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Kennedy Institute of Ethics Journal, Volume 19, Number 1, March 2009, pp. 41-62 (Article)

Published by Johns Hopkins University Press
DOI: 10.1353/ken.0.0273

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ABSTRACT. In September 2007, the Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom concluded that "there is no fundamental reason to prevent cytoplasmic hybrid research . . . this area of research can, with caution and careful scrutiny, be permitted." Later, in January 2008, HFEA issued two research licenses to create humanesque cytoplasmic hybrid embryos from which stem cells could be derived. This article critically examines the public consultation process that preceded these decisions, concluding that the process was flawed and demonstrating how the HFEA documents summarizing the findings of the public consultation process misrepresent the public's contributions to this policymaking initiative.

For the past few years, governments, professional organizations, research funders, researchers, clinicians, and patients the world over have followed the debate on the ethics of cross-species stem cell research involving the mixing of human and nonhuman animal genetic material (Robert and Baylis 2003; Baylis and Robert 2006). Of late, however, there has been particular interest in the evolving policies and practices of the Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom. HFEA is the national regulatory body responsible for licensing fertility clinics and embryo research, and there is widespread interest in its policies and practices owing to its international reputation as a world leader in the regulation of human embryo research.

In November 2006, HFEA simultaneously received two research license applications to derive stem cells from embryos created by somatic cell

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Kennedy Institute of Ethics Journal Vol. 19, No. 1, 41–62 © 2009 by The Johns Hopkins University Press

nuclear transfer—i.e., cloning. A unique feature of these two applications—one from Newcastle University and the other from King's College London—was the plan to create the cloned embryos by inserting human nuclei into enucleated nonhuman animal eggs[1] thereby creating cytoplasmic hybrid embryos. A hybrid embryo is an embryo created using egg and sperm from two different species. A cytoplasmic hybrid embryo is an embryo created using an enucleated egg from one species and a nucleus from another species.

The research license application from Newcastle University was for a project to study embryonic development and to compare the stem cell lines derived from cytoplasmic hybrid embryos with those derived from human embryos created by *in vitro* fertilization. The application from King's College was for research to derive stem cell lines from cloned embryos created using human nuclei from patients with neurodegenerative disorders such as Alzheimer's and Parkinson's diseases and spinal muscular atrophy in order to better understand the molecular and cellular basis of these disorders and to develop therapeutic interventions.

To say the least, these applications raised a number of challenging questions for HFEA. The first of these questions concerned the scope of HFEA's authority to license human embryo research as the embryos to be created would contain nonhuman mitochondrial DNA (mtDNA). In January 2007, HFEA (2007f) ruled that the proposed research "would potentially fall with the remit of the HFEA to regulate and license and would not be prohibited by the legislation." And a few months later, in April 2007, HFEA confirmed that it did indeed have the legal authority to accept or reject these license applications. Relying on the decision in *R (Quintavalle) v. Secretary of State for Health* ((2003) UKHL 13), which defined a human embryo as "a live human organism containing within its cell or cells a full set of 46 chromosomes with the normal potential to develop," HFEA (2007b, p. 11) affirmed that since cytoplasmic hybrid embryos would contain a full human genome, they would fall under the regulatory remit of HFEA.

As research to create cytoplasmic hybrid embryos would be a new kind of research in the United Kingdom, HFEA (2007f) elected not to exercise its licensing authority without first undertaking "a full and proper public debate and consultation as to whether, in principle, licences for these sorts of research could be granted." Following 12 weeks of public consultation (26 April to 20 July 2007), during which time a scientific literature review and a scientific consultation also were undertaken, HFEA (2007a)

concluded in September 2007 "there is no fundamental reason to prevent cytoplasmic hybrid research . . . this area of research can, with caution and careful scrutiny, be permitted." Having made the "in principle" decision that the proposed research was a licensable activity, HFEA (2007a) instructed its research license committee to review the details of the individual license applications submitted the previous year. In January 2008, both license applications were approved (HFEA 2008a), and since then, in July 2008, a third research license has been issued to the University of Warwick.[2]

In this article, I argue that the HFEA public consultation process on the ethical and social implications of creating human/animal embryos in research (HFEA 2007b) was flawed. HFEA had a clear policy preference in support of part-human interspecies embryo research and it failed to provide the public with an impartial assessment of the policy options. Moreover, HFEA did not undertake the public consultation with the hope or expectation that the public would inform any final policy choice. The public consultation was not conducted in the mode of communicative action, where genuine dialogue and deliberation are the hoped-for modes of interaction. Instead, the consultation was rule-guided and strategic. With either of these consultation modes, the public can have an impact on policy design, but only to the extent that the public's views are shared by those responsible for the consultation.

