DACA that raises concerns. For example, it was reported that the former DACA only filed 22 criminal charges against drug wholesalers and retail outlets in its eleven years of operation between 1999 – 2010.²⁵⁹ None of these charges are reported to have been positively adjudged by the courts.²⁶⁰ Even though no investigation was done to determine why, there are signals that the wealthy drug wholesalers (operated by pharmacists) may have corrupted the civil servants and law enforcement officials. There was an instance where DACA reported to

²⁵⁷ Estache & Wren- Lewis. “Theory and Evidence”, *supra* note 248 at 377; Baldwin *et al.*, *Understanding Regulation*, *supra* note 111 at 107.

²⁵⁸ The former DACA used to be dominated by pharmacists, in contrast to its few druggist staff. This was a determinative factor in the “turf” battle over the scope of practice of pharmacists and druggists. The druggists claimed their low level of influence in DACA partly accounted for their limited scope of practice. The professional employees of DACA manifested bias towards their respective professions due to conflicts of interest. Most pharmacists are members of the Ethiopian Pharmacists Association. The annual meeting of the Association seems a *de facto* holiday for DACA employees, as the office would be vacant on those days. A more evident form of conflict of interest is manifested in some staff members who also run pharmacy businesses. I personally know a former inspector at DACA who is a pharmacist and runs two pharmacies in urban areas far from Addis Ababa. Such information is not uncommon to hear, though no reliable and empirical study has been undertaken to show the extent of the problem. These are *prima facie* evidence that the state regulatory organ may be captured by the self-interest or the business interests of the regulated profession.

²⁵⁹ Abrehet Gidey, “Ethiopian Food, Medicine and Healthcare Control and Administration Authority, Regulatory Measures and Complaint Handling” (Lecture delivered at the Training of Regional Health Officials, Judges, Inspectors and Journalists on FMHACA Proclamations, Regulation and Guidelines, Adama- Ethiopia, 16 August 2010) [unpublished].

²⁶⁰ *Ibid.*

the court that an inspection report, upon which it filed a charge, was missing from its archive.²⁶¹ Analyzing these facts in light of the general gravity of the corruption problem in Ethiopia²⁶², there is good reason to fear that the regulation of health profession by the bureaucracy risks becoming submerged in corruption.

The limited accountability of the state regulatory organ, the risk of capture, and of corruption, heighten appeals to the value self-regulation could bring. Thus, in Ethiopia, it is difficult to make a strong argument either in favor of self-regulation, or regulation by the state, on the basis of accountability. A plurality of regulators in developing countries has been suggested as a solution for regulatory capture.²⁶³ However, the fragmentation cost that comes with pluralisation may be the larger concern.²⁶⁴

Nonetheless, the pluralisation of actors in health professions regulation may help mitigate the risk of capture and corruption in the state bureaucracy. This can be done using the existing state and professional institutions to avoid the cost of fragmenting regulatory activity between the state and new self-regulatory bodies. In this regard, the health professional associations, higher education institutions and consumer associations could

²⁶¹ *Ibid.*

²⁶² On Transparency International Corruption Perception Index , a tool that measures the public perception of how corrupt the public sector is, in 2011, Ethiopia scored 2.7/10 and ranked 120/183 countries assessed. The score range from 0 (highly corrupt) to 10 (very clean). This shows the seriousness of corruption problem in the public sector of Ethiopia. Transparency International, *Corruption by Country* (2011), online: Transparency International <http://www.transparency.org/country#ETH_DataResearch_SurveysIndices>.

²⁶³ Estache & Wren-Lewis, “Theory and Evidence”, *supra* note 248 at 384.

²⁶⁴ *Ibid.*

play significant roles. As discussed later I argue that health professional associations, particularly, should be proactively engaged in soft regulatory strategies. Their proactive engagement would bring the associations closer to the regulatory activities of the state. This provides information, including on capture and corruption involved in regulatory activities, which they could communicate to higher officials for remedial measures. The partnership of the associations with the state regulatory organ would also bring transparency to regulatory activities, as it would demand information sharing, and mutual and constructive review of each other's activities. Consumer associations can serve as watchdogs to ensure that the state regulator is not captured by the professional associations.

iv. Trust

In Ethiopia, there seems to be an agreement about the erosion of public trust and confidence in health care services. However, the extent of the problem has not been comprehensively studied and understood. At the 44th Annual Medical Conference of EMA, Dr. Yewondwossen Tadesse, renowned nephrologist who served in the Professional Ethics Sub-Committee of the Ethiopian Health Professions Council representing EMA, acknowledged the erosion of public confidence in medical services and underscored the need for the medical profession to prioritize activities to restore trust.²⁶⁵ He said that the public has become very suspicious of doctors. He blamed the media for reporting malpractice incidents without due consideration the problems that the

²⁶⁵ Yewondwossen Tadesse, "Medical Ethics and Current Medical Practice in Ethiopia" (Lecture delivered at the 44th Annual Medical Conference of the Ethiopian Medical Association, Addis Ababa, 4 June 2008) [unpublished].

health care system has to deal with.²⁶⁶ He also criticized the tendency of practitioners to regard malpractice as the result of poor health infrastructure, poor pay and other systemic problems.²⁶⁷ In a small survey in which 68 doctors participated, it was reported that the majority of the respondents identified work overload (42%) and unfavourable work environment (28%) as the main limitations for sound medical practice.²⁶⁸

At the same Conference, Dr. Gebre Yntiso, sociology professor at Addis Ababa University, presented the public perception from a small survey in one private and three public hospitals in Addis Ababa. He noted that public perceptions of the conduct of health professionals are mixed.²⁶⁹ Patients and caregivers responded that health professionals in the private hospitals were more caring than professionals in the public hospitals.²⁷⁰ He suggested that financial incentives may account for the ethical conduct of health professionals in the private hospital.²⁷¹ This explains why the private hospitals are generally regarded as providing speedy, quality and satisfactory health care services, in

²⁶⁶ *Ibid.* Dr. Berhan also criticized the media and other artistic works for their biased presentation of doctors' service. Berhan, *supra* note 26 at 74. The emotionally charged responses/debates over allegation of malpractice reporting in the media is sometimes perplexing. The results of such discussions are uncertain. It may be due to the shortage of well-researched survey which would show the extent of malpractice problem in Ethiopia.

²⁶⁷ Tadesse, *supra* note 265.

²⁶⁸ Bizunesh Tesfaye, "Physicians Perspective on Medical Ethics" (Paper delivered at the 44th Annual Medical Conference of the Ethiopian Medical Association, Addis Ababa, 4 June 2008) [unpublished].

²⁶⁹ Gebre Yntiso, "Public Opinion/Perception on Medical Practice in Addis Ababa" (Paper delivered at the 44th Annual Medical Conference of the Ethiopian Medical Association, Addis Ababa, 4 June 2008) [unpublished].

²⁷⁰ *Ibid.*

²⁷¹ *Ibid.*

contrast to the public hospitals. The private hospitals have a business interest to provide quality health care services. They have short waiting lists, which is far better than the situation in public hospitals. Their health professional employees are paid well. However, their fees are expensive and unaffordable to most people. Their profit-making interest is also a major source of criticism, as it commercializes health care services at the cost of ethical health care service delivery. Particularly, the private health care sector is blamed for over-servicing, over-charging and other unethical conduct. For example, Yntiso noted a case where a woman in labour was admitted to a private hospital with professional courtesy, and was rushed to undergo a caesarean section. However, she had to leave the hospital immediately when the hospital learned that she could not pay for the procedure.²⁷² He also concurred with the views of other presenters at the Conference that public confidence should be restored by addressing the “deep-rooted and widespread” unethical conduct of health professionals.²⁷³ As indicated in Chapter 2, the government also acknowledges the deterioration of public confidence in the quality and safety of health care services.

The erosion of public trust in health professionals should not be misunderstood. In Britain, where many medical scandals have undermined public trust in medical services, prompting reforms from the 1990s, health professionals still maintain considerable public trust.²⁷⁴ In 2009, a poll across Britain showed that 92 percent of the respondents trust doctors to tell the truth. This put doctors ahead of the respondents’ trust in teachers,

²⁷² *Ibid.*

²⁷³ *Ibid.*

²⁷⁴ Allsop & Saks, *supra* note 229 at 1; Healy, *supra* note 111 at 311.

professors and judges, clergy and priests on the same criterion.²⁷⁵ The 2008 Reader's Digest Survey in Australia found that nurses, pharmacists, doctors, and dentists were ranked the fourth, fifth, sixth, and twelfth trusted professions respectively.²⁷⁶ Chief Executive Officers were at the bottom of the list (33rd) while lawyers were 31st on the Australian list.²⁷⁷ These data do not tell us that the respondents' conception of trust was in reference to their doctors, the health professions, or the health system.²⁷⁸ Still, this does not undermine their relevance to the claim that the public continues to trust in health professionals in the countries in view, despite the reported medical scandals.²⁷⁹ However, the British survey showed that generally, there is a decline in public trust in most professions.²⁸⁰ Furthermore, there is evidence that relates the decline of public trust in the health care system to the general decline in trust in society and institutions (organizations and government). The degree to which this has been the case since the mid-1990s differs among countries.²⁸¹

²⁷⁵ *Ibid.*

²⁷⁶ The Leading Edge, "Australia's Most Trusted Professions 2008", Reader's Digest Magazine, 2008 cited in Mark Henaghan, *Health Professionals and Trust: The Cure for Healthcare Law and Policy* (New York: Rotledge, 2012) at 7.

²⁷⁷ *Ibid.*

²⁷⁸ *Ibid*; Healy, *supra* note 111 at 311.

²⁷⁹ *Ibid.*

²⁸⁰ Royal College of Physicians, *Trust in Doctors 2009: Annual Survey of Public Trust in Professions* (London: Ipsos MORI, 2009) cited in Henaghan, *supra* note 276 at 7.

²⁸¹ Calnan M & Stanford E, "Public trust in health care: the system or the doctor?" (2009) 13 *Quality and Safety in Health Care* 92-97 cited in Healy, *supra* note 111 at 311.

Though the extent of the erosion of public confidence in health professionals in Ethiopia has not been established, and indeed, it is difficult to establish, there is serious concern about the conduct of the nation's health professionals. It is necessary, therefore, to examine, in light of this, arguments for self-regulation on the basis of trust, and the role of external control in restoring trust in health professions.

The argument for self-regulation on the basis of trust is framed on three basic premises. First, trust flourishes from internal desire. Second, external efforts to restore trust in health professionals would not be effective. Third, patients should be involved as regulators and this assures good communication between patients and health professionals which is the best way to develop trust. Thus, the view is that trust is better developed in self-regulatory regimes by ensuring good communication between the patient and health professionals, and not through external control. Each premise and their implication are explained below.

First, Mark Henaghan philosophically argues that the trustworthiness of health professionals can more likely be strengthened where professionals act from an inner desire and assume responsibility for their conduct.²⁸² Extrapolating from economists, he argues that there should be an incentive to create that inner desire.²⁸³ He claims that the risk of health professionals becoming subject to external control where they cannot gain public trust is sufficient incentive to create that inner desire for them to assume

²⁸² Henaghan, *supra* note 276 at 11.

²⁸³ *Ibid.*

responsibility for their conduct.²⁸⁴ This perspective also highlights the need to not overlook the selfless service of the majority of health professionals in the face of the misdeeds of a few health professionals. The Right Honourable Patricia Hewitt, the former Secretary of Health-UK, explained why the regulation of the health professions should not emphasize the wrongdoings of a few professionals to the extent that it overshadows the respect and trustworthiness of the majority. In her words:

The danger is that in addressing the issue at all we risk highlighting too much the poor practice or unacceptable behaviour of a very small number of health professionals. It is all too easy to focus on the incompetent or malicious practice of individuals and seek to build a system from that starting point, instead of recognising that excellent health professionals far outnumber the few who let patients down substantially. For every time that Harold Shipman and Beverley Allitt are mentioned, we must recall the hundreds of thousands of extraordinary individuals who dedicate themselves impeccably to their patients every day. Most health professionals meet high standards routinely and have a lifelong appetite to be even better. That professionalism is an unquantifiable asset to our society, which rules, regulations and systems must support, not inhibit.²⁸⁵

In Ethiopia, the Minister of Health, Dr. Tedros Ghebreyesus, in his opening speech at the 50th Anniversary and 48th Annual Medical Conference of EMA, highlighted the altruistic services of health professionals to Ethiopians despite the stressful and uncomfortable

²⁸⁴ *Ibid.*

²⁸⁵ UK White Paper, *Trust, Assurance and Safety: The Regulation of Health Professionals in the 21st Century* (Crown, 2007) at 1.

conditions under which they work.²⁸⁶ He proposed that February 23 should be a national day for health professionals in recognition of their selfless services.²⁸⁷

The second premise for claiming that self-regulation would be effective to foster trust relies on the ineffectiveness of external control.²⁸⁸ Henaghan argues that though external control may bring compliance, “this compliance is not likely to be as enduring as a professional commitment to act in trustworthy ways.”²⁸⁹ He adds that there is no guarantee that external control will enhance the trustworthiness of health professionals.²⁹⁰ On the contrary, more external control supposes lesser trust in the internal control system, and consequently, weakens the trustworthiness of the health professions.²⁹¹ These arguments question the ability and effectiveness of the state to restore public confidence in health professionals.

The first premise argues for cultivating an internal system of professional control, but it does not deny the erosion of public trust in health professionals. The second premise argues that the restoration of public trust through external control is ineffective. The third premise offers a better way of restoring public trust in health care professionals.

²⁸⁶ EMA, “News: EMA Celebrates 50th Anniversary” (23 February 2012), online: EMA <http://www.emaethiopia.org/index.php?option=com_content&view=article&id=43&Itemid=5>.

²⁸⁷ *Ibid.*

²⁸⁸ Henaghan, *supra* note 276 at 11.

²⁸⁹ *Ibid.*

²⁹⁰ *Ibid.*

²⁹¹ *Ibid.*

Henaghan argues that trust is likely to develop where there is good communication between a patient and a health care professional.²⁹² This includes the empowerment of patients as regulators to proactively engage in their treatment by various means, such as by asking health professionals about their diagnosis and treatment plan, checking the professionals' credentials, reporting adverse events, and reading hospital performance reports.²⁹³ Henaghan suggests that:

Trust is most likely to thrive where there is a 'welcoming of equalisation of power' between healthcare professionals and their patients. Care, empathy and respect for each other, as equals, are the central ingredients of trust in any healthcare system. *These are internal attributes, which, once embedded, then external moderation and auditing will make no difference.*²⁹⁴

The three premises lead to a conclusion that reinforcement of an internal control system through effective communication between patients and health professionals, rather than the introduction of external control, is the best means to develop or restore trust. In other words, self-regulation that could empower patients as regulators is better than regulation by the state to develop trust in health care professionals.

Nonetheless, the premises that support the argument that self-regulation is best suited to develop trust, also have deficiencies. The claim that trust develops when the professional acts from an inner desire is a traditional reason that is used when health professions seek

²⁹² *Ibid* at 12.

²⁹³ Healy, *supra* note 111 at 313.

²⁹⁴ Henaghan, *supra* note 276 at 128 [emphasis added].

self-regulatory status.²⁹⁵ The concern about the erosion of public confidence in health professionals has prompted reforms in many countries with the goal to ensure that professionals are accountable.²⁹⁶ There is no necessary connection between introducing external control and undermining the altruistic services of most health professionals. The reforms rather focus on the failure of the traditional self-regulation system to handle the very few health professionals who do not live up to public expectation and trust. External control is meant to reinforce the strong internal control system. The neo-Weberians argue that the need for external control is not to devalue or discredit the altruistic services of many health professionals, but the claim for internal control should not be taken to the extent of undermining the need for external and independent accountability.²⁹⁷

Recognizing the altruistic and trustworthy services of most health professionals should be distinguished from the need to have external control as a means by which to handle the very few unethical professionals, and to assure public trust in health professionals. The former Secretary of Health makes this distinction, saying that “patients need to be assured that, when there are problems with health professionals, their concerns will be listened to and acted upon and that they will receive timely explanations.”²⁹⁸ This understanding justifies the White Paper’s proposal relating to ensuring membership parity of lay and

²⁹⁵ Healy, *supra* note 111 at 312.

²⁹⁶ *Ibid.*

²⁹⁷ Chamberlain, *supra* note 191 at 58.

²⁹⁸ UK White Paper, *supra* note 285 at 2.

professional members in the Councils (professional governing bodies), independent appointment of professional members and reporting obligation to Parliament.²⁹⁹

The second argument that questions the effectiveness of external control in restoring trust also muddles external control with untrustworthiness of all health professionals. It is hard to imagine that a health professional who is really committed to prioritize the interest of patient would get frustrated due to the introduction of an external control system. If that is the case, the professional's commitment may even be questioned. There may be no guarantee that external control enhances professional trustworthiness. Equally, there is no evidence that self-regulation can restore public trust. Rather, the reforms introduced in different jurisdictions recognize the importance of having external control to ensure accountability and hence, enhance public trust. Moreover, the public and media demand external control as an assurance for the accountability of health professionals. Henaghan's argument above claims that the incentive for motivating health professionals is to avoid more and more external control. This philosophical view acknowledges that the consequence of the failure of the internal system of control to restore public trust is external intervention.

The third argument that focuses on the empowerment of patients as the best means to enhance public trust has conceptual inconsistency with the rationale for regulation and practical difficulty. The market failure rationale for regulation is information asymmetry between the patient and health professionals. If empowerment of patients is capable of avoiding this information asymmetry, it may be argued that health professions regulation

²⁹⁹ *Ibid* at 5.

is unnecessary. But the practical difficulty of avoiding this information asymmetry implies sustaining regulation. Healy argues that most patients are reluctant or unable to proactively engage in their treatment plan and question their doctors.³⁰⁰ She further suggests that:

The basis of trust in one's doctor (and other health professionals) is as much emotional as rational. Any change will require considerable public education and will require the health system to put in place mechanisms that 'give permission' and that encourage people to become regulatory actors in their own health care.³⁰¹

The deficiencies of the three premises that support a claim to maintain self-regulation with an effective system of patient and health professional communication, also reveal the value of external control in restoring trust. Many countries have reformed their health professions' regulation to assure patients that oversight mechanisms are strengthened. External control should not be linked with statistical and superficial debate that most professional practices comply with ethical standards. It is the state's legitimate interest in the reduction of patient harm, improvement of health care quality, and responsiveness, where things went wrong. In Ethiopia, the public and media pressure calls for state intervention to assure trust. Particularly, the pressure emphasises the non-responsiveness of the disciplinary process against the unethical conduct of some health professionals. The opaque, infrequently used, and partial system of the Professional Ethics Subcommittee of the Ethiopian Health Professionals Council must be replaced with a

³⁰⁰ Healy, *supra* note 111 at 313.

³⁰¹ *Ibid.*

transparent, impartial and responsive disciplinary process. This requires avoiding the undue influence of representatives of professional associations in the disciplinary process, as this inheres in conflict of interest.

The statist approach mitigates the conflict, and is better suited to assure the public about the accountability of professionals when things go wrong. The empowerment of patients is an important ingredient in health professions regulation, but it is not sufficient to restore or maintain trust. In addition to Healy's argument about the reluctance or inability of patients to be proactive, and the difficulties to bring cultural change, it is also inefficient to rely on empowerment of patients in Ethiopia. This is because the time that the few doctors in the country have is better allocated equitably to a large number of patients. The number of patients a doctor should see per day should be kept at maximum in consideration of ensuring accessibility of doctors by many patients. If the doctor is excessively burdened to ensure his/her patient understands the treatment plan, doctor will only be seeing few patients per day. In turn, this would reduce accessibility of doctors in the country.

v. Due Process

Due process in health professions regulation refers to the regulatory organ's adherence to administrative law/natural justice and consultative democracy principles.³⁰² The former includes fairness, transparency, equality, accessibility, consistency and predictability of the regulatory organ's investigative and decision making process.³⁰³ Providing reasons for refusal to issue or renew licenses, and ensuring that adequate notice and opportunity to defend oneself is given to a health professional subjected to a disciplinary proceeding constitute, among other things, the application of natural justice principles. The notion of consultative democracy espouses that standard setting, and the policy and strategic decisions of the regulatory organ should be made in consultation with those affected by the decisions, such as the health professionals, consumers (the public), relevant government agencies and civil society.³⁰⁴ Adherence to due process principles ensures the legitimacy of health professions regulation, as this fulfils natural justice rights and provides the proper democratic forum to influence decision-making.³⁰⁵

In Ethiopia, the rarity of disciplinary proceedings before the Professional Ethics Sub-Committee of the Ethiopian Health Professions Council makes it difficult to assess the degree of adherence to due process principles. Moreover, Ethiopia does not have a comprehensive procedural administrative law. Instead, there are scattered provisions in various laws. The Ethiopian Health Professions Council Establishment Regulation No

³⁰² Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 29.

³⁰³ *Ibid.*

³⁰⁴ *Ibid.*

³⁰⁵ *Ibid.*

72/2002, which contains some due process principles, though inadequately elaborated, is one of these laws.³⁰⁶ There is some growth in the understanding and practice of good governance, though the level of progress here is arguable.³⁰⁷ This improvement in public sector service delivery and good governance practice needs continuous institutional strengthening. Its interruption by way of assigning regulatory power to self-regulatory professional bodies, may disrupt the institutional strengthening effort. The self-regulatory bodies may start to observe due process principles from a clean sheet. Also, it could cause unevenness in the development of procedural fairness, some self-regulatory bodies will do it well, other will not. It is better to keep on building the existing institutional practice of due process, than starting it in an institutional setting that is uncommon in the

³⁰⁶ For example, Article 16 (2) provides the opportunity to be heard for a health professional before the Professional Ethics Sub-Committee of the Council. The provision reads: “If [the Sub-Committee] finds sufficient evidence to support the complaint submitted as per Sub-Article (1) of this Article, it *may* instruct the professional, against whom the complaint is lodged, to come up with a defence in one month time.” The provision does not recognize the right to be heard of the defendant professional but left it to the discretion of the Sub-Committee. Another due principle in the Regulation is the principle of transparency in the disciplinary process. Article 19(2) provides for the Secretariat of the Council to register and keep professionals who must cease practice after suspension or cancellation. Article 24 (5) provides that such register shall be open. It also stipulates for publication of suspension or cancellation of the professional in the state-owned newspaper. However, the Regulation is silent about the transparency of the disciplinary proceeding, in particular whether the Sub-Committee held the proceeding in public or closed meeting. In practice, the meetings are held in closed sessions.

³⁰⁷ MoFED, *Growth and Transformation Plan 2010/11-2014/15*, Vol 1 (Addis Ababa: MoFED November 2010), online: MoFED <<http://www.mofed.gov.et/English/Resources/Documents/GTP%20English2.pdf>> at 19; UNDP, *Program Document for Ethiopia (2012-2015)*, online: UNDP <http://www.et.undp.org/index.php?option=com_m2c&Itemid=118> at 2.

existing public administration structure in Ethiopia.³⁰⁸ The introduction of self-regulatory bodies in health professions regulation may herald an innovative regulatory system that effectively complies with natural justice principles. Nonetheless, practically, self-regulatory bodies have been unfair and partial in disciplinary proceedings, because they show compassion and favoritism to health professionals.³⁰⁹ As mentioned earlier, such challenges prompted the reforms to ensure accountability and restore public confidence in self-regulation. Overall, the need to strengthen institutions, the promise of good governance practice in the public sector, the risk associated with introducing a non-existing self-regulatory system that is exacerbated by its failure elsewhere to ensure effective implementation of due process principles, favor the choice of a statist approach over self-regulation for health professions regulation in Ethiopia.

