6 International Legislative and Regulatory Approaches

In this chapter, we take a detailed look at legislative initiatives in four countries: Italy, Australia, Canada, and Britain. Each case provides a distinctive perspective on possible approaches to the regulation of reproductive technologies and biomedical research. Italy exemplifies a legislative approach to controversial biomedical developments that, while favored by some in the United States, in our view would be costly at best and counterproductive at worst. The Italian legislation goes well beyond simply targeting deeply troubling practices such as reproductive cloning and the creation of human embryos solely for research purposes. The scope of its prohibitions is very broad and its bans are sweeping. Not surprisingly, the Italian approach has triggered a considerable amount of controversy, and we present it here as an illustration of how not to approach controversial ethical dilemmas in the United States. Australia, by contrast, has passed legislation that seems to enjoy the support of all relevant constituencies and of the general public. Its approach to regulating controversial biomedical developments is restrictive – from an American perspective, perhaps too restrictive – but it also recognizes the importance of providing a legally protected space to controversial biomedical research. Finally, Canada and Britain provide an illustration of our claim that similar regulatory infrastructures are compatible with different ethical concerns. Both countries emphasize the need to closely monitor the field of reproductive medicine and biomedical research through a specialized regulatory entity, yet Britain is considerably more liberal in its regulatory stance than Canada. Britain is also the only country with many years of experience in regulating controversial reproductive technologies.

None of the legislative approaches examined in this chapter provides a template that could mechanically be used to implement a new regulatory structure in the American context. With the exception of Italy, each of these approaches does, however, provide important insights into how a U.S. system of regulation could be implemented. To facilitate this task, we have also examined legislative and regulatory approaches in 13 industrialized countries. Our analysis shows that there is virtually no agreement among these countries on what constitute the most appropriate legislative responses to new biomedical dilemmas, the notable exception being reproductive cloning. On the other end, there is considerable agreement on which reproductive practices and research protocols should be regulated.[1] For each of these practices, a majority of the reviewed countries has either adopted specific legislative measures or crafted regulation. Only one country – the United States – has taken little or no action. This observation underscores the need for the U.S. Congress to pay closer attention to medical and scientific developments in the area of reproductive medicine and biomedical research.

[1] In Appendix H, we have identified 10 activities pertaining to reproductive medicine and biomedical research that in recent times have been targeted for legislative or regulatory intervention in 13 OECD countries.

6.1 Italy – from the "Wild West" to "Politburo"?

On February 10, 2004, the Italian Chamber of Representatives passed a comprehensive bill titled "Norme in materia di procreazione medicalmente assistita" ("Norms concerning medically assisted procreation"). The bill, already passed by the Italian Senate in December of 2003, is now law.[2] We have chosen to examine in some depth the Italian case for one main reason: The new legislation provides an excellent illustration of the possible negative consequences of a *laissez-faire* approach to reproductive medicine, followed by a late and excessive legislative reaction. To put it simply, the longer a legislative body delays crafting a response to new scientific and medical developments, the likelier it becomes that legislators will overreact.

Until the passage of bill n.40, Italy exercised only minimal oversight over reproductive medicine and research. Not coincidentally, among ART practitioners and ART patients, Italy was known as the "Wild West" of reproductive medicine. The new law has changed all this. In terms of access restrictions to ART technologies, the types of reproductive technologies available to patients, and the ends that justify the recourse to assisted reproductive technologies, the Italian legislation is one of if not the most restrictive legislative frameworks worldwide. Hence the term "politburo" used by an Italian columnist to describe the new approach to regulating reproductive medicine.

The costs of this legislative overreaction are likely to be significant, and they are not only economic in nature. In the present case, the negative consequences of the new law will be felt by research institutions, by patients, and by ART practitioners. Scientists will find themselves incapable of conducting research that largely is considered legitimate in many other liberal democracies. Patients will be deprived of important reproductive services, and the industry likely will suffer considerable economic losses.

The law, though it does not explicitly discuss guiding principles, is informed by clear ethical standards. ART technologies can be used exclusively for the treatment of medically diagnosed infertility, and are not a means for individuals to meet their reproductive desires. Accordingly, IVF is considered a medical technology of last resort intended to help heterosexual couples have a baby. The protection of embryos has priority over the demands of non-traditional couples, singles, research institutions, and in some cases, over the interests of the couple. In this sense, the Italian law embodies very specific views of sexuality, of the family, and of the moral status of the embryo – views that are quite close to traditional Catholic teachings on these issues.

The law consists of 18 fairly straightforward articles. Unlike most other legislative approaches in the area of ART and biomedical research, the Italian statute is comprehensive. It limits access to ART technologies, it describes which ART procedures can be used and how, and it spells out the rationale for resorting to ART treatments. It also sets clear legislative boundaries to what researchers are entitled to do in this area. In addition, the legislation requires the implementation of a licensing scheme for all ART clinics, to be administered by the Italian

[2] Legge 19 febbraio 2004, n. 40, available at http://www.parlamento.it/parlam/leggi/04040l.htm (Medically Assisted Reproduction Law).

Health Ministry, and sets aside funds for conducting scientific research on the causes of infertility.

Taking a closer look at the law, article 5 establishes that only stable, adult, heterosexual couples, married or otherwise, have the right to receive ART treatments. In addition, both spouses must be alive. However, the access to reproductive treatments is not unconditional. Traditional couples have access to ART treatments only after they have demonstrated that their infertility cannot be cured by any other means. Demonstration of infertility requires medical examination and appropriate documentation.[3]

As for the means available to couples that qualify for an ART treatment, the statute contains several provisions. Gamete donation by a third party is prohibited.[4] Since only the couple's own gametes can be used for reproductive purpose, no provision is necessary to regulate the donation, import, or export of gametes and embryos. Performing IVF is subject to constraints. Only three embryos can be created for any one cycle, and all of them must be transferred.[5] In an effort to prevent the accumulation of excess embryos, the long-term cryopreservation of embryos is not allowed,[6] nor is their destruction. Embryo cryopreservation is permitted only for medical reasons, and only for a limited period of time, in any case until the embryo is transferred.[7] "Selective reduction" is prohibited, with some very limited exceptions.[8]

Since every in vitro embryo must be transferred and no embryo can be destroyed, any technique that leads to the destruction of an embryo is prohibited. This means that techniques of genetic screening such as pre-implantation genetic diagnosis are not allowed for any reason, including therapeutic treatments. Also banned is any eugenic application – i.e., any change in the genome of gametes or embryos not intended directly to benefit the latter.[9] Research on embryos is allowed only to benefit the health and development of the embryos themselves.[10]

Consistent with the narrow focus on procreation, the law leaves very little room for research involving reproductive tissues. Somatic cell nuclear transfer of any kind is prohibited.[11] Since embryos can only be created for procreative reasons and cannot be destroyed, the donation of embryos for research purposes is excluded. The law also explicitly prohibits the creation of embryos solely for research purposes.[12] The creation of human-animal chimeras or hybrids is

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[3] See Article 4, Section 1.
[4] See Article 4, Section 3.
[5] See Article 14, Section 2.
[6] See Article 14, Section 1.
[7] See Article 14, Section 3.
[8] See Article 14, Section 4.
[9] See Article 13, section 3b.
[10] See Article 13, section 2.
[11] See Article 13, Section 3c.
[12] See Article 13, Section 3a.

also prohibited.[13] The law actively supports and promotes research on the causes of infertility, including medical research on human gametes.[14]

As for regulatory measures, the law requires the administering agency, namely the Health Ministry, to establish a registry of all ART clinics. Also, ART programs are required to report the number of created embryos and babies born through ART on an annual basis.[15] In addition, ART clinics must provide the Health Ministry with the data necessary to monitor the health and well-being of babies born through ART. Unfortunately, this article is crafted in such general terms as to prevent an evaluation of the Italian approach to health monitoring. The law is much more specific in terms of the administrative and criminal sanctions imposed on violators. For example, an ART practitioner can be fined up to 600,000 euros (approximately $730,000) for using gametes extraneous to the couple. Trade in gametes or embryos can be punished by up to two years in prison, and attempts at reproductive cloning carry a sentence of up to 20 years in prison and fines up to a million Euros (approximately $1,218,000).

The Italian approach to new reproductive technologies is an excellent example of how not to legislate the field of reproductive science and medicine. As the preceding discussion demonstrates, many legislative provisions in this law seem guided by a desire to ensure better protection for ART children and for embryos. As we have argued in chapter 3, the well-being of ART children and the respect for human embryos are both important moral goods worthy of legislative attention. However, in our view the Italian statute achieves these goals by sacrificing several other moral goods worthy of legal protection. Access to standard ART technologies, even by heterosexual couples is severely limited, and promising new lines of medical research (including but not limited to stem cell research) are sacrificed for the sake of a very specific ethical perspective – an ethical perspective that may not be shared by a majority of the Italian public.[16] The law also prevents prospective parents affected by genetic diseases from having healthy children. In other words, it does not attempt to reconcile conflicting moral goods; it simply imposes on Italian citizens what amounts to traditional Catholic precepts of morality.

The Italian law is problematic for other reasons as well. Its rigid approach to controversial ethical questions makes it all but impossible to accommodate unanticipated future medical developments. For example, medical research likely will make it possible in the not-too-distant future to cryopreserve human oocytes. The cryopreservation of human eggs raises new and important ethical questions, but it is not obvious to us that this technology should simply be banned by legislative means. There may well be good medical and non-medical reasons for

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[13] See Article 13, Section 3d.