The point of this article is not to argue that HFEA could not or should not have had preconceived ideas about the merits of cytoplasmic hybrid embryo research. Rather, the point is to highlight facts about the HFEA public consultation process that are problematic relative to the goal of informed, effective, and meaningful public consultation. As Julia Abelson and colleagues (2004a; see also, 2004b) report, meaningful public involvement in policy making requires:

- clear communication about the purpose of the consultation and its relationship to the larger decision-making process;
- identifiable links between the consultation and the decision outcome;
- information presented clearly, honestly, and with integrity;
- procedural rules that promote power and information sharing among and between participants and decision makers; and
- processes that are viewed as legitimate by citizens and decision makers.

As will be shown, only the first of these criteria was met by the HFEA consultation process.

TERMINOLOGY: *HUMANESQUE CYTOPLASMIC HYBRID EMBRYOS*

Having determined that cloned embryos created by inserting human nuclei into nonhuman animal eggs would be *human* embryos (because the nonhuman animal DNA would be nonnuclear DNA) (HFEA 2007b, p. 11), HFEA initially took great care to write about cytoplasmic hybrid embryos without ever using the adjective "human-animal" to draw attention to the nonhuman animal mtDNA. Indeed, although the title of the initial consultation document, *Hybrids and Chimeras: A Consultation on the Ethical and Social Implications of Creating Human/Animal Embryos in Research*, makes clear reference to the mixing of human and animal material, and although there are references to human/animal embryos in the consultation document, there is no mention of "human/animal cytoplasmic hybrid embryos." This is problematic insofar as the definition of cytoplasmic hybrid embryos provided therein is at best incomplete. HFEA defines cytoplasmic hybrid embryos as "embryos which are created through cell nuclear replacement using animal eggs" (HFEA 2007b, p. 10). As noted previously, however, cytoplasmic hybrid embryos are embryos created using an enucleated egg from one species and a nucleus from another species. In strict terms, therefore, cytoplasmic hybrid embryos could be created without using human genetic material—e.g., rabbit-monkey cytoplasmic hybrid embryos—and if human genetic material were used it could be mtDNA or nuclear DNA.

In sharp contrast, in the post-consultation document, *Hybrids and Chimeras: A Report on the Findings of the Consultation*, HFEA defines cytoplasmic hybrid embryos as, "[e]mbryos created by removing the nucleus of an animal egg and inserting the nucleus of an adult cell from a different individual (and possibly of a different species)" (HFEA 2007d, p. 22). In this document, HFEA recognizes that there can be many types of interspecies cytoplasmic hybrid embryos. Moreover, HFEA does not avoid the use of relevant adjectives such as human-animal, human-rabbit, and human-cow in describing various types of interspecies cytoplasmic hybrid embryos.

In this article, as I have done elsewhere (see Baylis 2008), I write about *humanesque cytoplasmic hybrid embryos* instead of human-animal cytoplasmic hybrid embryos.[3] In my view, this description better captures the (perhaps unwarranted) intuition that part-human part-nonhuman animal embryos, where the nonhuman animal contribution is mtDNA, are essentially human-like—i.e., human-esque. I do not use the term "human admixed embryos," now entrenched in legislation in the United Kingdom,

as this term captures many different kinds of human and nonhuman animal combinations.[4]

HFEA'S PUBLIC CONSULTATION PROCESS

Contemporary rhetoric has it that public policy consultations typically are undertaken with a view to increasing the democratic legitimacy of policy choices. With modern governance, gone are the days of elitist policymaking based solely on the advice of policy experts and expert organizations—i.e., interest groups with complimentary expertise. Expert advice must now be carefully balanced with input from citizens. As Eric Montpetit (2003, p. 97) has observed, to the extent that policymakers

> adhere to the governance discourse, [they] are likely to consider insufficient any policy . . . designed by a narrow group of experts and treat as a failure any consultation that does not add up to embracing the views of a vast public. Clearly, the idea of governance presses for a shift from output-oriented legitimacy to input-oriented legitimacy.

Output-oriented legitimacy, according to Montpetit (2003, p. 97), "is conferred onto public policies to the extent that they are viewed as enhancing the public good, independently of who has conceived them. To obtain such policies, policymakers have traditionally relied on experts." Conversely, "[i]nput-oriented legitimacy . . . depends on the extensiveness and intensiveness of public participation in the making of policy. Legitimacy here is conferred upon policies when a large public feels it has been consulted and heard" (Montpetit 2003, p. 97).