With reference to consultative democracy principles, there has been an encouraging level of participation of stakeholders (health professional associations and higher education institutions), relevant government offices (other than EFMHACA) and civil society organizations in the development of legislation and standard setting under the new regulatory system. The health professional associations have been requested to send experts to the Ad-Hoc Technical Working Groups to help EFMHACA from initial drafting to the subsequent development of the instruments in stakeholder consultative workshops. The existing statist health professions regulatory system functions with

³⁰⁸ Self-regulating professional bodies do not exist in the public administration structure of Ethiopia. The state regulates the practice of lawyers, health professionals, accountants and engineers.

³⁰⁹ Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 145.

commendable respect for consultative democracy principles. Thus, there is no convincing reason to prefer self-regulatory professional bodies for ensuring consultative democracy principles in observing their legislative and standard setting mandate for the following reasons.

First, the state has the political interest to ensure the participation of citizens in legislative and standard development in every sector. Second, the participatory process falls in the general political framework of good governance, which is an uncommon notion in the activities of non-governmental bodies. There is evidence that self-regulators “have a sporadic, unstructured, and patchy record of consulting those with interests in the workings of their systems.”³¹⁰ Third, the legislative and standard setting mandate of self-regulators requires the approval of government. This means that legislative and standard setting processes would be long and expensive, involving different levels of consultation led by the self-regulatory body, and then by the state. This is inefficient, and disregards the financial limitations of the state. Currently, even the one level process of consultation coordinated by EFMHACA is mostly financed by international organizations, such as the WHO and charitable organizations. Therefore, the regulation of the health professions by the state is an effective and efficient system for institutionalizing consultative decision making process.

³¹⁰ *Ibid.*

Summary

The preceding discussion has shown that for Ethiopia, health professions regulation by the state is a better option than self-regulation in terms of most accounts of the ‘good’ regulation criteria. It was established that self-regulation has the strongest claim on the basis of expertise and efficiency.³¹¹ Even so, based on expertise, the claim should be tempered with the fact that the bureaucracy employs modest expertise for regulatory functions. Where there is a need for high expertise, which happens infrequently, ad-hoc consultative/participatory processes with professional associations and/or higher teaching institutions can make up the expertise deficit in the bureaucracy. In terms of efficiency, regulation by the state is better, especially because it saves high cost of fragmentation and a larger allocation of limited health care resources that establishing self-regulatory professional bodies would impose.

In terms of accountability, trust and due process, self-regulation comes out as ineffective.³¹² The global trend provides a good lesson in these respects. As such, Ethiopia should not repeat the mistakes of other countries where self-regulation was the norm. As shown, these countries have introduced various measures to ensure the accountability and procedural fairness of the self-regulatory bodies and to restore public confidence. Indeed, as discussed in the next chapter, the global trend is moving away from self-regulation towards greater state intervention and oversight over health professions regulation.

³¹¹ *Ibid.*

³¹² *Ibid.*

Overall, therefore, health professions regulation by the state is a better option for Ethiopia than self-regulation, for purposes of establishing an accountable and procedurally fair regulatory system and to strengthen public confidence in the system. This does not overlook the concern that the state bureaucracy may be captured by the regulated health professionals to undermine accountability and procedural fairness. The pluralisation of actors in the enforcement of health professions regulation, and the subsequent transparency of regulatory activities, would mitigate the risk of capture. The more eyes that watch the regulatory system, the lesser the risk of capture. The state's institutional and political interest and capacity to promote consultative democracy also fosters accountability and enhances trust in its regulatory activities.

The evaluation of the advantages and concerns of self-regulation, as against the statist approach to health professions regulation, and in light of the criteria of 'good' regulation, favors the statist approach. The Ethiopian government's statist approach to health professions regulation is therefore commendable. The one issue to highlight for attention, however, is that, within the framework of statist approach of regulation, the Ethiopian government should make room for elements of self-regulation that would help achieve better regulatory outcomes, *i.e.*, safety and quality of health care services.³¹³ This can be done by promoting compliance with the relevant laws and standards designed to shape the conduct of the health professionals.³¹⁴ The next section discusses how the Ethiopian

³¹³ Baggot noted an approach that rejects the theoretical comparison between self-regulation and direct regulation mentioning the practical presence of both systems. This approach, rather, "focus on how self-regulation might contribute to improved outcomes." My argument resembles this approach. Baggott, *supra* note 166 at 35.

³¹⁴ *Ibid.*

government can promote compliance through effective enforcement strategy for health professions regulation.

3. Enforcement Strategy

On the basis of regulatory theories and the ‘good’ regulation criteria, I have concluded that generally, the regulation of health professions by the state, rather than self-regulation, is the proper policy choice for Ethiopia. The success of the statist approach, however, depends on an effective design and operation of an enforcement strategy. The literature on regulation provides that the traditional regulatory enforcement strategies have been deterrent/punishment or compliance/persuasion approach. In the last two decades, regulatory discourse has transcended this dichotomous conception of enforcement strategy upon introduction of the influential responsive regulation theory. Before exploring the relevance of this debate to the thesis, it is important to identify the existence or character of the EFMHACA’s enforcement strategy in its health regulatory activities, particularly for health professions regulation.

The reform blue-print adopts the responsive regulation model as an enforcement strategy. It identified the absence or inadequacy of enforcement mechanisms in health regulatory activities as being responsible for the inadequate enforcement of health regulatory laws and standards. It has been underscored that there should be a consistent standard for public and private sector practice. Moreover, “no compromise on quality” was made one of the values and beliefs of EFMHACA. However, this important blue print does not provide adequate enforcement strategy for EFMHACA. Neither, EFMHACA issues other comprehensive and adequate enforcement strategy.

Unless EFMHACA clarifies the situation, the absence of an enforcement strategy may continue to challenge the effectiveness of the reform. For example, what does “no compromise on quality” mean? Does it refer to aggressive measures against health facilities which fail to satisfy certain aspects of the minimum regulatory standards, though generally, they may provide commendable medical services to the public? Would it make a difference if a health facility is the only institution in an area? This would be a challenge for the inspectors and other officials of EFMHACA. The interplay between persuasion and deterrence in enforcement has to be clarified, to the extent possible, through the enforcement strategy.

Meanwhile, the general understanding and practice of regulation in EFMHACA suggests the character of its enforcement strategy with respect to health professions regulation. As noted in Chapter 2, health professions regulation in Ethiopia has been dysfunctional except for regulation of pharmacy practice. Currently, EFMHACA focus on legislative and standard development, staffing the regulatory organs and training them on regulatory laws and standards, expanding the coverage and frequency of health facilities inspection, and organizing national health professionals’ database. Yet, there is no system for inspecting the performance of health professionals, though the blue-print requires such inspection. The monitoring of health professionals’ performance remains limited to license renewal and disciplining. The renewal of a professional license requires evidence that the professional has been in active practice during the five years since the last licensure. The discipline process is seldom used when patients or their family member complain against unprofessional conduct on the part of a health professional. The BPR provides for the empowerment of the public to participate as regulators by which to

detect and respond to allegations of unprofessional conduct. EFMHACA's view on health professions regulation prior to the reform is that health professionals were not regulated except for pharmacists. After EFMHACA finalizes the legal and standard setting, capacity and system building efforts, it would focus on enforcement of the regulatory standards. At that time, there is good reason to believe that a more interventionist and deterrent model may become its enforcement strategy.

Having the proper enforcement strategy is as necessary as establishing the legislative, structural and systemic foundations for health professions regulation. Thus, EFHMACA needs to clarify, or come up with, a comprehensive enforcement strategy which should be based on responsive regulation theory as incorporated in the reform blue-print. The emergence and notion of responsive regulation, and its contribution to health professions regulation in Ethiopia is offered next.

i. Responsive Regulation

The scholarly debate on effective enforcement strategies started in regard to the compliance of businesses with the law.³¹⁵ On the one hand, it was argued that deterrence was an effective model to ensure business compliance.³¹⁶ Deterrence regulators basically view people to be driven by self-interest for profit making, and only comply with the law when forced to do so.³¹⁷ As such, regulators had formal and adversarial relationships with

³¹⁵ Ian Ayres & John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (New York: Oxford University Press, 1992) at 20.

³¹⁶ *Ibid.*

³¹⁷ Robert A Kagan, "The 'criminology of the corporation' and regulatory enforcement strategies" in Keith Hawkins & John M Thomas, eds, *Enforcing Regulation* (Boston: Kluwer-Nijhoff Publishing, 1984) 67.

regulated businesses and frequently used sanctions against non-compliance.³¹⁸ On the other hand, compliance regulators argued that gentle persuasion ensures the compliance of businesses with the law.³¹⁹ These regulators have an optimistic view of people as “fundamentally ethical and well-intentioned and who do their best to comply with rules.”³²⁰ The compliance versus deterrence model of enforcement strategies were ideal conceptions of regulatory enforcement strategies, and in reality, most regulators fall in between the two extremes.³²¹

The deterrence model overlooks the fact that business executives are not only driven by profit-maximizing motives, but that they also possess law-abiding commitments.³²² Thus, punishment may “undermine the good-will of actors when they are motivated by a sense of responsibility.” In addition, punishment creates the regulatory cat-and-mouse game, as businesses would develop resistance to regulatory authority and resort to exploiting the loopholes in regulatory rules, forcing the regulatory organ to continuously issue specific rules to fill the loopholes.³²³ In contrast, compliance regulators rely wholly on persuasion and self-regulation, and thus, they may not ensure compliance where the regulated

³¹⁸ Kieran Walshe, *Regulating Healthcare: A Prescription for Improvement?* (Maidenhead: Open University Press, 2003) at 36 [Walshe, *Regulating Healthcare*].

³¹⁹ Ayres & Braithwaite, *supra* note 315 at 20.

³²⁰ Healy, *supra* note 111 at 62.

³²¹ Walshe, *Regulating Healthcare*, *supra* note 318 at 35. The description of deterrence *versus* compliance models of enforcement is attributed to A J Reiss. A J Reiss, “Selecting Strategies of Social Control Over Organizational Life” in Hawkins & Thomas, *supra* note 317.

³²² Ayres & Braithwaite, *supra* note 315 at 19.

³²³ *Ibid* at 20.

business is motivated by a profit-maximization rational.³²⁴ Consequently, Ayres and Braithwaite argued that an enforcement strategy should consist of a sophisticated balance between persuasion and punishment to ensure business compliance with the law.³²⁵ The critical question is “[w]hen to punish; when to persuade?”³²⁶ Responsive regulation was suggested as the solution to address this question. In Ayres and Braithwaite’s theory of responsive regulation, the main argument is captured in the following paragraph:

...compliance is more likely when a regulatory agency operates an explicit enforcement pyramid - a range of enforcement sanctions extending from persuasion, at its base, through warning and civil penalties up to criminal penalties, license suspensions, and then license revocations.... There would be a presumption that regulation should always start at the base of the pyramid. Regulatory interventions would thus commence with non-penal actions and escalate with more punitive responses where prior control efforts had failed to secure compliance.³²⁷

The enforcement pyramid (see Figure 3.1) indicates when to persuade and when to punish. The regulatory organ should start with persuasion and a dialogue-based approach.³²⁸ Where persuasion fails, the regulatory organ should scale up its intervention in the ascending order.³²⁹ Because a single enforcement measure cannot be sufficient, a weakness of the less interventionist measure should be complemented by the strength of

³²⁴ *Ibid.*

³²⁵ *Ibid* at 21.

³²⁶ *Ibid.*

³²⁷ Baldwin *et al.*, *Understanding Regulation*, *supra* note 122 at 259.

³²⁸ Judith Healy & John Braithwaite, “Designing safer Health Care through Responsive Regulation” (2006) 184:10 *Medical Journal of Australia* S56 at S56.

³²⁹ *Ibid.*

another.³³⁰ First, a respectful option should be given a chance.³³¹ Healy and Braithwaite note that “[p]olite requests followed by threats are more likely to work when everyone knows that non-compliance will result in an inexorable progression up the enforcement pyramid, and that ‘owning up’ results in learning, while cover-up risks escalation.”³³²

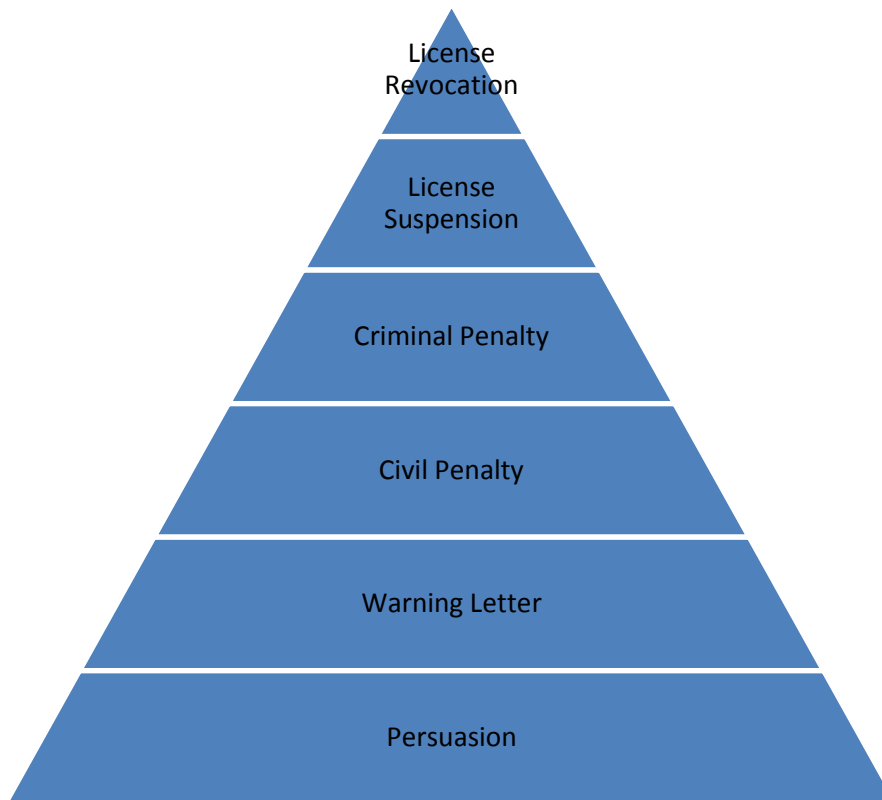


Figure 3.1 An example of the enforcement pyramid. (Ayres & Braithwaite, 1992:35)

Figure 3.1 provides a pyramid of sanctions applicable against a given firm. Ayres and Braithwaite also provide a pyramid of enforcement strategies applicable to the entire

³³⁰ *Ibid.*

³³¹ *Ibid.*

³³² *Ibid* at S56-S57.

industry (Figure 3.2 below).³³³ They argue that the state should rely on self-regulation as a preferred strategy for any regulatory system. If the industry exploits self-regulation, the state should communicate its intention to intervene through enforced self-regulation, and continue to utilize even more coercive measures. The state should continue to move on command regulation with discretionary punishment, and finally to command regulation with non-discretionary punishment if the more respectful approach is not working.³³⁴

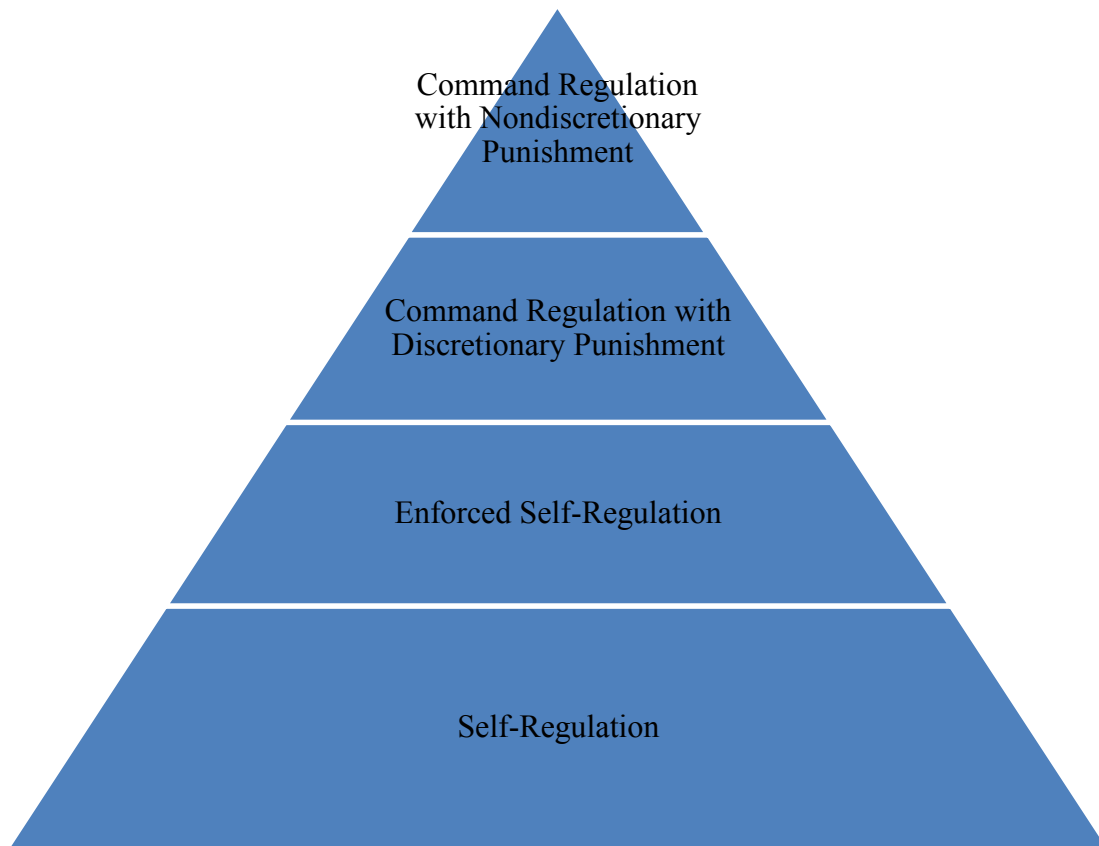


Figure 3.2 Example of Pyramid of Enforcement Strategies (Ayres & Braithwaite, 1992: 39)

³³³ Ayres & Braithwaite, *supra* note 315 at 38.

³³⁴ *Ibid.*

Responsive regulation argues that both the state and industry have the incentive to prefer the less interventionist approach, *i.e.*, persuasion and self-regulation, at the base of the pyramid.³³⁵ The industry is aware that non-compliance would entail adversarial and expensive litigation costs, and punishment.³³⁶ Thus, it will have a rational calculation to avoid the loss that state intervention would bring. The state's capacity to enforce compliance is also limited, and self-regulation and informal strategies consume less state resources.³³⁷

ii. Responsive Regulation in Health Care Regulation

Responsive regulation underscores that “regulators are more likely to succeed when they respond to the context, conduct, and culture of those being regulated.”³³⁸ Healy and Braithwaite argue that responsive regulation is applicable to health care regulation where there are multiple regulatory actors and strategies, the tradition of self-regulation, strong ethical norms and reflective practices by health professionals.³³⁹ Indeed, responsive regulation is applicable to health professions regulation given the altruistic motivations of many health professionals to provide standard and ethical services.

The original formulation of responsive regulation has been expanded to include multiple actors using various regulatory strategies that range from “soft” regulation to “hard”

³³⁵ *Ibid* at 39.

³³⁶ *Ibid*.

³³⁷ John Braithwaite, *To Punish or Persuade: Enforcement of Coal Mine Safety* (Albany: State University of New York Press, 1985) at 147.

³³⁸ Healy, *supra* note 111 at 3; Ayres & Braithwaite, *supra* note 315 at 5.

³³⁹ Healy & Braithwaite, *supra* note 328 at S56; Healy, *supra* note 111 at xviii & 3.

regulation. Neil Gunningham, Peter Grabosky, and Darren Sinclair advance a smart regulation theory that proposes a three-sided pyramid as the best enforcement strategy that would allow three parties to utilize various regulatory instruments.³⁴⁰ The three parties are the government (as a regulator), business (as self-regulator) and third parties (quasi-regulatory organs like public interest groups, and professional associations).³⁴¹ Smart Regulation identifies broad categories of regulatory instruments of command and control, economic instruments, self-regulation, voluntarism and information and education strategies.³⁴² Command and control regulation may include the licensing of health professionals, and suspending or revoking their licenses.³⁴³ Economic instruments may include purchasing health care services from an accredited health care facility, or providing information to consumers to enable them to purchase quality health care services.³⁴⁴ Self-regulation may refer to an organized group that regulates the behavior of its members, like a health professional setting a code of ethics for its members, and providing regular ethical guidance.³⁴⁵ Voluntarism refers to the situation where a unilateral individual action without any basis of coercion may be initiated or facilitated

³⁴⁰ Gunningham & Grabosky, *supra* note 116 at 398.

³⁴¹ *Ibid.*

³⁴² *Ibid* at 424-6.

³⁴³ John Braithwaite *et al.*, *The Governance of Health Safety and Quality: A Discussion Paper* (Canberra: Commonwealth of Australia, 2005), online: Temple University Law School <http://www.temple.edu/lawschool/phrhcs/salzburg/Braithwaite_Governance0705.pdf> at 13.

³⁴⁴ *Ibid.*

³⁴⁵ Gunningham & Grabosky, *supra* note 116 at 50.

by the government.³⁴⁶ It may include a health professional regularly monitoring his/her own practice or continuously updating his/her knowledge by reading medical journals and attending Continuing Professional Development (CPD) programs. Information and education strategies include various activities that overlap with other categories but, specifically, may refer to education and training on professional ethics, public reporting of health facility performance, and health care facilities quality award.³⁴⁷

Smart Regulation argues for regulation using different instruments by a number of parties.³⁴⁸ It provides for escalation “to higher levels of coerciveness not only within a single instrument, but also across several different instruments.”³⁴⁹ Gunningham and Sinclair argue that a three dimensional pyramid presents the possibility of “escalating degrees of coercion through the interaction of different but complementary instruments and parties.”³⁵⁰ For instance, the state may begin with less intrusive instruments like voluntarism and education (using professional associations). It may then escalate its response where such instruments exhaust their responsive capacity to self-regulation mechanisms like peer-review, and may end up escalating to the most coercive instrument

³⁴⁶ *Ibid* at 56.

³⁴⁷ *Ibid* at 60.

³⁴⁸ Baldwin *et al.*, *Handbook of Regulation*, *supra* note 111 at 266.

³⁴⁹ Gunningham & Grabosky, *supra* note 116 at 400.