[14] See Article 2 Sections 1 and 2.

[15] See Article 11.

[16] The failure of four referenda to revoke several provisions of this statute could be interpreted as an indication of broad popular support for this new statute. However, the initiators made clear that theirs was not a fundamental opposition to the regulation of reproductive medicine, per se. Rather, the referenda targeted specific prohibitions of the new law deemed too broad – the use of human embryos for research, the cryopreservation of human embryos, any form of pre-implantation genetic diagnosis, and ART procedures using donated gametes and embryos – as well as the recognition of pre-embryos as legal entities with the same rights as human beings.

allowing the cryopreservation of oocytes, at least in some cases. A sweeping ban on new medical developments in our view is an ill-informed response to biomedical developments that cannot be unambiguously condemned or unconditionally embraced.

6.2 Australia – Regulated Self-Regulation

6.2.1 Regulatory Precedents

A unique feature of the Australian system of government is its extensive reliance on self-regulation. In the Australian context, self-regulation is not synonymous with lax regulation. The Australian government codifies standards developed by the private sector and relies on trade associations and other accredited third parties to ensure compliance. Procedures of compliance assurance are no different from those adopted by government regulators in other countries, and include inspections and various forms of sanctions.[17] The Australian ART industry provides an excellent illustration of this approach. Australia, with approximately 20 million inhabitants, has 34 ART programs – almost twice as many per million inhabitants as the United States. By all accounts, the Australian ART industry is very dynamic, on both the clinical and the research fronts. The industry began regulating itself in 1987, when the Fertility Society of Australia established the Reproductive Technology Accreditation Committee (RTAC).[18] The committee produced a set of guidelines, the "Code of Practice for Centres Using Assisted Reproductive Technology" (or "Code of Practice" for short), which was revised in April of 2002 and can be regarded as a comprehensive set of binding recommendations for the operation of an ART program in Australia. Its adherence is monitored and enforced by the RTAC.

In 1996, the Code of Practice was supplemented by the "Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research" (or "Guidelines"), published by the Australian Health Ethics Committee (AHEC) and updated in September of 2004. The AHEC is a principal committee of the National Health and Medical Research Council (NHMRC), the Australian equivalent of the NIH, which was established under the NHMRC Act of 1992. The Guidelines address numerous ethical questions not specifically discussed in the Code of Practice, and not included in two statutes to be examined below, the Prohibition of Human Cloning Act of 2002 (PHCA) and the Research Involving Human Embryos Act of 2002 (RIHEA). They are reminiscent of many guidelines developed by the American Society for Reproductive Medicine, differing only in that they, unlike their American counterparts, are being enforced.

The ethical standards espoused in the Australian Guidelines are indicative of a rather conservative approach to the access and use of ART technologies, but they are certainly not as rigid as their Italian counterpart. For example, the Australian Guidelines ban the use of sex-

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[17] See, for example, Toni Makkai and John Braithwaite, "Reintegrative Shaming and Compliance with Regulatory Standards," *Criminology* 32 (1994).

[18] See http://www.fsa.au.com/rtac/.

selection technologies, but only for non-therapeutic uses. They deem the commercial trade of human gametes and embryos unacceptable, but allow the donation of such tissues. They proscribe surrogacy as a commercial service, recognize that it remains a controversial practice even for non-commercial reasons, and refer to state-level laws and regulations for additional guidance. As for pre-implantation genetic diagnosis, they proscribe its use for elective sex selection but allow it to prevent or reduce the chance of inheriting a serious genetic condition. The Guidelines do not provide any guidance on other unconventional reproductive technologies such as ooplasm transfer, embryo splitting, or reproductive cloning. Nor do they address the creation of embryos and chimeras or genetic engineering. These issues are dealt with by the two new statutes mentioned earlier, the PHCA and the RIHEA.

By the end of 2002, the Australian Parliament had passed both the PHCA and the RIHEA, and did so in less than two years, apparently without major societal traumas. The two laws complement each other: The PHCA identifies ethically unacceptable and therefore prohibited practices in the ART industry, whereas the RIHEA outlines a regulatory system for conducting research on human embryos, including but not limited to stem cell research. The actual regulation of the ART industry is covered by the Code of Practice and by the Guidelines.

The PHCA and the RIHEA reflect a genuine effort by the Australian authority to balance ethical concerns and freedom of research. The centerpiece of this balancing act is the Embryo Research Licensing Committee (ERLC), a principal committee of the NHMRC responsible for overseeing research protocols involving human embryos. The ERLC is modeled after the British Human Fertilization and Embryology Authority, but differs from the latter in some important respects. Unlike the HFEA, the ERLC oversees exclusively research activities, not the ART industry proper. Appointment and operational rules also differ, as do the criteria for approving and rejecting research proposals.

6.2.2 The Prohibition of Human Cloning Act of 2002

The stated purpose of the PHCA is to identify in a clear and unambiguous fashion reproductive practices and technologies deemed unethical or otherwise unacceptable.[19] PHCA does so by distinguishing between cloning[20] and prohibited activities.[21] Cloning a human embryo for any purpose is prohibited. This means that Australia, unlike Britain but like Canada, has banned both reproductive and research cloning. PHCA speaks of the "human embryo clone" and defines this term as the "genetic copy" of another living or dead human being, excluding "copies" created by the fertilization of an egg by a sperm, thus ensuring that twins are not inadvertently declared clones.

In Section 8(2), the legislators clarify the definition of "genetic copy." For an embryo to be a genetic copy, it is sufficient for the genes in the nucleus of a cell to be copied; it is not necessary

[19] See Section 3.
[20] See Division 1.
[21] See Division 2.

that the cloned embryo have an identical copy of the genome of the original cell. This means that cloning could not legally be performed on the grounds that cloned embryos have different mitochondrial DNA and therefore are not genetic copies. Section 8(4) establishes that "embryo splitting" – the process by which an embryo at a very early stage is split into two embryos – does produce a human embryo clone and is therefore also banned. The PHCA prohibits the implantation of cloned embryos in a human body,[22] and the import or export of cloned embryos.[23] It also preempts the argument that cloning an embryo is not punishable because the embryo in question would not have been viable, an argument that in the United States enjoys some popularity.[24] In sum, Australia has closed all doors on the creation and use of cloned human embryos.

The creation of human embryos is otherwise permitted but severely restricted. Embryos can be created, but exclusively for reproductive purposes.[25] The PHCA forbids the creation of human embryos by means other than the union of a human oocyte and human sperm.[26] It also prohibits retrieving a viable human embryo from the body of a woman.[27] This procedure, known as "embryo flushing," is common in animal husbandry, but it has yet to be used in humans. The PHCA makes it illegal to implant a human embryo in an animal,[28] and finally, it prohibits the import and export of human embryos,[29] as well as the trade of embryos, human eggs, and human sperm.[30] There are a few important exceptions to these prohibitions. In particular, neither embryo nor stem cell research are covered by these bans, but both are strictly regulated. Terms and conditions for conducting this type of research are laid out in RIHEA (see the next section). Furthermore, the PHCA revised explanatory memorandum clarifies that screening embryos for medical purposes, as for certain uses of PGD, remains legal.

With regard to reproductive technologies in Australia, the PHCA prohibits the creation of human embryos with genetic material from more than two persons.[31] The revised explanatory memorandum makes clear that Section 15 is intended to ban reproductive techniques such as ooplasm transfer. This seems in keeping with the FDA suspension of this procedure in the United States out of concern that it may not be safe. Another preventive measure is Section 16, which bans the development of a human embryo outside the body of a woman for more than 14 days. While it may be difficult to see the need for this prohibition at this time, our discussion of new

[22] See Section 10.
[23] See Section 11.
[24] See Section 12.
[25] See Section 14.
[26] See Section 13.
[27] See Section 19.
[28] See Section 21.
[29] See Section 22.
[30] See Section 23.
[31] See Section 15.

reproductive technologies in section 4.5.4 has shown that in the not too-distant future, it may indeed be possible to grow human embryos for extended periods of time outside the body of a woman.

Like Canada, Britain, and most other OECD countries, the Australian legislation bans genetic engineering, defined as a heritable alteration of the human genome.[32] PHCA deals extensively with chimerism, as well, precisely defining what constitutes a chimeric animal and how chimeric animals differ from hybrids and transgenic embryos. It is worthwhile delving into some of these technicalities, as these definitional questions are of some import to our discussion.

PHCA Section 8(1) defines chimeric embryos as human embryos "in which a cell, or any component of a cell, of an animal" has been introduced.[33] It appears that Australian legislators were concerned about being outpaced by scientific progress, as they empowered regulators to introduce additional definition of chimeric embryos, if necessary. The definition of a hybrid embryo consists of four distinct categories: (a) an embryo created by fertilizing a human egg with an animal sperm, (b) an embryo created by fertilizing an animal egg with human sperm, (c) a human egg in which the nucleus of an animal cell has been inserted, and (d) an animal egg in which the nucleus of a human cell has been introduced. Most importantly, the legislators have allowed the regulators to introduce new definitions of hybrid embryos as necessary. Section 20 of PHCA makes it an offense punishable by up to 10 years in prison to create a chimeric embryo or a hybrid embryo, as defined above.

In keeping with well-established laboratory practices, PHCA does not prohibit the creation of transgenic embryos, defined as animal embryos in which human genes or fractions thereof have been introduced, nor does it address the case of an animal embryo in which human cells have been introduced. The PHCA revised explanatory memorandum describes these embryos as instances of genetically manipulated organisms, a somewhat misleading terminology in our opinion. This case is dealt with in a separate Act, the Gene Technology Act of 2000, which is beyond the scope of the present report.

