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Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries*

ROSARIO M. ISASI** & BARTHA M. KNOPPERS***

In his *Nicomachean Ethics*, Aristotle highlighted the connection between ethics and politics.[1] This intersection between ethics and public policy remains important more than two thousand years later. For instance, in the stem cell and cloning debate, the boundaries between science, religion, ethics and politics are often blurred. The recent adoption of the United Nations *Declaration on Human Cloning* demonstrates the polarization of worldviews on this controversial topic.[2]

Few scientific discoveries have elicited more enduring concern among scholars, government officials, and the general public than the permissibility of conducting research on embryos in general, and human embryonic stem cells (hESC) and cloning research in particular. Governments are challenged to with the vexing question of how to balance the therapeutic prospects of hESC and cloning research with the complex socio-ethical and moral issues involved.

Countries have framed the policy debates surrounding embryo, stem cell and cloning research differently. The historical, cultural and sociological context, the institutional framework, and the mobilization of stakeholders are factors that help explain why countries that seemingly share similar socio-religious beliefs have adopted diametrically opposite public policies.

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* The appendix to this document can be found here: <http://www.stemgen.org>

** Postdoctoral Fellow, Centre de recherche en droit public, Faculte de droit, Universite de Montreal.

*** Canada Research Chair in Law and Medicine, Professor at the Faculté de droit, Universite de Montreal and Senior Researcher Centre de recherche en droit public. Corresponding author: rosario.isasi@umontreal.ca

1 Aristotle, *Nicomachean Ethics*, trans. by Chase D. P. (New York: Dover Publications, 1998) at 229.

2 *United Nations Declaration on Human Cloning*, GA Res., UNGAOR, 59th Sess., UN Doc. A/280 (2005).

Central to the framing of the debate has been the social construction of the human embryo. The political evaluation of stem cell lines derived from human embryos necessarily involves determining the moral – and, *a fortiori*, the legal—standing of the embryo. However, most national policies regulating embryonic and stem cell research lack internal consistency with respect to their views regarding the moral and legal status attributed to the embryo.

Though embryonic and stem cell research are closely linked to the broader debate about human cloning, and although government funding of research implicitly encourages such research, few countries have adopted a systematic, comprehensive legal and ethical framework governing the regulation of these technologies.

While adopting legislation is often difficult to achieve in this sensitive area, setting ethical, professional as well as quality and safety assurances and standards that are reasonable or coherent for all members of a pluralistic society should be an achievable goal. Otherwise, we risk being entrapped in a *dialogue of the deaf*, a policy stalemate, in which market forces undermine democratic processes.[3]

We maintain that public policies should be designed to adapt to both changing social circumstances and to scientific progress. However, they often fail to address issues in a prospective manner. A good example of this is the absence of public policies addressing the socio-ethical (and legal) issues that potential clinical, experimental, and therapeutic applications of stem cell and cloning research could pose. For instance, which safeguards should be in place to ensure that only safe and effective cell therapies will be brought to the bedside?[4] Many governments justify their public policies based on an alleged scientific consensus that the potential benefits of hESC and therapeutic/research cloning (as opposed to reproductive cloning) outweigh moral reservations. These governments are further challenged to deliver results expeditiously in light of heightened public expectations for cures and treatments, while ensuring protections of the rights of research

3 An example of this is the failure of the United States Congress to adopt legislation regulating embryo research, stem cells and cloning research. Absent federal policy, the private sector has been largely unregulated and left to market forces. Alice Ouellete, Arthur Caplan et. al., "Lessons Across the Pond: Assisted Reproductive Technologies in the United Kingdom and United States" (2005) 31:4, American Journal of Law and Medicine 419-28.

4 Kathleen Lindell & Susan Wallace, "Emerging Issues for Human Stem Cell Medicine" (2005) 1:1 Genomics, Society and Policy 54-73.

subjects and patients,[5] the recent scandal in South Korea being the most notorious example.[6]

Discussions about the ethics of using stem cells derived from embryos will always persist. Is this an insurmountable problem? Is public policy on morally contentious issues only feasible when there is a high level of consensus? Can we overcome this challenge while still respecting democratic principles? A society's choice regarding which scientific advances to foster and which to discourage also reflects its ethical priorities. As Laritzen points out,

> "the fundamental question raised by stem cell research is not about the embryo. Instead, it is about the future toward which biotechnology beckons us. Most succinctly, the question is: Does contemporary biotechnology, including or perhaps especially stem cell research, open the door to a posthuman future?"[7]

This article provides an overview of (I) the moral and legal status of the human embryo and of the (II) regulatory approaches to embryonic stem cells and cloning research by comparing the regulatory frameworks of 50 countries.[8] The major goal of this study is to provide and analytical understanding of the policy landscape

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5 As noted in a recent editorial: "the drive to be the first one to provide cell lines for therapy could compromise safety for recipients and could lead this technology into the realms of quackery." Peter Braude, Stephen Minger & Ruth Warwick, "Stem Cell Therapy: Hope or Hype?" Editorial, (2005) 330 BMJ 1159.