³⁵⁰ *Ibid*.

of government command and control by suspending or revoking the health professional license.³⁵¹

Responsive regulation theorists argue that the multiple actors and strategies envisaged in smart regulation are consistent with their theory.³⁵² Braithwaite presents that responsive regulation is an applicable theory in developing countries where regulatory capacity is limited, particularly as it could mobilize the capacity of NGOs and business actors to achieve regulatory objectives.³⁵³ Moreover, Braithwaite et al. formulate responsive regulation to improve health care quality and safety by involving multiple actors and multiple strategies that include soft and hard interventions.³⁵⁴ Their customized enforcement strategies pyramid of responsive regulation, as applied in health care, is presented in Figure 3.3 below.

³⁵¹ *Ibid.*

³⁵² Baldwin *et al.*, *Handbook of Regulation*, *supra* note 111 at 266.

³⁵³ Braithwaite, “Developing Economies”, *supra* note 250 at 896.

³⁵⁴ Braithwaite *et al.*, *supra* note 343 at 13.

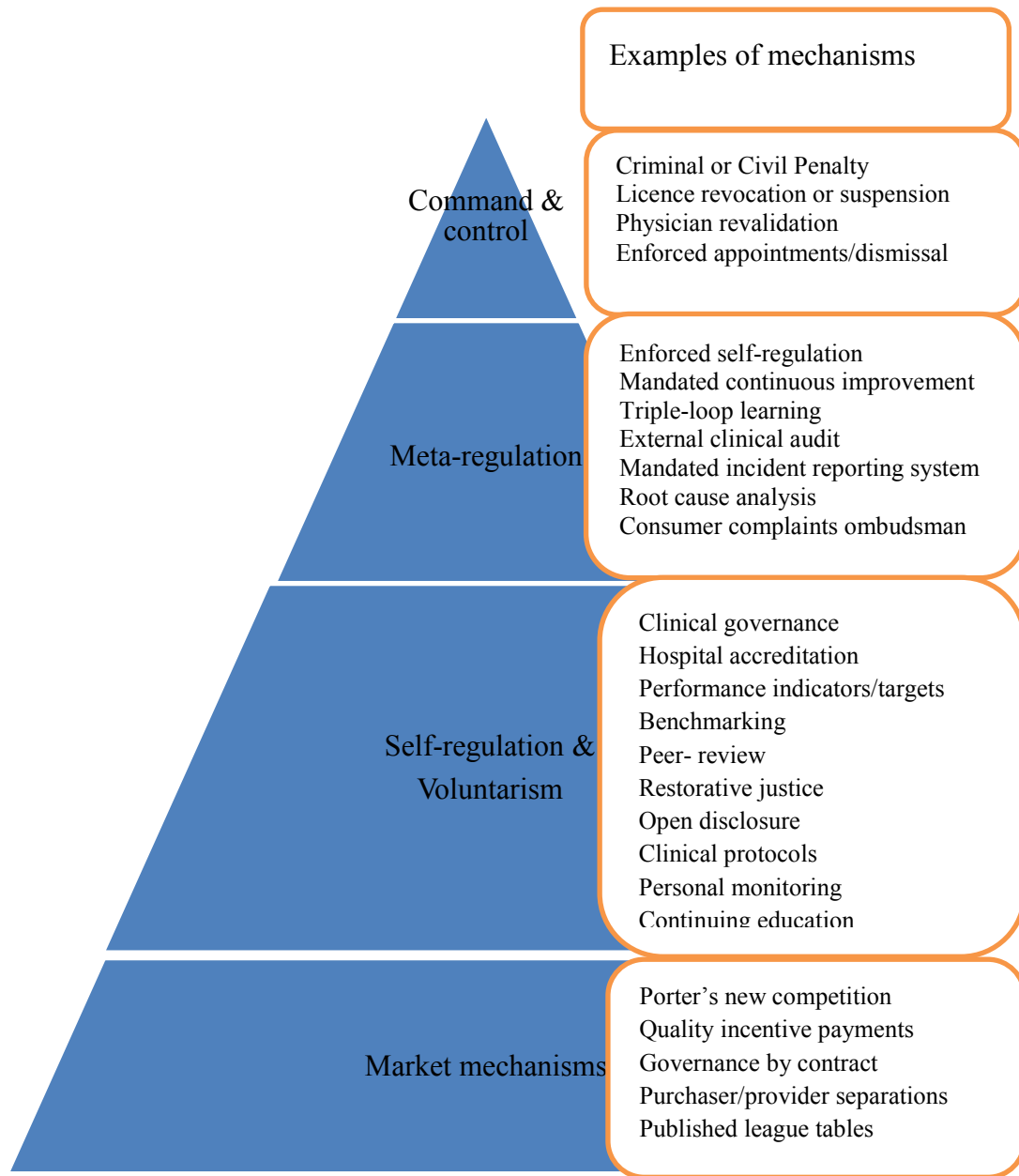


Figure 3.3 Regulatory pyramid and health care safety and quality mechanisms (Braithwaite *et al.*, 2005: 15)

Figure 3.3 was developed to provide a responsive regulatory framework for Australian health sector regulation. As such, some regulatory mechanisms may be specific to the Australian context. Nonetheless, the main theme that emerges from the pyramid is the importance of reliance on less interventionist or soft regulation mechanisms, but with the ability to escalate regulatory measures upward to the most coercive or hardest measures.

A persuasive and dialogue-based approach, like publication of health facility performance, health facility accreditation, personal monitoring, continuing education, and peer-review mechanisms, should constitute the major activities of a health regulatory regime. Where these soft strategies fail, the state should escalate its intervention to the point of suspending or revoking the health facility or professional license. The core message of responsive regulation is that:

... a regulator must have the capacity to escalate upwards if necessary from soft words to hard deeds. Those being regulated must believe in the inexorable nature of sanctions, as polite requests followed by threats only work when everyone knows that sanctions will follow non-compliance. Responsive regulation argues that stern sanctions must loom as a threat in order to ensure that people comply with softer and more conciliatory approaches.³⁵⁵

iii. Applying Responsive Regulation to Health Professions Regulation in Ethiopia

Braithwaite argues that responsive regulation is an effective enforcement strategy for developing countries, seeing that the capacity of regulators in developing countries is limited.³⁵⁶ Regulators can overcome this challenge, among other things, by effectively coordinating and utilizing the potentials of civil societies and business.³⁵⁷ The activities of these non-state actors would make up the state regulators' capacity deficit. The state

³⁵⁵ Healy, *supra* note 111 at 4. See also Christine Parker's application of responsive regulation to regulate lawyers in Australia. She argues that self-regulation and dialogue-based approach should be taken seriously, but the inexorability of external reform should be communicated in case lawyers fail to reform their internal regulation. Christine Parker, *Just Lawyers: Regulation and Access to Justice* (New York: Oxford University Press, 1999) at 108-139.

³⁵⁶ Braithwaite, "Developing Economies", *supra* note 250 at 886-9.

³⁵⁷ *Ibid* at 888.

regulator should target its limited resources to the coercive measures at the peak of the responsive regulation enforcement pyramid.³⁵⁸ The state should facilitate and co-ordinate the non-state actors to use multiple enforcement strategies that can assure compliance.³⁵⁹ Responsive regulation can be used by the state and non-state actors to determine when to persuade and when to punish.³⁶⁰ Accordingly, the enforcement strategy would not focus on the expensive and highly intrusive inspection and command and control system of regulation. Rather, the non-state actors can put emphasis on the persuasion and dialogue-based approach. This is a less costly option for the regulator, and more respectful of the regulated business. The regulator, however, must have the capacity to escalate its response upwards to deterrent measures, where the persuasive and dialogue-based approach fails.

In the Ethiopian health care context, the reform blueprint's recognition of the pyramid of responsive regulation enforcement strategies provides general guidance for the enforcement strategy to be adopted to regulate the health professions. In this sense, it appears anomalous that the reform adopted a statist approach to health professions regulation while recognizing self-regulation as an important enforcement strategy through its recognition of responsive regulation. In my view, the two apparently contradictory approaches can coexist in the health professions regulatory system in Ethiopia. Indeed, I have argued that the statist approach to health professions regulation is a better option for Ethiopia, as it is a more efficient system than self-regulation. Also,

³⁵⁸ *Ibid* at 896.

³⁵⁹ *Ibid* at 890.

³⁶⁰ *Ibid* at 888.

the statist approach is a better choice than self-regulation in enhancing public trust, and ensuring accountability and due process in the health professions regulatory system. Thus, I have concluded that the health professions regulatory framework in Ethiopia should remain statist. At the same time, the health professions regulation enforcement strategy should be based on responsive regulation which prioritizes self-regulation. The apparent contradiction of these claims can be resolved with two alternative arguments.

First, the health professions regulatory framework should be distinguished from the regulatory framework's enforcement strategy. Of course, the distinction may be elusive but not uncommon. The regulatory framework refers to the regulator organ that runs the core regulatory functions. These functions include standard setting, licensing and relicensing, inspection and disciplining. These functions are often coercive regulatory instruments. They may be given to professional bodies, state organs, or distributed to both organs. On the other hand, enforcement strategy refers to a strategy within a given health profession's regulatory framework that ensures compliance with regulatory laws and standards. A health profession's regulatory organ, be it a state or a professional body, needs to draw an enforcement strategy to ensure compliance with the laws and standards they enforce. The enforcement strategies range from a persuasive, dialogue-based approach, to coercive measures of professional license suspension or revocation.

Therefore, the statist health professions regulation system in Ethiopia refers to EFMHACA and State regulatory organs' mandate to set standards, issue and renew professional licenses, inspect and discipline health professionals. These functions highly intervene in professional autonomy and are coercive by nature. But they are not sufficient

to achieve the health professions' regulatory objective of quality improvement. Also, they are more or less reactive. The exception may be inspection or monitoring of health professionals' practices. Even the inspection or monitoring activity can hardly cover the practices of all health professionals, given the limited capacity the state regulators possess. Therefore, EFMHACA should focus its limited capacity on the coercive measures located at the peak of the responsive regulation enforcement pyramid, and coordinate and facilitate the mobilization of civil societies to effectively undertake a persuasive and dialogue-based approach to ensure compliance with regulatory standards and ethics.

The civil societies include organizations with vested interest in the promotion of professional standards and ethics, and health care quality improvement. In this regard, the professional associations, higher education institutions, and development partners are very important civil societies in Ethiopia. Consumer associations are relatively new organizations with little capacity and influence in today's health care market in Ethiopia. But they can also contribute their share to implementing persuasive and dialogue-based approach by making patients aware of their rights.

It should be clear from the foregoing that Ethiopia's statist health professions regulatory framework can adopt responsive regulation as its enforcement strategy. Secondly, even if it could be claimed that it is difficult to make a distinction between a regulatory framework and enforcement strategy because they conceptually overlap, statist regulation is a cheaper option than self-regulation in Ethiopia. As earlier pointed out, self-regulation would entail high fragmentation costs, while statist regulation can be undertaken cost

effectively by the existing state infrastructure. The assumption behind responsive regulation's argument, that self-regulation should be tried before resorting to command and control regulation (or statist approach), is the inability of the state to undertake effective regulation.³⁶¹ In other words, Ayres and Braithwaite assume that self-regulation is a cheaper option than a statist approach. However, in the Ethiopian health professions context, I have showed that self-regulation would probably be a more expensive choice than statist regulation, and should not be the framework adopted for health professions regulation.

Again, as argued earlier, this does not mean that professional associations should not play a role in health professions regulation. Responsive regulation argues that effective regulation should involve multiple actors that implement multiple instruments. It should be applied to health professions regulation in Ethiopia. These actors include the state, and non-state actors such as the professional associations, higher education institutions, development partners, and consumer associations. Indeed, in Ethiopia, the professional associations have been fairly well engaged in standard setting and professional ethics development and promotion. They have also contributed to health professions regulation under the Ethiopian Health Professionals Council. Thus, they should be coordinated and supported to be proactively engaged in health professions regulation in Ethiopia.

The multiple strategies range from persuasive, dialogue-based ones, to coercive command and control regulation. Most soft regulation instruments fall outside fitness to practice process. The fitness to practice process involves some soft regulation instruments

³⁶¹ Ayres & Braithwaite, *supra* note 315 at 103.

in the form of educational measures for professional misconduct, and remedial measures for health professionals with health and incompetence problems.

Accordingly, EFMHACA should emphasize persuasion, and create continuing dialogue with the health professionals to ensure their compliance with the regulatory rules and ethical standards. The non-state actors have more capacity and expertise than the state to implement the persuasion and dialogue-based approach. The state should facilitate, coordinate and support their activities to ensure health care quality improvement. The range of regulatory functions exercised, whether by the state or self-regulatory professional bodies, are not sufficient by themselves to engage the professionals in reflective practices and other activities to increase their understanding and compliance with standards. The strategy that emphasizes persuasion taps the expertise, motivation and innovation of professional associations. In different health professions regulatory models, there are multiple actors working to ensure quality of health care services and patient safety. The next chapter will show that even in countries that rely on the statist approach, like the Ethiopian system, significant contributions are made by non-state actors, particularly health professional associations, to ensure the improvement of health care services and patient safety.

The engagement of non-state actors in persuasive and dialogue-based activities will enable EFMHACA to focus its limited resources on the activities at the peak of the enforcement pyramid. Responsive regulation provides evidence that these soft regulation strategies solicit compliance from health professionals. Where they fail, EFMHACA may resort to coercive measures that would be viewed as more legitimate and fair. The

professional associations need less intervention in the practice of their respective members, and thus, will strive to ensure their compliance with soft regulation activities. But where they fail, the consequence is coercive intervention in their members' autonomy. This possibility adds an incentive to seriously engage in compliance assurance activities so as to avoid state intervention.

In sum, the Ethiopian statist framework of health professions regulation should devise enforcement strategies that emphasizes compliance/persuasion, and only resort to deterrent measures where persuasion fails. The following chapter examines the role of health professional associations in different frameworks for health professions regulation. Lessons from the comparison are drawn to solidify the argument that Ethiopia should not move to a self-regulation model, more so because the countries that originated the model are moving away from it towards co-regulation, meta-regulation or greater oversight over self-regulation.

CHAPTER 5

MEDICAL REGULATION FRAMEWORK AND ENFORCEMENT STRATEGIES: A COMPARATIVE PERSPECTIVE

In Chapter 4, I argued that a statist approach to health professions regulation is a better option for Ethiopia than self-regulation, and that the Ethiopian statist approach should devise proper enforcement strategies to ensure its effectiveness. In particular, the responsive regulation model that focuses on soft regulatory strategies or persuasion and dialogue-based strategies, and involves multiple actors, should be at the center of the enforcement strategy. This chapter reinforces these arguments from a global perspective by drawing on developments in health professions regulation in other jurisdictions.

A large part of the Chapter presents evidence on medical regulation in selected countries with focus on regulatory power allocation and enforcement strategies. Due to similarity of approach to health professions regulation in the jurisdictions studied, the discussion of medical regulation will generally present each jurisdiction's system of health professions regulation. It will also maintain the focus of analysis. Overall the aim is to support two arguments.

First, that the ineffectiveness of self-regulation, globally, has resulted in greater state intervention and oversight over self-regulation. The trend is evident even in those jurisdictions where self-regulation had been dominant for a long time. This is the situation in the United Kingdom, New South Wales (Australia) and Ontario (Canada). These jurisdictions are chosen for three main reasons. To start with, state sanctioned self-regulation had been the norm in these jurisdictions for regulating health professions for a long time. But reforms in the last two or three decades brought significant changes to the

self-regulation system. Accordingly, experiences from these jurisdictions offer important insights as to the effectiveness of self-regulation. Secondly, the jurisdictions are generally regarded as among the global leaders in health professions regulation reforms and quality improvement initiatives. Thirdly, these jurisdictions appear frequently in health professional regulation literature. Their pervasiveness in the literature acts as a limitation as to what jurisdictions to select for comparative analysis, as it confines the researcher, on this score, to the “mainstream” medical regulation literature.

The second argument that the discussion of medical regulation in the different jurisdictions supports is that soft regulatory strategies or persuasive and educative strategies constitute effective enforcement strategies for health professions regulation, and the statist regulation needs to proactively involve non-state actors, *i.e.*, professional bodies, in the use of these strategies. To this end, the role of persuasion and dialogue in enforcement in the UK, New South Wales (NSW), and Ontario is discussed. Moreover, to explore the relationship between the utilization of soft regulatory strategies, and actors proactively using these strategies, the statist medical regulation systems of Finland and the Netherlands are selected. In other words, the extent of self-regulation in statist approach to health profession regulation is explored by discussing medical regulation in Finland and the Netherlands. The countries are selected for their unique systems of medical regulation, which contrast with the traditional self-regulation systems in the UK, NSW and Ontario. Their systems of medical regulation are effective though the state plays a significant role, as in Finland particularly. Though there is a relative lack of information in English regarding medical regulation in Finland and the Netherlands, what I have found enables me to make some general observations relevant to my arguments.

The final section of the Chapter consists of two sub-sections that analyze medical regulation lessons from the jurisdictions studied in relation to the regulatory framework and enforcement strategies for health professions regulation in Ethiopia. The first sub-Section argues that the global trend is greater state intervention and oversight over self-regulation, as in the UK, NSW (Australia) and Ontario (Canada), and other countries. Among other things, this trend is prompted by the shortcomings of traditional self-regulation to protect public interest, particularly as judged according to the criteria of accountability, due process and public trust. This global trend offers practical evidence to reinforce the conceptual arguments that caution Ethiopia about the demerits of self-regulation. It also shows that the state's role as the ultimate guardian of the public interest in ensuring the effective functioning of self-regulation. Recalling the merits of statist regulation relative to self-regulation in Ethiopia, the evidence ultimately reinforces the main argument that the statist approach is a better option for health professions regulation in Ethiopia.

The second sub-Section argues that the utilization of soft regulatory strategies as part of a statist approach to health professions regulation requires the proactive involvement of professional bodies. It establishes a direct relationship between persuasive and educational activities in medical regulation, and the actors primarily engaged in these activities. It argues that in the UK, NSW and Ontario, the self-regulating professional bodies carry out the "hard" regulatory functions and soft regulatory strategies. In contrast, in Finland and the Netherlands, the state primarily assumes the "hard" regulatory functions, while professional bodies, such as medical associations or speciality societies, proactively engage in soft regulatory strategies. The expertise and capacity deficits of the

state may have prompted the professional bodies to play this role. This observation reinforces the argument in Chapter 3 that the statist health professions regulation system in Ethiopia should effectively utilize the motivation and capacity of professional associations to implement a less interventionist enforcement strategy. The comparative perspective underscores the practical need for non-state actors to be proactively involved in the utilization of persuasive and educative strategies to secure compliance with professional standards. The next Section begins with the discussion of medical regulation in the selected countries.

1. Country Experiences in Medical Regulation

i. Medical Regulation in UK

The regulation of medicine in the UK goes as far back as the sixteenth century when the College of Physicians was incorporated in 1518.³⁶² In 1540, surgeons joined the Barbers Guild of London, but separated from them in 1745.³⁶³ Later in 1800, the Royal College of Surgeons was chartered.³⁶⁴ These organs were guilds that controlled their membership, practice and fixed prices for their services.³⁶⁵

³⁶² Moran & Wood, *supra* note 167 at 35-6.

³⁶³ Judith Allsop, “Regulation and the Medical Profession” in Allsop & Saks, *supra* note 166 at 81.

³⁶⁴ *Ibid.*

³⁶⁵ Moran & Wood, *supra* note 167 at 36; Duboise et al., *supra* note 253 at 176 & 181.

In 1855, the British Medical Association (BMA) took over the Provincial Medical and Surgical Association that was established in 1832.³⁶⁶ Acting like a trade union, its objectives were the protection of its members and the profession's interests.³⁶⁷ Its Medical Reform Committee succeeded, after 20 years of negotiation, to secure the passage of the 1858 Medical Act which established the General Medical Council (GMC). By this, the state sanctioned medical self-regulation in the UK.³⁶⁸ The GMC was given two main functions – approving medical schools, and licensing and registering medical practitioners. Only registered practitioners were authorized to use the title “medical practitioner.”³⁶⁹ Other healers continued to practice but they could not use the title “registered medical practitioner.”³⁷⁰ This brought social and economic rewards to the registered practitioners.³⁷¹

In exchange for the privilege of self-regulation, the GMC promised that it would ensure the delivery of good public services.³⁷² The GMC was given the responsibility to set

³⁶⁶ British Medical Association (BMA), “An Outline History of the British Medical Association”, online: BMA <<http://www.bma.org.uk>>.

³⁶⁷ *Ibid.*

³⁶⁸ *Ibid.* The GMC was then called the General Council on Medical Education and Registration. Allsop, *supra* note 363 at 80.

³⁶⁹ Moran & Wood, *supra* note 167 at 36.

³⁷⁰ Meg Stacey, “The General Medical Council and Professional Self-Regulation,” in David Gladstone, ed, *Regulating Doctors* (The Institute for the Study of Civil Society, 2008) 28 at 28.

³⁷¹ *Ibid.*

³⁷² *Ibid* at 30.

standards of training and practice, and their enforcement.³⁷³ Its disciplinary proceedings were also used for cases involving sexual offences.³⁷⁴ On its establishment, the governing body of GMC exclusively consisted of doctors appointed by the professional societies and academic institutions.³⁷⁵ The GMC enjoyed great autonomy and remained the prominent example for a state-licensed self-regulatory system.

However, the GMC came under attention and scrutiny in the 1990s followed by reforms that changed its structural and operational autonomy.³⁷⁶ The reforms were driven by the increasing voice of patients, reform within the National Health Services (NHS) to efficiently use health care resources, and infamous shocking medical scandals.³⁷⁷ More importantly, the Bristol Royal Infirmary and the Harold Shipman inquiries resulted in profound change in medical self-regulation.³⁷⁸

In the Bristol case, the GMC examined the conduct of three doctors in relation to the death of 29 babies who underwent elective surgery between 1991 and 1995 at the pediatric heart surgery unit of Bristol Royal Infirmary.³⁷⁹ It found that all the doctors committed serious professional misconduct.³⁸⁰ A public inquiry into the case criticized

³⁷³ Duboise *et al.*, *supra* note 253 at 181.

³⁷⁴ Stacey, *supra* note 370 at 29.

³⁷⁵ Moran & Wood, *supra* note 167 at 37.

³⁷⁶ Duboise *et al.*, *supra* note 253 at 182.

³⁷⁷ *Ibid*; Allsop, *supra* note 363 at 87.

³⁷⁸ Healy, *supra* note 111 at 28-9; Stacey, *supra* note 370 at 35.

³⁷⁹ Healy, *supra* note 111 at 28; Stacey, *supra* note 370 at 36.

³⁸⁰ *Ibid*.

systemic failures in medical self-regulation, particularly the “club culture” of silence and loyalty to colleagues over patient safety, and the absence of effective monitoring mechanisms of clinical performance.³⁸¹ The survival of self-regulation was even challenged.³⁸² Eventually, the inquiry recommended the establishment of an independent government organ to oversee the activities of self-regulating health professional bodies such as the GMC.³⁸³ Accordingly, in 2003, the Council for Healthcare Regulatory Excellence (CHRE) was established as a meta-regulatory organ to oversee the performance of the nine health professions’ regulatory bodies.³⁸⁴ The GMC’s President at that time, Donald Irvine, used the Bristol case to reform GMC for transparency and accountability, and to introduce doctors’ license revalidation every five years to ensure their continued competence.³⁸⁵ Nonetheless, the practitioners resisted and delayed the President’s reforms, particularly, the license revalidation initiative.³⁸⁶

The Shipman Inquiry was conducted following the conviction of Dr. Harold Shipman for murdering 15 elderly female patients by prescribing an overdose of morphine.³⁸⁷ The number of his victims found by the Inquiry was many more (215 patients), and by the separate Department of Health investigation, at least 236 patients were found to be

³⁸¹ *Ibid*; Allsop, *supra* note 363 at 87; Walshe, “Regulating”, *supra* note 150 at 161.