6.2.3 The Research Involving Human Embryos Act of 2002

The main purpose of the RIHEA, defined in Section 3, is to "…address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilization of human embryos by regulating activities that involve the use of certain human embryos created by assisted reproductive technology." If the proposed research could damage or destroy the embryo, research on human embryos is permitted only on excess embryos, and only on those created prior to April 5, 2002.[34] This clause is more flexible than President Bush's 2001 directive on human stem cell research. It allows the creation of new stem cell lines if these are

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[32] See Section 18.

[33] Note that the terms "introduce" and "fertilize" are not synonymous. The former indicates a process by which an some extraneous cells are mixed to the cell of an existing embryo.

[34] See Paragraph 21(3)(b).

derived from embryos created before the April 2002 cutoff. In addition, paragraph 21(3)(b) was repealed on April 5, 2005, thus allowing legislators to revisit the policy and update it, if necessary. The moratorium has not been extended, thus allowing Australian researchers to derive new stem cell lines using embryos created after April 5, 2002.[35]

As mentioned above, Australia regulates human embryo research by means of a licensing system overseen by the Embryo Research Licensing Committee, located within the NHMRC. The ERLC has the authority to grant licenses for conducting embryo research and to monitor research activities, licensed or not. In addition, it must maintain a public database of licensed research projects. Its operations must be reviewed on a regular basis, and an activity report must be submitted to both houses of the Australian Parliament.

The ERLC could be described as a hybrid between the British Human Fertilisation and Embryology Authority and the U.S. Recombinant DNA Advisory Committee. Like the RAC, the ERLC operates within the NHMRC.[36] Like the HFEA, the ERLC licenses all research activities involving human embryos, not just publicly funded projects. And as with the HFEA, ERLC members include representatives of the scientific community, the general public, and other constituencies. Unlike the RAC, however, the ERLC has extensive monitoring and enforcement powers backed by administrative and criminal sanctions.

The Australian approach to defining the composition of the ERLC departs significantly from the British model. While the British HFEA is an idiosyncratic mix of corporatism and direct popular representation, the Australian ERLC takes a clear corporatist approach. Sections 13 through 19 govern its establishment and operation. Section 16 establishes the committee's composition as follows:

(a) A member of the Australian Health Ethics Committee
(b) An expert in research ethics
(c) A person with expertise in a relevant area of research
(d) An ART expert
(e) A legal expert
(f) A representative of a consumer organization specialized in disability and disease
(g) A representative of a consumer and patient group focused on assisted reproductive medicine
(h) An expert in the regulation of ART
(i) An embryologist

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[35] *No Need for More Stem Cell Embryos* (Sydney Morning Herald, March 29, 2005 [cited September 22, 2005]); available from http://www.smh.com.au/news/National/No-need-for-more-stem-cell-embryos-MPs/2005/03/29/1111862384922.html?oneclick=true.

[36] It should be noted that in recent times, the British government has extracted the licensing of scientific projects involving human embryos from the HFEA and entrusted this activity to a new regulatory body within the National Health Service (NHS), the British equivalent of the NIH.

Neither the RIHEA nor its explanatory memorandum shed any light on which criteria were behind this choice of experts. Most of the choices may be regarded as both obvious and necessary. Appointing an ART expert, a legal expert, an expert in research ethics, a scientist, an embryologist, and representatives of consumers and patients groups seem rather straightforward choices. On the other hand, taken together, these choices produce a committee that is unique in its structure. Unlike the HFEA, the ERLC is a committee of experts with no pretension of including and/or consulting with the general public. Public views are not excluded from this committee, but are limited to those societal groups most directly affected by research in this area – i.e., to representatives of infertility patients and advocates of disabled persons. Individuals who do not represent the medical profession or the research community and who are likely to represent the views of the public are a clear minority. Depending on how the slots are filled, they range between two and three out of nine members. Given the often rather self-interested nature of organized groups, and the generally sympathetic approach displayed by the bioethics profession toward the research community, this number could conceivably shrink to zero.

The technocratic approach taken by the Australian legislation in establishing the composition of the ERLC can partly be explained by the committee's charge. The ERLC is responsible exclusively for approving research protocols on human embryos, not for untangling difficult ethical dilemmas created by new reproductive technologies. In this sense, the committee's scope is relatively narrow and may not require extensive public input as required, for example, for the promulgation of new ethical guidelines by the RTAC or the Human Research Ethics Committee (HREC), which is similar to an institutional review board.

The Australian appointment process ensures that only broadly acceptable candidates will be appointed. The appointment process is not governed by rigid administrative rules, nor are appointments simply the result of an arbitrary choice made by the responsible minister. The RIHEA assigns the minister the responsibility for making the actual appointments, but viable candidates can be suggested only by a predefined list of organized interest groups and by the states (Paragraph 16(3)(a)). In addition, the minister must "consult, and have regard to the views expressed by, the States on the proposed appointment."[37] How exactly this clause is being interpreted in practice is not entirely clear, but it appears that the purpose of this consultation process is to ensure that the appointed candidate is supported by all relevant political constituencies. In other words, the states must not only be consulted, but should also be represented. Sub-clause 16(5) requires that the committee chair only be appointed with a majority of states agreeing, while sub-clause 16(6) instructs the minister as to the "desirability of ensuring that the Committee as a whole comprises members from different States." The combination of formal and informal appointment rules seems to be designed to produce consensus candidates. This approach can be relatively slow, but it guarantees that most constituencies will regard the committee as a whole as a credible and trustworthy institution of government.

[37] See Paragraph 16(3)(b).

RIHEA Sections 20 through 28 govern the issuance, change, and revocation of licenses. Of particular interest to the present discussion are the conditions for obtaining a research license.[38] Some of these criteria are purely procedural; others are of a more substantive nature. The procedural requirements include obtaining informed consent from the donors of excess embryos,[39] and approval by the HREC in accordance with the NHRMC National Statement on Ethical Conduct in Research Involving Humans.[40] In examining the merits of a research proposal, RIHEA Section 21(4) requires (a) the committee to examine whether the number of embryos to be used in the proposed research is commensurate to the research goals, and (b) whether the proposed research is likely to advance scientific knowledge or improve medical technologies and treatments that could not be achieved by other means. In addition, if the research protocol involves the damage or destruction of human embryos, the applicant can use only excess embryos created prior to April 5, 2002. Sub-clause 21(40(b) provides considerable room for interpretation, and it is by no means clear how the ERLC members may resolve the uncertainties that any attempt at assessing possible benefits and relative merits of different medical research protocols inevitably will produce. Neither the RIHEA nor the accompanying explanatory memorandum touches on this question. Surprisingly to us, the RIHEA does not include any guidance on how the ERLC should resolve internal disagreement, or on what the role the committee chair should play in this process.

The RIHEA also addresses conflicts between demands for transparency and commercial expectations of confidentiality, conflicts that in the past have severely constrained the ability of the U.S. RAC to review research protocols submitted by private companies.[41] The act does require the ERLC to maintain a publicly accessible online database of granted licenses, but the information required to be included in this database is minimal. It includes the applicant's name, a short description of the proposed research, the number of excess embryos whose use has been authorized by the license, and the period of time during which the license is valid, but explicitly excludes any commercially sensitive information. These provisions seem to suggest that the review process is not open to the public. The RIHEA does not delve into questions of transparency and public access to the review process. Whether a closed review process will undermine the public confidence in this new institution of government remains to be seen.

RIHEA Sections 33 through 41 lay out the rules that govern monitoring activities. As with the Canadian legislation described below, these sections leave many implementation details unspecified. For example, the RIHEA does not state whether it is possible and/or necessary to

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[38] See Section 21.

[39] See Paragraph 21(3)(i). Section 9 defines an excess embryo not only as an embryo that is not needed by the woman for whom it was created, but also as an embryo no longer needed by her spouse (if any) (Paragraph 9(1)(b)).

[40] The statement is available at http://www.nhmrc.gov.au/publications/synopses/e35syn.htm. The criteria, both procedural and substantive, laid out by this document are not too different from the Common Rule or the FDA regulations governing the establishment of operation of an institutional review board.

[41] See Sections 29 and 30.

inspect all licensees, or how often should they be inspected. Implementation questions are to be addressed in future regulations. As for administrative and criminal penalties, the penalties imposed by Australia, compared to Italy and Canada, are severe. Violating a provision of Division 1 of the PHCA is punishable by up to 15 years in prison; other violations of the PHCA call for up to 10 years. Criminal penalties in the RIHEA are not as severe, but could still land a scientist in prison for up to five years.

6.3 Canada: Groping Toward a New Regulatory Structure

The Canadian response to the ethical dilemmas raised by new reproductive technologies has been more than 10 years in the making. In the early 1990s, the Royal Commission on New Reproductive Technologies on behalf of the Canadian government spearheaded a broad national conversation on the risks and benefits of new options in reproductive medicine. It organized numerous town hall meetings around the country, listened carefully to the views and opinions of the general public, and summarized this experience in a highly regarded report, "Proceed with Care," published in 1993. The report was the basis for several legislative proposals, the last of which – Bill C-6, the Assisted Human Reproduction Act respecting assisted human reproduction and related research – was finally passed on February 11, 2004, by the Canadian House of Commons.