The most engaging mode of public consultation is that of communicative action where those who are responsible for the consultation see it as an opportunity to engage in genuine problem solving. Here, the initial policy preferences of those responsible for the public consultation, and those consulted, are both subject to challenge in pursuit of the best policy option. This problem-solving mode of consultation is a rare occurrence however, largely because it requires a commitment to genuine discourse and a willingness to set aside policy preferences. In many (most) instances, this is either not feasible or not desired. More common modes of public consultation are rule-guided consultation and strategic consultation (Montpetit 2003). With rule-guided consultation, the goal is to satisfy political obligations; for example, the obligation to increase the input-oriented legitimacy of policies that will be promulgated. Depending upon the fit between the preferences of those who undertake the consultation and the public that is consulted, this mode of public consultation may or may not

have an impact on the original policy intent and orientation. Alternatively, with strategic consultation, the persons responsible for policy design have clear policy preferences for which they are seeking input-oriented legitimacy. The goal of this type of public consultation is to communicate policy preferences and persuade those who are consulted to support the preferred policy option. HFEA's consultation on the ethical and social implications of creating human/animal embryos in research includes elements of both rule-guided and strategic consultation.

First, HFEA's consultation is rule-guided insofar as it was clearly undertaken to satisfy legal (and political) obligations. The minutes for the 10 January 2007 HFEA meeting suggest a general reluctance to proceed with public consultation. For example, some HFEA members worried that although conducting a public consultation might be fair to the opponents of such research, it might be unfair to the applicants. In response to this concern, legal counsel explained "that fairness requires consultation" (HFEA 2007e, p. 13), and that "[a] policy decision now [i.e., prior to consultation] would leave the HFEA open to legal challenge on the basis that full and proper consultation of the public and scientific view had not taken place" (HFEA 2007e, p. 10). At this same meeting, in response to a question about the shortest possible time frame for such a consultation, HFEA learned that general Government guidance was 12 to 14 weeks. And, in answer to a question about "what weight that consultation would have in policy making," HFEA was told that "a consultation has to be undertaken before a decision is made. The decision must take into account responses to the consultation, but does not have to follow the majority view" (HFEA 2007e, p. 10). On the basis of the information provided, HFEA elected to proceed with the minimum consultation period that hopefully would insulate HFEA from legal challenge—i.e., 12 weeks. And, in the public consultation document, HFEA explained that although it was interested in public opinion, it was not committed to acting in concert with that opinion. The consultation was not a referendum, and the final policy choice would be made by HFEA, not by majority opinion.

> Through this consultation, we want to hear the views of members of the public as well as those with special interests in this research and its potential outcomes. . . . However, it is important to remember that this is not a referendum. We will not be counting "votes" for or against any particular type of hybrid or chimera embryo research. Instead, we want to understand why people feel worried or enthusiastic about this research in order to help us make a judgement about the best way to proceed. (HFEA 2007b, p. 4)

In this way, HFEA provided "clear communication about the purpose of the consultation and its relationship to the larger decision-making process," as required by Abelson and colleagues' (2004a) first criterion for informed, effective, and meaningful consultation.

Second, HFEA's consultation is strategic insofar as HFEA had a clear policy preference in support of research involving the creation of part-human interspecies embryos, and it sought to communicate this preference to those who were consulted. Indeed, in many respects, the HFEA consultation process can be seen as an exercise in strategic public relations, in which an organization strategically develops communication programs for publics "that provide the greatest threats to and opportunities for the organization" (Grunig 1990, p. 18). According to James Grunig (1990), a noted public relations academic and author, the aim of strategic public relations is to enhance organizational autonomy by carefully designing communications for (1) publics that might limit the organization's ability to pursue its goals, and (2) publics that can be mobilized to support the organization's goals.

One effective model of strategic public relations involves asymmetrical communication. With this type of communication the objective is "to change the ideas, attitudes and behaviors of publics but not those of the organization" (Grunig 1990, p. 21). The presumption with asymmetrical communication is that the organization knows best—i.e., the leaders of the organization have more knowledge than members of the public—and the goal is to persuade—i.e., "to bring the public's point of view in line with that of the organization" (Childers 1989, p. 87). Of note, asymmetrical communication can involve two-way communication as when research—e.g., attitude surveys, focus groups, media content analyses, opinion leader reports—is conducted "to determine the messages most likely to affect publics but not to determine how the organization can change to accommodate the interests of its publics" (Grunig 1990, p. 21).

Asymmetrical communication contrasts markedly with symmetrical communication, where there is an attempt "to reach a compromise between the interests of the organization and its publics [and where] . . . change is likely in the ideas, attitudes, and behaviors of both" (Grunig 1990, p. 21). Symmetrical communication aims to facilitate negotiation and compromise. Understanding, informed debate, and agreement are the hallmarks of successful symmetrical communication. Following Grunig, "symmetrical public relations is more ethically and socially responsible than asymmetrical public relations because it manages conflict rather than wages war" (Grunig 1990, pp. 20–21).