³⁸² Stacey, *supra* note 370 at 38; Duboise *et al.*, *supra* note 253 at 182.

³⁸³ Walshe, “Regulating”, *supra* note 150 at 161.

³⁸⁴ *Ibid*; Healy, *supra* note 111 at 70.

³⁸⁵ Walshe, “Regulating”, *supra* note 150 at 161; Stacey, *supra* note 370 at 39.

³⁸⁶ Walshe, “Regulating”, *supra* note 150 at 161.

³⁸⁷ Healy, *supra* note 111 at 29.

victims.³⁸⁸ The Inquiry Report was very critical of the GMC's operations, its ability to reform and even to stand as a regulator.³⁸⁹ Some gaps were identified, including inadequate statistical monitoring of poor or even bad performances, and the absence of a system for following-up the performance of doctors with previous records of misconduct.³⁹⁰ The inquiry also considered the fitness to practice process, and the proposed revalidation mechanism for detecting poor performance and maintaining the competence of doctors.³⁹¹ In short, the inquiry called for a series of reforms, upon which the government conducted a further review of the system of health professions regulation in the UK.³⁹² The process produced the 2007 White Paper, entitled *Trust, Assurance and Safety: The Regulation of Health Professionals*, prepared by the Department of Health. This Paper proposed many reforms.

In order to ensure the accountability and impartiality of the GMC, the White Paper proposed equal membership of lay and professional persons in its governing Council, and independent appointment for all members.³⁹³ The composition of CHRE's Council was to be independently, and not by the regulatory organs.³⁹⁴ It was recommended that the GMC

³⁸⁸ *Ibid.*

³⁸⁹ Walshe, "Regulating", *supra* note 150 at 162.

³⁹⁰ Allsop, *supra* note 363 at 89.

³⁹¹ Walshe, "Regulating", *supra* note 150 at 162.

³⁹² *Ibid.*

³⁹³ UK White Paper, *supra* note 285 at 5.

³⁹⁴ *Ibid* at 28.

be required to report to Parliament annually.³⁹⁵ It was proposed that the revalidation of doctors' registration to ensure their continued fitness to practice must involve an appraisal process and be made against objective and clear standards and thresholds.³⁹⁶ The White Paper noted professional and public attitude about the relevance of revalidation in assuring continued fitness to practice was changing.³⁹⁷ As well, it sought to separate the investigation and adjudication roles of the GMC in the fitness to practice process.³⁹⁸ It also suggested that the burden of proof in fitness to practice cases must be lowered to the civil standard of a balance of probabilities, instead of the criminal standard of proof beyond reasonable doubt.³⁹⁹

Accordingly, since 2009, the GMC's governing Council has consisted of 12 lay and 12 medical members appointed by an independent Appointments Commission, acting on behalf of the Privy Council.⁴⁰⁰ The composition reflects who the stakeholders are in medical regulation, including patients/public, the NHS and other health care employers, medical schools and Royal Colleges.⁴⁰¹ In its 2012 business plan, the GMC prioritized

³⁹⁵ *Ibid.*

³⁹⁶ *Ibid* at 6-7 & 31.

³⁹⁷ *Ibid* at 31.

³⁹⁸ *Ibid* at 9.

³⁹⁹ *Ibid.*

⁴⁰⁰ GMC, Press Release, "GMC First Meeting of A Fully Representative Council" (28 Jan 2009), online: GMC News Centre News Archive <<http://www.gmc-uk.org/news/1531.asp>>.

⁴⁰¹ *Ibid.*

the launching of the revalidation of doctors' licenses at the end of the year.⁴⁰² The system of revalidation requires a doctor to undergo a regular appraisal by a responsible officer of a designated health organization.⁴⁰³ Mostly, the responsible officer is the medical director of the doctor's employer health organization.⁴⁰⁴ The appraisal is done on the basis of the GMC's Good Medical Practice booklet.⁴⁰⁵ At least every five years, a doctor is expected to provide six types of supporting information to his/her appraiser.⁴⁰⁶ These are CPD, quality improvement activity, significant events, feedback from colleagues and patients, and review of complaints and complements.⁴⁰⁷

Recently, the GMC also launched its biggest reform on the fitness to practice procedure since its establishment: it separated its investigation and prosecution role from its adjudicative functions.⁴⁰⁸ It established a new Medical Practitioners Tribunal Service

⁴⁰² GMC, Press Release, "Smooth Start to Revalidation Tops GMC's 2012 Priorities" (24 Jan 2012), online: GMC News Centre News Archive <<http://www.gmc-uk.org/news/11869.asp>>.

⁴⁰³ GMC, "Revalidation - Information for Licensed Doctors", online: GMC <<http://www.gmc-uk.org>>.

⁴⁰⁴ *Ibid.*

⁴⁰⁵ GMC, "The Good Medical Practice Framework for Appraisal and Revalidation" (April 2011), online: GMC <http://www.gmc-uk.org/GMP_framework_for_appraisal_and_revalidation.pdf_41326960.pdf_48283876.pdf>.

⁴⁰⁶ GMC, "Supporting Information for Appraisal and Revalidation" (March 2012), online: GMC <http://www.gmc-uk.org/Supporting_information_11052012.pdf_48709863.pdf>.

⁴⁰⁷ *Ibid.*

⁴⁰⁸ GMC, Press Release, "GMC Launches New Tribunal Service for UK Doctors" (11 June 2012), online: GMC News Centre News Archive <<http://www.gmc-uk.org/news/13286.asp>>.

(MPTS) to hear fitness to practice cases.⁴⁰⁹ The purpose of this reform is “to strengthen professional and public confidence that hearings are impartial, fair and transparent.”⁴¹⁰ The MPTS is accountable to parliament (via the Privy Council) and the Council of the GMC, which also finances its operation.⁴¹¹ It is managed by a three member Committee chaired by an independently appointed person with a legal background, and two other members, one medical, and the other a lay person.⁴¹² It has a broad list of panelists from which three panelists are drawn to adjudicate each case.⁴¹³ A panel consists of one medical and one lay panelist, and the chair of the panel (who may be a lay or a medical person), and assisted by a legal assessor.⁴¹⁴ The GMC retains the investigation and prosecution roles. The laws governing medical regulation and the GMC’s Good Medical Practice and other guidance for doctors are the basis of the MPTS adjudication process.

⁴⁰⁹ *Ibid.*

⁴¹⁰ *Ibid.*

⁴¹¹ MPTS, “The Chair of the MPTS and the MPTS Committee”, online: MPTS <<http://www.mpts-uk.org>>

⁴¹² *Ibid.*

⁴¹³ MPTS, “Information about Panelists and Legal Assessors”, online: MPTS <<http://www.mpts-uk.org>>.

⁴¹⁴ *Ibid.*

Summary

The GMC has undergone significant reform in the last two decades.⁴¹⁵ This substantially changed its structure and autonomy since its establishment in 1858. It has changed from “an elite, closed and inflexible organization towards a more transparent and accountable body representing a wider range of interests, as well as the medical community.”⁴¹⁶ The classic form of self-regulation on the basis of informality, collegiality and confidentiality has been replaced by the introduction of standards of practice, measures to ensure greater transparency and accountability of the GMC, and due process principles. When the CHRE was introduced to check the performance of the GMC, the state-sanctioned self-regulation system became a meta-regulatory system. Subsequent reforms continue to reduce or abandon the traits of traditional self-regulation in the GMC. Particularly, the equality of medical and lay representations on the Council and adjudicative panels, and the separation of the constitutive parts of the adjudication process have transformed its self-regulatory structure. The GMC’s activities aimed at guiding the profession’s standard of practice and its extensive revalidation process have changed its operation from a reactive organization to a proactive regulator striving to ensure good medical practice.

⁴¹⁵ In UK, other health professions are also self-regulatory, and they have also been subjected to state oversight and intervention to ensure public interest protection. In general, the trends observed in medical regulation in UK shades light on regulatory developments pertaining to other health profession too. Allsop & Saks, *supra* note 229 at 1.

⁴¹⁶ Allsop, *supra* note 363 at 88.

Enforcement Strategy

Two of the four functions of the GMC emphasize the importance of persuasion as an enforcement strategy. These functions are “fostering good medical practice” and “promoting high standards of medical education and training.”⁴¹⁷ The GMC logo, *i.e.*, *regulating doctors, ensuring good medical practice*, also reflects the underlying place persuasion has in the functions of the GMC. There are ranges of activities that have been accomplished by the GMC to translate these general statements into outcomes to reveal its emphasis on persuasion.

The GMC made the teaching of ethics compulsory in medical education.⁴¹⁸ It also published the booklet, *Tomorrow’s Doctor*, first in 1993 and revised in 2009, as guidance regarding the skills, knowledge and behavior a medical student should gain from medical education. According to the Booklet, medical schools are expected to teach patient-centered professional values. This would improve the ethical understanding and reflection of graduates and to ensure compliance with good practice standards.

A *Good Medical Practice* booklet was first published in 1995 and revised in 2006, to guide the practice of doctors. Its new revision is expected to be published in 2012. The GMC website provides innovative ways for learning the principles and values espoused in the booklet. It also publishes guidance on controversial ethical issues. Helping doctors by guiding them through all the stages of their careers and enhancing their

⁴¹⁷ GMC, “The Role of the GMC”, online: GMC <<http://www.gmc-uk.org>>.

⁴¹⁸ Allsop, *supra* note 363 at 83.

professionalism, is one of the major themes in the GMC's Corporate Strategy.⁴¹⁹ Particularly, guidance on professional standards and ethics is one of the strategic priorities.⁴²⁰ Since an interactive learning system, *Good Medical Practice in Action*, was launched in the GMC's guidance on good practice webpage, a 20 percent increase in visits was reported.⁴²¹ The guidance is believed to help doctors in responding to the daily ethical and other professional challenges of medical practice. The GMC is also planning to ensure its wider and effective dissemination through innovative mechanisms.⁴²²

The integration of the Good Medical Practice booklet into the revalidation process also shows the emphasis the GMC has placed on compliance as an effective enforcement strategy in medical regulation. The booklet serves as the framework for the appraisal system, which is made prerequisite for revalidation. Regular appraisal seeks to engage the doctor to reflect on his or her own practice and to dialogue with his or her appraiser regarding standards of good practice. This provides an extensive system for utilizing persuasion's potential to ensure compliance with medical regulation rules and standards. Generally, in the last two decades, the GMC's proactive initiatives to ensure patient protection by regulating doctors emphasize making sure doctors are cognizant of professional and ethical standards in their practices.

⁴¹⁹ GMC, "Corporate Strategy 2010-2013," online: GMC <http://www.gmc-uk.org/Corporate_Strategy_2010_13.pdf_29731738.pdf> at 8.

⁴²⁰ *Ibid* at 18.

⁴²¹ *Ibid*.

⁴²² *Ibid* at 19.

ii. Medical Regulation in New South Wales (NSW)

The regulation of medicine in Australia started in the nineteenth century on the basis of the UK model of state-sanctioned self-regulation.⁴²³ Until 2010, medical regulation in Australia was the mandate of the states of the Commonwealth of Australia. The self-regulatory organs, called medical boards in each of the federation's states and territories, undertook the registration, standard setting, monitoring, and disciplining of doctors. The medical boards consisted entirely of doctors, operated independently from the state, and maintained great autonomy.⁴²⁴ However, the 1960s and 1970s consumerism movement and reported medical scandals over three decades brought significant impact on the structure and autonomy of self-regulatory medical boards.⁴²⁵ Generally, it resulted in greater intervention by the state in medical regulation, including the establishment of new regulatory organs, increased monitoring of performance indicators, and a move toward co-regulation of medical practice between the medical boards and the state.⁴²⁶

The consumerism movement challenged the professions' altruistic claim.⁴²⁷ The 1982 NSW Law Reform Commission report reflected this development, saying that the "proposition that professionals can be trusted to always put the public interest ahead of

⁴²³ Healy, *supra* note 111 at 103.

⁴²⁴ David Thomas, "Peer Review as an Outmoded Model for Health Practitioner Regulation" in Ian Freckleton, ed, *Regulating Health Practitioners: Law In Context* (The Federation Press: Annandale, 2005) 52 at 55.

⁴²⁵ *Ibid* at 62; Healy, *supra* note 111 at 30.

⁴²⁶ *Ibid.*

⁴²⁷ Thomas, *supra* note 424 at 62.

sectional professional interests is one which few people [would still] accept.”⁴²⁸ In the 1980s, the medical scandal reported in the Chelmsford Hospital about the deep-sleep therapy, a non-experimented treatment done by Dr. Harry Bailey, brought some reforms to the self-regulatory system of the NSW Medical Board.⁴²⁹ The deep-sleep therapy puts the patient into a drug-induced sleep, sometimes up to three weeks, together with electric shock to the unconscious patient.⁴³⁰ The procedure was applied, without informed consent, to hundreds of patients between 1963 and 1979.⁴³¹ After a successful lawsuit against the intervention by a patient who suffered brain damage, the media brought the matter to the public and, subsequently, a public inquiry was held.⁴³² The inquiry concluded that 24 patients died directly due to the deep-sleep therapy, and their death certificates were written untruthfully.⁴³³

Nonetheless, the NSW Medical Board failed to take any disciplinary action against the responsible doctors, because its legislation only covered infamous conduct and that kind of misconduct did not include professional incompetency as a disciplinary violation.⁴³⁴ Together with the Medical Board’s non-responsiveness to patient complaints in the 1960s

⁴²⁸ New South Wales Law Reform Commission, *Complaints, Discipline and Professional Standards: Second Report on the Legal Profession* (Sydney: New South Wales Law Commission, 1982) at 122 cited in *ibid*.

⁴²⁹ *Ibid* at 63; Healy, *supra* note 111 at 31.

⁴³⁰ *Ibid*.

⁴³¹ *Ibid*.

⁴³² *Ibid*.

⁴³³ *Ibid*.

⁴³⁴ Thomas, *supra* note 424 at 63.

and 1970s, this case “created long-lasting suspicion in both the public and governmental minds that professional autonomy was synonymous with non-accountability.”⁴³⁵ As a result, the government introduced legislative reform relating to the appointment and membership of the Medical Board and for the disciplinary process. By the Medical Practitioners (Amendment) Act 1983 (NSW), the membership of the Medical Board was raised from nine to eleven to ensure the representation of consumer interests. Appointment to vacancies was made the sole authority of the Minister of Health so as to reduce domination by the NSW branch of the Australian Medical Association and the Royal Colleges.⁴³⁶

The disciplinary process reform took two streams. First, the 1987 Medical Practitioners (Amendment) Act replaced the notion of infamous conduct with a notion of professional misconduct that includes professional incompetence. Second, in 1984, the government had already established a Complaint Unit in the Health Department to entertain consumer complaints on health care.⁴³⁷ The Unit received many complaints from consumers on the practice of doctors, and this increased the number of cases referred to the Medical Board.⁴³⁸ Its role was increased by the Health Care Complaints Act 1993, which changed the Unit into an independent statutory organ called the Health Care Complaints Commission (HCCC). Since then, the HCCC has been responsible for receiving and investigating complaints on health care providers, and prosecuting serious complaints

⁴³⁵ *Ibid.*

⁴³⁶ *Ibid* at 63.

⁴³⁷ *Ibid* at 63-4.

⁴³⁸ *Ibid.*

before the Medical Tribunal.⁴³⁹ The establishment of HCCC, and its joint responsibility with the Medical Board, introduced a unique system of co-regulation into the disciplinary process of medical regulation in NSW.⁴⁴⁰ David Thomas argues that “because responsibility was now being shared by the Medical Board with a non-medical body, autonomous peer review [self-regulation] had been extinguished in New South Wales.”⁴⁴¹

Currently, medical regulation in NSW (and also in other Australian States and Territories) is undertaken at the national and states levels.⁴⁴² At the national level, the Medical Board of Australia took the primary responsibility of registering doctors and setting standards, codes and guidelines to direct the practice of doctors. It is composed of eight practitioner members and four community members appointed by the Australian Health Workforce Ministerial Council.⁴⁴³ The NSW Board of the Medical Board of Australia supports its mandate to register doctors in the state. This Board consists of four practitioner members and two community members appointed by the NSW Minister of

⁴³⁹ Health Care Complaints Commission, “About the Commission”, online: HCCC About Us <<http://www.hccc.nsw.gov.au>>.

⁴⁴⁰ Thomas, *supra* note 424 at 65.

⁴⁴¹ *Ibid* [emphasis added].

⁴⁴² Health Practitioner Regulation National Law Act 2009 establishes a uniform system of health professions regulation in Australia. It creates consistent and national system of regulation across different health professions that transcend provincial and territorial differences. Thus, the discussion of medical regulation in NSW, also generally presents the system of other health professions regulation in the province.

⁴⁴³ *Health Practitioner Regulation National Law Act 2009* (NSW), s 33 (1) [*Health Practitioner Regulation*]; Medical Board of Australia, “Members of the Board”, online: Medical Board of Australia: About <<http://www.medicalboard.gov.au>>.

Health.⁴⁴⁴ The Australian Health Practitioners Regulation Agency (AHPRA) provides the secretariat and other support for regulatory functions of registration and standard setting to the Medical Board of Australia.

At the state level, NSW chose to continue its disciplinary process rather than integrate it with the National Scheme that came into force on 1 July 2010.⁴⁴⁵ The disciplinary responsibilities of the former Medical Board of NSW are now assumed by the Medical Council of NSW.⁴⁴⁶ The Medical Council consists of 15 medical practitioners and 5 non-medical members appointed by the Governor of NSW upon nomination by the Minister of Health.⁴⁴⁷ Its main function is to administer complaints about practitioners' conduct, health and performance.⁴⁴⁸ The Medical Council assesses complaints jointly with the HCCC in a co-regulatory fashion.⁴⁴⁹ Where the complaints warrant investigation, the HCCC will investigate them and consult on the result with the Medical Council.⁴⁵⁰ If a

⁴⁴⁴ *Health Practitioner Regulation*, *supra* note 443 s 36(2); Medical Board of Australia, "The New South Wales Board of the Medical Board of Australia", online: Medical Board of Australia <<http://www.medicalboard.gov.au>>.

⁴⁴⁵ Freckelton, *supra* note 247 at 207.

⁴⁴⁶ Medical Council of New South Wales, "About the Council: Overview", online: Medical Council of New South Wales <<http://www.mcnsw.org.au>>.

⁴⁴⁷ *Ibid.*

⁴⁴⁸ *Ibid.*

⁴⁴⁹ Medical Council of New South Wales, "Professional Conduct", online: Medical Council of New South Wales <<http://www.mcnsw.org.au>>.

⁴⁵⁰ *Ibid.*

case is referred to a disciplinary hearing, the HCCC will prosecute the doctor before the Professional Standards Committee (PSC) or the Medical Tribunal.⁴⁵¹

The PSC and Medical Tribunal are separate and independent of the Medical Council, which provides them with administrative and technical support.⁴⁵² The PSC entertains professional conduct cases which do not result in the suspension or de-registration of a doctor.⁴⁵³ It consists of a legal practitioner, two medical members, and one non-medical member.⁴⁵⁴ The Medical Tribunal adjudicates on professional conduct cases which could result in suspension or de-registration of doctors, and on appeals from the Medical Council's decisions.⁴⁵⁵ The Medical Tribunal consists of four members, including a Chairperson appointed by the Governor of NSW from the judges of a District Court.⁴⁵⁶ The Medical Council appoints the other three members, two medical practitioners and one lay person nominated by the Minister of Health.⁴⁵⁷

⁴⁵¹ *Ibid.*

⁴⁵² *Ibid.*

⁴⁵³ Medical Council of New South Wales, "Disciplinary Hearing: Overview", online: Medical Council of New South Wales <<http://www.mcnsw.org.au>>.

⁴⁵⁴ *Ibid.*

⁴⁵⁵ *Ibid.*

⁴⁵⁶ *Ibid.*

⁴⁵⁷ *Ibid.*

Summary

Concerns about the effectiveness of the self-regulation model of medical regulation in NSW have brought significant change in its structure and operation. The state's intervention through legislative reform has reduced the autonomy of the medical profession to regulate itself. The main medical regulatory functions are divided among different organs. The standard setting role is mainly undertaken by the national Medical Board of Australia. The NSW Board of the Medical Board registers doctors under a national law that establishes country wide uniformity on registration standards and processes. The composition of these Boards includes lay members. In departure from the previous trend of appointment by professional bodies, members' appointment to these Boards is made the primary responsibility of the state, through the Australian Health Workforce Advisory Council or the NSW Minister of Health. To ensure transparency, the accessibility of the medical registry is enhanced.⁴⁵⁸ More importantly, the fitness to practice process has become a typical example of the co-regulation model.⁴⁵⁹ There are, at least, four organs (the Medical Council, HCCC, PCS and Medical Tribunal) that are responsible for parts of the fitness to practice process. The HCCC is a state organ. The other three organs are independent from each other, and consist of medical and non-medical members appointed by the state. The archaic wording of infamous conduct has been abolished and replaced by the notion of professional misconduct, health and competence of the practitioner. The investigation and adjudication processes of

⁴⁵⁸ Healy, *supra* note 111 at 106.

⁴⁵⁹ Allsop & Jones, *supra* note 128 at 34; Thomas, *supra* note 424 at 65; Healy, *supra* note 111 at 127.

professional conduct are separated. All in all, driven by the public and media pressure, there has been great state intervention into, and oversight of medical self-regulation in NSW.

Enforcement Strategy

The enforcement strategy for medical regulation in NSW focuses on doctors' continuing development, and on remedial measures proportionate to complaints. CPD is the requirement to ensure the development of doctors. The Medical Board of Australia defines CPD as "the means by which members of the profession maintain, improve and broaden their knowledge, expertise and competence, and develop the personal qualities required in their professional lives."⁴⁶⁰ Since 1 July 2010, the requirement of regularly taking accredited CPD programs has become mandatory for doctors for purposes of their annual re-registration in Australia.⁴⁶¹ The CPD that would be acceptable for re-registration must be relevant to the doctor's obligation "to maintain, develop, update and enhance [his or her] knowledge, skills and performance to ensure that [he or she] deliver[s] appropriate and safe care."⁴⁶² The Board also stipulated that the CPD programs must meet individual learning needs focusing on practice-based reflective elements, in addition to activities designed to update the knowledge of the doctor.⁴⁶³ The underlying assumption is based on evidence that doctors who took CPD programs provide better

⁴⁶⁰ Medical Board of Australia, "Continuing Professional Development Registration Standard" (2010), online: Medical Board of Australia <<http://www.medicalboard.gov.au/Registration-Standards.aspx>> at 2.

⁴⁶¹ *Ibid* at 1.

⁴⁶² *Ibid* [emphasis added].