6 In two *Science* papers published in 2004, Dr. Woo Suk Hwang claimed to have created patient-specific stem cells by somatic cell nuclear transfer (research cloning). Later, on December 2005, a Seoul National University (SNU) investigative committee issued a report concluding that Dr. Hwang and his team had fabricated those results. Moreover, the committee also concluded that Hwang's had used over 2,000 oocytes for his experiments and not the 427 oocytes he had claimed. Furthermore, oocyte donors were not properly informed about the health risks that may result from the donations, some of them were coerced to donate and 66 of them received financial compensation.
Following the conclusions of the SNU committee – and with the agreement of few of the authors– the editors of *Science* decided to retract both papers. The Hwang scandal has prompted the Korean National Bioethics Committee to reconsider whether to permit further cloning research.

7 Paul Laritzen, "Stem Cell Biotechnology, and Human Rights: Implications for a Posthuman Future" (2005) 35:2 Hastings Center Report 31.

8 Australia, Argentina, Austria, Belgium, Brazil, Bulgaria, Canada, China, Colombia, Costa Rica, Cyprus, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Latvia, Lithuania, New Zealand, Norway, Panama, Peru, Poland, Portugal, Singapore, Slovenia, Slovakia, Spain, Romania, Russia, South Africa, South Korea, Sweden, Switzerland, The Netherlands, Tunisia, Turkey, Ukraine, United Kingdom, United States and Vietnam. The criterion for selection was based on the adoption of policy regarding embryo, stem cell and/or cloning research.

around the globe, with an aim to contribute to worldwide policy debates. The comparison of these policies underscores the hurdles that scientific consortia involving international jurisdictions and policy frameworks have to confront, as well as the challenges facing the international harmonization of such policies.

I. The Human Embryo: Moral and Legal Status

Much of the ethical and policy debate has focused on the moral status of the human embryo. The puzzling question as to whether the human embryo should be granted full personhood status, or at minimum, be recognized as a potential person, has no simple answer. The dilemma itself provides an explanation of how the regulatory models surrounding this issue differ: some countries have used the moral status criterion explicitly for the framing of public policy,[9] while others have used the criterion implicitly.

It has proven to be difficult to render an account of when human life begins and what moral –and, a fortiori, legal – status should be ascribed to the human embryo. In the majority of the countries surveyed, the human embryo has been bestowed with an intermediate or gradualist moral status; that is, the embryo is considered more than a simple clump of cells[10] but less than a full human person. Though some recognition is present across the restrictive-liberal policy design continuum, this view is most compatible with an intermediate policy approach.

Under a gradualist position, embryo research is prima facie ethically acceptable. Yet it is restricted to a demonstration of the 'special respect' or 'serious moral consideration' the embryo is deemed to have due to its potential to become a human being .[11] The language adopted in some policy provisions constitutes

9 E.g., the constitutions of Ireland and Ecuador which maintain the right to life from conception. See also the Costa Rican Supreme Court ruling unconstitutional a decree regulating human assisted reproductive technologies. Sala Constitucional de la Corte Suprema de Justicia, Exp. No. 95-0012734-0007-CO (March 3, 1995).

10 E.g. the Australian National Health and Medical Research Council (NHMRC) prescribe: "while there are different views in our community about the moral status of a human embryo, one that is very widely shared is that embryos are not to be treated as mere tissue." National Health and Medical Research Council (NHMRC), Ethical *Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, (September 2004).

11 Steinbock B., "Respect for Human Embryo" in Laritzen P., ed., *Cloning and the Future of Human Embryo Research* (Oxford: Oxford University Press, 2001).

illustrative examples of the special respect conferred on the human embryo.[12] For instance, guidelines in India state that, "respect for the embryo's moral status can be shown by careful regulation of conditions of research and safeguards".[13] The French National Consultative Ethics Committee recommends that, "the human embryo must, as soon as it is formed, receive the respect owed to its status,"[14] without providing further explanation.

Paradoxically, appeals to 'human dignity' as a criterion for embryo policy are not infrequent.[15] For example, Estonian, Finish, Swedish and Swiss policies prohibit "abusing" or "damaging" the embryo with the aim to protect its "dignity".[16] Moreover, guidelines adopted in Japan assert, "human embryos and hES cells shall be handled carefully and conscientiously without violating human dignity."[17] Australian ethical guidelines prescribe that "respect for the dignity and wellbeing of the mother and the embryo must take precedence over any expected benefits of knowledge."[18]

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12 "…the embryo's value is symbolic rather than intrinsic or independent. The imprudent, instrumental use of embryos is prohibited since this might otherwise undermine the protection of other, more developed forms of human life. This means that the embryo is entitled to a certain degree of protection, due to 'importance by association'." The Health Council of the Netherlands, *The Health Council report on "Stem Cells for Tissue Repair, Research on Therapy Using Somatic and Embryonic Stem Cells"* (2002). And, "All embryos subjected to research must be treated with respect and are prohibited from being treated as merchandise." Comité Consultatif de Bioéthique, *Opinion No.18 regarding human embryo research,* (2002).