An important reason for examining the Canadian statute in some detail is its regulatory stance. The Assisted Human Reproduction Act (AHRA) not only distinguishes between acceptable and unacceptable reproductive practices, it also establishes a new regulatory institution responsible for regulating reproductive medicine. The Canadian case is interesting for another reason as well: It is similar to the approach taken by Britain. The Canadian statute shares with the British approach several key features, including the adoption of a licensing scheme and the creation of a board of directors responsible for managing the new agency. But the Canadian AHRA also differs from the British legislation in that it takes a much more restrictive approach to several controversial reproductive and research techniques: It is more restrictive toward the use of sex-selection technologies, it does not allow the creation of embryos solely for research purposes, and it bans research cloning (which the British HFEA has legalized).

6.3.1 The Assisted Human Reproduction Act of 2004

The AHRA expounds what may be called a transitional morality, meaning a mix of ethical norms informed by traditionalist moral sensibilities and contemporary notions of individual moral autonomy. It prohibits all forms of human cloning, for research or reproductive purposes. In addition, it explicitly proscribes the commercial trade in human gametes and embryos. In this, it is quite similar to the position taken by the Australian legislators. On the other hand, it does not prohibit surrogacy or other forms of assisted reproduction that require the use of extraneous gametes. It also bans discrimination on the basis of sexual orientation and marital status, thus

guaranteeing access to procreative technologies to gay and lesbian couples and to singles. In this sense, the AHRA seems to accurately reflect prevailing Canadian moral sensibilities.[42]

The AHRA takes what may be described as a principled approach to regulating reproductive technologies and biomedical research. In this, the Canadian statute stands alone; neither the British nor the Australian legislation nor any other legislative approach, to our knowledge, has attempted to infer legislative prohibitions and to distinguish between banned and regulated activities from a set of fairly general ethical principles. The seven principles enumerated in Section 2 of the AHRA are worth quoting in some detail:

(a) The health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use;
(b) The benefits of assisted human reproductive technologies and related research for individuals, for families, and for society in general can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity, and rights in the use of these technologies and in related research;
(c) While all persons are affected by these technologies, women more than men are directly and significantly affected by their application, and the health and well-being of women must be protected in the application of these technologies;
(d) The principle of free and informed consent must be promoted and applied as a fundamental condition of the use of human reproductive technologies;
(e) Persons who seek to undergo assisted reproduction procedures must not be discriminated against, including on the basis of their sexual orientation or marital status;
(f) Trade in the reproductive capabilities of women and men and the exploitation of children, women, and men for commercial ends raise health and ethical concerns that justify their prohibition; and
(g) Human individuality and diversity, and the integrity of the human genome, must be preserved and protected.

These principles are remarkable for several reasons. They explicitly acknowledge the need to protect those most directly affected by reproductive procedures, namely the ART children and women who undergo these treatments (principles (a) and (c)). They subordinate the benefits of reproductive technologies and biomedical research to the protection of human health, safety, dignity, and the rights of those affected by these technologies and the public in general (principle (b)). And they resolve controversies over differential access to reproductive technologies

[42] Not everybody would agree with this statement. For example, it has been argued that the Canadian public is actually not opposed to research cloning, and that by passing Bill C-6, the Parliament simply ignored the voice of the public. Cf. Timothy Caulfield, "Politics, Prohibitions and the Lost Public Perspective: A Comment on Bill C-56: The Assisted Human Reproduction Act," *Alberta Law Review* 40 (2002). Caulfield's comments refer to an earlier version of the bill, but most of his arguments apply to Bill C-6 as well.

(principle (e)).[43] Canada affords equal access to ART technologies to any (presumably adult) individual independent of sexual orientation and marital status. Accordingly, couples – heterosexual or not – as well as singles are granted equal access to ART technologies.

A deductive approach to ethical controversies is not without problems however, especially for the regulators charged with implementing the provisions of the AHRA. For example, principle (a) is clearly intended to protect the health and well-being of children. As a matter of principle, very few would disagree that the health and well-being of children is a moral good worthy of protection, yet any attempt to give the terms "health" and "well-being" a precise operational meaning is likely to be controversial. Principle (b) identifies human dignity and human rights as two moral goods deserving protection, but leaves entirely unspecified the notion of human dignity, and does not bother to identify which human rights should be protected. Again, it would be only too easy to fault regulators for not adequately protecting human rights, or for taking too expansive a view of human dignity for that matter. Furthermore, it is quite possible that some of these principles may inspire conflicting regulatory interventions.

That guiding principles leave considerable room for interpretation does not justify dismissing a deductive approach to modern ethical dilemmas as irrelevant or impracticable. It is, however, a good reason for establishing specific rules and institutions for addressing these interpretive ambiguities. In this regard, the AHRA leaves much to be desired, as it does not include any provisions as to how regulators may go about resolving the ambiguities that a principled approach inevitably will produce.

The principles themselves are only in minimal part derived from a consistent ethical framework, and they seem to reflect the outcome of a political compromise. An American observer might regard them as politically liberal, for example, when they afford gay and lesbian couples equal access to reproductive technologies. On the other end, the principles prohibit the commercial trade of human gametes and embryos, a measure many Americans would find too restrictive. Being the result of a political compromise, these principles ignore some important issues. For example, the distinction between therapeutic and enhancing applications of new reproductive technologies has not been formalized, though it seems to inform several provisions of this act. At the same time, the fact that these principles represent a political compromise suggests that they will likely enjoy broad public support.

Prohibited Activities

AHRA Sections 5 through 9 enumerate proscribed reproductive procedures and research activities. Taken together, these prohibitions suggest a restrictive approach to reproductive medicine; the act prohibits many reproductive treatments now common in the United States. These prohibitions are remarkable for two main reasons. First, they apply to certain procreative ends, not to the specific technological means to achieve them. While scientific and medical

[43] Principle (e) does not completely resolve this thorny issue. For example, it is not entirely clear whether this principle would afford a woman the right to become impregnated with the sperm of her deceased husband.

progress over time may provide new means, they will not undermine the corresponding prohibitions. Second, the prohibitions are worded in such a way as to ensure that reproductive technologies are used exclusively for reproductive purposes narrowly defined, though as we show below, the intent to reproduce does not justify the use of each and every reproductive technology.

The centerpiece of these prohibitions is Section 5. Section 5(1)(a) bans any kind of cloning, including research cloning, but does so not by specifically prohibiting somatic cell nuclear transfer. Rather, it defines cloning in functional terms. Thus, this section simply proscribes the creation of "a human clone, by using any technique." Consistent with its focus on human reproduction, Section 5 bans the creation of embryos for any purpose other then procreation, medical training, or the improvement of reproductive technologies.[44] Medical and clinical research on human embryos remains legal, though it may be difficult, as a matter of practice, to determine whether a research protocol involving human embryos is indeed designed to improve the safety and efficacy of existing reproductive technologies. This distinction becomes particularly problematic when research protocols are designed to explore questions impinging only indirectly on actual medical practice.[45]

Reproductive intent alone does not justify resorting to any and every reproductive technology. Accordingly, Section 5 prohibits several reproductive procedures. For example, it bans any technique that could lead to the creation of embryos from fetuses or from embryonic stem cells.[46] This prohibition is a direct response to the announcement made in 2003 by an Israeli research group that it had successfully retrieved viable oocytes from aborted fetuses, and to other experiments in mice showing that it may be possible to derive sperm-like cells and oocytes from stem cells (see chapter 4 for details). In keeping with a narrow understanding of reproduction, Section 5 also proscribes the use of sex-selection technologies except for preventing sex-linked diseases.[47] As with other prohibitions discussed in this section, this ban does not refer to a specific sex-selection technology; it simply proscribes the use of any and all technological means for elective sex selection. Also proscribed are all forms of genetic engineering that would produce an inheritable genetic modification.[48] Presumably this prohibition extends to ooplasm transfer, as this procedure indeed produces an inheritable genetic modification by passing on mitochondrial DNA from a third party. Furthermore, innovative reproductive approaches that involve the use of animal tissues, such as co-culture, are also prohibited.[49] In keeping with

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[44] See Section 5(1)(b).

[45] The AHRA does not ban stem cell research, however. Section 5(1)(b) only bans the *creation* of in vitro embryos for any purpose other than human reproduction. The act does not explicitly require the transfer of all in vitro embryos into a woman's uterus. This introduces the possibility that *existing*, cryopreserved embryos can be donated for research, a solution that is reminiscent of the Australian approach to legalizing stem cell research.

[46] See Section 5(1)(c).

[47] See Section 5(1)(e).

[48] See Section 5(1)(f).

[49] See Section 5(1)(h).

traditional views of reproduction, Sections 6 through 9 place numerous restrictions on the use of third party gametes and embryos and on surrogacy services. The commercial trade of gametes and embryos is proscribed, as are commercial offerings of surrogacy services, but gametes and embryos can be donated, and surrogacy may be provided on a non-commercial basis.

Sections 5(1)(i) and 5(1)(j) ban the creation of chimeras and hybrids, respectively. Section 5(1)(i) only bans the creation of a human chimera (i.e., one created by inserting non-human cells into a human embryos), but the converse procedure is legal, in keeping with common scientific practice. By contrast, Section 5(1)(j) bans any form of hybrid (i.e., fertilizing a human oocyte with non-human sperm, or fertilizing a non-human oocyte with human sperm), but also somatic cell nuclear transplantation using human and non-human cells.