⁴⁶³ *Ibid*.

health care services to patients.⁴⁶⁴ A systematic review of the evidence by Paul Mazmanian and David Davis concluded that CPD can bring improvement as long as it engages the doctor in reflective exercise and tailored to the doctor's needs.⁴⁶⁵ They submit that CPD could significantly improve the doctor's practice if it is "truly continuing, not casual, sporadic, or opportunistic."⁴⁶⁶ Recently, the examination of studies that explored the effect of CPD on doctors' practice in the Cochrane Database of Systemic Review shows that interactive CPD programs improve doctors' practice.⁴⁶⁷ The review observes that:

Interactive workshops alone or with other interventions are likely to improve the professional practice and health care outcomes compared with didactic lectures alone.... Interactive workshops result in moderately large changes in professional practice. Didactic sessions alone are unlikely to change professional practice.⁴⁶⁸

CPD programs that merely require participation in conferences and workshops may not be productive enough to help improve doctors' practice.⁴⁶⁹ In contrast, interactive workshops and practice-based learning activities, such as peer-review and clinical audit,

⁴⁶⁴ Healy, *supra* note 111 at 128.

⁴⁶⁵ Paul E Mazmanian & David A Davis, "Continuing medical education and the physician as a learner: guide to the evidence" (2002) 288:9 *Journal of American Medical Association AMA* 1057 at 1059.

⁴⁶⁶ *Ibid.*

⁴⁶⁷ M Fernanda Bellolio & Latha G Stead, "Continuing Education Meetings and Workshops: Effects on Professional Practice and Health Care Outcomes" (2009) 53:5 *Annals of Emergency Medicine* 685 at 686.

⁴⁶⁸ *Ibid.*

⁴⁶⁹ *Ibid.*

improve the clinical performance of doctors.⁴⁷⁰ That is why the CPD programs should be flexible and diversified enough to ensure effective individual learning. This approach is incorporated in the Australian Medical Council's accreditation standard for CPD programs.⁴⁷¹ CPD makes medical regulation in Australia proactive and engaging for the doctors. It consists of a persuasive strategy of enforcement in the form of training and education to improve doctor clinical performance.

The fitness to practice process in NSW consists of a disciplinary and a remedial pathway. It recognizes the importance of persuasion, along with a range of support mechanisms.⁴⁷² The disciplinary process is only used to punish doctors against whom "there is evidence of unethical, reckless, wilful or criminal behavior in either clinical or non-clinical domains."⁴⁷³ In other cases, the Medical Council of NSW believes that "public protection can be achieved and professional standards maintained through the application of non-disciplinary and educative responses."⁴⁷⁴ This seems to result in few serious disciplinary sanctions being applied by the Medical Council.⁴⁷⁵ The non-disciplinary and remedial measures include conciliation, performance and health pathway.

⁴⁷⁰ *Ibid.*

⁴⁷¹ Australian Medical Council, "Accreditation of Specialist Medical Education and Training and Professional Development Programs: Standards and Procedures" (2010), online: Australian Medical Council <<http://www.medicalboard.gov.au/Accreditation.aspx>> at 20.

⁴⁷² Healy, *supra* note 111 at 129.

⁴⁷³ Medical Council of New South Wales, "Complaint Management", online: Medical Council of New South Wales <<http://www.mcnsw.org.au>>.

⁴⁷⁴ *Ibid.*

⁴⁷⁵ Healy, *supra* note 111 at 129.

The conciliation process is overseen by the Health Conciliation Registry, an organ that is independent from the Medical Council and HCCC, established by the Health Care Complaints Act 1993.⁴⁷⁶ Complaints are referred to the Registry by the Medical Council and HCCC.⁴⁷⁷ It is a voluntary, informal and confidential process facilitated by a conciliator.⁴⁷⁸ Its aim is to engage the parties in an open and honest communication and to resolve the issue so as to meet the needs of the parties.⁴⁷⁹ The outcomes of the conciliation may include providing explanations and apology, and a commitment to provide better health care in the future.⁴⁸⁰ This constructive engagement is a good opportunity for a doctor to understand and reflect on his/her practice, and to improve for the future. Thus, the conciliation process is a form of the persuasive enforcement strategy at work in the NSW medical regulation system.

The Medical Council runs the Performance Assessment Program for complaints or notifications about doctors with unsatisfactory professional performance.⁴⁸¹ A doctor's professional performance is unsatisfactory "if he/she practices below the standard reasonably expected of a practitioner of an equivalent level of training or experience."⁴⁸²

⁴⁷⁶ Allsop & Jones, *supra* note 128 at 32.

⁴⁷⁷ *Ibid.*

⁴⁷⁸ New South Wales Health Care Complaints Commission, "Resolving Complaints: Conciliation", online: NSW HCCC <<http://www.hccc.nsw.gov.au>>

⁴⁷⁹ *Ibid.*

⁴⁸⁰ *Ibid.*

⁴⁸¹ Medical Council of New South Wales, "Professional Performance", online: Medical Council of NSW <<http://www.mcnsw.org.au>>.

⁴⁸² *Ibid.*

The program is not a disciplinary but a remedial pathway. It is an alternative pathway for doctors who are neither impaired nor guilty of professional misconduct.⁴⁸³ The Medical Council believes that the common causes of poor practices are professional isolation and inattention to CPD.⁴⁸⁴ Thus, it emphasizes remedial measures that provide education and training targeting the identified poor practice while also ensuring public protection.⁴⁸⁵

The Medical Council also runs a non-disciplinary Health Program to deal with impaired doctors. Impairment refers to “a physical or mental impairment, disability, condition or disorder (including substance abuse or dependence) that detrimentally affects or is likely to affect [a doctor’s] capacity to practice.”⁴⁸⁶ The purpose of the program is to ensure public protection while maintaining impaired doctors in practice through proper support and monitoring.⁴⁸⁷ The common outcome of the health pathway is putting conditions on a doctor’s practice, and sometimes, suspension for a period of time may be prescribed.⁴⁸⁸ The conditions placed on the registration will be relaxed with evidence of progress in the doctor’s health condition.⁴⁸⁹ The Performance Assessment and Health Program are good

⁴⁸³ *Ibid.*

⁴⁸⁴ *Ibid.*

⁴⁸⁵ *Ibid.*

⁴⁸⁶ Medical Council of New South Wales, “Doctors’ Health”, online: Medical Council of New South Wales <<http://www.mcnsw.org.au>>.

⁴⁸⁷ *Ibid.*

⁴⁸⁸ *Ibid.*

⁴⁸⁹ *Ibid.*

means of encouraging the reporting of poor practice and of doctors' health problems by medical colleagues, thus ensuring early intervention.⁴⁹⁰

In essence, the NSW medical regulation system reflects responsive regulation ideals by its reliance on ensuring continued competence through CPD, and via the range of fitness to practice measures. CPD is an educational strategy that seeks to improve professionals' knowledge, skill and competence. The conciliation, performance and health pathways are educational and remedial processes that engage the doctor in reflective or/and remedial activities. It appears that many regulatory activities are persuasive and dialogue-based initiatives that promote compliance with regulatory standards and laws. Punishment is reserved only for few serious cases of professional misconduct.

iii. Medical Regulation in Ontario

Medical regulation in Canada is a provincial mandate. Ontario is the most populous province of Canada, and is considered to be a leader in health professions self-regulation.⁴⁹¹ State-sanctioned medical self-regulation in Ontario started in the 1860s.⁴⁹² The College of Physicians and Surgeons of Ontario (CPSO) was established in 1869 to license and register doctors.⁴⁹³ Its governing Council consisted entirely of practitioners

⁴⁹⁰ Healy, *supra* note 111 at 126.

⁴⁹¹ HPRAC, *supra* note 189 at 21.

⁴⁹² David Coburn, "State Authority, Medical Dominance, and Trends in the Regulation of the Health Professions; The Ontario Case" (1993) 37:7 *Social Science and Medicine* 841 at 842.

⁴⁹³ Committee on the Healing Arts, *Report – Volume 1* (Ontario, 1970) at 58.

and medical school representatives.⁴⁹⁴ This continued until the reforms introduced by the Health Disciplines Act of 1974. The law was issued following the 1970 Report of the Committee on the Healing Arts, which reviewed the education and regulation of the health arts (health professions) in Ontario.⁴⁹⁵ The reform was initiated to effectively re-organize the health care system along with developments such as the introduction of medical insurance, the advancement of health care technology, increase in the number and type of health professionals, and changing community expectations and attitudes towards health care services.⁴⁹⁶ Underscoring the striking problem of coordination and integrity of health care services, the Committee noted that “increased government participation in determining levels of service and in coordinating the health system is both necessary and desirable.”⁴⁹⁷ The public attitude supported an increased government role in health care services planning and coordination.⁴⁹⁸ The Committee was concerned about the conflict of interest in the working of self-regulating professional bodies, between their public protection mandate and promoting the professions’ interest.⁴⁹⁹ Though the importance of self-regulation was acknowledged, oversight mechanisms to ensure the CPSO’s function, primarily for the public interest, was recommended. Particularly, the review of the rules of the CPSO’s governing Council by the Minister of

⁴⁹⁴ *Ibid.*

⁴⁹⁵ *Ibid* at v.

⁴⁹⁶ *Ibid* at 2-3.

⁴⁹⁷ *Ibid* at 10.

⁴⁹⁸ *Ibid.*

⁴⁹⁹ Committee on the Healing Arts, *Report – Volume 4* (Ontario, 1970) at 44-5.

Health, and lay representation and participation in the Council, were recommended.⁵⁰⁰ These recommendations were incorporated in the Health Disciplines Act (1974).⁵⁰¹

In 1982, further reform was initiated under the auspices of the Health Professions Legislation Review. Its objective was to ensure efficient utilization of health professions, and create a coordinated and consistent system of health professions regulation. It was also in response to the public demand for “a more open, responsive and accountable regulatory system, especially in relation to complaints investigation and discipline process.”⁵⁰² The Review also acknowledged the choice of self-regulation in Ontario, but suggested effective mechanisms to safeguard the public interest.⁵⁰³ The Review suggested measures that could foster the College’s accountability and transparency: these included increasing lay participation in the College’s Council and Committees; holding the Council meeting, discipline hearing and complaints review in public; and publicizing disciplinary decisions.⁵⁰⁴ Eventually, the framework legislation, *i.e.*, the Regulated Health Professions Act (RHPA) 1991, was promulgated to regulate 23 health professions, including medicine.⁵⁰⁵ The Medicine Act 1991 was also promulgated within the

⁵⁰⁰ *Ibid* at 55 & 63.

⁵⁰¹ Coburn, *supra* note 492 at 847.

⁵⁰² Legislation Review, *supra* note 140 at 2.

⁵⁰³ *Ibid* at 11.

⁵⁰⁴ *Ibid* at 12.

⁵⁰⁵ This Act is a framework legislation that applies to regulation of all health professions in Ontario. It established a consistent and uniform system of regulation across professions. Thus, the discussion about medical regulation in Ontario also presents the general system of health professions regulation in the province.

framework of RHPA specifically to govern medical practice. These Acts and subsequent amendments introduced different oversight mechanisms to ensure the CPSO's accountability and transparency. The following are the major oversight mechanisms.

The Minister for Health and Long-Term Care and the cabinet have some oversight power over the College. The Minister has the power to require the Council of the College to investigate medical practice in a given locality or institution; review the Council's activities; require the Council to provide reports and information for regulatory standards development.⁵⁰⁶ More importantly, the Minister has the power to "require the Council to do anything" to ensure that medical regulation protects the public interest.⁵⁰⁷

In 2009, Bill 179 expanded government oversight power over the College by allowing the appointment of a supervisor of the College by the cabinet, upon the recommendation of the Minister.⁵⁰⁸ The cabinet may authorize the College supervisor to have the "exclusive right to exercise all the powers of a Council and every person employed, retained or appointed for the purposes of the administration of" the laws relating to medical regulation.⁵⁰⁹ It was introduced as an accountability mechanism to be used as a last resort where patient safety is compromised.⁵¹⁰ The College opposed the amendment, arguing that there were already adequate oversight mechanisms to ensure its accountability, and

⁵⁰⁶ *RHPA*, *supra* note 129 ss 5(1) (a)-(c).

⁵⁰⁷ *Ibid* ss 5(1)(d).

⁵⁰⁸ *Ibid* ss 5.0.1 (1).

⁵⁰⁹ *Ibid* s 6.

⁵¹⁰ Ann Silversides, "Government Make Inroads into Medical Self-Regulation" (2009) 181:11 CMAJ 784.

the appointment of the College supervisor “fundamentally undermines professional self-regulation in Ontario.”⁵¹¹

The Minister is assisted by an independent advisory organ established by the RHPA, called the Health Professions Regulatory Advisory Council. The Advisory Council consists of 5-7 persons appointed by the provincial government upon the Minister’s nomination.⁵¹² It provides advisory services to, and upon the written request of, the Minister on policy and legislative amendment issues relating to health professions regulation in Ontario.⁵¹³ It also advises the Minister about the effectiveness of the Colleges’ quality assurance and patient relations program.⁵¹⁴ Upon the Minister’s written request, it provides advice on any matter relating to the regulation of the health professions.⁵¹⁵ The Advisory Council operates independently of the Colleges and the Minister.

The CPSO Council has the greatest number of lay representation of any professional regulator in Ontario.⁵¹⁶ It consists of 13-15 public representatives appointed by the

⁵¹¹ Epps, *supra* note 122 at 99; CPSO, “The CPSO’s Submission On Bill 179 – The Regulated Health Professions Statute Law Amendment Act, 2009” (September 25, 2009), online: CPSO <http://cpso.on.ca/uploadedFiles/policies/positions/Bill179Submission_Sep09.pdf> at 3 [CPSO, “Submission on Bill 179”].

⁵¹² *RHPA*, *supra* note 129 ss 7(2).

⁵¹³ *Ibid* ss (1) & (2).

⁵¹⁴ *Ibid*.

⁵¹⁵ *Ibid*.

⁵¹⁶ CPSO, “Submission On Bill 179”, *supra* note 511 at 4.

provincial government out of the 31- 34 members of the Council.⁵¹⁷ Public representatives are included on all the Committees of the College.⁵¹⁸ The quorum of each Committee requires the presence of, at least, one public member.

Another important oversight mechanism is the right of appeal to the Health Professions Review and Appeal Board against a decision of the College over complaints or registration.⁵¹⁹ The Board is an independent adjudicative body that consists entirely of lay persons appointed by the provincial government upon the recommendation of the Minister.⁵²⁰ It was first established by the Health Disciplines Act of 1974, and was named the Health Professions Board by the RHPA. In 1998, by virtue of the Ministry of Health and Long-Term Care Appeal and Review Boards Act, it was amalgamated with the Hospitals Appeal Board and gained its present name. The Ministry provides administrative and financial support to the Board.

The Health Systems Improvement Act 2007 amended the RHPA to significantly expand the availability of information about doctors to the public.⁵²¹ Accordingly, there is extensive information on the CSPO official website about doctors practicing in

⁵¹⁷ *The Medicine Act*, SO 1991, c 30, ss 6(1).

⁵¹⁸ CPSO, “Submission On Bill 179”, *supra* note 511 at 4.

⁵¹⁹ Epps, *supra* note 122 at 97.

⁵²⁰ Health Professions Appeal and Review Board, “About Us”, online: <<http://www.hparb.on.ca>>.

⁵²¹ Kathryn Frelick & Jesstina McFadden, “Significant Changes to Ontario’s Regulated Health Professions Act, 1991 IN Effect” (2009) 30:1 Health L Can 24 at 25.

Ontario.⁵²² The doctors' training and qualification, conditions on their registration, referral to the College Discipline Committee, result of disciplinary process, fitness to practice, and malpractice cases are some of the information available online about any doctor regulated by the College. The publication aims to make the College's regulatory system more transparent, accountable and trustworthy. It is also a regulatory strategy that empowers patients to make more informed decisions.

Summary

Medical regulation in Ontario has undergone reforms to introduce a range of oversight mechanisms to its traditional self-regulation model. The government's power to control the activities of the College has increased; significant public participation and openness in the College Council's membership and activities has been established; the role of an external adjudicative organ has been enhanced to hear appeals against the College's decision on complaints; and most information about doctors practicing in the province has been made public on the College's website. Therefore, while the reforms acknowledge and maintain the self-regulation system, they mostly seek to enhance the College's accountability and transparency.

Enforcement Strategy

The quality assurance system of the CPSO constitutes its major enforcement strategy. The Peer Assessment Program is a notable component of the quality assurance system adopted by the College. The program's main objective is to continuously improve the

⁵²² CPSO, "Doctors Search", online: <<http://www.cpso.on.ca>>.

doctors' practice in providing quality of care. It was first launched in 1980, and is claimed to be successful and internationally recognized program.⁵²³ However, some argue that the program focuses more on detecting poor practices than improving practice.⁵²⁴ The College maintains the effectiveness of the Program by reference to informal studies that show better performance of doctors who received assistance from the program than doctors who underwent peer assessment for the first time.⁵²⁵ Furthermore, positive feedbacks from doctors after their assessments indicate the benefit of the program in terms of improving their practices.⁵²⁶

There are two main processes by which doctors are selected to be assessed by their peers.⁵²⁷ First, through random selection, ten percent of doctors in the College Registry are selected. Second, a doctor who turned 70 and was not assessed in the preceding five years will be selected. A doctor who wants to be an assessor has to complete the assessment. The College has made it a strategic priority to ensure that each doctor is assessed every 10 years.⁵²⁸ The assessment involves an extensive review of the doctor's

⁵²³ CPSO, "Annual Report 2009:Partnerships", online: CPSO <http://www.cpsso.on.ca/uploadedFiles/policies/publications/AR2009_web2.pdf> at 14.

⁵²⁴ Allsop & Jones, *supra* note 128 at 52.

⁵²⁵ CPSO, "Annual Report 2010: Advancing Patient Safety", online: CPSO <http://www.cpsso.on.ca/uploadedFiles/policies/publications/Annual-Report_10.pdf> at 12 [CPSO, "Annual report 2010"].

⁵²⁶ CPSO, "Peer Assessment", online: CPSO <<http://www.cpsso.on.ca>>.

⁵²⁷ *Ibid.*

⁵²⁸ CPSO, "Strategic Priorities 2011 – 2014", online: CPSO <<http://www.cpsso.on.ca/uploadedFiles/aboutus/strategicplan/strategic-plan2011-14.pdf>> at 2 [CPSO, "Strategic Priorities 2011 – 2014"].

medical record-keeping system.⁵²⁹ The assessor, who is a practicing colleague, also discusses quality of patient care issues with the doctor.⁵³⁰ The assessment is a “productive, collegial and constructive” engagement that emphasises its educational purpose.⁵³¹

The assessment report is reviewed by the Quality Assurance Committee of the College and shared with the assessed doctors. It is reported that most doctors (about 90 percent) assessed in the program are found to be practicing in a satisfactory manner and believed to benefit from the collegial feedback on their practice.⁵³² The common deficits identified in doctors’ practice are minor record-keeping and patient care concerns. The Quality Assurance Committee may provide suggestions for improvement and may subject the doctor to re-assessment after 12 months.⁵³³ If the assessment finds that the doctor’s practice is not satisfactory, the Quality Assurance Committee will interview the doctor.⁵³⁴ Where the Committee is concerned about the doctor’s practice after the interview, it may order a comprehensive assessment.⁵³⁵ If the practice of the doctor is below the minimum standard, the Committee prescribes remedial measures and monitors the doctors’ progress

⁵²⁹ CPSO, “Peer Assessment”, online: CPSO <<http://www.cpso.on.ca>>.

⁵³⁰ *Ibid.*

⁵³¹ *Ibid.*

⁵³² *Ibid*; CPSO, “Strategic Priorities 2011 – 2014”, *supra* note 528 at 2.

⁵³³ CPSO, “Annual Report 2010”, *supra* note 525 at 13.

⁵³⁴ *Ibid.*

⁵³⁵ *Ibid.*

regarding improvement in his or her practice.⁵³⁶ The Committee usually refers non-cooperative doctors with severe or critical practice deficiencies to the Inquires, Complaints and Reports Committee of the College.⁵³⁷

The College also provides policy guidance and direction to the profession.⁵³⁸ It published the Practice Guide in September 2007. The Guide contains the foundational values and principles applicable to medical practice. It provides the framework within which doctors can reason and reflect on ethical and legal challenges they practically face. The College also regularly publishes policy directions on specific practices or other related issues. These instruments contain interpretations and application of the medical professionalism values broadly stated in the Practice Guide. They provide specific guidance to controversial ethical and legal issues.

The emphasis of the CPSO on quality assurance, and on educational mechanisms shows its reliance on persuasion as an effective enforcement strategy of medical regulation in Ontario. These proactive processes engage the doctors in updating their knowledge and skills. Doctors assessed in the quality assurance system have expressed satisfaction with the assessment and for improving their practice. Informal studies show that those doctors' practices improved after engagement with the assessment. This can be analogized to the studies that show interactive CPD programs, tailored to the learning needs of doctors and engaging them in self-reflection, improve doctors' practice. The studies appear to shape

⁵³⁶ *Ibid.*

⁵³⁷ *Ibid* at 15; Allsop & Jones, *supra* note 128 at 53.

⁵³⁸ CSPO, "Policies and Publication", online: <<http://www.cpsso.on.ca>>; CSPO, "Strategic Priorities 2011-2014", *supra* note 528 at 3.

the compulsory, interactive and learners' needs-based CPD programs that doctors have to fulfil for their annual re-registration in Australia.

iv. Medical Regulation in Finland

The health professions in Finland are governed by framework legislation, the Health Care Professionals Act No 559/1994, and the Health Care Professionals Decree 564/1994.⁵³⁹

There are also laws that set out the rights of patients in relation to health professions regulation. The focus of this discussion, however, is medical regulation, though the regulatory system for Finnish doctors is generally similar to what applies to other health professionals in the country.

The National Supervisory Authority for Welfare and Health, *Valvira* in its Finnish abbreviation, is the major organ responsible for the regulation of doctors. It is an executive organ of the State accountable to the Ministry of Social Affairs and Health.⁵⁴⁰

It has the broad regulatory mandate to “supervise and provide guidance to healthcare and social services providers, alcohol administration authorities and environmental health bodies and to manage related licensing activities.”⁵⁴¹ The regulation of doctors and other health professionals generally, is one of its many regulatory activities.

⁵³⁹ *Health Care Professionals Act*, no 559 (Finland), 1994, online: <<http://www.finlex.fi/en/laki/kaannokset/1994/en19940559>> [Unofficial translation][*Health Care Professionals Act*]; *Health Care Professionals Decree*, no 564 (Finland), 1994, online: <<http://www.finlex.fi/en/laki/kaannokset/1994/en19940564>> [Unofficial translation].

⁵⁴⁰ National Supervisory Authority for Welfare and Health, “What is *valvira*”, online: *Valvira* <<http://www.valvira.fi/en>>.