13 Indian Council of Medical Research, *Consultative Document on Ethical Guidelines for Biomedical Research on Human Subjects*, (2000).

14 National Consultative Ethics Committee (CCNE), *Opinion (No 67) on the Preliminary Draft Revision of the Laws on Bioethics,* (2001) and *Opinion (No 53) on the establishment of collections of human embryo cells and their use for therapeutic or scientific purposes*, (1997).

15 Timothy Caulfield, Roger Brownsword, "Human Dignity: A Guide to Policy Making in the Biotechnology Era?", (2006) *Nature Reviews Genetics* (7) 72-76. Bartha Knoppers, "Human Dignity: In Danger of Banality?" (The Case of Cloning), (2005) Case Western Reserve, *Journal of International Law* 35(3), 385-395.

16 Estonia – *Embryo Protection and Artificial Fertilisation Act*, (1997). Finland – *Medical Research Act No. 488*, (1999). Sweden – *Act 1991:115 on Measures for Purposes of Research and Treatment Involving Fertilized Human Ova,* (amendment in force 1 April 2005). Switzerland – *Federal Act on Research on Surplus Embryos and Embryonic Stem Cells (Embryonic Research Act),* (Approved by referendum November 2004).

17 Japan Ministry of Education, Culture, Sports, Science and Technology, Guidelines for Derivation and Utilization of Human Embryonic Stem Cells, (25 September 2001).

18 National Health and Medical Research Council (NHMRC), *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research,* (September 2004).

With the embryo as the locus of ethical (and legal) concern, it is therefore critically important how the term is defined. Yet many countries have failed to incorporate a definition of the term 'embryo' into their policies or, have provided a definition that left certain human embryos (e.g. created by somatic cell nuclear transfer) outside the scope of the legal definition. Moreover, those that have a definition often lack a consistent and precise use of the term or they rely on a "circular" definition that contains the same concept that is supposed to be defined.[19]

Some countries have defined the embryo by reference to a particular point in time. For instance, legislation in South Africa, Australia, and Singapore, along with Indian guidelines, refer to the 'embryo' as a human offspring in the first 8 weeks from the moment of conception.[20] In Canadian legislation, the embryo is referred to as a "human organism during the first 56 days of its development following fertilization or creation."[21] Whereas in other jurisdictions, the embryo is defined in reference to a broad time frame: a "fertilised ovum at all stages of development" (Iceland, Estonia, United Kingdom, Finland, South Korea).[22] Final-

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19 E.g., Australian legislation states that: *"a human embryo* means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means." *Act No. 145 – An Act to regulate certain activities involving the use of human embryos, and for related purposes (2002)* and the *Act No. 144- An Act to prohibit human cloning and other unacceptable practices associated with reproductive technology, and for related purpose (2002).* Moreover, Estonia's *Embryo Protection and Artificial Fertilisation Act*, 1997 (Amended 2003), Chapter 1, Section 3, states that an "Embryo means an (human) embryo in its early stage of development from the time of fertilisation of the ovum."

20 South Africa – *National Health Act*, (31 December 2003), Section 1. Australia – *Research Involving Human Embryos Act No. 145, An Act to regulate certain activities involving the use of human embryos, and for related purposes,* (2002). Singapore – *Human Cloning and Other Prohibited Practices Act*, (2 September 2004). India – Council of Medical Research, *Consultative Document on Ethical Guidelines for Biomedical Research on Human Subjects* (2000).

21 *An Act Respecting Assisted Human Reproduction and Related Research*, (2004), Art. 3.

22 Iceland – *Artificial Fertilisation Act No. 55/1996*, (29 May 1996). Estonia – *Embryo Protection and Artificial Fertilisation Act*, (1997). United Kingdom – *Human Fertilisation and Embryology Act*, (1990) (c.37), Article 1 "(a) embryo means a live human embryo where fertilisation is complete, and (b) references to an embryo include an egg in the process of fertilisation, and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote." Finland – *Medical Research Act,* (1999), Section 2, "Embryo means a living group of cells resulting from fertilization not implanted into a woman's body." South Korea – *Life Ethics Law*, (29 January 2004), Article 2, "'Embryo' refers

ly, recognizing that any precise indication of time is always arbitrary, other countries have opted to define the embryo according to its capacity to develop into an individual or a human being (e.g. New Zealand, Belgium, Japan and Germany).[23]

As we will see, attempts to create a moral (and legal) separation between embryo protection, destruction and use (e.g. for medically assisted procreation, to derive embryonic stem cell lines or to study cell lines already derived) are often artificial and lack moral consistency.