HFEA'S POLICY PREFERENCE

The nature and scope of HFEA's policy preference for cytoplasmic hybrid embryo research is examined below with reference to the following documents: (1) HFEA's November 2005 response to the United Kingdom government review of the Human Fertilisation and Embryology Act (HFEA 2005b); (2) the April 2007 HFEA consultation document *Hybrids and Chimeras: A Consultation on the Ethical and Social Implications of Creating Human/Animal Embryos in Research* (hereafter *Hybrids and Chimeras: A Consultation*) (HFEA 2007a); (3) the two HFEA reports on the findings of the consultation—the September 2007 HFEA Authority Paper, *Hybrids and Chimeras: Findings of the Consultation*, distributed to HFEA members to assist them in their decision making (HFEA 2007c), and the October 2007 HFEA public report *Hybrids and Chimeras: A Report on the Findings of the Consultation* (HFEA 2007d); and (4) the January 2008 minutes of the HFEA research license committee meeting at which the decision to issue the first two licenses for humanesque cytoplasmic hybrid embryo research was made (HFEA 2008b).

November 2005

In August 2005, the United Kingdom Department of Health initiated a consultation on the Review of the Human Fertilisation and Embryology Act 1990. In November of the same year, HFEA issued a formal response to the Department of Health consultation. In answer to the question about creating human/animal hybrid or chimera embryos for research purposes, HFEA (2005b, p. 39) offered the following measured comments:

> The creation of human-animal hybrids is permitted until the two cell stage under the current Act and the HFEA considers that research within the constraints outlined by the Government should be permitted.
>
> As long as it can be ensured that such entities would never be implanted into a woman or allowed to develop beyond the 14 day stage, and as long as the research would fall under current research purposes, it could be argued that the ethical justification for the creation of such entities is consistent with research as it is currently allowed.
>
> Nevertheless, we recommend that the Government has proper consideration to the diversity of views on this issue. The HFEA would recommend that hybrids and chimeras are defined in the new Act.

In more general terms, HFEA (2005a, p. 3) described its response to the various proposals on the regulation of embryo research in the following way:

> Our response takes the view that the legislative framework should be broadly permissive of research on human embryos on the condition that this remains within the 14 day limit. We are, however, very aware that public opinion remains cautious and divided over the ethics of human embryo research.

On the basis of the 2005 Department of Health consultation, which held the general view that hybrid and chimera research should be prohibited, the United Kingdom government issued a White Paper in 2006 in which it proposed a ban on the creation of hybrid and chimera embryos. It also proposed, however, that under certain circumstances—in accordance with the regulations and a license—it would be possible to create hybrid and chimera embryos *in vitro* for research purposes.

Shortly thereafter, in a move that could be perceived as incompatible with the government's proposed legislation, HFEA decided in January 2007 to initiate its own public consultation on the ethical and social implications of creating human/animal embryos in research. At this same time, HFEA decided that it would be important to "issue a statement acknowledging the previous view of the Authority" (HFEA 2007e, p. 14). This statement can be found in HFEA's April 2007 document *Hybrids and Chimeras: A Consultation*, in which HFEA's original response to the Department of Health's 2005 consultation is described as follows: "the HFEA recommended that the current law, which permits the creation of hybrids only for very limited purposes, should be extended so that hybrid embryos can be created for the same research purposes as other embryos" (HFEA 2007b, p. 13).

Now, if one compares HFEA's original 2005 contributions to the Department of Health consultation (as previously cited) with this clear 2007 statement in support of research involving the creation of hybrid embryos, HFEA's restatement of its position might seem like revisionist history. It is also plausible, however, to interpret the restatement as an effort at both transparency and persuasion. Here, HFEA makes transparent the implications of its 2005 statement "that the legislative framework should be broadly permissive of research on human embryos on the condition that this remains within the 14 day limit" (HFEA 2005a, p. 3) in the hope that others will support its policy preference.

April 2007

The HFEA claim—in its April 2007 document *Hybrids and Chimeras: A Consultation*—to have previously called for an extension of the Human Fertilisation and Embryology Act in order to permit the creation of hybrid embryos "for the same research purposes as other embryos" (HFEA 2007b, p. 13) is strong evidence of a policy preference in support of a permissive legislative framework for human/animal embryo research. But there is more. Additional evidence of this policy preference can be found in the way information is presented in the consultation document. Of particular interest are: (1) the exclusive use of pull quotes that are favorable to the research enterprise; (2) the unusual reverse ordering of information "against" and "for" research involving the creation of human/animal embryos, and more specifically the creation of humanesque cytoplasmic hybrid embryos; and (3) efforts to undercut arguments "'against" human/animal embryo research, and more particularly humanesque cytoplasmic hybrid embryo research, while arguments "for" such research remain unchallenged.

Pull Quotes

Pull quotes are graphically emphasized quotations run in larger type than the rest of the text or set off in background boxes. From a design perspective, pull quotes catch the reader's eye and direct his/her attention to specific information. From a content perspective, pull quotes help "readers efficiently process and recall information" (Gibson, Hester, and Stewart 2001, p. 77).