⁵⁴¹ *Ibid.*

Valvira is responsible for licensing and registration of doctors in Finland. It keeps the Register of all licensed doctors, and makes basic information about registered doctors' qualification available on its website. Doctors are legally bound to develop their knowledge and skills through training sponsored and facilitated by their employers.⁵⁴² The Finnish Medical Association (FMA) also provides that doctors are ethically responsible to participate in CPD programs, and strongly holds that this ensures continued competence and health care quality improvement.⁵⁴³

Valvira also has the statutory responsibility to guide and supervise doctors.⁵⁴⁴ Finland has six administrative regions. *Valvira's* guidance and supervision is co-ordinated with the Regional State Administrative Agency of the territory where the doctor practices. The guidance and supervision role of *Valvira* focus on the detection of poor practices and taking corrective measures.⁵⁴⁵ It consists of a health pathway, incompetence assessment, and a disciplinary process.

Valvira addresses concerns relating to a doctor's health, if this affects his/her practice, by ordering the doctor to go for a medical checkup.⁵⁴⁶ Where there is concern about the professional competence of a doctor, *Valvira* may order the doctor to sit for an

⁵⁴² *Health Care Professionals Act, supra* note 539 s 18; Allsop & Jones, *supra* note 128 at 78.

⁵⁴³ *Ibid.*

⁵⁴⁴ *Health Care Professionals Act, supra* note 539 s 24.

⁵⁴⁵ Allsop & Jones, *supra* note 128 at 84.

⁵⁴⁶ *Health Care Professionals Act, supra* note 539 s 25; Allsop & Jones, *supra* note 128 at 80.

examination, demonstrate his/her skills, or be assessed by impartial experts.⁵⁴⁷ On the basis of the assessment result, *Valvira* may take remedial measures, such as giving orders or instructions to the doctor with a view to ensure patient protection. Or, it may impose sanctions on the doctor, including restrictions on his/her practice, or suspension or revocation of his/her registration.⁵⁴⁸ Non-cooperation with the order of assessment may result in the revocation of a doctor's registration.⁵⁴⁹ The assessment process seeks the opinion of internal and, where necessary, external experts.⁵⁵⁰ *Valvira* has more than 300 non-permanent experts to provide opinion to resolve issues in the discharge of its broad regulatory mandate.⁵⁵¹ They are selected for four years of service to provide support for *Valvira*'s activities where their expertise is necessary.⁵⁵²

A complaint about professional misconduct by a doctor can be lodged with the Regional State Administrative Agency or *Valvira*.⁵⁵³ Mostly, complaints are made by a patient or a next of kin who is unsatisfied with treatment. Before the filing of a complaint, *Valvira* encourages discussion between the complainant and the doctor or his/her supervisor. This

⁵⁴⁷ *Health Care Professionals Act*, *supra* note 539 s 25; Allsop & Jones, *supra* note 128 at 82.

⁵⁴⁸ *Health Care Professionals Act*, *supra* note 539 s 26; Allsop & Jones, *supra* note 128 at 81-3.

⁵⁴⁹ *Health Care Professionals Act*, *supra* note 539 s 25.

⁵⁵⁰ Allsop & Jones, *supra* note 128 at 83.

⁵⁵¹ *Valvira*, "Professional Supervision", online: <<http://www.valvira.fi/>> [Google Unofficial Translation]

⁵⁵² *Ibid.*

⁵⁵³ National Supervisory Authority for Welfare and Health, "Healthcare: Complaints Procedure", online: <<http://www.valvira.fi/en>>.

engagement commonly resolves misunderstandings and corrects shortcomings. A patient ombudsman in the health facility helps the patient in the discussion or/and complaint filing process.⁵⁵⁴ Complaints relating to a severely and permanently injured patient or a patient who died after a suspected medical error are to be filed with *Valvira*.⁵⁵⁵ Other complaints should be submitted to the appropriate regional state administrative agency. The majority of the complaints are processed by the regional state administrative agencies.⁵⁵⁶

Where the complaint is justified, the outcome of a disciplinary process is, mostly, to provide administrative guidance to the doctor.⁵⁵⁷ This includes giving an admonition and drawing attention to the proper conduct. Moreover, *Valvira* may give a written warning to the doctor, restrict his/her practice, suspend or revoke his/her license.⁵⁵⁸ *Valvira's* disciplinary decisions are made by a Board for the Supervision of Health Care Professionals.⁵⁵⁹ It is chaired by *Valvira* Director General, and consists of four other members, including health care professionals.⁵⁶⁰

⁵⁵⁴ *Ibid.*

⁵⁵⁵ *Ibid.*

⁵⁵⁶ Allsop & Jones, *supra* note 128 at 81.

⁵⁵⁷ National Supervisory Authority for Welfare and Health, "Healthcare: Consequences of a Complaint", online: <<http://www.valvira.fi/en>>.

⁵⁵⁸ *Ibid.*

⁵⁵⁹ Allsop & Jones, *supra* note 128 at 83.

⁵⁶⁰ *Ibid.*

Summary

Medical regulation in Finland is undertaken by the state. *Valvira* licenses and registers doctors, and assesses impaired and incompetent doctors. It manages complaints about doctors' misconduct in cooperation with the regional state administrative agencies. The Finnish statist approach acknowledges its deficiency in expertise. This is why it devised a system of an external pool of experts who provide advice to its fitness to practice procedures and other activities as necessary.

Nonetheless, Allsop and Jones note that the role of the state in guiding the medical profession is minimal.⁵⁶¹ My research from the official English version and the unofficial Google translation of *Valvira's* website supports this argument. *Valvira* does not have comprehensive practice standards to guide doctors in addressing practical and ethical challenges they face in their daily practices. Its organizational structure consists of a Department of Guidance, and a Department of Supervision.⁵⁶² With respect to medical regulation, the supervision department, which focuses on fitness to practice processes in regard to doctors' health, incompetence and misconduct, is more proactive than the guidance department. This may be related to the expertise deficiency in *Valvira*. If the regulatory organ were a professional body, it may have been more proactive in guiding the profession's practice. Meanwhile, the expertise deficiency limitation of *Valvira* may

⁵⁶¹ *Ibid* at 84.

⁵⁶² *Valvira*, "Valvria's Organizational Structure", online:
<http://www.valvira.fi/en/valvira/organisational_structure>.

have created the opportunity for the FMA to play a proactive role, as discussed below, in guiding the profession on ethics and quality improvement issues.

Enforcement Strategy

Persuasion plays a significant role in medical regulation in Finland. The FMA plays a key role in promoting ethical standards and self-assessment. It is an independent professional organization, and functions as a trade union in promoting its members' interests. The mission of the FMA is to work for the "advancement of medical expertise, humanity, ethics and collegiality."⁵⁶³ Its membership consists of almost all Finnish doctors (about 94 %) practicing in all specialities.⁵⁶⁴

The FMA has been strongly promoting high standards of professional ethics.⁵⁶⁵ In 2005, it published its latest edition of a Code of Ethics that member must comply with as their ethical obligation.⁵⁶⁶ The Ethics Committee of the FMA publishes ethical opinions on new challenges in health care. Every few years, the FMA publishes a compilation of these ethical opinions and the ethical guidelines it has issued. This publication is distributed to its members free of charge and used as a course material in medical schools.⁵⁶⁷ Together with other medical organizations, the association also set up an

⁵⁶³ Finnish Medical Association (FMA), "Brochure", online: <<http://www.laakariliitto.fi/files/Englanti.pdf>> at 2 [FMA, "Brochure"].

⁵⁶⁴ *Ibid.*

⁵⁶⁵ Allsop & Jones, *supra* note 128 at 85.

⁵⁶⁶ Finnish Medical Association, "Ethics and Guidelines", online: <<http://www.laakariliitto.fi/etiikka/>> [Unofficial Google Translation].

⁵⁶⁷ FMA, "Brochure", *supra* note 563 at 5.

online Ethics Forum where a doctor can raise ethical challenges and receive reflections from experienced colleagues. An ethical challenge of general importance is debated in the medical journal and in ethical committees.⁵⁶⁸

The FMA also works in health care quality improvement. In 1996, it published the Ethical Guidelines for the Quality Assessment of Health Care with the approval of its Board of Directors. The Guidelines state that “each doctor must continually evaluate the quality of his/her work and the level of [his/her] ability by self-assessment methods.”⁵⁶⁹ The FMA also has a quality award program for projects that advance health care and patient treatment.⁵⁷⁰

The medical organizations in Finland proactively engage in promoting and monitoring CPD. In 2002, the FMA, Finnish Medical Society (scientific community of Swedish-speaking doctors) and the Finnish Medical Society *Duodecim* (the scientific community of Finnish doctors) jointly established the Council for the Evaluation of Continuous Professional Medical Development in Finland.⁵⁷¹ Its aim was to ensure that the development, support and follow-up relating to CPD programs remain responsibilities of

⁵⁶⁸ The link to the Ethics Forum can be found in Finnish Medical Association, “Ethics and Guidelines”, online: <<http://www.laakariliitto.fi/etiikka/>> [Unofficial Google Translation]; Physicians Ethics Forum, online: <http://www.duodecim.fi/kotisivut/kotisivut.sivut.koti?p_sivusto=69>.

⁵⁶⁹ Finnish Medical Association, “Ethical Guidelines for the Quality Assessment of Health Care”, online: <<http://www.laakariliitto.fi/e>>.

⁵⁷⁰ FMA, “Brochure”, *supra* note 563 at 4.

⁵⁷¹ *Pro Medico*, “About the Association”, <<http://www.promedico.fi>>.

the profession.⁵⁷² The Council published national recommendations for CPD implementation.⁵⁷³ The recommendations were embraced by CPD providers, which are mainly medical speciality societies.⁵⁷⁴ In 2007, the medical associations formed the Association for Continuous Professional Medical Development in Finland (*Pro Medico*).⁵⁷⁵ *Pro Medico* is financed by the medical associations and aims at furthering and coordinating the progress of CPD in Finland.⁵⁷⁶ Its functions include evaluation and development of CPD, maintaining and developing CPD calendars, documentation of CPD, promoting and developing appropriate and interactive methods for CPD, tracking and evaluating implementation of CPD, and evaluating the impact of CPD.⁵⁷⁷ According to the annual surveys of the FMA, the majority of doctors in Finland spend about eight days per year in external training, in contrast to the FMA's recommendation of two weeks of annual CPD trainings.⁵⁷⁸ The medical associations have taken a lead in the delivery, coordination, facilitation, and promotion of CPD programs for doctors.

As described above, the fitness to practice processes of *Valvira* emphasize the importance of persuasion and dialogue to improve a doctor's performance. The health or competence assessment pathway aims at remedial measures that ensure that a doctor maintains the

⁵⁷² *Ibid.*

⁵⁷³ Allsop & Jones, *supra* note 128 at 78.

⁵⁷⁴ *Pro Medico*, "About the Association", online: <<http://www.promedico.fi>>.

⁵⁷⁵ *Ibid.*

⁵⁷⁶ *Ibid.*

⁵⁷⁷ *Pro Medico*, "About the Association- Tasks", online: <<http://www.promedico.fi>>.

⁵⁷⁸ *Pro Medico*, "CME/CPD in Finland", online: <<http://www.promedico.fi>>.

required standard in his/her practice. The process requires dialogue with the doctor and expert opinion on the proper remedial measures in the specific case. The measures include a doctor undergoing treatment for illness affecting his/her practice, taking some training to improve his/her skill and knowledge, and working under supervision. Allsop and Jones note that very few cases entail restriction or suspension of a doctor's registration.⁵⁷⁹ This shows *Valvira's* reliance on remedial and educational measures.

The complaint handling procedure also encourages dialogue between the patient and the doctor. This process has the benefit of engaging the doctor in reflective thinking about his/her practice. Where a complaint about a doctor is pursued and justified, *Valvira* and the regional state administrative agencies mostly provide administrative guidance to improve the doctor's practice. Administrative guidance is an educational measure that draws the attention of the doctor to proper conduct. Punishment is reserved for a few cases of professional misconduct. This shows that persuasion plays a significant role in the disciplinary process of medical regulation in Finland.

Overall, persuasion, in the form of promotion of ethical standards, quality improvement, CPD, remedial and educational measures in the fitness to practice process, is entrenched in Finland medical regulation. The statist framework of medical regulation is generally reactive. It focuses on the licensing and fitness to practice processes, probably because of lack of expertise, unlike where professionals are in charge of their regulation. But the voluntarily constituted professional organizations complement the limited role of *Valvira* in the guidance and development of doctors. These organizations proactively engage in

⁵⁷⁹ Allsop & Jones, *supra* note 128 at 85.

promoting ethical standards, quality improvement and CPD, and their initiatives in these respects are commendable.

v. Medical Regulation in the Netherlands

The Individual Health Care Professions Act of 1993, commonly identified in its Dutch abbreviation as the BIG Act, is a framework legislation that governs the health professions, including doctors in the Netherlands.⁵⁸⁰ The licensing and registration of doctors is the responsibility of both the state and professional associations. The state licenses and registers doctors without specialization, while professional associations are in charge of licensing and registering doctors with specialization. Doctors without specialization are graduates of medical schools who pass the Doctor of Medicine examinations. They are allowed to practice medicine, but they cannot work as general practitioners or in any other medical speciality.⁵⁸¹ About 60% of these doctors continue postgraduate training in medicine for specialization.⁵⁸² Most doctors are enrolled in four years of postgraduate training leading to specialization in 28 medical specialities.⁵⁸³ About 20 % of medical graduates are enrolled in postgraduate training to be qualified as

⁵⁸⁰ RMJ Schepers & HEGM Hermans, “The Medical Profession and Alternative Medicine in the Netherlands: Its History and Recent Developments” (1999) 48 *Social Science & Medicine* 343 at 343.

⁵⁸¹ Willeminjn Shafer *et al.*, *The Netherlands: Health System Review* (European Observatory on Health Systems and Policies, 2010) at 136.

⁵⁸² *Ibid.*

⁵⁸³ *Ibid.*

General Practitioners.⁵⁸⁴ Social medicine also has three specialities that enrol about 6 % of medical graduates for two years of postgraduate training.⁵⁸⁵

The licensing of doctors without specialization is undertaken by the Central Information Center for Professional Practitioners in Health Care (abbreviated as CIBG in its Dutch designation). The CIBG is an executive agency within the Ministry of Health, Welfare and Sport. It collects, manages and provides data on a range of health issues that lead to licensing, permitting and making other decisions. It has a broad mandate, including registration and processing of data relating to licensed health professionals, cannabis use, abortion, artificial insemination and euthanasia. To implement the BIG Act, the CIBG established and runs the BIG-register.⁵⁸⁶ A doctor's registration in the BIG-register serves as a professional license entitling him/her to practice medicine. The BIG-register contains information about the qualification and speciality, if any, of the doctor. It also includes any restriction or condition placed on the doctor's registration. The public has access to the BIG-register online or by telephone service. The CIBG is also responsible for the process of registering foreign trained doctors in the BIG-register. This includes assessing their credentials, issuing a Declaration of Professional Competence, and deciding on the need for working under supervision or additional training.⁵⁸⁷

⁵⁸⁴ *Ibid.*

⁵⁸⁵ *Ibid.*

⁵⁸⁶ MJMH Lombarts, "Medical Regulation in the Netherlands" in Allsop & Jones, eds, *supra* note 128 at 97; Shafer *et al.*, *supra* note 581 at 139; CIBG, "CIBG In Brief", online: CIBG <<http://www.cibg.nl>>.

⁵⁸⁷ BIG-register, "About BIG-register", online: BIG-register <<http://www.bigregister.nl>> [Unofficial Google Translation].

The licensing and registration of doctors with specialization is the responsibility of professional associations approved by the Minister of Health, Welfare and Sport.⁵⁸⁸ The Medical Specialist Registration Committee of the Royal Dutch Medical Association (KNMG) is the organ responsible for licensing and the registration of medical specialists.⁵⁸⁹ The General Practitioners Registration Committee of the KNMG licenses and registers general practitioners.⁵⁹⁰ The KNMG is the federation of the Netherlands professional medical associations, including the association of general practitioners and medical specialists.⁵⁹¹ A general practitioner or medical specialist who is not a member of the KNMG can also be licensed and registered on the Specialist Registration Committees register.⁵⁹² The KNMG establishes and amends the procedures for the licensing and registration of doctors' specializations.⁵⁹³

To ensure continued competence of doctors and improve the provision of quality health care, the Netherlands has a compulsory system of re-registration for doctors. Re-registration of doctors, and doctors with specialization, is the responsibility of CIBG and

⁵⁸⁸ *The Individual Health Care Professions Act* (Netherlands), 1993, art 14 [*Professions Act*].

⁵⁸⁹ Shafer *et al.*, *supra* note 581 at 141; Lombarts, *supra* note 586 at 99.

⁵⁹⁰ R van Herk *et al.*, "Medical Audit: Threat or Opportunity for the Medical Profession- A Comparative Study of Medical Audit among Medical Specialists in General Hospitals in the Netherlands and England, 1970-1999" (2001) 53 *Social Science & Medicine* 1721 at 1725.

⁵⁹¹ KNMG, "The Royal Dutch Medical Association (KNMG)", online: KNMG <<http://knmg.artsennet.nl/Over-KNMG/English.htm>>.

⁵⁹² Herk *et al.*, *supra* note 590 at 1725.

⁵⁹³ *Professions Act*, *supra* note 588 art 14 (2); Shafer *et al.*, *supra* note 581 at 140.

Specialist Registration Committees respectively. A compulsory system of re-registration every five years, has been enforced since January 1, 2012 for doctors without specialization.⁵⁹⁴ There are two alternative criteria, *i.e.*, the experience, or the training requirement, for re-registration of doctors.⁵⁹⁵ During the five years after initial registration, a doctor has to work for 2080 hours in his/her profession.⁵⁹⁶ If the doctor did not practice for the 2080 hours, he/she may be eligible to take a training program designed for re-registration.⁵⁹⁷

The system for re-registration for doctors emerged from the re-registration process that evolved more than two decades ago under the Medical Specialist Societies.⁵⁹⁸ In 1991, the Central College of Medical Specialities of the Dutch Order of Medical Specialities (which is a member of KNMG) introduced mandatory re-registration of medical specialities every five years.⁵⁹⁹ The re-registration system emerged “to accommodate the growing need for external accountability, the ageing of specialists and the notion that doctors should stop practising at 65, the rapid expansion of medical knowledge and technology, and the expansion of activities to assure the quality of specialist care, such as

⁵⁹⁴ BIG-register, “Re-registration as a Doctor”, online: BIG-register <<http://www.bigregister.nl>> [Unofficial Google Translation].

⁵⁹⁵ *Ibid.*

⁵⁹⁶ *Ibid.*

⁵⁹⁷ *Ibid.*

⁵⁹⁸ Allsop & Jones, *supra* note 128 at 187.

⁵⁹⁹ Lombarts, *supra* note 586 at 99.

continuing medical education and peer review.”⁶⁰⁰ When it started, the requirement for re-registration was quantitatively prescribed in terms of time spent in practice.⁶⁰¹ Currently, two additional requirements have to be fulfilled for re-registration in the medical specialists register. These are participation in accredited CPD programs and the quality *visitatie* program.⁶⁰² The *visitatie* program is an external peer-review undertaken by site-visits.⁶⁰³ It is initiated and led by doctors as a quality assurance mechanism.⁶⁰⁴ As a self-regulation mechanism promoting compliance with professional standards, it is briefly discussed as an enforcement strategy below.

Medical professional organizations take the lead in guiding the profession.⁶⁰⁵ The KNMG provides the standards of practice and code of ethics.⁶⁰⁶ The Dutch College of General Practitioners has produced over seventy practice guidelines to improve the quality of health care.⁶⁰⁷ It is claimed that over 70 % of these guidelines are followed by general

⁶⁰⁰ J A Swinkels, “Reregistration of Medical Specialists in the Netherlands” (1999) 319 *British Medical Journal* 1191 at 1191.

⁶⁰¹ *Ibid.*

⁶⁰² Lombarts, *supra* note 586 at 99.

⁶⁰³ MJMH Lombarts & NS Klazinga, “A Policy Analysis of the Introduction and Dissemination of External Peer Review (*Visitatie*) as a Means of Professional Self-regulation amongst Medical Specialists in the Netherlands in the Period 1985-2000” (2001) 58 *Health Policy* 191 at 192.

⁶⁰⁴ MJMH Lombarts & FCB Van Wijmen, “External Peer Review by Medical Specialists (*Visitatie*) in Legal Perspective” (2003) 10 *European Journal of Health Law* 43 at 43.

⁶⁰⁵ Lombarts, *supra* note 586 at 93.

⁶⁰⁶ Herk *et al.*, *supra* note 590 at 1724.

⁶⁰⁷ Lombarts, *supra* note 586 at 102.

practitioners.⁶⁰⁸ The College is a professional scientific organization with voluntary membership of over 95 % of general practitioners in the Netherlands.⁶⁰⁹

The Health Care Inspectorate monitors the quality and safety of doctors' practice. The Inspectorate is a state organ accountable to the Ministry of Health, Welfare and Sport, and responsible to promote public health by overseeing the quality of prevention measures, health services, and medical products.⁶¹⁰ About half of the Inspectorate staff consists of inspectors with powers, among others, to enter the premises of health care providers and investigate complaints against a health care provider or doctor.⁶¹¹ Where the Inspectorate finds serious professional misconduct, it can submit a complaint about the doctor to the Disciplinary Tribunal in accordance with the BIG Act. Where the Inspectorate finds health problems, such as substance abuse or physical or mental conditions that affect the doctor's practice, it initiates a procedure before a Medical Supervision Board. The Medical Supervision Board may impose conditions on the doctor's practice, or suspend or revoke the doctor's registration (Article 80 of the BIG Act).

The BIG Act provides for the disciplinary process and measures for regulating a doctor's professional misconduct. Disciplinary proceedings can be submitted to the five Regional

⁶⁰⁸ Dutch College of General Practitioners, "English Summary", online: Dutch College of General Practitioners <<http://nhg.artsennet.nl/English.htm>>.

⁶⁰⁹ *Ibid.*

⁶¹⁰ Health Care Inspectorate, "The Health Care Inspectorate in Short", online: Health Care Inspectorate <<http://www.igz.nl/english/>>.

⁶¹¹ Lombarts, *supra* note 586 at 94.

Disciplinary Tribunals, each having jurisdiction over complaints arising in their respective administrative geographical territory. A Disciplinary Committee that hears a complaint consists of two lawyers (one of whom is the Chairman of the Tribunal) and three health care professionals of the same profession as that of the defendant. In less complex cases, the Disciplinary Committee may be formed by the Chairman of the Tribunal and two health professionals. Each Regional Disciplinary Tribunal has a pool of doctors, other health professionals, and lawyers serving as alternate members to the Tribunals (Article 55 of the BIG Act).⁶¹² Where a complaint is found to be justified, the Disciplinary Committee may impose a range of disciplinary measures stipulated in the Article 48 (1) of the BIG Act. The measures that can be taken against a doctor include warning, reprimand, fine, suspension from the BIG-register for one year, restriction on the practice of the doctor, or revocation from the BIG-register.

