

IMAGINING ARGENTINA: FROM THE MORAL TO THE LEGAL IN CLONING AND STEM CELL RESEARCH GOVERNANCE IN ARGENTINA

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Abstract: Given its intimate relationship to the human body, genomic innovation implicates diverse ethical issues, and this is particularly so with respect to human stem cell research, which relies on material harvested from the body. This paper outlines the domestic and international social setting within which stem cell research and cloning debates are held, explores the contested ethical positions articulated in response to stem cell research and cloning, then considers whether and how the moral values underlying those positions are dealt with in Argentina's governance of this science. Ultimately, these values are not well embodied in the very limited and minimalist Argentine regulation which exists.

Keywords: Ethical issues; Human cloning and stem cell research; Legality.

Introduction

Innovation is the backbone of the modern, accelerating, knowledge-based society. Biotech innovation (viewed as essential ingredient for achieving good health and longevity) is one of the cornerstones of this new society, and this is equally true of developing countries as of developed countries. An important and controversial field of inquiry within biotech is human embryonic stem cell research ("hESCR"), and the closely associated practice of somatic cell nuclear replacement ("cloning"). This paper considers the governance of ESCR and cloning in Argentina, a jurisdiction often overlooked in legal assessments. However, Argentina is a valuable case study because, though a southern developing country and technology importer only slowly emerging from a recent multi-faceted national social crisis,¹ it has aspirations of

[♦] The author would like to thank Dr. Graeme Laurie, Chair of Medical Jurisprudence, University of Edinburgh, and Director of SCRIPT, the AHRC Research Centre for Studies in Intellectual Property and Technology Law.

¹ In the 1990s, Argentina's new democratic institutions, struggling with the realities of globalization, relinquished many of their economic and social welfare management roles. In 2001/02, Argentina's escalating economic failures culminated in general social collapse which continues to hamper individuals and public institutions. See Inter-American Development Bank, "Country Paper: Argentina" (2000), at www.iadb.org/regions/re1/ar/argentinaeng.pdf (Feb. 14/07), World Bank, "The Argentine Health Sector in the Context of the Crisis", Background Paper No. 6, November 2002, at [http://wbIn0018.worldbank.org/lac/lacinfoclient.nsf/d29684951174975c85256735007fef12/3d29a0ed02294a8b85256db10058dbdd/\\$file/argentinapapp6.pdf](http://wbIn0018.worldbank.org/lac/lacinfoclient.nsf/d29684951174975c85256735007fef12/3d29a0ed02294a8b85256db10058dbdd/$file/argentinapapp6.pdf) (Feb. 15/07), and World Bank, "Argentina –

becoming a regional scientific leader. Indeed, it has targeted biotech innovation as a fundamental pillar of sustainable development.² Additionally, it has aspirations of becoming a regional governance leader (ie: a model to be emulated by its neighbours, much like the UK is in Europe and worldwide). Given the above, Part I explores the scientific, social and moral setting in and against which ESCR and cloning are debated (and practiced). In response to this background, a governance approach and framework are suggested. Part II then explores the structure and content of ESCR and cloning research governance in Argentina. It characterises the regulatory model adopted and considers how (and whether) the moral positions identified in Part I have manifested within the regulation, and how (and whether) the regulation enhances or realises the values on which these positions rest (ie: does the Argentine regime translate these moral values into binding action-guiding legal rules). By considering existing governance, one can better appreciate Argentina's legal position within the international scene and make some preliminary suggestions as to how to improve its governance structure.

Analysis

1. What dreams may come: hopes, risks and contested positions

The debates around ESCR and cloning are a confusing morass of hopes and hype, risk and rhetoric, often ill-informed claims and equally ill-formed moral outrage. The following makes some sense of the social and moral context by briefly considering the scientific background and the moral background.

1.1. The Scientific Background

As suggested above, SCR and cloning are the repository of many of our hopes and dreams for "regenerative medicine".³ SCs are cells that divide asymmetrically, giving rise to an identical daughter cell and to a differentiated cell. Different SCs exhibit different levels of plasticity and are characterised as "totipotent",⁴ "pluripotent",⁵ and "multipotent"⁶. ESCs are so-called because of the very early stage in human

Crisis and Poverty 2003", Report No. 26127-AR, July 2003, at [http://wbln0018.worldbank.org/lac/lacinfoclient.nsf/d29684951174975c85256735007fef12/3d29a0ed02294a8b85256db10058dbdd/\\$file/argentinapamainreport.pdf](http://wbln0018.worldbank.org/lac/lacinfoclient.nsf/d29684951174975c85256735007fef12/3d29a0ed02294a8b85256db10058dbdd/$file/argentinapamainreport.pdf) (Feb. 15/07).

² See the Declaration of Buenos Aires, March 2005, at www.unesco.org/science/psd/thm_innov/forums/l_america.shtml (Feb. 15/07), and the Plan Nacional de Ciencia Tecnología e Innovación Productiva 2006, at www.secyt.gov.ar/PNCTIP_2006/PNCTIP_2006_08ago05.doc (Jul. 11/07).