Surprisingly, Sections 5 through 9 do not address the legality of pre-implantation genetic diagnosis, explicitly or implicitly. Section 5(1)(b) forbids the creation of embryos for any reasons other than reproductive purposes. PGD requires the creation of several embryos for the stated purpose of selecting a few with specific characteristics. Those not meeting certain criteria are by definition not used for reproductive purposes, making PGD, in principle at least, illegal under the AHRA. However, Health Canada has made clear that under the AHRA, PGD is a regulated activity, not a prohibited one.[50] Performing PGD will be controlled by a set of guidelines for which Health Canada was seeking public feedback at the time of this writing.[51]

Regulated Activities

In AHRA terminology, regulated activities are referred to as "controlled" activities and are described in Sections 10 through 19. Sections 10 through 13 sketch the architecture of the Canadian system of licensing. Section 10(1) requires that any persons in the business of altering, manipulating, or treating human reproductive tissues for the purpose of creating an embryo be licensed. Also licensed must be any persons involved in altering, manipulating, or treating in vitro embryos,[52] and any persons involved in storing, handling, transferring, importing, or exporting reproductive materials and in vitro embryos.[53] A license is required to produce transgenic animals.[54] Facilities must also be licensed.[55] Finally, reimbursement for transporting and donating gametes and embryos and for surrogacy services is also subject to regulation.[56]

Compared to the British licensing scheme, the Canadian approach is less demanding. Licenses are granted to perform regulated reproductive activities *in toto*, not for specific reproductive treatments, as is the case in Britain. At present, licenses have unlimited validity,

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[50] Health Canada is the Federal department responsible for protecting and improving pubic health in Canada.

[51] See http://www.hc-sc.gc.ca/ahc-asc/public-consult/col/pgd-dgp/pgd-dgp_e.html.

[52] See Section 10(2).

[53] See Section 10(3).

[54] See Section 11.

[55] See Section 13.

[56] See Section 12.

whereas in Britain they must be renewed periodically. The Canadian approach to licensing, unlike its British counterpart, does not distinguish between licenses to perform ART procedures and licenses to store and distribute gametes and embryos. The Canadian approach to the licensing of reproductive medicine is of course much stricter than its U.S. counterpart, in which reproductive endocrinologists may be (but often are not required to be) specifically licensed to perform ART procedures on a state-by-state basis, and where no such licensing requirements exist at the federal level.

AHRA Sections 14 through 19 establish what may be called a system of health monitoring. A key concept of this system is "health reporting information," a term that in the act identifies what information ART practitioners must report to federal regulators. Health reporting information is a comprehensive concept that refers mainly to individuals. Individuals affected by reporting requirements fall into two categories. In the first, the AHRA includes donors of gametes and embryos, persons who have undergone an ART treatment (namely, the patients), and persons conceived through ART (i.e., the ART children proper).[57] Information regarding these individuals includes biographical, medical, and legal elements. The second category consists of individuals responsible for the custody of gametes and embryos.

The AHRA stops short of requiring the implementation of a comprehensive tracking system that includes both affected individuals and reproductive tissues. The regulatory agency is required to establish and maintain a personal health information registry. However, the reporting requirements are limited to individuals directly affected by ART procedures – i.e., donors of reproductive tissues, patients, and ART children.[58] It appears that the act does not attempt to track the history of each and every in vitro embryo. Section 15(3)(1) does, however, mandate that regulators be notified when in vitro embryos are transferred between licensees. Reproductive tissues are not affected by this requirement. Section 18 defines the purposes of these reporting requirements, calling for regulators to use health reporting information for enforcement and for public health purposes.

The AHRA specifies in some detail the rules governing the collection, access, and disclosure of health reporting information. A licensee is not allowed to accept donated gametes or embryos without obtaining the relevant health reporting information.[59] Conversely, the licensee is not allowed to disclose health reporting information without written consent of the individual whose information would be disclosed.[60] In addition, a person is entitled to obtain access to his or her own health reporting information, and to request that any corrections be made to his or her health reporting information.[61] Unfortunately, at the time of this writing, the regulations to implement these provisions have not yet been finalized. The types of information to be regarded as critical

[57] See Section 3 – definitions.
[58] See Section 17.
[59] See Section 14.
[60] See Section 15.
[61] See Section 16.

by the Canadian authorities and the specific data that must be reported to regulators remain to be determined.

The Assisted Human Reproduction Agency of Canada

Sections 21 through 39 establish a new regulatory agency, the Assisted Human Reproduction Agency of Canada (AHRAC). Section 22 sets forth two objectives for the agency – "to protect and promote the health and safety, and the human dignity and human rights, of Canadians" and to "foster the application of ethical principles" in the practice of human reproduction. The AHRAC bears some similarities to the British HFEA. It is governed by a board of directors consisting of 13 members (at the most), including the chairperson and the president. Appointments are for three-year terms and are renewable. The Canadian Governor in Council appoints both the board members and the chairperson.[62] The AHRAC is managed by a president, who is also appointed by the Governor in Council, for a term of five years, and can be reappointed.

Unlike the British Human Fertilisation and Embryology Act, the Canadian AHRA does not specify in any detail the rules that should inform the appointment of the board members, the chairperson, or the president. Nor does the AHRA touch on the composition of the board – whether it should be constituted as a body of specialists (as in the Australian case), or whether it should be inclusive of all societal views, above and beyond the views represented by organized interest groups (as in the British case). It only precludes individuals directly affected by AHRAC decisions from becoming board members.

Canada takes a rather different approach than Britain in promulgating new rules and regulations. Technically, the AHRAC does not have any authority to autonomously craft new regulations; that responsibility falls to the Canadian minister of health. Yet it would be wrong to conclude that the AHRAC is simply an administrative arm of the cabinet. Section 30(a) stipulates that one of the board's responsibilities is to advise "the Minister on assisted human reproduction and other matters to which this Act applies, or on any matter referred to the Agency by the Minister." So while the formal authority for promulgating new regulations and revolving controversial issues rests with the minister of health, the minister's decisions may be heavily influenced by the AHRAC, especially if the agency recommendations are based on a broad process of public consultation. Thus, while from a legal standpoint the agency has very limited regulatory authority, its influence on the regulatory process is likely to be significant.

The AHRA considerably restricts the authority of the executive to promulgate new regulations. Section 66 requires the minister of health to submit new regulations for approval to both houses of Parliament, a measure considered unusual by Canadian commentators. And Section 70 requires that the act be reviewed by the overseeing parliamentary committees every

[62] In Canada, the "Governor in Council" is the governor general acting on the advice of the federal cabinet (in other words, the government executive). The cabinet is made up of the prime minister and members of parliament, and sometimes senators, chosen by the prime minister. Each member of cabinet is assigned a portfolio of responsibilities, usually the subject matter of a government department.

three instead of the usual five years. Both provisions seem to reflect the highly contentious nature of the act and the Parliament's desire to maintain a tight control over the AHRAC.

The minister of health retains some administrative discretion in that he has the power to promulgate so-called policy directions. The AHRA explicitly maintains that policy directions are not statutory instruments – i.e., that they are not regulations subject to parliamentary approval.[63] Policy directions are meant to provide broad guidance in the implementation of the statute, and should not intrude on specific administrative decisions. The issuance of policy directions is the Canadian way of attenuating the tension between the desire to avoid politicizing administrative procedures and the need to provide guidance to regulatory agencies.

In sum, compared to the HFEA, the Canadian AHRAC has a rather limited formal regulatory authority. Regulation is the province of the minister of health, and not of the agency. And unlike the U.S. Congress, which controls the administrative system mainly by indirect means, the Canadian Parliament retains direct control over the regulatory process. In this sense, the Canadian AHRAC and the British HFEA, while formally similar, have vastly different authority. Nevertheless, the AHRAC is not entirely inconsequential, as it retains considerable (albeit indirect) influence over the regulatory process by playing a crucial mediating role between societal interests and the health ministry.

Among the AHRAC's main operational responsibilities are monitoring and evaluating clinical developments in reproductive medicine,[64] gathering and analyzing health reporting information,[65] and informing and educating the public.[66] A central task for the agency is of course the licensing of individuals, organizations, and facilities.[67] Another important agency responsibility is taking measures to "prevent, reduce, or mitigate" threats to human health and safety that may result from regulated activities.[68] In spite of this deceptively simple statutory language, the implementation of this provision is likely to prove both complex and costly. Few countries have implemented a system of surveillance that meets these requirements. In the United States, surveillance is limited largely to measuring success rates on a clinic-by-clinic basis. Britain comes closest to implementing a similarly comprehensive system, but as of this writing, Health Canada has not made public any implementation details.

The AHRA requires that the AHRAC not only oversee the ART industry, but also that it review research protocols involving human embryos. Since the AHRA mainly governs the use of ART technologies and deals only tangentially with research on human reproductive tissues, this area of medical research is regulated by a separate document, the "Human Pluripotent Stem Cell Research Guidelines." The AHRA, however, does contain two provisions relevant to conducting

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[63] See Section 25(3).
[64] See Section 24(1)(c).
[65] See Section 24(1)(e).
[66] See Section 24(1)(f).
[67] See Section 40.
[68] See Section 44.

research on human embryos. It requires written and informed consent from the gamete or embryo donors (s. 40(3.1). And, crucially, Section 40(2) provides that scientists must satisfy the agency that the proposed research goals cannot be achieved by any means other than using human embryos. How this process is supposed to be implemented is an unresolved matter. In particular, it is unclear whether the review process should be conducted exclusively by members of the scientific community, or whether the review panel should also include representatives of organized interest groups or even of the general public. Also unclear is whether and to what extent proponents of rejected proposals should have access to judicial review.