An appeal from the Regional Disciplinary Tribunal may be made to the Central Disciplinary Board of Health based in the Hague. The appeal can be submitted by the complainant, the health professional who was the defendant at the first instance proceeding, or the Inspectorate (Article 73 (1) of the BIG Act). A Central Disciplinary Committee that hears an appeal consists of three lawyers (one of whom is also Chairman of the Board) and two health professionals from the same profession as the defendant or appellant. The Board has a pool of alternate lawyer members and health professionals (Article 56 of the BIG Act). The Board also hears appeal over the decisions of the

⁶¹² Disciplinary Tribunals for Health Care, “Disciplinary Tribunal Groningen: College Composition”, online: Disciplinary Tribunals for Health Care <<http://www.tuchtcollege-gezondheidszorg.nl/>> [Unofficial Google Translation].

Medical Supervision Board that deals with health professionals with mental or physical health problems that affect their practice (Article 84 of the BIG Act).

The Chairman and his/her deputy or deputies of the Regional Disciplinary Tribunals and of the Central Disciplinary Board of Health are appointed for life by the Royal Decree upon the recommendation of the Minister for Health, Welfare and Sport, and the Minister of Justice. They retire upon turning 70, and are granted early discharge by the Royal Decree upon their request (Articles 55(3) *cum* 56 (3) of the BIG Act). Article 55 (4) *cum* 56 (3) of the BIG Act generally provide for the same procedure of appointment for other members and alternate members of the Tribunal and Board. The differences are that the recommendation is made solely by the Minister for Health, Welfare and Sport, and the appointment is made for a six year term. Health professional members are appointed from practitioners in the BIG-register. The Ministry of Health, Welfare and Sport provides financial and technical assistance to the Tribunals and the Board. However, the Tribunals and Board function independently of the influence of the Ministry.⁶¹³

Summary

Medical regulation in the Netherlands displays cooperation between the state and the medical profession through the profession's own associations. The state has the role of licensing, registration and re-registration of doctors without specialization. The professional associations are responsible for licensing, registration and re-registration of

⁶¹³ Disciplinary Tribunals for Health Care, "Central Disciplinary Board of Health - Task of the CTG", online: Disciplinary Tribunals for Health Care <<http://www.tuchtcollege-gezondheidszorg.nl/>> [Unofficial Google Translation].

doctors with specialization, i.e., general practitioners and medical specialities. The professional associations also take the lead in setting standards of care for the profession and quality improvement activities. The state monitors compliance of doctors with the quality requirements and investigates complaints. Adjudication of complaints against doctors is done within the state structure involving professionals by independent tribunals.

Enforcement Strategy

The emphasis of medical regulation in the Netherlands is on activities designed to ensure doctor compliance with professional and quality improvement standards. In this regard, the proactive engagement of the medical associations in guiding the profession through setting and promoting professional standards, guidelines and code of ethics is notable. Moreover, the external peer review system, i.e., *visitatie*, has become the brand for quality assurance in the Netherlands, built on principles of persuasion and dialogue.

The *visitatie* program has been established and is run by medical speciality societies. The Society of Surgeons was the first speciality society to introduce *visitatie* in 1989.⁶¹⁴ Today, all medical speciality societies have *visitatie* programs which have significant similarity.⁶¹⁵ Each speciality society develops, implements and maintains its *visitatie* program as approved by the general meeting of its members.⁶¹⁶ The speciality societies set quality standards, undertake assessment, and provide recommendation for

⁶¹⁴ Lombarts, *supra* note 586 at 100.

⁶¹⁵ *Ibid*; Lombarts & Wijimen, *supra* note 604 at 44.

⁶¹⁶ *Ibid*.

improvement, or take measures to cancel a specialist membership in the society and report to the Health Care Inspectorate.⁶¹⁷ A visit to a specialist practice is undertaken by a team of 2-4 peers.⁶¹⁸ The peers meet with the specialist, the district general practitioners, the board and the medical staff chairman of the hospital where the specialist practices.⁶¹⁹ They also visit the specialist's department and assess the diagnostic facilities the specialist uses.⁶²⁰ A study has shown that Dutch specialists view the *visitatie* program as a positive tool to improve quality, and they welcome assessment recommendations.⁶²¹ Since its introduction two decades ago, the *visitatie* program has undergone continuous development by the medical specialities to ensure its effectiveness in quality improvement. The state also partly financed the *visitatie* program to support the specialist societies' initiative of voluntary self-regulation.⁶²²

If the *visitatie* assessment result is negative, there are a range of measures the medical speciality would take. These include revisits within one or two years, mandatory improvement progress reports, specified training program, reporting to the hospital management or the Health Care Inspectorate, or termination of the doctor's membership

⁶¹⁷ Lombarts, *supra* note 586 at 100.

⁶¹⁸ Lombarts & Wijmen, *supra* note 604 at 44.

⁶¹⁹ Swinkels, *supra* note 600 at 1192.

⁶²⁰ *Ibid.*

⁶²¹ M J M H Lombarts & N S Klazinga, "Inside Self-regulation: Peer Review (Visitatie) by Dutch Medical Specialists" (2003) 8:4 *Clinical Governance: An International Journal* 318 at 328.

⁶²² Swinkels, *supra* note 600 at 1192.

in the society.⁶²³ Generally, the process and outcome of the *visitatie* program is a form of self-regulation that involves dialogue and persuasion as an enforcement strategy.

The complaint handling system encourages dialogue through informal and formal mechanisms. The informal mechanism refers to the involvement of a complaint officer or mediator to help facilitate dialogue to resolve a misunderstanding between a patient and a doctor.⁶²⁴ This process engages the doctor in reflective thinking about his/her practice and communication with the patient. A patient may also bring his/her complaint to the health care facility Complaints Committee established in accordance with the Clients' Right of Complaint Act 1995. This Act obliges health care facilities to establish or join a Complaints Committee. The Complaints Committee emphasize restoring the relationship between a patient and a doctor.⁶²⁵ The outcome from the consideration of a complaint may also include a recommendation to improve the quality of health care in the facility.⁶²⁶ With the objective of improving quality, the disciplinary process can also require educational measures, such as providing guidance on proper conduct.⁶²⁷

To sum up, the enforcement strategy of the Netherland's medical regulatory model consists of proactive engagement of the professions in quality improvement. The medical

⁶²³ Lombarts, *supra* note 586 at 100.

⁶²⁴ FY Alhafaji *et al.*, "Concurrence between Complaints Procedures in the Dutch Health Care System" (2011) 18 Eur J Health L 127 at 127.

⁶²⁵ *Ibid* at 129; Allsop & Jones, *supra* note 128 at 103.

⁶²⁶ *Ibid.*

⁶²⁷ Health Care Inspectorate, "Enforcement Measures: Disciplinary Measures", online: Health Care Inspectorate <<http://www.igz.nl/english/>>.

professions' organizations play a leading role in guiding and promoting doctors' adherence to professional and quality standards. Particularly, the external peer assessment (*visitatie*) system proactively engages doctors in self-reflective exercises and in constructive dialogues with peers. The state's primary role in the complaint management system also focuses on the educational aspect of the compliant and disciplinary processes.

The expertise and capacity of the professional medical organization is utilized to mobilize doctors and to promote compliance with professional and quality standards. In this regard, the professional medical associations took the initiative to produce and promote practice guidelines and to engage in quality improvement activities. The state supports these initiatives. The state's reactive role in monitoring professional performance, and in the investigation and adjudication of professional misconduct, is harnessed with the proactive engagement of professional medical associations in promoting professional and quality standards.

2. Lessons for Health Professions Regulation in Ethiopia

i. A Framework for Ethiopian Health Professions Regulation

Medical regulation based on self-regulation in the UK, NSW, and Ontario has been found ineffective in ensuring accountability, due process and trust. Consequently, the reforms introduced to address these concerns have resulted in greater state intervention and oversight over self-regulation.

Conventionally, self-regulation is understood as a system where the majority on the professional governing body is elected practitioners.⁶²⁸ By this understanding, the UK's GMC may no longer be thought of as a self-regulatory organ, since half of its Council consists of lay members appointed by an independent Appointment Commission. The other half of the membership of the Council is also independently appointed. As well, not only is the GMC required to report to parliament annually; it is also subject to oversight and audit by a meta-regulatory organ, the CHRE. The GMC introduced a revalidation process involving multiple actors to ensure timely detection of poor performance and continued competence of doctors. These changes are designed to ensure accountability and public trust in the medical regulation system. To address public confidence concerns over adherence to due process principles of fairness, transparency and impartiality, the investigative and prosecutorial role of the GMC is separated from its former adjudicative role, now assumed by the MPTS.

In NSW, the concern over accountability and trust prompted reform in the composition and appointment of the Medical Board. Lay representation was introduced and the state assumed the responsibility to appoint the Medical Board's medical members. The fitness to practice process has been the focus of the reform. The unfairness in the narrow notion of infamous conduct was replaced with the broader notion of professional misconduct, and the professional competence and health pathway are incorporated into the fitness to practice process. The role of the Medical Board (now Medical Council) in investigating complaints is shared with the state HCCC, which also took on the prosecutorial role. The

⁶²⁸ Epps, *supra* note 122 at 83.

PSC and Medical Tribunal, a separate and independent organ that only receives technical and administrative support from the Medical Council, further diminished the latter's role in the fitness to practice process. Hence, the fitness to practice process has become a typical example of the co-regulatory model.

Meanwhile, the pursuit of efficiency has been the driver to the new national scheme approach to health practitioner regulation in Australia with the goal to ensure consistency and simplicity. This, however, does not overshadow the reforms in NSW prompted by the ineffectiveness of self-regulation as assessed against the accountability, trust and due process criteria of 'good' regulation.

The reforms in Ontario's medical self-regulation system have been designed, primarily to address concerns over accountability and transparency (due process). The oversight power of the Minister for Health and Long-Term Care over the Council of CPSO has been increased. This power has been further strengthened under the state's mandate to appoint a College supervisor with broad oversight power in exceptional cases. The Health Professions Regulatory Advisory Council has been established as an advisory body with power to audit the activities of the CPSO in some areas. Lay participation in the College Council and Committees has been strengthened, and an external adjudicative organ has been established to hear appeals from the College's registration and disciplinary decisions. As well, information on a doctor practicing in Ontario is, by law, made public.

Unlike the UK and NSW, self-regulation remains strong in Ontario. Indeed, in that Canadian province, the reforms acknowledge and maintain principles of professional self-regulation. Fiona McDonald argues that the relatively few significant events (*i.e.*,

scandals) in Canada, in contrast to what happened in the UK, may explain the relatively modest reform.⁶²⁹ CSPO has acted promptly to address public concerns about its effectiveness and has thus, maintained relative public trust.⁶³⁰ In contrast, the GMC of UK and the Medical Board of NSW did not act promptly and adequately to maintain public trust. In addition, the Canadian approaches to health care system management and financing do not affect the professional autonomy of the medical profession.⁶³¹ In contrast, they do in the UK's NHS, leading to broad managerial control over clinical practice.⁶³²

Despite these differences, the past two or three decades have witnessed common reforms that have resulted in greater state intervention and oversight over medical self-regulation in Ontario, UK and NSW. This direction is also evident in Ontario though, as said earlier, it maintains a relatively strong medical self-regulation system. State intervention and oversight has been stronger in the UK and NSW. In the UK, traditional medical self-regulation has been subjected to audit and oversight by a meta-regulatory organ, and in NSW, the fitness to practice process has taken on a co-regulatory shape. In all three jurisdictions, the driver of reform has been ineffectiveness of self-regulation as manifested in lack of accountability and failures in due process. In the UK and NSW, scandals eroded public trust in medical self-regulation, and the resulting pressure

⁶²⁹ Fiona McDonald, *Patient Safety Law: Regulatory Change in Britain and Canada* (SJD Dissertation, Schulich School of Law, Dalhousie University, 2010) at 283 [unpublished].

⁶³⁰ *Ibid* at 251 & 261.

⁶³¹ *Ibid* at 137.

⁶³² *Ibid* at 136; Dubois *et al.*, *supra* note 253 at 183.

necessitated significant structural changes to the traditional self-regulation model that had been in place.

The trend from self-regulation towards state intervention and oversight is not limited to the UK, Ontario, and NSW; it represents a broader global development in health professions regulation. Allsop and Jones, after studying medical regulation in NSW, Ontario, New Zealand, Finland, the Netherlands, the USA (New York) and France, identified that the traditional state-sanctioned self-regulation model has been replaced with a partnership and co-regulation system.⁶³³ They reason that the move away from traditional self-regulation and medical autonomy is pursued to achieve cost-effective health care, and for four major reasons.⁶³⁴ First, that serious poor clinical practice has not been detected or adequately addressed by self-regulation. Along with the public outrage or pressure, this led to “seismic changes in medical regulation” prompting measures to ensure greater accountability and transparency.⁶³⁵ The other three factors that, in their view challenged the traditional self-regulatory model and medical autonomy more generally are: the changing perception of health care as a “high risk industry”; advances in evidence-based health care; and the complexity of health care regulation.⁶³⁶ Carl-Ardy Dubois *et al.* also identified the shift from self-regulation in European countries as due to

⁶³³ Allsop & Jones, *supra* note 128 at 171.

⁶³⁴ Judith Allsop & Kathryn Jones, “Protecting Patients: International Trends in Medical Governance” in Ellen Kuhlmann & Mike Saks, eds, *Rethinking Professional Governance: International Directions in Healthcare* (The Policy Press: Bristol, 2008) 15 at 17.

⁶³⁵ *Ibid* at 18.

⁶³⁶ *Ibid* at 16.

a failure to ensure public protection.⁶³⁷ Their study notes, however, that the trend does not apply to all European countries, particularly as post-communist countries are still at the early stage of building professional institutions.⁶³⁸

Nonetheless, where medical self-regulation is performing poorly on the accountability and due process criteria, and fails to maintain public trust, the question that arises is whether state intervention and oversight is the proper response. Self-regulation is not a right for doctors but a privilege conferred by society, in exchange for good public service. In a democratic order, the state is the legitimate organ functioning in the public interest. However, the role of the state in a given jurisdiction depends on the prevailing political philosophy. Traditionally, the UK, Canada and Australia have been shaped by the political philosophy of liberalism, where individual freedom is highly recognized. State intervention in public life is an exception that has to be justified. This has been one of the reasons for the limited role of the state in health professions regulation. However, currently, there is a general agreement that is reflected in WHO's argument that "the state has a duty of 'stewardship' in ensuring that its population has access to good quality health care."⁶³⁹ This idea has given legitimacy to the increasing role of the state in health professions regulation so as to safeguard the public interest.

The international move away from the traditional self-regulation of the health professions to an accommodation of greater state intervention and regulatory oversight should not,

⁶³⁷ Dubois *et al.*, *supra* note 253 at 188.

⁶³⁸ *Ibid.*

⁶³⁹ Healy, *supra* note 111 at xv.

however, be construed as a complete abandonment of self-regulation. Dubois et. al. note that,

[d]espite self-regulation's failure to ensure public protection, no reform has attempted to replace it entirely with alternative regulatory forms. The aim of the reforms has instead been to consolidate, complement or renew the prevailing professional and bureaucratic mechanisms.⁶⁴⁰

It is also hardly possible to make a universal argument that self-regulation is not a proper way for regulating health professions. The regulatory framework in each country depends on its peculiar history, culture, legal and governmental systems.⁶⁴¹ The differences in these variables have shaped the extent of state intervention and oversight over traditional self-regulation in the UK, Ontario, NSW, and other jurisdictions. However, despite these differences, there is a global trend and understanding that there are inherent problems relating to accountability, due process and trust in self-regulatory systems for health professions. As a result, health professions regulation in the last two decades has been heading towards greater state intervention and oversight over self-regulatory systems.

As explained in Chapter 2, the traditional approach to health professions regulation in Ethiopia was generally dysfunctional. In 2002, the health professions regulation system was modernized under the direction of the Ethiopian Health Professionals Council. The system incorporated elements of self-regulation operating under state bureaucracy. However, the regulatory system remained ineffective, except for the paper work of licensing and registering health professionals. The political system, during this period,

⁶⁴⁰ Dubois *et al.*, *supra* note 253 at 188.

⁶⁴¹ Healy, *supra* note 111 at 10.

gave the state a prominent role in directing the nation's social development. This philosophy, now reformulated under the developmental state rhetoric, continues to shape the reform of the regulatory system. The context of Ethiopia's political development legitimizes a greater social development role for the state, particularly in health professions regulation. The state should define health care priorities, and coordinate and mobilize its limited resources for application to the prioritized issues. The role of civil society should fit within the priorities of the state, and fill gaps the state is unable to address. The state's institutions should be strengthened for this task, as they are better organized than emerging civil society organizations to take the lead in this matter.

The ineffectiveness of self-regulation in other countries on the criteria of accountability, due process and trust should caution Ethiopia not to repeat their mistakes. When Ethiopia began to reform health professions regulation, it had to choose between self-regulation and statist regulation. That Ethiopia chose a statist approach is supported by the demerits of self-regulation in terms of accountability, due process and trust.

As discussed, the global trend seeks to balance greater state intervention and oversight with self-regulation. The trend is not to replace self-regulation with a statist approach. In sum, therefore, it may be said that Ethiopia should choose self-regulation for health professions regulation along with an adequate state intervention and oversight mechanism. This argument may consider my claim, which submits the global trend as an important lesson to Ethiopia not to go through self-regulation, as overstretched argument. A problem that can be fixed with adequate state intervention and oversight mechanisms,

does not provide grounds for centralizing health professions regulation under statist approach.

The response to this counter-argument is to locate the contribution of the global trend in relation to the main argument of this thesis. That argument recognizes that the international move towards greater state intervention and oversight does not imply regulatory control of the health professions by the state. But the international direction reinforces the main argument that the statist approach to health professions regulation is the proper framework for Ethiopia, in two respects. First, the global trend highlights the demerits of self-regulation, and, secondly, accentuates the greater role of the state in health professions regulation. These points are expanded below.

First, the global experience unequivocally proves that self-regulation of the health professions has shortcomings mainly in regard to accountability, due process and trust. This reinforces the conceptual analysis in Chapter 4 on the demerits of self-regulation as contextualized in practical country experiences. At a theoretical level, it has been earlier argued that private interest theories, utilizing economic and sociological perspectives, demonstrate that self-regulation tends inexorably to promote professional self-interest instead of protecting public interest. The global experience is evidence that shows the demerits of self-regulation validating these conceptual arguments.

The demerits of self-regulation do not mean that the statist approach is an automatic better option for Ethiopia. Rather, they offer the opportunity to demonstrate the merits of statist regulation in ensuring accountability, due process and trust in health professions regulation in Ethiopia. Chapter 4 presented these merits of statist regulation in Ethiopia.

First, that the state bureaucracy has a better institutional capacity and practice that can ensure accountability and adherence to due process principles than newly established self-regulatory bodies can do. And, the public demand for restoring trust calls for the state to intervene as well.

Secondly, the global experience shows that the state's role to safeguard the public interest is expressed through its intervention and oversight of the activities of the health professions' self-regulatory bodies. Traditionally, Ethiopian health professions regulation was built in the state bureaucracy but with strong elements of self-regulation. Reforming this system to make it effective naturally requires assigning more roles to the state. Alternatively, it requires introducing new professional regulatory bodies, that is, retaining a self-regulation model, but with an adequate and effective system of state oversight. As have shown in Chapter 3, adopting self-regulation in Ethiopia involves the significant cost of fragmentation and thinner spread of the limited health care resources. Statist regulation in Ethiopia would be more efficient than self-regulation.

Even so, institutionalizing such a system in Ethiopia requires proper safeguards to protect it against capture, and it also demands devising effective enforcement strategies. The global practice examined also provides some insights in this regard, and these are discussed below with application to Ethiopia.

ii. Ethiopian Health Professions Regulation: An Enforcement Strategy

Responsive regulation is an influential theory of regulatory enforcement that have gained wide acceptance. The Ethiopian reform also envisages a responsive regulation model for an enforcement strategy. The various jurisdictions studied in this Chapter show that soft

regulatory strategies, or persuasive and dialogue-based enforcement strategies, are well entrenched in medical regulation irrespective of the differences in the regulatory frameworks adopted by the various jurisdictions. These strategies are used within the fitness to practice process that emphasizes educative and remedial measures and limits disciplinary process to few cases of professional misconduct. There also many soft regulatory strategies outside of the fitness to practice process that promote compliance and quality improvement. These include promotion of ethical standards and guidelines, interactive CPD programs, and peer-review mechanisms. As such, the contribution of responsive regulation to shaping a regulatory framework and its enforcement strategy is, in these jurisdictions, characterized by emphasis on and proactive use of persuasive and dialogue-based strategies to achieve quality improvement in health care.

Common to all the jurisdictions is their utilization of soft regulatory strategies in their respective health professions regulation system. However, they differ strikingly as to the identity of the main actors that proactively use the strategies, as this depends on the regulatory framework of each jurisdiction. A responsive regulatory system that focuses on compliance and remedial measures requires the participation of multiple actors, particularly the professional bodies. In jurisdictions where the professional self-regulatory bodies are primarily in charge of the main regulatory functions, i.e., standard setting, licensing, relicensing, fitness to practice processes, the same bodies also proactively utilize soft regulatory measures. This is the common pattern in the UK, Ontario, and NSW. In contrast, in Finland and the Netherlands, the main regulatory functions, and the soft regulatory strategies, are primarily undertaken by the state, and the professional bodies, respectively. The professional bodies in Finland and the Netherlands

that proactively engage in regulatory activities by using soft regulatory strategies, are different from professional self-regulatory bodies in the UK, Ontario and NSW. In the former jurisdictions, they are voluntary professional or scientific associations or speciality societies, but in the latter, the professional self-regulatory bodies are statutory bodies. The professional bodies in Finland and Netherlands appear to jointly work with the state, and the health professions regulation in these countries appears to involve multiple actors and strategies.

This demonstrates the direct relation between persuasive and educational activities in medical regulation and the actors primarily engaged in the activities. This direct relationship does not apply to soft regulatory strategies utilized in the fitness to practice process. Generally, the fitness to practice process is undertaken by professional self-regulatory bodies in the UK, NSW and Ontario, and by the state in Finland and the Netherlands. In all these jurisdictions, the fitness to practice process involves educational and remedial measures, and also incorporates coercive measures for cases of professional misconduct. As such, it makes for a limited involvement for multiple actors in the regulatory system.

However, the direct relationship between persuasive and educational activities in medical regulation, and the actors primarily engaged in them, becomes evident in soft regulatory strategies outside of the fitness to practice process. Professional bodies and self-regulatory professional bodies are the major organs in charge of persuasive and educational activities outside of fitness to practice process. In the UK, NSW and Ontario, since the professional self-regulatory bodies have, historically, been responsible for the

main medical regulation activities, their engagement in persuasive, educational and remedial activities is not surprising. Their proactive engagement and utilization of the soft regulatory strategies fall within their broader statutory mandate of regulation. In contrast, in Finland and the Netherlands where the state has a strong direct role in medical regulation, the persuasive and educational activities are mainly undertaken by medical associations. This may be because the state lacks expertise and capacity to devise and implement soft regulatory strategies. This means that soft regulatory strategies outside of the fitness to practice process require the involvement of professional organizations. Chapter 4 showed that self-regulation makes a stronger claim on expertise than statist regulation does. Given that, responsive regulation assumes that the state has limited resources or capacity, the expectation is for it to use its limited resources to implement coercive measures. Consequently, it should ensure the mobilization of the resources of other actors to carry out the many regulatory activities at the base of the enforcement pyramid, *i.e.*, the use of soft regulatory strategies. This conceptual analysis appears to have been practically translated into the Finland and the Netherlands' medical regulation systems showing the involvement of state and non-state actors (professional bodies) using multiple regulatory strategies. The expertise and capacity of the medical associations appears to complement the deficits in the state's institutional capacities. Plurality of actors also reduces the state regulatory organs susceptibility to capture.