There are three pull quotes in the HFEA document *Hybrids and Chimeras: A Consultation*:

> We don't want to hold research up unnecessarily. On the contrary, we want research to prosper. But it can only do so in an environment of public support and trust, something which has a long tradition in the UK. (HFEA 2007b, p. 4)

> Research teams around the world are now using stem cells from human embryos in research to develop their understanding of a number of different diseases. (HFEA 2007b, p. 5)

> The HFEA has a dedicated research licence committee which decides, on the basis of the legislation, whether applications for licences should be accepted or rejected. (HFEA 2007b, p. 11)

These pull quotes place particular emphasis on the importance of: (1) encouraging a dynamic research environment; (2) being part of the international embryonic stem cell research community; and (3) moving forward with confidence knowing that there is a sound regulatory system in place as well as proper oversight for embryo research.

Given what is known about the effectiveness of pull quotes in directing readers' attention and in improving their processing and recall of information, it is reasonable to believe that readers of the HFEA consultation document will have noticed the information in the pull quotes and may even have perceived HFEA's partiality for embryonic stem cell research. But is it also reasonable to believe that readers will have been influenced by the information in the pull quotes? Yes. Recent research confirms that information presented in pull quotes can influence readers' understanding, perceptions, and judgments. Gibson, Hester and Stewart (2001, pp. 77, 76, respectively) show that it is "comparatively easy to influence individuals' perceptions of social reality through the use of extracted quotation" and more particularly that " . . . partiality in extracted quotations will lead to relatively higher levels of support for the position advocated in the extracted quotations." Although the information in the pull quotes is not specifically supportive of interspecies embryo research, it is specifically supportive of embryonic stem cell research and elsewhere in the consultation document the link is made between interspecies embryo research and the future success of embryonic stem cell research.

Arguments "Against" and "For"

Although the HFEA public consultation document is described by HFEA as a document that "explained some of the social and ethical arguments *for and against* the research" (HFEA 2007d, p. 7, emphasis added), the information in the document does not follow the presentation format suggested by the familiar locution "for and against." Instead, brief summaries of arguments "against" human/animal embryo research and humanesque cytoplasmic hybrid embryo research precede equally brief summaries of arguments "for" such research. This unusual ordering serves the goal of promoting the HFEA's policy preference in support of humanesque cytoplasmic hybrid embryo research insofar as the arguments for interspecies research are conspicuous (and easier to recall) by virtue of their placement. Indeed, the invitation to complete the HFEA online questionnaire on the creation of different types of hybrids and chimeras follows immediately on the discussion of "Arguments *for* the creation of human/animal embryos"

and "Arguments *for* the creation of [humanesque] cytoplasmic hybrid embryos" (HFEA 2007b, p. 16, emphasis added).

The first argument presented in support of research involving the creation of humanesque cytoplasmic hybrid embryos suggests that it is more ethical to source eggs for stem cell research from nonhuman animals than from humans. This argument rests on the following claims: there is a limited supply of human eggs for cloning research; there are significant harms to women associated with hormonal stimulation and surgical egg retrieval; and the eggs collected from women for stem cell research are likely to be wasted given the high inefficiency of cloning technology. The benefit of humanesque cytoplasmic hybrid embryo research—assuming the research findings are transposable across species—is that it will allow scientists interested in deriving stem cell lines from cloned embryos to improve the technical efficiency of cloning using animal eggs, so that in future a smaller number of human eggs will be needed to generate cloned hES cells.

A second argument in support of the proposed interspecies cytoplasmic hybrid research holds that, "There is no moral difference between [humanesque] cytoplasmic hybrid embryos and normal CNR [i.e., cloned] embryos (made with human eggs); the creation of any human/animal embryo is acceptable as long as the embryo is never transferred to a woman; and the potential research benefits outweigh any ethical concerns" (HFEA 2007b, p. 17). This argument insists on the moral equivalence of cloned embryos irrespective of whether human or animal eggs are used. On this view, the animal mtDNA in humanesque cytoplasmic hybrid embryos is inconsequential; the resulting embryos are essentially human embryos.

The last section of the HFEA consultation document summarizes the more general arguments for the creation of human/animal embryos. The principal argument in support of this research is a straightforward utilitarian argument according to which the research is ethically acceptable when "the potential research benefits outweigh any ethical concerns" (HFEA 2007b, p. 16). In general terms, this is presumed to be the case for all human/animal embryo research aimed at benefiting human health, provided the part-human interspecies embryos are never put into women. Potential scientific and medical benefits of cloning research—using human or animal eggs—include a better understanding of human disease, a better understanding of the mechanisms involved in reprogramming DNA to its pluripotent state, as well as a better understanding of mitochondrial disease and of the interaction between mitochondria and the nucleus.

Additional potential benefits of cloning-based hES cell research include: the development of disease specific embryonic stem cell lines to screen for new drugs and the development of cell-based therapies.