Some scientists may find this requirement too intrusive, or even consider it an unacceptable infringement on their scientific autonomy and professional independence. However, as a matter of practice, this approach is neither exceptional nor unreasonable. The British HFEA has been approving research protocols on human embryos in a similar fashion for many years. By distinguishing between the ends of a proposed research protocol and the means to achieve these ends, the Canadian AHRA protects a key aspect of research freedom while introducing a measure of accountability.

Finally, a significant portion of the AHRA is dedicated to inspection and enforcement procedures and to enumerating sanctions.[69] The order of magnitude of the fines imposed for many violations is similar to other cases discussed in this chapter. For example, violators of proscribed activities may be fined up to 500,000 Canadian dollars and may be imprisoned for up to 10 years.

6.4 The Human Fertilisation and Embryology Act – Blueprint for Action or a Case of British Peculiarity?

6.4.1 Introduction

Britain recognized earlier than any other OECD country that scientific developments in genetics and reproductive medicine would call for the creation of new regulatory institutions. In 1990, the British Parliament passed the Human Fertilisation and Embryology Act (the HFE Act).[70] The passage of the HFE Act was the culmination of a protracted public debate initiated by the 1998 publication of the Warnock Report on the social, ethical, and legal challenges raised by new reproductive technologies and biomedical research.[71] The report recognized that human embryos are entitled to "some protection" under the law, consistent with the view that they are neither simply clumps of human cells nor entitled to full human status. The report acknowledged that in modern, pluralistic societies, reaching a consensus on ethical controversies is a very difficult task, and recommended the creation of a regulatory institution specifically designed to

[69] See Sections 45-59 and 60-64, respectively.

[70] The full text of the HFE Act is available at http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm.

[71] Report of the Committee of Inquiry into Human Fertilisation and Embryology, Cm 9314, July 1984, also known as the Warnock report.

address ethical controversies – the Human Fertilisation and Embryology Authority. The HFEA was charged with monitoring scientific and medical advances, and is responsible for licensing any activity that involves the in vitro creation of human embryos, the storage and donation of gametes and embryos, and medical research involving human embryos. It is also charged with enforcing the provisions of the HFE Act and its regulations.

The HFE Act, based in large measure on the recommendations of the Warnock report, has stood the test of time. To date, Britain is the only country with extensive experience in the regulation of both reproductive medicine and biomedical research. The British experience in this area, therefore, is of considerable interest to any government confronted with the task of designing a regulatory structure for reproductive medicine and biomedical research.

In its 15 years of existence, the HFE Act has rarely been updated. For this reason, in 2004, the British government announced that it planned to review the act and to conduct a public consultation on this matter in 2005.[72] That it has remained largely untouched for such a long period of time is itself an indication of broad public support for this approach to resolving societal controversies produced by advances in reproductive medicine. The HFEA may not be able to craft a consensus on each and every ethical controversy, and its policies have often been criticized alternatively by pro-life groups, scientists, and the ART industry, but few have questioned the legitimacy of the HFEA as a regulatory institution.

The special position occupied by the HFEA in the British system of government is itself an expression of mild distrust in the ability of traditional administrative bodies to regulate biomedicine.[73] The HFEA enjoys a measure of regulatory discretion unknown to other British ministries.[74] The Parliament's decision to shield the HFEA from traditional mechanisms of oversight can be explained partly by the desire to protect this regulatory body against the vagaries of interest group politics. It would seem only appropriate that a regulatory body charged with resolving highly controversial moral dilemmas not be perceived as being captured by the one or the other political constituency. While in other regulatory contexts the competition for power and influence among politicians and organized interest groups can be described as normal and even healthy, in the present case, the perception that the HFEA might cater to the interests of a specific political constituency would *ipso facto* undermine its moral authority as a regulatory body. In this sense, the partial regulatory autonomy enjoyed by the HFEA reflects the Parliament's intention to minimize regulatory capture.

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[72] See http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4123863&chk=zy5dcI.

[73] Note that for brevity, we at times use the term "biomedicine" to mean reproductive medicine and biomedical research.

[74] The HFE Act delegates responsibility for promulgating the necessary regulations to the ministry of health. Regulations crafted by this ministry are subject to parliamentary review, as is the case for any other ministry. The HFEA does not have the authority to autonomously craft regulations. However, the agency does have the authority to formulate and enforce its own policies. HFEA policies, unlike regulations, are not subject to parliamentary review. In this sense, the HFEA enjoys considerably more regulatory discretion than its Canadian and Australian counterparts.

This argument is not likely to convince American commentators of administrative law who may describe the HFEA as a classic example of an "unaccountable" regulatory institution. Formally, the HFEA may be less accountable than other regulatory institutions, but in practice, its policies can hardly be described as "arbitrary and capricious." The HFEA, mindful of its unique position, traditionally has taken accountability seriously. An extensive process of public consultation always precedes the adoption of controversial new policies. Among the subjects selected by the HFEA for consultation are sex-selection and screening technologies, gamete and embryo donation, and pre-implantation genetic diagnosis.[75] Through the appointment process, the government can affect, at least in general terms, the future direction of the agency. Moreover, the HFE Act requires the HFEA to prepare an annual report for the minister of health. The reports are submitted to both houses of the Parliament for review.[76] Finally, HFEA policies are subject to judicial review. In sum, while the HFEA enjoys more regulatory discretion than other administrative entities, it cannot be described as an unaccountable regulatory institution in the sense attributed to this term by U.S. scholars of administrative law.

6.4.2 The HFE Act

Any human embryo created outside the human body falls under the jurisdiction of the HFE Act. This means that certain types of ART treatments that do not require the creation of an in vitro embryo are not subject to the act's provisions. Artificial insemination is an example; the sale of fresh sperm is another.

Like other statutes discussed in this chapter, the HFE Act distinguishes between prohibited and regulated activities. Prohibitions contemplated by the act are broadly consistent with activities banned by statutes passed in other countries. Section 3 identifies prohibited activities pertaining to the use of embryos, and Section 4 does the same for gametes. More specifically, Section 3(2)(a) and (b) prohibits transferring a non-human embryo or any non-human gametes to a woman's uterus. Section 3(3)(a) also prohibits storing or using an embryo after the appearance of the primitive streak, but in any case no later than 14 days. Section 3(3)(b) prohibits transferring a human embryo to an animal, and Section 3(3)(d) was intended to prohibit any form of cloning, though at the time cloning technologies did not yet exist. Section 12 prohibits, with some qualifications, the commercial trade of embryos and gametes. Finally, Schedule 2, Section (1)(4) prohibits the genetic modification of embryos.

Activities not explicitly prohibited by the HFE Act are regulated. The act regulates the artificial creation of embryos, the storage of gametes and embryos, and the use of embryos for research purposes by requiring ART practitioners and researchers to obtain a license for each of these three types of activities.[77] This means that research on human embryos, either privately or publicly funded, it legal under the act. In addition to the donation of human gametes and

[75] See http://www.hfea.gov.uk/AboutHFEA/Consultations.

[76] See Sections 7(1), (2) and (3) of the Act.

[77] See Sections 3(1)(a) and (b) and Section 11.

embryos,[78] the act regulates the creation of human-animal hybrids.[79] This is not as grotesque as it seems. Human-animal hybrids are created to test human gametes in animals, a well-established practice in reproductive medicine. The HFE Act is silent on the creation and use of chimeric embryos (embryos consisting of both human and animal cells). As part of a recently launched consultation on the revision of the HFE Act, the British department of health has solicited comments on the creation of human-animal hybrid or chimeric embryos for research purposes.[80]

A unique feature of the HFE Act is the absence of any reference to specific reproductive procedures, and with one exception (reproductive cloning), it has never been amended to include any such reference. For the last 15 years, it has been the HFEA's task to craft policies designed to distinguish between permissible and impermissible uses of reproductive technologies. In part, this is due to fact that at the time the legislation was enacted, there were few if any controversial reproductive technologies. According to HFEA officials, the generic structure of the HFE Act was regarded by legislators as one if its main strengths. The act was designed to give the HFEA authority to promulgate new policies in response to new scientific and medical developments in a timely manner. This the HFEA has done with effectiveness. Among the most recent initiatives are a public consultation on the use of PGD in 2002, another public consultation in 2002-2003 on sex-selection technologies, and in 2004 a review of its policy on donated gametes and embryos.[81]

6.4.3 The Human Fertilisation and Embryology Authority

The HFE Act defines the statutory functions of the Human Fertilisation and Embryology Authority as follows:

- Review information about human embryos and any subsequent development of such embryos, and the provision of treatment services and activities governed by the HFE Act. The HFEA should also advise the secretary of state on relevant developments in treatments and research.[82]
- Promote its services and the services offered by the licensees to the public.[83]
- Provide relevant advice and information to patients, donors, and clinics in the UK.[84]
- Produce a code of practice which gives guidelines to infertility clinics about the proper conduct of licensed activities.[85]

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[78] See Art. 4(1)(b).

[79] See Art. 4(1)(c).

[80] The consultation documents can be found at http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4123863&chk=zy5dcI.

[81] See http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy for additional information about these consultations processes.

[82] See Art. 8(a).

[83] See Art. 8(b).

[84] See Art. 8(c).