Probably the most ethically coherent – albeit contentious – policy regarding embryo protection and use is found in countries adopting a very restrictive policy framework. Under this approach, embryo research, cryopreservation and destruction is prohibited (e.g. Austria, Ireland and Italy).[24] Certainly, this assessment does not take into account the medical (e.g. health) and broader social consequences arising from these policies. Indeed, here, all embryos created through assisted reproductive techniques must be implanted, regardless of medical indication or the couples' wishes.

In most of the jurisdictions surveyed, regardless of their policy design, there are provisions mandating the destruction of cryopreserved embryos (created either for reproductive and/or research purposes) after the expiration of the statutory storage period,[25] or at the embryo donor's request.[26]

Though the destruction of embryos after long storage periods is often inevitable due to safety concerns, the ethical consistency of provisions that forego their donation for reproductive purposes, or for its use in research, while at the same time claiming to confer a 'special respect' to the human embryo is questionable. Allowing childless couples to procreate or, using embryos for ethically approved and scientifically sound research would be the most appropriate way to grant 'serious moral consideration' to human embryos already created for reproductive

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to a fertilized egg (or segmented cell) from the moment of fertilization to the point of time at which all organs of the given organism have developed embryologically."

23 New Zealand – *Human Reproductive Technology Act No. 92*, (2004). Belgium – *Law on research on human embryos in vitro*, (April 2003). Japan – Japan Ministry of Education, Culture, Sports, Science and Technology, Guidelines for Derivation and Utilization of Human Embryonic Stem Cells, (25 September 2001). Germany – *The Embryo Protection Law*, (1990).

24 Austria – Federal Law of 1992 (Serial No. 275) regulating medically assisted procreation (the Reproductive Medicine Law), (1993). Ireland – *Irish Constitution 1937* (as amended in 1983). Italy – *Medical Assisted Procreation Law No. 40*, (19 February 2004).

25 The length of storage varies widely, ranging from 5 (e.g. Iceland, Norway, South Korea, Sweden and United Kingdom) to 15 years (e.g. Finland). See e.g.Estonia, Finland, Greece, Norway, Slovenia, Sweden, UK Canada, Iceland, Japan and South Korea.

26 E.g. Canada , Switzerland, and UK.

purposes.[27] Otherwise, ethical consistency would mandate the adoption of policies that avoid the existence of supernumerary embryos by limiting or regulating their creation through assisted reproductive technologies.

Moreover, irrespective of moral and legal embryo status, another additional safeguard to the prohibition on developing a human embryo beyond 14 days from fertilization – or until the formation of the primitive streak – , is that a number of jurisdictions explicitly require the destruction of embryo after the aforementioned period.[28]

Regardless of attempts to legislate it away, direct or indirect inducement and complicity are necessarily involved in the research enterprise. The special respect or moral value attributed to the human embryo in most of the public policies surveyed would be considered morally consistent when such policies also require a scientific and ethical justification for embryo use and destruction.[29]

II. Regulatory Approaches

Two approaches shape emerging policy trends: a public and a private public ordering approach. A public ordering approach involves state-led initiatives to frame emerging biotechnologies. Due to the different regulatory systems adopted throughout the world, it is difficult to make broad generalizations about the current legitimacy or acceptability of hESC in both public and private ordering systems. These systems are a reflection of the legal traditions, cultural and socio-religious beliefs, and economic interests which inform and shape public policy on embryonic,

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27 Legislation adopted in Estonia, Finland, Greece, Slovenia. Sweden, UK, Canada, Japan and South Korea allow for the donation of embryos for research when no longer needed for reproductive purposes or after the expiration of their statutory storage period. In Switzerland the *Embryonic Research Act* (2004) explicitly allows the donation of 'excess' or supernumerary embryos for stem cell derivation. In this order of ideas, the Portuguese National Council of Ethics for the Life Sciences in "Opinion No. 44/CNECV/04 on Assisted Medical Reproduction" (July 2004) states:
"The National Council has taken the position that research with no benefit for the embryo concerned is illegitimate. Exceptionally, when no other alternative than the destruction of the embryo is possible, scientific research with no benefit to the embryo could be conducted for the benefit of humanity."

28 E.g. Australia, Canada, Estonia, Finland, France, Hungary, Iceland, India, Israel, Japan, Slovenia, Singapore, South Africa, Spain, Sweden, Switzerland and United Kingdom.

29 For example, Israeli guidelines require that "the research and possible applications (of the research) be justified in terms of the benefit that it offers to humanity'. Report from the Bioethics Advisory Committee of the Israel Academy of Sciences and Humanities, *The Use of Embryonic Stem Cells for Therapeutic Research* ,(8 August 2001).

cloning, and stem cell research. Those traditions, values and interests "operate symbiotically in the crafting of legislative parameters for stem cell and cloning science."[30]

Within this category, legislative approaches can range from liberal to restrictive (both of which use administrative oversight), and usually involve criminal prohibitions. For example, Australia, Canada, New Zealand, Japan, and the United Kingdom, with different degrees of permissiveness and oversight, have enacted comprehensive laws regulating and setting conditions for embryonic, stem cell, and cloning research. However, even among public ordering countries that have adopted statutory requirements in relation to oversight and enforcement mechanisms for hESC research and cloning research, we will see that there are significant differences as well as similarities.