In summary, the last words from HFEA before the reader is invited to complete the online questionnaire are that:

- Human eggs should not be used in CNR research because it is inefficient
- There is no moral difference between cytoplasmic hybrid embryos and normal CNR embryos (made with human eggs)
- The creation of any human/animal embryo is acceptable as long as the embryo is never transferred to a woman
- The potential research benefits outweigh any ethical concerns. (HFEA 2007b, p. 17)

Counterpoints

Further evidence of partiality on the part of HFEA can be seen in the efforts it made to dismiss or undermine some of the arguments "against" the creation of part-human interspecies embryos. Indeed, before moving on to present arguments "for" the creation of human/animal embryos and humanesque cytoplasmic hybrid embryos—which are presented without being challenged—HFEA attempts to rebut several of the arguments "against" such research. Consider, for example, the argument about the "wisdom of repugnance." On this view, the creation of human/animal embryos is instinctively repugnant. This instinctive revulsion is an important moral intuition that should not be ignored. In dismissing this concern, HFEA indicates that "because this sentiment is based upon an instinctive reaction to something, it is very difficult to characterise or, more importantly, to engage with in discussion" (HFEA 2007b, p. 14).

Additional arguments "against" research involving the creation of human/animal embryos underline the worry that such research will put us on a slippery slope to a number of undesirable activities. One such argument highlights the risk that human/animal embryos will be put into women to create "babies with some animal DNA in them." Another slippery slope argument concerns the risk that cytoplasmic hybrid embryo research will lead to other ethically objectionable human/animal research—such as research to create human/animal hybrid embryos or human chimera embryos. As well, there is the worry that: (1) if HFEA accepts the creation of humanesque cytoplasmic hybrid embryos, then it is logically committed to

allowing the creation of other types of part-human interspecies embryos; and (2) if HFEA accepts humanesque cytoplasmic hybrid embryo research to overcome the shortage of human eggs for research, then it is logically committed to allowing other types of controversial research for the same reason. In response to these slippery slope arguments HFEA insists that,

> No scientist or clinician has ever expressed a desire to create a hybrid or chimera baby. However, even if anyone did wish to do so, they would be committing a criminal offence if they transferred either a hybrid embryo (created by mixing human and animal gametes) or a [humanesque] cytoplasmic hybrid embryo (created through CNR using animal eggs) to a woman . . . . (HFEA 2007b, p. 12)

> No scientist has ever expressed an interest in transferring [humanesque cytoplasmic hybrid] embryos in the hope that a baby, if that were medically possible, would develop. Even if they did, it would be a criminal offence to do so. . . . Similarly, a concern that research creating [humanesque] cytoplasmic hybrid embryos might lead to research creating human chimera embryos could beaddressed by banning the creation of human chimeras in the legislation. (HFEA 2007b, p. 15)

In very general terms, these are dismissive responses (Baylis forthcoming 2009). The message from HFEA is that nobody has ever expressed a desire/interest in creating and transferring part-human hybrid or chimera embryos, or humanesque cytoplasmic hybrid embryos, to a woman. If such embryos were transferred to a woman, they probably would not develop into a baby. In any case, in most instances the imagined activity would be illegal and, if not illegal at the present time, it could be made illegal. On this view, there is no slippery slope, or if there is one, then it could be prevented by legislation.

In addition to the foregoing arguments "against" interspecies embryo research, there is a further argument concerning animal welfare. In response to this concern, HFEA first insists that the use of animals in research is beyond the scope of the consultation (HFEA 2007b, p. 15). Later, however, HFEA points out that for some people at least "obtaining eggs from animals is ethically more acceptable than obtaining them from humans because of the risks, though small, of egg donation to the women who undergo it" (HFEA 2007b, p. 16).

In summary, the HFEA document *Hybrids and Chimeras: A Consultation* outlines some of the arguments "against" human/animal embryo research, and more particularly humanesque cytoplasmic hybrid embryo research. However, none of the arguments presented are given their stron-

gest formulation, and, moreover, some of the arguments are specifically undermined by HFEA. Add to this the exclusive use of pull quotes that are favorable to the research enterprise, and the unusual ordering of the arguments "against" and "for" interspecies embryo research and it is reasonable to conclude that the background information provided to the public may not have been "presented clearly, honestly, and with integrity"—the third criterion identified by Abelson and colleagues (2004a) for informed, effective, and meaningful public involvement in policymaking.

September and October 2007

Support for the creation of part-human interspecies embryos for research purposes is not only evident in the HFEA consultation document, but also in the findings of the consultation as reported by HFEA. Evidence of bias can be found in: (1) the privileged reporting of findings that are consonant with HFEA's preferred policy option, and (2) the lack of concordance between the HFEA conclusion regarding the findings of the public consultation and the data actually generated by the consultation.