- Maintain a formal register of information about donors, treatments, and children born as a result of those treatments.[86]

To discharge these functions, the HFEA has the authority to establish additional, specialized committees. As of this writing, seven committees exist – the Regulation Committee, the Scientific and Clinical Advances Group, the Ethics and Law Committee, the Organization and Finance Committee, the Information Management Program Board, the Audit Committee, and the License Committee.[87] The first three committees discharge the core HFEA functions. Members of any of these committees are also members of the HFEA proper. Committees can establish specialized subcommittees. Participation in a subcommittee is not restricted to HFEA members. Outside members can be appointed to subcommittees, but HFEA members must remain in the majority.[88]

The HFE Act specifies in considerable detail the composition, responsibilities, and procedures governing the Human Fertilisation and Embryology Authority. The HFEA, unlike its Australian counterpart, is not designed to be exclusively a technocratic body of governance. The Act tries to strike a balance between two partially conflicting goals, technical competence, including scientific, medical, legal and ethical expertise, and legitimacy. A regulatory body consisting exclusively of technical specialists obviously would be highly competent, but the general public may view the policies promulgated by this body with suspicion. On the other end, a regulatory body dominated by laypersons would most likely be regarded as legitimate, but its technical competence would be very limited.

Currently, the HFEA has 18 members, including the chairperson and the deputy. Schedule 1 of the Act ("The Authority: Supplementary Provisions") does not specify the size of this board; that decision is left to the "Secretary of State for Health", i.e. the health minister. It does, however, offer considerable guidance regarding its composition. Article 4(2) of Schedule 1 requires that the views of both men and women be "adequately represented." As of this writing, the HFEA consists of exactly nine women and nine men. Article 4(3) establishes that three categories of individuals are not eligible for the positions of chairperson or deputy chairperson: (a) medical practitioners, (b) individuals involved in "keeping or using gametes or embryos outside the body," and (c) individuals with an interest in the funding of research on keeping or using gametes or embryos. The health minister must also ensure that medical and ART practitioners (categories (a) and (b)) are represented by at least one person on the board. Finally and most importantly, the health minister must ensure that at least one-third but less than half of HFEA members represent the medical profession, the ART industry, and the research community (categories (a), (b), and (c)).

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[85] See Art. 25. The sixth edition of the code is available at http://www.hfea.gov.uk/HFEAPublications/CodeofPractice.

[86] See Art. 31.

[87] See http://www.hfea.gov.uk/AboutHFEA/OrganisationalStructure.

[88] See Sections 9(1) – 9(6).

This provision has important consequences. It severely limits the health minister's ability to appoint medical and scientific specialists. More specifically, it forces the minister to select individuals who do not represent the medical profession, the ART industry, or the scientific community. In this narrow but important sense, the health minister must appoint a majority of individuals that in some sense represent the general public. This is a very unusual approach to filling important administrative positions, and as such deserves some scrutiny.

It is the health minister's responsibility to appoint a qualified individual to the HFEA. Schedule 1 does not include any appointment rules. The HFEA simply conducts a nationwide public search open to any qualified British citizen. The health minister selects new HFEA members from the pool of qualified individuals. The appointment is for a three-year term. A member of the HFEA can be reappointed, but not for consecutive terms. What constitutes a suitable candidate and what rules inform the appointment process are not entirely clear. It appears that the health minister enjoys considerable discretion in appointing new board members. In this regard, the HFEA is no exception. In the recent past, appointments to boards of "executive and advisory non-departmental public bodies" such as the HFEA have generated considerable discomfort in the general public. In response to the charge that appointments to these bodies often appear to be arbitrary and capricious, the British Government established an Office of the Commissioner for Public Appointments charged with developing a code of practice intended to increase the legitimacy and credibility of these appointments.[89] On its Web site, the HFEA states that its members are appointed in accordance with guidance from the Commissioner for Public Appointments, but the guidelines are rather generic and offer little insight into how members are actually selected. Conversations with HFEA officials have confirmed that the appointment process remains very much a discretionary activity of the health minister, as nominees do not need to be confirmed by the Parliament and no specific guidelines exist for the selection of suitable candidates.

In our view, the appointment process remains the weakest element of the British approach to regulating reproductive medicine and medical technologies. To appreciate the limits of current appointment rules, one should try to identify those HFEA members that do not represent the fertility industry, the medical profession, or the scientific community. The HFEA Web site provides a list of current members complete with short biographical abstracts, but it does not supply any information about the slot occupied by each member.[90] There are seven members who are obviously not representing the three main constituencies – the chairperson (a consumer group advocate), a reverend, the UK's financial Ombudsman, a broadcast journalist, a finance and business professional, a very senior career politician, and a senior editor. These are accomplished senior individuals, all of whom can be expected to appreciate the complexities involved in regulating reproductive medicine and medical research. However, they can hardly be regarded as typical representatives of the general public.

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[89] See http://www.ocpa.gov.uk/the_code_of_practice/index.asp.

[90] See http://www.hfea.gov.uk/AboutHFEA/HFEAMembers.

The remaining three positions reserved to laypersons are occupied by a representative of an infertility group, a professor of medical law, and a professor of philosophy and ethics. These are certainly highly qualified individuals, but one could legitimately wonder to what extent they may be viewed as representatives of the general public. An unsympathetic reading of these appointments could easily come to the conclusion that the HFEA lay members are neither lay nor representative of the general public. Infertility groups, far from playing a mediating role between the public and the ART industry, often are focused exclusively on their narrow interest. Whether a professor specialized in medical law is more likely to take a broad public view of bioethical dilemmas is an open question. As for the philosophy professor, it is difficult to imagine a profile more distant from common conceptions of a layperson.

It is certainly not our intention to disparage the integrity and the professionalism of the HFEA board members. What this short discussion shows is how problematic the notion of a layperson can be. As it is now constituted, the HFEA is not too dissimilar from any other technical advisory board – impressive in terms of the scope and depth of medical and scientific expertise but hardly inclusive of lay views. These shortcomings notwithstanding, it must be emphasized that HFEA appointments have rarely been controversial. Perhaps the British are less distrustful of public officials than the American public.

It would have been interesting to examine in some detail the rules governing the HFEA decision-making process. Unfortunately, we were unable to identify any. Schedule 1 leaves it to the HFEA to constitute itself as it sees fit, but the HFEA has never spelled out these rules. It is plausible to assume that the HFEA devotes a considerable amount of time to deliberating controversial ethical questions – in other words, that it operates in a deliberative fashion. Whether deliberation, on balance, leads to consensual positions or whether this regulatory body remains divided most of the time is unclear. Asked about this issue, HFEA officials have generally been evasive, a reaction suggesting that the decision-making process is not informed by clear and unambiguous rules, that conflicts may be common, and that their resolution may depend on a vote or on an executive decision by the chairperson.

6.4.4 Licensing

The HFE Act specifies both general requirements[91] and specific criteria for obtaining a treatment,[92] a storage license,[93] and a research license.[94] Additional licensing requirements are introduced in Schedules 2 and 3. Article 12 lays out the basic provisions for obtaining a license, including record-keeping requirements, the right of the HFEA to inspect a licensed facility, and the obligation of a licensed facility to provide records to the HFEA upon request.

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[91] See Art. 12.

[92] See Art. 13.

[93] See Art. 14.

[94] See Art. 15.

Schedule 2, Article 1 enumerates the activities a treatment license authorizes a licensee to conduct – creating human embryos,[95] keeping embryos,[96] using gametes,[97] testing embryos before implantation,[98] placing an embryo in a woman,[99] and mixing human sperm with animal eggs (to test the viability of the sperm).[100] The validity of a treatment license is limited to five years.

Article 13 spells out the requirements for obtaining a treatment license, and specifies the record-keeping requirements[101] – it requires protecting the integrity of personal records[102] and taking into account the welfare of the prospective child when considering treatment;[103] it mandates counseling for the woman and/or the couple prior to treatment;[104] and it demands that procedures be put in place for determining the identify of gametes and embryo donors.[105]

Of some interest to an American audience is Article 13(5). As mentioned above, this Article 13 sanctions the principle that the welfare of ART children is be taken explicitly into account when considering the pros and cons of a reproductive treatment. What exactly constitutes "welfare" is defined more precisely in the code of practice discussed below.[106] For example, the HFEA considers protecting the well-being of future children incompatible with single women and lesbian couples seeking reproductive services. This policy has been very controversial from the beginning, but it has remained in place. Whether it will survive the ongoing review process remains to be seen.

Licensing requirements for the storage of gametes and embryos are relatively straight-forward: They simply require that storage be performed by licensed persons only, and that reproductive materials be supplied or transferred only to individuals in possession of a license for storage or treatment. Gametes can be stored for up to 10 years, embryos for five years.