Other countries have opted for a private ordering approach through self-regulation, thus permitting these technologies if they follow professional guidelines, often set by national bioethics committees. The regulation of embryonic stem cell and cloning research in India, Israel, and China are examples of a private ordering approach since these countries have adopted professional guidelines.

The following analysis of the 50 countries under study demonstrates a mix of private-public ordering approaches in the case of human embryonic research. Before turning to embryonic research specifically, it should be noted that the debate on human reproductive cloning is without a doubt influential in the framing of policy responses. Indeed, an emerging pattern found in all these countries is to adopt prohibitions on the reproductive cloning of human beings and/or embryos. The debate that took place at the United Nations on the adoption of an international instrument banning human reproductive cloning indicates that an effective consensus exists among the 191 U.N. member states regarding human reproductive cloning. This consensus deems human reproductive cloning "ethically repugnant and contrary to human rights and dignity."[31]

In terms of national policies, all countries surveyed (45 by national laws[32]

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30 Angela Campbell, "Ethos and Economics: Examining the Rationale Underlying Stem Cell and Cloning Research Policies in the United States, Germany and Japan" (2005) 31 American Journal of Law and Medicine, 85.

31 Supra note 2. For a review of the United Nations process, see Rosario M. Isasi, George J. Annas, "Arbitrage, Bioethics and Cloning: The ABCs of Gestating a United Nations Cloning Convention" (Fall 2003) 35:3 Case Western Reserve Journal of International Law 397-414.

32 See legislation in: Australia, Argentina, Austria, Belgium, Brazil, Bulgaria, Canada, Colombia, Costa Rica, Cyprus, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Latvia, Lithuania, New Zealand, Norway, Panama, Peru, Poland, Portugal, Singapore, Slovenia, Slovakia, Spain, Romania,

and 5 by national guidelines[33]) prohibit the reproductive cloning of human beings, while a smaller number ban human cloning for research or therapeutic purposes (32 by national laws[34] and 5 by national guidelines[35]). The aforementioned prohibitions adopt a variety of approaches,[36] from banning "upstream"[37] or "downstream"[38] cloning to criminalizing it entirely.[39] Moreover, in countries where therapeutic human cloning is not explicitly addressed it can still be banned through prohibiting the creation of embryos for research purposes[40] or through a positive injunction that allows embryonic research only for therapeutic purposes for the embryo.[41]

Russia, South Africa, South Korea, Sweden, Switzerland, The Netherlands, Turkey, Ukraine, United Kingdom and Vietnam.

33 See national guidelines in: China, India, Taiwan, Tunisia and the United States.

34 See legislation in: Argentina, Australia, Austria, Brazil, Canada, Colombia, Costa Rica, Cyprus, Denmark, Estonia, Finland, France, Georgia, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Norway, Panama, Peru, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Switzerland, and The Netherlands.

35 China, India, Taiwan, Tunisia and United States.

36 George J. Annas, Lori B. Andrews & Rosario M. Isasi, "*Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations*" (2002) 28 *Am. J. Law & Med.* 154-157.

37 "Upstream" policies prohibit human cloning regardless of its purpose. For instance, Lithuania's *Law of Biomedical Research No. VIII-1679* (2000) states that "cloning of a human being shall be prohibited," while Panama's *Law No. 3 Human Cloning Prohibition* (2004), forbids "in all forms the promotion, financing and/or donating, using public funds or private investments, of experiments, research and developments of all forms of human cloning."

38 In public policies that apply "downstream" methods, embryos or gametes that have been subjected to research are prohibited from being implanted. For example, in Australia's *Prohibition of Human Cloning Act No. 144* (2002), doing research on gametes and embryos is not banned as such, but it is forbidden to create a human embryo other than by fertilization, implantation, and carrying to term such embryo. Another example is found in legislation adopted in New Zealand (*Act on Human Assisted Reproductive Technology*, 2004) and Germany (*Federal Embryo Protection Law*, 1990) where both the implantation and the development of a cloned or genetically altered human embryo is prohibited.

39 Legislation in Austria, Australia, Belgium, Canada, Denmark, Estonia, Finland, New Zealand, Spain, South Africa, Switzerland, Sweden, Germany, Slovakia, Israel, Italy, and France establish criminal sanctions for using, creating, developing or implanting a human embryo in contravention to their laws, as well as for the conduct of certain research and interventions.

40 Moreover, some countries, such as Cyprus, Ireland, Georgia, Portugal and Slovakia, prohibit the creation of human embryos for research purposes and for the procurement of stem cells through the ratification of the 1997 *Council of Europe Convention on Human Rights and Biomedicine*.