Four different consultation mechanisms were used by HFEA in its public consultation exercise: (1) an HFEA document *Hybrids and Chimeras: A Consultation* with an online questionnaire (HFEA 2007b); (2) deliberative work in group meetings held in different cities; (3) an opinion poll involving 2,000 residents of Great Britain and 60 residents of Northern Ireland; and (4) a public meeting using electronic voting. Not surprisingly, the different consultation mechanisms generated somewhat different findings. HFEA reports on the findings of each of these consultation mechanisms, but emphasizes the findings of the deliberative work:

> at the outset . . . many of the participants expressed an initial repugnance in reaction to the suggestion of mixing human and animal material. Associations were drawn with incidents such as the Northwick Park drug trials, myths and legends, and the elephant man. However, when further factual information was provided and further discussion took place, the majority of participants became more at ease with the idea, although as one participant observed, "The gut reaction is hard to overcome." (HFEA 2007c, p. 10; 2007d, p. 11)

A plausible explanation for the privileged reporting of the findings of the deliberative work—ultimately based on the views of 44 participants—is that only these findings potentially accord with the HFEA conclusion "that public opinion is very finely divided with people generally opposed to this research unless it is tightly regulated and likely to lead to scientific

or medical advancements" (HFEA 2007a; 2007d, p. 21). Indeed, the deliberative work suggests that although a gut reaction against humanesque cytoplasmic hybrid embryo research is hard to overcome, it is not impossible; a majority can be made "more at ease with the idea" of this type of research. Meanwhile, the bulk of the available data belies the HFEA conclusion "that public opinion is very finely divided." Participants in the online questionnaire were asked: "Do you think that the HFEA should issue licences to allow research using [humanesque] cytoplasmic embryos?" Of the 736 individuals who responded, 494 responded "no," and 129 responded "yes;" the rest were unsure or did not respond (HFEA 2007d, p. 65). If one does the math, 67 percent said "no" to research using humanesque cytoplasmic hybrid embryos, while only 17.5 percent said "yes." With the public opinion poll, HFEA (2007d, p. 78) reports that "Just over a third of people agree with scientists creating an embryo which contains mostly human with a small amount of animal genetic material purely for research (35%); just under half disagree (48%)." And finally, at the public meeting, in response to the question "Is using animal eggs to create embryos an acceptable alternative to using human eggs?" 39 percent said "yes," while 47 percent said "no" (HFEA 2007d, p. 88).

As such, the data from three of the four consultation mechanisms showed 67 percent, 48 percent, and 47 percent "against" humanesque cytoplasmic hybrid embryo research, compared with 17.5 percent, 35 percent, and 39 percent "for" such research. (There are no percentages reported for the deliberative work.) These numbers are hardly consonant with the HFEA claim "that public opinion is very finely divided." Rather, these numbers are more in-line with the United Kingdom Department of Health finding from consultations conducted in 2005 and 2006 that "there is *considerable public unease* with the possible creation of embryos combining human and animal material, and particularly to the prospect that such entities could be brought to term" (Department of Health 2006, p. 24, emphasis added). Moreover, the data from the HFEA public consultation do not fit well with the HFEA claim that "[w]e have gained a valuable insight into public opinion as a result of this consultation and this has enabled us to make a policy decision based on robust evidence" (HFEA 2007c, p. 2). These claims notwithstanding, there would appear to be no "identifiable links between the consultation and the decision outcome"—the second criterion for informed, effective, and meaningful public involvement in policymaking identified by Abelson and colleagues (2004a). The robust evidence, such as it is, is against the creation of humanesque cytoplasmic

hybrid embryos for research, yet this is the policy choice that HFEA endorses following the public consultation initiative. Furthermore, failure to accurately report public opinions, values, concerns, and priorities also would be inconsistent with the fourth criterion for informed, effective, and meaningful public involvement in policymaking, namely that there be "procedural rules that promote power and information sharing among and between participants and decision makers" (Abelson et al. 2004a). Instead, with this public consultation there is evidence of a robust policy preference in support of humanesque cytoplasmic hybrid embryo research—a preference that ultimately proved unshakable in the face of significant public opposition.

With respect to the fifth and final criterion for informed, effective, and meaningful public involvement in policymaking, namely that there be "processes that are viewed as legitimate by citizens and decision makers" (Abelson 2004a), there is reason to laud the range of consultation instruments used by HFEA to facilitate public involvement, including an online questionnaire, focus groups, opinion polling, and traditional public meetings. But, as Montpetit (2003, p. 96) notes "devising innovative instruments might not suffice to achieve successful public consultations." It is not so much the range of instruments that matters, but the orientation of the consultation. That is, what matters is HFEA's preference for rule-guided and strategic public consultation over communicative action.