Thus, the major perspective that emerges from the comparative study of enforcement strategy is that the responsive regulation model that promotes the use of soft regulatory strategies or persuasive and educational activities, requires proactive participation by professional bodies. It was argued in Chapter 4 that adopting the responsive regulation

model in Ethiopia would mean that the state must use its limited resources to enforce coercive regulatory measures. It would also need to rely on the professional associations that, therefore, would strive to ensure that the soft regulatory measures promote quality improvement in health care so that the state would use its coercive regulatory powers only rarely. This theoretical discussion is reinforced by the practical evidence that shows statist regulation requires the proactive engagement of professional bodies in soft regulatory strategies. The Ethiopian statist health professions regulatory system should therefore devise mechanisms to proactively involve professional associations in promoting compliance with professional standards and quality improvement activities, and mobilize them to employ their expertise and capacity to improve quality in health care.

CHAPTER 6

CONCLUSION

This thesis examined the best system of regulatory power allocation between state and non-state actors for regulating health professions in Ethiopia. The power allocation should be made with view to establish an effective system that is capable of achieving the objectives of health professions regulation. Relevant literature including experiences of other countries has been explored, and their importance to the Ethiopian context is examined. The followings are the major findings of this investigation in relation to the notion of regulation, the preferred regulatory framework and enforcement strategy in health professions regulation in Ethiopia. All of these are interrelated issues that have an impact on allocation of regulatory power.

1. The Notion of Regulation

The reform of health professions regulation holds the promise to improve the quality of health care services and patient safety in Ethiopia. The reform seeks to achieve ambitious objectives as protection of patients from harm, and quality improvement in health care services delivery. As well, it seeks to accommodate the special health care needs of disadvantaged groups by ensuring the responsiveness of the regulatory system to the reorganization of health care delivery system to these groups.

But the regulatory functions that are designed to achieve these objectives are generally confined to standard setting, licensing and license renewal processes, inspection and disciplinary activities. All these functions are primarily being undertaken by EFMHACA or/and state regulatory organs.

In this sense, Seznick's classic definition of regulation as a "sustained and focused control exercised by a public agency over activities that are valued by a community," underlies the reform's conception of regulation. This definition narrowly conceives regulation and would not enable the reform to pursue its broad objective of improving quality and patient safety in health care.

Quality improvement requires a broader conception of regulation that recognizes the need for multiple strategies that must be implemented by multiple actors to bring behavioral modification in the complex health care system. Ethiopia's health professions regulation reform seeks to achieve a broad set of objectives within the confines of a narrow notion of regulation. Clearly, EFMHACA must resolve this contradiction by adopting of a broader notion of regulation that creates an enabling framework for the achievement of the objectives of the reform. In other words, regulation should be understood as a sustained and focused attempt to alter the behavior of health professionals according to defined standards or purposes with the intent to protect the public interest.

2. On the Regulatory Framework

In the Ethiopian health professions regulatory system, the issue of regulatory power allocation among different actors should be approached within the framework of this expanded notion of regulation. The government and health professional associations must share the broader objectives it offers. The debate on self-regulation vis-à-vis statist regulation should be undertaken on the basis of pragmatic considerations. In particular, the government's decision to adopt a statist regulatory regime should be seen beyond its ideological determination to lead the social development of the country. Even so, the

merits of the professional associations' claim for self-regulation must be critically examined. In sum, these associations offer expertise and legitimacy which the state bureaucracy lacks, but which it must benefit from through co-operation with the associations.

As argued, however, the statist approach to health professions regulation is the best regulatory framework for Ethiopia, in contrast to self-regulation. However, that the statist approach should devise its enforcement strategy on the basis of the responsive regulation model that focuses on soft strategies or persuasion and dialogue-based approaches. This requires the involvement of multiple actors.

Theoretically speaking, the inherent tension between public protection on the one hand and private interest protection under self-regulation, is a reason for Ethiopia not to adopt self-regulation as its regulatory framework. Capture theory argues that occupations use regulation to mainly advance their economic self-interests through a rhetoric of public interest protection. The two most common instances of the self-interest driven action of organized health professionals are their efforts to restrict entry to the practice, and their “turf” battles over scope of practice.

Self-regulation in Ethiopia may create a barrier to entry into health professions practice, as the self-regulating bodies would exercise control over admission to education and training. This would challenge the country's effort to turn out sufficient numbers of health professionals. In contrast, statist regulation would not create a barrier to recruiting more health professionals. The state regulatory organ is better positioned to ensure distributive justice in this matter – it would be more responsive to government strategies

such as its “flooding strategy” for the training of doctors and health officers with emergency surgical skills.

Also, self-regulation in Ethiopia may be utilized for expanding or protecting the health profession’s scope of practice with the goal to promote the profession’s status and to gain economic reward from it. Ethiopia does not have a comprehensive and clear scope of practice law for health professions. The most important guidance remains the conventional understanding of the profession’s responsibilities imparted and gained during professional training, such as in regard to medicine, pharmacy, nursing and midwifery practice. However, currently, health professions in Ethiopia are being diversified, and the training of the old professions has advanced, leading to the emergence of new health professions. For example, dental professionals are sharing the practice area of dentists; and ophthalmic professionals, and ophthalmic nurses practice share ophthalmologists’ scope of practice. Nurses who completed graduate studies are claiming more areas of practice, including some diagnosis and prescription roles, areas of practice conventionally reserved for doctors and health officers in Ethiopia.

Overall, this is a time of serious “turf” battles to establish the scope of practice for various health professions in the history of the Ethiopian health care system. It would be unwise to hand over a self-regulatory status to the professional bodies before a comprehensive and a clear scope of practice is produced that would best serve the public interest. Statist regulation would appear a better option for the time, as the state is a relatively disinterested arbiter positioned to resolve “turf” battles among different professions’ claims to broader scopes of practice. In sum, the capture theory argument

that self-regulation is basically driven by the economic self-interest of the health professions is a valid concern for Ethiopia, and necessitates that it opts for a statist regulatory regime by which it could better protect the public interest.

The influential theoretical literature from neo-Weberian sociologists suggests considering the promise of self-regulation with scepticism. These sociologists argue that professionalism promotes the self-interests of the profession rather than the protection of the public interest. Particularly, they show how medical professionalism has operated ideologically to ensure exclusive control over the practice in order to reap its economic and social benefits. The claim for self-regulation advanced by health professional associations in Ethiopia shows the collective solidarity of the professionals for greater autonomy. Once they gain that autonomy, they would embark on professional projects to ultimately control the practice of their respective professions and to reap the economic and social benefits that accrue from the control. Similar to the insights offered by capture theory, sociologists' perspectives also fundamentally challenge the public interest arguments advanced in support of the claim for self-regulation in Ethiopia. Both theoretical insights highlight the inherent conflict there is between the pursuit of the professions' interest, and their claim that they would protect the public under self-regulation arrangement in Ethiopia. The conflict reiterates that the state is better capable of ensuring protection for public interest as a relatively disinterested party.

Preference for statist regulation is reinforced by the strength that the statist approach displays, when compared to self-regulation, in light of 'good' regulation criteria. Compared to self-regulation, the statist approach offers more advantages in terms of

efficiency, ensuring accountability and due process, and restoring public trust in health professions regulation in Ethiopia. Traditionally self-regulation is assumed to be more efficient than regulation by the state as it externalizes the cost of regulation. Nonetheless, this may not necessarily be true, as the cost of approving standards and auditing the effectiveness of the system by the state may be considerable. Also, the high cost of licensing and relicensing that self-regulatory bodies would charge to finance their activities may be externalized by the regulated, and this would increase the cost of health care services. Above all, self-regulation in Ethiopia would not be efficient due to the higher cost of fragmentation that self-regulation could entail. Self-regulation would require the establishment of a new regulatory body for each health profession or cluster of health professions, and providing these bodies with start-up financial and logistic support. Eventually, the fragmentation may result in complex and inconsistent regulatory regimes. This, in turn, would necessitate harmonization, co-ordination and re-organization of the regimes and, thus, impose cost on society a second time.

The efficiency debate should also consider the challenges of limited capacity and commitment to health professions regulation in Ethiopia. Self-regulatory bodies may be able to attract and retain qualified professionals, as they could generate high revenue and have managerial flexibility. In contrast, the state regulatory organs have difficulty attracting and retaining qualified professionals, as their salary and benefit packages are generally low, compared to the private sector. However, the cost of starting-up and maintaining self-regulatory bodies may be high, and result in price increase in health care services. Moreover, the Ethiopian government's level of commitment to health professions regulation, in comparison to other top health sector priorities, is low, and

hence, allocated with limited resources. Establishing various self-regulatory bodies to be supported with the limited resources available for health professions regulation is hardly possible. It would also be an inefficient use of scarce resources to the detriment of other priorities of the health sector. Generally, there is limited capacity and commitment to health professions regulation. As such, it is better for state regulators to carry out the regulation with the available limited resources.

As to accountability, it is difficult to make a strong argument either in favor of self-regulation, or regulation by the state. Lack of accountability has been the major criticism against self-regulatory bodies. As well, regulation by the state faces the risk of capture and corruption in Ethiopia. Lack of accountability on the part of the self-regulatory bodies would call for state intervention and oversight. In any case, the state bears the ultimate responsibility to ensure accountability. And, the risk of capture and corruption of state regulatory organs can be mitigated by pluralizing the actors who participate in regulating the health professions. This means the involvement of health professional associations, higher education institutions and consumers associations to bring transparency in regulation, and to mitigate the risk of capture and corruption.

Regulation by the state bureaucracy could do better in restoring public trust in the health professions than self-regulation may do. It is said that trust is better developed in self-regulatory regimes by ensuring good communication between the patient and health professionals without external control. Though the empowerment of patients is important in health professions regulation, it is not sufficient to restore trust. Particularly in Ethiopia, patients are reluctant or unable to proactively participate in the implementation

of their treatment plans. Getting them to participate would also be inefficient, as the limited time the few doctors in the country have is better allocated equitably among the large number of patients they see. Reliance on self-regulation to restore trust extends the traditional argument that legitimizes self-regulation. Today, external control is introduced by many countries to assure patients that oversight mechanisms are being strengthened, and that quality improvement initiatives are being taken. In Ethiopia, the public and media apply pressure and call for state intervention to assure the public of the accountability of health professionals. That is why a statist approach would do better than self-regulation to assure trust in the health professionals in Ethiopia.

In terms of due process, statist regulation is the preferred option. The state better ensures adherence to natural justice principles. There is some improvement in public sector service delivery and practice of good governance in Ethiopia. This needs to be continuously improved, and not disrupted by the introduction of self-regulatory bodies. Self-regulatory bodies would be new organs in the public administration structure in Ethiopia, and they would need to internalize afresh the notion of natural justice in their operations. It should be noted that their performance in other countries is not exemplary enough in this area to merit experimenting in Ethiopia.

To ensure compliance with consultative democracy principles, the existing statist approach is doing well in ensuring the participation of stakeholders in legislative and standards development. The state has the political interest to ensure the participation of citizens in these efforts in every sector of national life. In contrast, the participatory process is uncommon notion in the working of non-governmental bodies because it falls

within the general political framework of good governance. Resort to consultative democracy by self-regulatory bodies would, inevitably, require a further level of discussion under state leadership to endorse the laws and standards these bodies propose. This process would also be an inefficient use of the limited resources of the state. In any case, the direct involvement of state officials and institutions in the consultation process helps to address concerns about regulatory capture. Overall, regulation by the state is an effective and efficient system for institutionalizing consultative decision making in Ethiopia.

As argued, the statist approach to regulation in Ethiopia is further supported by the global trend in health professions regulation in the last two or three decades. That trend has shown increasing state intervention and oversight over self-regulation. This trend is evident even in those jurisdictions where self-regulation was traditionally the norm - as shown in the significant reforms in the UK, NSW (Australia) and Ontario (Canada), and other countries. These reforms have been promoted, among other things, by the ineffectiveness of self-regulation as assessed on the basis of accountability, due process and trust. They are practical evidence that tells Ethiopia about the demerits of self-regulation. And, as shown, the statist system in Ethiopia would better ensure accountability, due process and trust in health professions regulation.

Indeed, although, the global trend in health professions regulation is towards greater state intervention and exercise of oversight over self-regulatory bodies, it does not show the total abandonment of self-regulation. However, it should be noted that the starting point in the jurisdictions where significant reforms of self-regulation have been introduced is

generally rooted in a belief in the limited role of the state in the health care system and professional regulation. Reforming such systems requires a changing attitude about the role of the state in health care delivery and health professions regulation. The global trend affirms that the state must be ready to act as the ultimate guardian of the public interest in health professions regulation. In Ethiopia where, health professions regulation has been undertaken within the state bureaucracy, albeit with strong elements of self-regulation, reforming such a system to ensure public interest protection implies assigning more roles to the state. This includes reforming the dysfunctional health professions regulation system under a statist regulatory framework.

However, the effectiveness of the statist approach to health professions regulation may be affected by lack of expertise, legitimacy, and risk of capture and corruption. Self-regulatory bodies possess expertise that is generally closer to the practice and the regulated professionals. These bodies also are respected and considered legitimate by the regulated professionals. In terms of accountability, the state regulatory organs have the risk of capture and corruption.

Meanwhile, these problems with statist regulation do not imply the choice of self-regulation as system for health professions regulation to Ethiopia. Rather, they require ways to make the statist regulation overcome these challenges. The state could draw expertise and legitimacy by increasing the involvement and ownership of health professionals associations in their respective professions regulation. The involvement of these non-state actors, and others would pluralize regulator actors in health professions regulation. In turn, this could mitigate the problem of capture and corruption that state

regulatory organs may encounter. The Ethiopian statist approach could pursue these measures through devising enforcement strategies rooted in responsive regulation theory.

3. On Enforcement Strategy

Ethiopia's health professions regulation reform adopts the responsive regulation model as an enforcement strategy, though it does not provide sufficient details on how to apply it. Also, EFMHACA has not produced a comprehensive and adequate enforcement strategy for health professions regulation. It is obvious that this agency should devise strategies for health professions regulation enforcement that elaborate its use of responsive regulation model.

Responsive regulation has become a common enforcement strategy for health professions regulation. This is because it recognizes the contribution of multiple regulatory actors, ensures observance of strong ethical norms and reflective practices of health professionals, and allows room for traditions of self-regulation. It answers the question: when to punish and when to persuade, and provides that enforcement should focus on persuasion and dialogue-based approach, and to resort to coercion only where soft measures fail to ensure compliance. It makes provision for the regulator's capacity to escalate upwards to measures such as license suspension and revocation. Responsive regulation theory is relevant in developing countries like Ethiopia that lack capacity, as it enables regulators to utilize the potentials of non-state actors to fill their capacity deficits.

To ensure improvement in the quality of health care services in Ethiopia, statist regulation that relies on standard setting, licensing and relicensing, inspection and disciplining of health professionals is not sufficient. These functions intervene in

professional autonomy and are coercive and reactive by nature. An effective regime that could achieve quality improvement should involve multiple actors wielding multiple regulatory instruments. In Ethiopia, the capacity of the government regulatory organs, *i.e.*, EFMHACA and state regulatory organs, is limited and should be utilized to carry out the coercive regulatory activities. The non-state actors, including health professional associations, higher education institutions and consumer associations, have more capacity and expertise than the state to implement soft regulatory strategies. They should be proactively engaged in persuasive and dialogue-based activities to improve health care quality. Particularly, health professional associations in Ethiopia can be leaders in implementing these soft regulatory strategies, as they have relevant experience and high interest in a less interventionist regulatory approach. The professional associations would be committed to strive to ensure their members' compliance with regulatory laws and standards to avoid coercive intervention by the state.

As discussed in Chapter 5, there is evidence that in countries that take a statist approach to health professions regulation, non-state actors, particularly health professional organizations, are proactively engaged in implementing soft regulatory strategies to improve quality of health care. In such a system, the utilization of such strategies requires the proactive involvement of professional bodies. Indeed, soft regulatory strategies outside of fitness to practice processes demand a direct relationship between implementation of strategies and the actors primarily engaged in the implementation. As shown, in the UK, NSW and Ontario, self-regulating professional bodies carry out both core regulatory functions (standard setting, licensing and fitness to practice) and soft regulatory strategies. In contrast, in Finland and the Netherlands, the state primarily

assumes the core regulatory functions, while professional bodies, such as medical association or speciality societies proactively implement soft regulatory strategies. In light of this practical necessity, it is recommended that the Ethiopian health professions regulatory framework must utilize the capacity, expertise and motivation of health professional associations by ensuring their proactive engagement in implementing soft regulatory strategies.

The foregoing general exploration of regulatory power allocation between state and non-state actors in Ethiopia leads to the conclusion that the state should carry out the core regulatory functions, while non-state actors, particularly health professional associations, should devise and implement soft regulatory strategies. The resulting system of health professions regulation could be demonstrated by Figure 3.4 below.⁶⁴²

At the bottom of the pyramid, market mechanisms that positively reinforce improvement in the practice of health professionals may be carried out by consumer associations and private health facility association. A health professional(s) initiative to improve quality in a given health facility may be encouraged and awarded. The publication of league tables by consumer associations or private health facility association could also motivate health care facilities to improve their standing, and consequently motivating their health professionals to provide ethical and competent services. The newly introduced health insurance system can also be aligned with the regulatory system to influence performance of health care facilities.

⁶⁴² The regulatory pyramid captures the main argument of the thesis. It is a modified version of Figure 3.3 above that presented the application of responsive regulation theory in Australian health care setting.

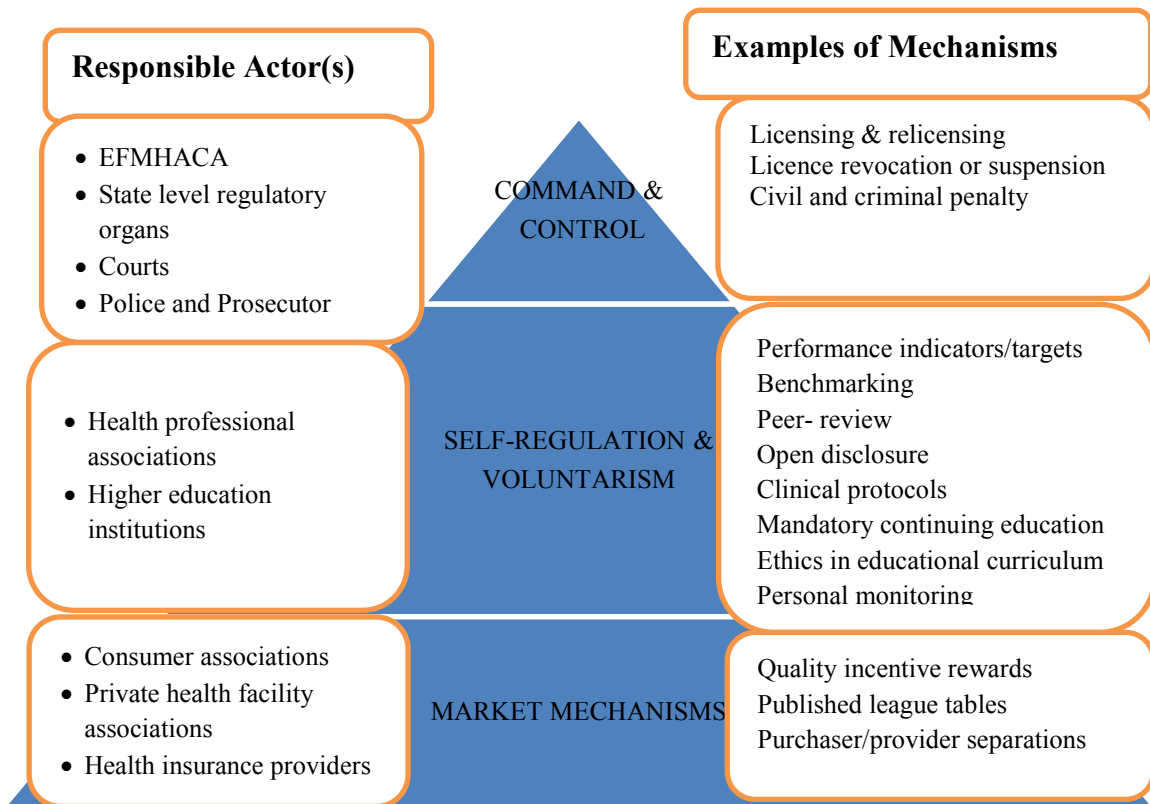


Figure 3.4 Regulatory pyramid for health professions in Ethiopia

The health professional associations and higher education institutions may implement a range of soft regulatory instruments. The associations could establish system of peer-review or produce clinical protocols with a view to improve health care quality. Higher education institutions could incorporate strong ethical education in their curriculum. These actors could implement mechanisms that encourage reflective practice by health professionals. They could also design and deliver effective CPD courses, the fulfillment of which is mandatory for professional license renewal. Generally, the non-state actors should assume more roles in carrying out soft regulatory strategies that could improve quality of health care services. This will enable the state to focus its regulatory resources to undertaking “hard” regulatory activities. This framework would create a platform for more constructive engagement by all parties towards the achievement of the common

goals of the regulation, *i.e.*, patient protection from harm and improvement in quality of health care.

A dialogue among state regulatory organs, professional associations, higher education institutions, consumer associations, and other important actors should be started. And, there should be an open discussion about the capacity and contribution of each actor in health professions regulation in Ethiopia. This thesis informs this dialogue by explaining the pros and cons of different alternative system of regulatory power allocation. It avoids misunderstanding and mistrust among the different actors. I believe the analysis of the theoretical and practical implications of the choice of statist regulatory framework over self-regulation could create a better understanding on the side of professional associations, and develop their trust on the new statist regulatory design. It would also enhance their cooperation with state regulatory organs. On the other hand, my emphasis on enforcement strategy that aspire responsive regulation ideals could create a better understanding on side of the state regulatory organs in acknowledging the elements of self-regulation that the new design should enhance. Particularly, the capacity of professional associations to innovate and implement soft regulatory strategies must be utilized to ensure the effectiveness of the new design.

The dialogue between the state and non-state actors will likely produce a memorandum of understanding that spell out specific responsibilities of each actor, and means of monitoring and evaluating its implementation. This thesis explores the responsibilities that multiple actors should play in regulation in general manner. It asserted that the state should carry out “hard” regulatory functions, while non-state actors should primarily

assume responsibility to implement soft regulatory strategies. Thus, further research is required to investigate specific and effective soft enforcement strategies that may be utilized in the Ethiopian health professions regulatory system. For example, the Peer Assessment Program in Ontario or the *visitatie* in the Netherland may be studied in detail to determine their value, and adoption to health professions regulation in Ethiopia. These specific issues could be dealt once an informed dialogue on regulatory power allocation is started between state and non-state actors. The major contribution of this thesis is therefore to enable informed dialogue centered on ensuring the effectiveness of the new regulatory design.

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