41 See e.g. Austria's *Federal Reproductive Medicine Law* (1992).

It is striking that a negligible number of countries have adopted national laws (6) or guidelines (1) specifically allowing human cloning for therapeutic or research purposes.[42] Still, the majority of countries worldwide have no explicit policy regarding research cloning.

In relation to human embryonic research generally, where public policy has been adopted, the majority of countries allow research on human embryos or gametes under strict conditions (16 countries by national laws,[43] 7 by guidelines[44]), while a few countries explicitly prohibit research on embryos by law.[45] The remaining (21) countries surveyed have no explicit policy on embryonic research.

An interesting pattern is evident in the regulation of human embryonic stem cell research: where public policy has been adopted, the majority of countries allow the procurement of hESC lines and research on supernumerary embryos (16 countries by law,[46] 4 by guidelines[47]). In addition, only 8 countries explicitly prohibit by law the procurement of hESC from surplus embryos and subsequent research.[48] A very small number of countries prohibit research on embryos to create hESC lines but allow the importation of hESC lines (e.g. Germany,[49] France[50]). The remaining countries surveyed have no explicit policy regarding hESC research.

Having briefly surveyed the "cloning" landscape, we can identify three approaches as characterizing emerging policy trends in the broad area of research into human reproduction.[51] In categorizing countries according to their policy design, we found that the majority of countries that have adopted public policies on embryonic, stem cell, and cloning research could be labelled "intermediate"[52]

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42 Belgium, Japan, Singapore, South Korea, Sweden and United Kingdom (by law)and Israel (by national guidelines).

43 See for example legislation in Iceland, Latvia and Lithuania.

44 See e.g. India and Taiwan.

45 Austria, Ireland, Cyprus, Costa Rica and Italy by law.

46 Australia, Brazil, Canada, Denmark, Estonia, Finland, Greece, Hungary, New Zealand, Slovenia, South Africa, Spain, Switzerland and The Netherlands.

47 China, India, Taiwan and the United States.

48 Lithuania, Norway, Poland, Italy, Austria, Ireland, Costa Rica, and Slovak Republic.

49 *Act ensuring the protection of embryos in connection with the importation and utilization of human embryonic stem cells (Stem Cell Act),* (28 June 2002).

50 *Bioethics Law No. 2004-800*, (6 August 2004).

51 Knoppers BM, "Reflections: The Challenge of Biotechnology and Public Policy" (2000) 45:2 McGill Law J. 559-566.

52 Australia, Brazil, Bulgaria, Canada, Cyprus, Latvia, Greece, Estonia, Finland, Hungary, New Zealand, Spain, South Africa, Switzerland, The Netherlands, Portugal, India, United States, Argentina, Peru, Mexico, Panama, Thailand, Turkey, Ukraine, Tunisia, and Vietnam.

(b); while the minority of countries are at the edge of the spectrum, meaning they adopt either a restrictive[53] (a) or a liberal[54] (c) public policy approach. Finally, since 2002, an emerging pattern in the legal landscape reveals a move towards the liberalization of national policies[55] across the restrictive-liberal spectrum. However, some countries have still opted to pass very restrictive laws.[56]

a) Restrictive Policies

In a *restrictive policy* framework, many techniques are prohibited (i.e. reproductive and therapeutic cloning, embryonic research) via tight regulations or blank prohibitions.[57] These countries[58] advocate strong government intervention and have a very critical attitude towards scientific discoveries. A closer scrutiny of the principles underlying their policies demonstrates that restrictive policies, in general, aim to strongly protect the human embryo. Their goal is to protect human life (and dignity) and society at large from the potential negative effects and presumed dangers of these technologies (e.g. instrumentalisation and commodification of potential human life, as well as the exploitation of women and children).[59]

We can further sub-divide restrictive policies into 3 types: namely, policies prescribing the impermissibility (prohibition) of human embryonic stem cell derivation, the impermissibility of using hESC lines or their products, though some

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53 Iceland, Lithuania, Denmark, Slovenia, Germany, France, Ireland, Georgia, Taiwan, Austria, Italy, Norway, Poland, Costa Rica, Colombia, and Panama.

54 Belgium, China, Japan, Israel, Singapore, South Korea and United Kingdom.

55 E.g. Australia, Belgium, Denmark, France, Germany, Greece, Brazil, Japan, Netherlands, New Zealand, Singapore, South Korea, Spain, Switzerland and United Kingdom. This trend toward liberalization of policies is also noted in proposed legislation currently under debate (e.g. Czech Republic, France, Malta, Mexico, Spain and Ukraine).

56 E.g. Italy, Panama and Colombia.

57 E.g., legislation adopted in Austria, Georgia and Italy prescribe that fertilized human oocytes and cells may be used only for medically assisted procreation. Moreover, in Slovakia, "research without medical indication is not permitted on human embryos or fetuses."