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Following the September 2007 decision that humanesque cytoplasmic hybrid embryo research was a licensable activity, HFEA instructed its research license committee to review the two license applications submitted the previous year. In November 2007, while the review process was underway, two independent research teams—one led by Shinya Yamanaka and another led by James Thomson—simultaneously reported (online) the successful reprogramming of human somatic nuclei to create human induced pluripotent stem (iPS) cells (Takahashi et al. 2007; Yu et al. 2007). Arguably, this success in creating patient-specific pluripotent stem cells without creating and destroying cloned human embryos suggested that the proposed humanesque cytoplasmic hybrid embryo research might no longer be "necessary and desirable in both scientific and ethical terms" (HFEA 2007a). The HFEA research license committee discussed the relevance of the iPS cell research at its 28 November 2007 and 9 January 2008 meetings and ultimately decided that although "the emergence of

new technologies for the reprogramming of adult somatic cells . . . [is] very promising, these new technologies do not obviate the need for the basic research into differentiation of pluripotential embryonic stem cells" (HFEA 2008b). On this reasoning, in January 2008, the HFEA research license committee granted the first two research licenses permitting the creation of humanesque cytoplasmic hybrid embryos.

Meanwhile, some stem cell scientists remain less sanguine about the purported benefits of this research for the development of stem cell therapies. Consider, for example, the following excerpt from a public letter penned by stem cell scientists from around the world in their efforts to contribute to the debate in the United Kingdom about the Human Fertilisation and Embryology Bill. The text below was published in *The Times* (16 May 2008) and cited in debate in the United Kingdom House of Lords (19 May 2008):

> . . . given the current state of more conventional embryonic stem-cell research, of adult stem-cell research and induced pluripotent stem-cell research, there is no demonstrable scientific or medical case for insisting on creating, without any clear scientific precedent, a wide spectrum of human-non-human hybrid entities or "human admixed embryos.". . . As scientists and clinicians actively involved in stem-cell research and regenerative medicine, we do not hold a single common view about the relative merits, ethics and potential of adult v (conventional) embryonic stem cells. But we all believe that extravagant claims regarding the purported merits of human-non-human interspecies embryos are mistaken and misleading, and that such research would damage public confidence and support, to the detriment both of the cause of stem-cell science and, ultimately, of patients. (Scolding et al. 2008; House of Commons 2008)

CONCLUSION

HFEA has long supported a permissive legislative framework for human embryo research—all such research should proceed on condition that the purpose of the research is legally permitted and the research is limited to 14 days. Moreover, since 2005, HFEA arguably also has supported part-human interspecies embryo research with the additional caveat that such embryos never be transferred to a woman.

From this standpoint it is not surprising that HFEA would have been reluctant to undertake a public consultation on the ethical and social implications of creating human/animal embryos in research. As detailed above, HFEA did not perceive a need for advice from the general public

and, indeed, was more worried about delayed decision making than soliciting public opinion. HFEA undertook the public consultation not for the purpose of soliciting information about public opinions, values, concerns and priorities, but in order to insulate itself from a future legal challenge. This accounts for the decision to limit the public consultation process to the minimum 12-week period and to make it clear from the outset that the policy decision would not be constrained by majority opinion. In addition, the timing of the HFEA public consultation—i.e., following on the heels of the Department of Health consultations—and the effort to change (more than to solicit) public opinions, values, concerns, and priorities, points to the strategic nature of the HFEA initiative. The problem with all of this is that it hardly amounts to a legitimate effort at informed, effective, and meaningful public consultation.

It follows that although HFEA's rule-guided and strategic modes of public consultation on the ethical and social implications of creating human/animal embryos in research may be legitimate in a strict sense, they fall far short of embracing the democratic ideal of input-oriented legitimacy that "depends on the extensiveness and intensiveness of public participation in the making of policy" (Montpetit 2003, p. 97).

This work is supported by a research grant from the Australian Research Council (to Susan Dodds), a grant from the Canadian Institutes of Health Research (CIHR) (to Françoise Baylis), and a salary award from the Canada Research Chairs program (to Françoise Baylis). An early version of this paper was presented at a PEALS (Policy, Ethics and Life Sciences Research Centre) Symposium, "The Identification, Regulation and Implications of Risk Within Stem Cell Research," Durham Castle, United Kingdom, April 2008. Thanks to Erica Haimes and three anonymous reviewers for helpful comments on subsequent drafts. Thanks to Terrence McEachern for research assistance.

NOTES

1. The presumed divide between humans and animals is problematic insofar as humans are animals. Ideally, the reference should be to "human animals" and "nonhuman animals." For ease of reading, however, I sometimes use the vernacular "humans" and "animals."
2. Lay summaries of these three projects are available at: *www.hfea.gov.uk/en/1652.html*; *www.hfea.gov.uk/en/1653.html*; and *www.hfea.gov.uk/en/1699.html*, accessed 20 January 2009.
3. To my knowledge, the adjective "humanesque" is first used in the context of the human embryonic stem (hES) cell debate by Jason Scott Robert (2006) to describe an embryo created by transferring a nucleus from a human somatic cell into an enucleated nonhuman animal egg.

4. A human admixed embryo is defined in Section 4A(6) of the Human Fertilisation and Embryology Act 2008.

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