More interesting to the present discussion are the provisions of Schedule 2, Article 3 concerning the granting of research licenses. Britain has been able to solve the conflict between the scientists' desire to protect the freedom of research and public demands for increased accountability in controversial areas of medical research. Article 3 explicitly authorizes conducting research on human embryos, but it severely restricts the scope for conducting this

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[95] See (1)(1)(a).
[96] See (1)(1)(b).
[97] See (1)(1)(c).
[98] See (1)(1)(d).
[99] See (1)(1)(e).
[100] See (1)(1)(f).
[101] See Art. 13(2).
[102] See Art. 13(4).
[103] See Art. 13(5).
[104] See Art. 13(6).
[105] See Art. 13(7).
[106] See Articles 25 and 26.

type of research. The HFEA is required by the HFE Act to ensure that the proposed research meets any of the following criteria:[107]

- It promotes advances in the treatment of infertility
- It increases knowledge about the causes of congenital disease
- It increases knowledge about the causes of miscarriages
- It aims to develop more effective methods of contraception
- It aims at developing methods for detecting gene or chromosomal abnormalities in embryos
- Other such purposes as may be specified in regulations

In November of 2000, following the recommendations of a report by the Chief Medical Officer's Expert Advisory Group titled "Stem Cell Research: Medical Progress with Responsibility,"[108] the Parliament passed new regulations known as the Human Fertilisation and Embryology (Research Purposes) Regulations 2001.[109] The new regulations, effective January 31, 2001, allow the HFEA the grant a research license for the following additional activities:

- Research involving embryos for the purpose of increasing knowledge about the development of embryos
- Increasing knowledge about the development of disease
- Enabling any such knowledge to be applied in developing treatment for serious disease

These regulations are meant to legalize research cloning – to allow the creation of embryos by somatic cell nuclear transfer for research purposes. Following the passage of the Human Fertilisation and Embryology (Research Purposes) Regulations 2001, several members of Parliament grew concerned that these new regulations would open the door to reproductive cloning. To prevent this possibility, in the same year, the Parliament explicitly banned human reproductive cloning.[110]

Based on our conversations with HFEA staff, obtaining a license to conduct research on human embryos is no easy task. For example, the HFEA requires applicants to demonstrate that their research goals cannot be achieved without sacrificing human embryos. By imposing this requirement, the HFEA, for all intents and purposes, separates (scientific) means and ends. The HFEA does not question the ends (the research goals), but it probes whether the means are commensurate with these goals. The HFE Act also establishes specific rules for appealing a

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[107] See Art. 3(2).

[108] See http://www.dh.gov.uk/AboutUs/MinistersAndDepartmentLeaders/ChiefMedicalOfficer/ProgressOnPolicy/ProgressBrowsableDocument/fs/en?CONTENT_ID=4108203&MULTIPAGE_ID=5123869&chk=JCMyhP.

[109] See http://www.opsi.gov.uk/si/si2001/20010188.htm.

[110] See http://www.opsi.gov.uk/acts/acts2001/20010023.htm.

decision by the licensing committee.[111] Researchers whose applications have been turned down can first request to give an oral presentation to this committee. If the licensing committee persists in refusing to grant a license, researchers can appeal to the HFEA. Finally, researchers can challenge the decision by appealing to the High Court.

American scientists may find the British approach to granting research licenses too restrictive. They may believe that the HFE Act excessively limits research freedom by granting too much discretion to the HFEA, leading to "capricious and arbitrary" decisions. They may also perceive this approach to be too bureaucratic and cumbersome. Others commentators may find the utilitarian orientation underlying granting research licenses unacceptable. Still others may be disturbed by the notion that the government is involved in the business of sanctioning the destruction of human embryos.

To all those who oppose conducting research on human embryos, the British approach will remain unacceptable. To other critics, however, this approach also has some attractive features. It greatly reduces the need for scrutiny by universities and hospitals, a considerable burden according to some scientists. It establishes clear and consistent criteria for conducting embryo research, and it ensures equal treatment for publicly and privately funded research. Importantly, the utilitarian approach to evaluating research proposals ensures that the researchers must justify their methodological choices in some detail. In sum, the British approach to granting research licenses protects the freedom of research while satisfying public demands for holding scientists accountable.

6.4.5 The Code of Practice

Under the HFE Act, the HFEA has a statutory duty to prepare a Code of Practice. The Code of Practice provides considerable guidance to licensees (ART clinics, research institutions, and gametes and embryo banks) and to patients concerning the proper implementation of the act itself. It is in this area that the HFEA regulatory autonomy manifests itself. The HFEA uses the code to promulgate specific policies on a wide range of reproductive practices and ethical questions. The sixth edition of the Code of Practice, published in 2003, covers most aspects of the HFE Act.[112] New to this edition are Sections 14 (on pre-implantation genetic testing), 15 (on witnessing clinical and laboratory procedures), and 16 (on intra-cytoplasmic sperm injection). The legal status of the Code of Practice is somewhat ambiguous; its provisions do not have the force of law, but licensees are well-advised to take its recommendations seriously, as disregarding its provisions may have serious negative consequences.[113]

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[111] See Articles 20 and 21.

[112] These include staff, facilities, and administrative procedures, welfare of the child, assessing and screening potential donors, information, consent, counseling, use of gametes and embryos, storage and handling of gametes and embryos, research, records, confidentiality, complaints, pre-implantation genetic testing, witnessing clinical and laboratory procedures, and intra-cytoplasmic sperm injection.

[113] Article 25(5) states: "A failure on the part of any person to observe any provision of the Code shall not of itself render the person liable to any proceedings, but: (a) a License Committee shall, in considering whether there has

The relevance of the Code of Practice can hardly be overemphasized. It makes it much easier for licensees to comply with the HFE Act by reducing legal uncertainty. It also demonstrates how a regulatory body can promote the adoption of best practices without crafting rigid rules and regulations. The code accomplishes this through the HFEA system of monitoring and compliance assurance. Clinics are audited on a regular basis, typically yearly. Inspections are unannounced, and violations can lead to suspension of the license. In this regard, the HFEA's approach to compliance assurance is no different than any other enforcement system. However, many inspections are conducted not by HFEA officials but ART professionals themselves, typically colleagues at other ART clinics. This measure was taken not to increase economic efficiency or to reduce personnel costs, but to promote reciprocal learning and the adoption of best practices. According to HFEA officials, this approach has proven very successful in ensuring that clinics become aware of potential areas of concern, and has indeed promoted the adoption of best practices among ART practitioners.[114] The HFEA capitalizes on this process by carefully scrutinizing audit results and by using this information to improve existing policies and practices.

6.5 Summary and Conclusions

Our review of legislative initiatives at the international level provides several lessons. Most industrialized countries and many developing nations have responded to the ethical dilemmas raised by reproductive medicine and biomedical research not only by appointing ethics commissions, but also by passing new legislation. As Appendix H demonstrates, there is a remarkable agreement among legislative bodies around the world on which reproductive practices and scientific developments may call for governmental interventions. These include embryo research, reproductive cloning, research cloning, stem cell research, pre-implantation genetic diagnosis, the creation of chimeric animals, the creation of hybrids, germ-line genetic modifications, surrogacy, and the trade or sale of gametes and embryos. The United States is the exception, having refrained to adopting any specific measures for most of these developments.

Among the countries included in our survey, there is little agreement on how to respond to new developments in biomedicine. Most countries have banned reproductive cloning. In other respects, however, important differences remain. Interestingly, prevailing religious and cultural orientations seem to be weak predictors of legislative choices. Spain, for example, has much more liberal stem cell research legislation than France or Italy. Important differences exist

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been a failure to comply with the conditions of a license and, in particular, conditions requiring anything to be "proper" or "suitable," take account of any relevant provision of the Code, and (b) a License Committee may, in considering, where it has power to do so, whether or not to vary or revoke a license, take into account any observance or failure to observe the provisions of the Code.

[114] This practice is not as uncommon as one might think. In many industrial sectors that have adopted voluntary environmental and safety codes, "compliance" is often ensured through an analogous mechanism. For example, in the United States, the National Paint and Coatings Association, an organization that has adopted a comprehensive and mandatory system of environmental management known as "Coating Care," relies on reciprocal audits to monitor compliance and promote the adoption of best practices.

among Scandinavian countries; Sweden has embraced stem cell research and research cloning, whereas Norway has adopted a much more cautious and restrictive approach. Similar differences exist among Asian countries. These diverging legislative paths suggest that it would be premature to envisage comprehensive international treaties in this area save for a ban on human reproductive cloning.

Relatively few countries have adopted a regulatory approach or have created new regulatory institutions. This may reflect important differences in national administrative systems and in legal traditions, not to mention imperfect knowledge of these systems on our part. It appears that in many cases, existing ministries have been given the authority to craft regulations in the area of reproductive medicine and biomedical research. Switzerland is a case in point. The Australian, Canadian, and British cases demonstrate that the delegation of legislative authority is a realistic but not unproblematic legislative response. How these regulatory bodies can preserve their moral authority without being perceived as unaccountable institutions is a question that has not yet received an entirely satisfactory answer.

It has also become clear that neither the British HFEA nor its Australian and Canadian cousins offer a template for building an analogous regulatory institution in the United States. The HFEA decision-making process is probably too informal and not sufficiently transparent for the U.S. public. Nor is an 18-member regulatory body likely to garner much support. The Australian approach is more considerate of regional differences and could therefore be considered a better fit, but it also reflects Australian peculiarities that would make it unsuitable to the U.S. administrative context. Finally, the Canadian approach, though promising in many ways, is still being implemented and cannot be properly evaluated. In short, while these three countries have demonstrated the soundness and viability of a regulatory approach to reproductive medicine and biomedical research, their respective approaches cannot easily be adapted to the U.S. administrative and legal system.

6.6 Bibliography

Caulfield, Timothy. "Politics, Prohibitions and the Lost Public Perspective: A Comment on Bill C-56: The Assisted Human Reproduction Act." *Alberta Law Review* 40 (2002): 451-62.

Makkai, Toni, and John Braithwaite. "Reintegrative Shaming and Compliance with Regulatory Standards." *Criminology* 32 (1994): 361-85.

No Need for More Stem Cell Embryos Sydney Morning Herald, March 29, 2005 [cited September 22, 2005]. Available from http://www.smh.com.au/news/National/No-need-for-more-stem-cell-embryos-MPs/2005/03/29/1111862384922.html?oneclick=true.