58 Supra note 45.

59 For example, Lithuania's *Law on Ethics of Biomedical Research No. VIII-1679*, (11 May 2000), states in its preamble that "biomedical research must be conducted according to the principle whereby the interests of the human being prevail over the interests of society and science." Whereas, the purpose of Norway's *Biotechnology Law (Law No. 100 of 5 December 2003 on the Use of Biotechnology in Human Medicine)* is "to ensure that medical applications of biotechnology are utilized for the benefit of everyone in an inclusive society. This shall be done in accordance with the principles of respect for human dignity, human rights and personal integrity (…)."

exceptions exist for imported hESC lines; and finally, the impermissibility of government funding.

Policies under the first type ban all embryonic research, with the possible exception of treatment beneficial to that particular embryo or treatments necessary to achieve a pregnancy (e.g. Italy,[60] Austria[61]). In all practicality this constitutes a ban and, thus, research migrates elsewhere (sometimes to countries where there is minimal ethical oversight).

The second type attempts to satisfy all sides by setting a cut-off date after which stem cells may not be taken from surplus embryos, but permits research on stem cells that were derived before the cut-off date, and then, only when they come from outside the country. This compromised approach found in France[62] and Germany[63] for example, is a partial antidote to prohibition. Still, these policies set a dubious ethical standard by deeming unethical both embryo use and the derivation of embryonic stem cell lines from embryos from the home country while allowing the importation of embryonic stem cell lines derived elsewhere.

Finally, under the third type, the state cannot allow or use public funds for certain activities. This approach, found in the restrictions on federal government funding in the USA, is problematic because it sets two standards for the governance of research. In some cases the private sector is then left unregulated, thus constituting in reality a *"laissez-faire"* policy.[64]

Under the last two sub-typologies of restrictive approaches, governments, while presenting themselves as virtuous protectors of ethics and morality by withholding direct involvement on embryo destruction, set artificial boundaries in order to

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60 The Italian *Medical Assisted Procreation Law No. 40* (2004) stipulates that clinical and experimental research on a human embryo can be conducted only for therapeutic or diagnostic purposes which are exclusively directed to the protection of the embryo's health and development, and when no other technologies are available.

61 Federal Law of 1992 (Serial No. 275) regulating medically assisted procreation (the Reproductive Medicine Law), and amending the General Civil Code, the Marriage Law, and the Rules of Jurisdiction*, June 4, 1992, (1993) 44 no. 2 Int. Dig. Hlth. Leg. 247.*

62 *Bioethics Law No. 2004-800,* (6 August 2004).

63 *Act ensuring the protection of embryos in connection with the importation and utilization of human embryonic stem cells (Stem Cell Act*), (28 June 2002).

64 The United States constitutes the best example of this *"laissez-faire"* approach with its unregulated private sector (with the exception of some state laws such as in California, New Jersey and Massachusetts).
(*See,* The National Institute of Health, National Human Genome Research Institute, Policy and Legislation Database http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm)
The disadvantage of the *"laissez-faire"* approach is that it precludes oversight for safety/quality concerns and provokes regulatory arbitrage—seeking overseas venues to avoid local research regulation.

benefit from practices that are deemed unethical. Thus, it is clear why these policy approaches are deemed hypocritical as they rest their ethical grounding on the lack of ethics elsewhere. For instance, if the importation of embryonic stem cell lines is allowed because somebody else has destroyed embryos, are the importers not complicit in the destruction of embryos?

b) Intermediate Policies

As mentioned above, the majority of countries surveyed fall under the *intermediate policy* approach.[65] Hereunder, a wide range of techniques are allowed but controlled and closely monitored by modest state intervention. Under this approach, stem cell research on supernumerary embryos from IVF treatment is permitted, but the creation of embryos specifically for research purposes is prohibited.[66]

The overall goal of these policies is to provide efficient and safe mechanisms for conducting research. New Zealand's Act on Human Assisted Reproductive Technology No. 92, 2004 provides an illustrative example of these goals by stating that its purpose is, "to provide a robust and flexible framework for regulating and guiding the performance of medical assisted reproductive procedures and the conduct of human reproductive research." Similar rationale is found in India's Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects (2000), which state, "any system of ethical guidelines on research needs to be cognizant of, and informed by, a sensitive balance of the risks and benefits" for society.

Intermediate policies are often the result of political compromises and trade-offs and seek to balance diverse – if not conflicting – interests and values that could otherwise thwart the adoption of any legal framework. Because of this, they are at risk of being ambiguous and internally inconsistent. The latter is commonly reflected in policies granting moral and legal status to the human embryo, and in policies regulating embryo destruction following research or medically assisted reproduction.

c) Liberal Policies

Finally, in *liberal policies*, most technologies are permitted provided procedural rules and governance are observed. These policies permit the creation of embryos

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65 Supra note 44.

66 E.g. Canada, Denmark, Estonia and Australia.

for research purposes as well as for the derivation of stem cell lines and for research cloning (mostly by *de facto* or by case-by-case approval by a governmental agency or licensing authority). Yet, even under this more permissive approach, human reproductive cloning is banned.[67]

The overall goal of liberal policies is to promote scientific and medical progress with the belief that it is beneficial to humanity. At the same time these policies seek to regulate the interest of patients and the public health, in addition to addressing societal concerns[68] (e.g. Singapore,[69] South Korea,[70] United Kingdom,[71] and Japan[72]). Unfortunately, these policies usually "fail to explicitly enunciate the value-choices underlying their acceptance or to explain why certain constraints have been instituted."[73]

The challenge for countries adopting a liberal policy framework is to provide a coherent, transparent and flexible, yet enforceable, system that also takes into

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67 E.g. Belgium, Sweden and the UK.

68 Régnier M-H, Knoppers BM, "International Initiatives" (2002) 11:1 Health Law Review 67-71.

69 "The BAC also believes that the recommendations strike a proper balance between allowing research with tremendous potential therapeutic benefits to mankind to proceed while affording a measure of respect and level of protection to human embryos which takes into consideration the diversity of views on the status of the human embryo." Bioethics Advisory Committee of Singapore (BAC), *Report "Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*, (21 June 2002).

70 The South Korean *Bioethics and Biosafety Act No. 7150* (2005), "aims to enhance the health of human beings and the quality of human life by creating conditions that allow for the development of life sciences and biotechnologies that can be used to prevent or cure human diseases. Additionally, this Act aims to protect human dignity and to prevent harm to human beings by ensuring that these life sciences and biotechnologies are developed safely and in accordance with the principles of bioethics."

71 "The object of the HFEA Code of Practice is … to secure the safety or efficacy of particular clinical or scientific practices. It is concerned with areas of practice which raise fundamental ethical and social questions. In framing the Code of Practice, the HFEA has been guided both by the requirements of the HFEA Act and by:

- The respect which is due to human life at all states of development.
- A recognition of the benefits, both to individuals and to society, which can flow from the responsible pursuit of medical and scientific knowledge".

The Human Fertilisation and Embryology Authority, *Code of Practice*, 6th Edition, 2003.

72 For instance, Japan's *Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques*, (June 2001), while allowing a wide range of technologies, including cloning for research purposes, recognizes that cloning and other similar techniques, "could have a severe influence on preservation of human dignity, safety for human life and body, and maintenance of social order."

73 Knoppers B.M., Hirtle M. et. al., "Genetic Technologies: Commercialization of Genetic Research and Public Policy" (17 December 1999) 286:5448 Science 2277-2278.

account opposing socio-cultural and ethical values or beliefs. Moreover, when governance depends on regulatory agencies that decide on a case-by-case basis, there is flexibility but also the risk of arbitrary applications or inconsistencies; and if governed by guidelines or professional codes alone, without active monitoring and sanctions, the risk is to end up as self-serving and following a market-consumer model.

Conclusion

At first glance, the determination of the moral status of the human embryo influences possible responses to questions of the permissibility of, restrictions on, and prohibitions on embryonic research. No matter what policy framework is adopted—whether liberal, intermediate or restrictive—the mechanisms for assessing and regulating embryonic, stem cell and cloning research must keep pace with the scientific discoveries. They must also address ethical concerns, with a flexible and transparent regulatory system able to both prospectively cover new scientific advances, to regulate both private and public funds to ensure against double standards, and finally to be enforceable. "Good" guidelines are useless if they can be disregarded with impunity.

In an era of globalize science, common scientific, regulatory and ethical standards are necessary. These (minimal) common denominators are required to foster collaboration in stem cell research (and its future therapeutic applications) at the national and international levels. Most importantly, harmonization of these standards is needed to avoid negative repercussions for health, safety, and patient rights.[74] Yet, considering the multiplicity of laws and guidelines already in existence, the lack of moral and legal consistency within these documents, and the politics involved in the embryo debate, the harmonization of scientific, regulatory and ethical standards will be very difficult.

The consequences of discord are too high to allow the inconsistency to continue. If the idealistic pursuit of knowledge and the desire to improve health are not sufficient motivation for international discussion and harmonization, perhaps the spectre of a *dialogue of the deaf*, with market forces driving progress on this ethically sensitive issue will bring stakeholders to the discussion table.

Aristotle warned humanity that ethics and politics are connected. Two thousand years later, we have yet to move beyond that observation. Advances in science force us to determine whether morally contentious issues require consensus,

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74 D.B. Resnik. "The Need for International Stem Cell Agreements" (October 2004) 22:10 Nature Biotechnology 1207.

compromise and political conviction. Can we address such divisive issues while holding intact our democratic principles and socio-cultural values? In short, the challenges is to defend the integrity of ethical and legal principles – the sooner the better.

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