³ Regenerative medicine refers to the interdisciplinary and collaborative field of healthcare focusing on the repair, replacement or regeneration of cells, tissues and organs so as to restore function caused by defects, disease, trauma and aging: H. Greenwood *et al.*, "Regenerative Medicine: New Opportunities for Developing Countries" (2006) 8 *Int. J. Biotechnology* 60-77, at 62-63.

⁴ Totipotent SCs can give rise to an entirely new organism, including the cells needed for human development. The only known totipotent SCs are the 8 cells of the zygote at approximately 36-hours post-fertilisation. A single zygote can give rise to identical twins and the necessary extra-embryonic material such as the placenta and umbilical cord.

⁵ Pluripotent SCs can differentiate into any and all of the 200+ cell types which comprise the human body, but cannot give rise to the extra-embryonic cells necessary to support the development of a foetus *in utero*. They are harvested during the brief period when the inner cell mass of the blastocyst (ie: the mass which could otherwise form the embryo and evolve into the foetus) reaches approximately 25 cells.

⁶ Multipotent SCs, harvested from the primordial germline cells of early aborted fetuses or from

development at which they become available. SCs are considered to be valuable research tools. For example, they can be cultured and used as models to study: (1) the pharmacological utility and toxicity of drugs; (2) the course of pathogenic viruses and/or diseases in human tissue; (3) the function of specific genes and proteins; and (4) the development of human tissue and organs more generally.⁷ Cloning is a process whereby the nucleus of an adult cell is inserted into an enucleated egg, which is then induced to divide, thereby producing a blastocyst that is a genetic match to the nucleus donor. The pluripotent ESCs are then harvested from the resulting cloned blastocyst, thereby increasing the supply of SCs for research purposes and relieving researchers of the need to recruit donor women or source embryos from IVF clinics.

Both the increasing rates at which SC advances are being realised, and the terrible economic and psychological cost of chronic, degenerative and acute diseases, are increasing the interest of stakeholders (eg: governments, researchers, commercial enterprises, healthcarers, patients groups) in expanding SC knowledge and translating that knowledge into novel healthcare deliverables. As such, although SC comprehension is in its infancy and significant hurdles remain to their effective clinical use,⁸ SC therapies have leapt from lab to clinic in defiance of the normal and more ponderous hypothesis-to-trial process.⁹ In short, SC treatments are being developed and administered despite significant gaps in our understanding of basic functionality.

This utilisation is as true in Argentina as it is in developed countries. For example, although Argentina enjoys a comparative advantage in agro-biotech,¹⁰ it is also

mature tissue (eg: from any post-foetal stage of life of the organism, including the late foetus, umbilical cord blood, children and adults), can give rise to the cell types regenerative of the tissue in which they normally reside. Some studies suggest that they may have greater plasticity than originally thought: L. Epatko, "Adult Stem Cells: Conflicting Research" (2004) at www.pbs.org/newshour/science/stem-cells/conflicting-research.html (Oct. 3/06).

⁷ A. Chapman *et al.*, "Report: Stem Cell Research and Applications: Monitoring Frontiers of Biomedical Research" (1999) at www.aaas.org/spp/sfrl/projects/stem/report.pdf (Oct. 2/06), K. Devolder, "Human Embryonic Stem Cell Research: Why the Discarded-Created-Distinction Cannot be Based on the Potentiality Argument" (2005) 19 *Bioethics* 169-186, S. Kadereit & P. Hines, "An Overview of Stem Cell Research" (2005) 39 *New Eng. L.R.* 607-622, and E. Singer, "The Real Stem Cell Hope" (2006) at www.technologyreview.com/printer_friendly_article.aspx?id=16558 (Sep. 29/06).

⁸ Fundamental hurdles remain to our understanding of how SCs work both inside and outside the body: UK Stem Cell Initiative, "Report & Recommendations" (2005) at www.advisorybodies.doh.gov.uk/uksci/uksci-reportnov05.pdf (Sep. 3/06), at 25-27, Select Committee, *Stem Cell Research Report* (UK: House of Lords, 2002), available at www.parliament.the-stationary-office.co.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Sep. 26/06), at para. 2.13, J. Shaw, "Stem Cell Science: When Medicine Meets Moral Philosophy" (2004) at www.harvardmagazine.com/online/070483.html (Sep. 29/06), at 37, E. Singer, "Turning Stem Cells into Tissues" (2006) at www.technologyreview.com/printer_friendly_article.aspx?id=16374 (Sep. 29/06).

⁹ L. Epatko, *supra*, note 7, quotes Dr. Amit Patel, University of Pittsburgh Medical Centre, who states, "Usually you do the basic science and slowly evolve to human trials. In cardiac stem cell therapy, it's happening at the same time."

¹⁰ World Bank (2004), *supra*, note 59, World Bank, "Argentina: Agriculture and Rural Development: Selected Issues" Report No. 32763-AR, July 2006, at www.wds.worldbank.org/external/default/wdscontentserver/wdsp/ib/2006/10/18/000090341_20061018084304/rendered.pdf/32763.pdf (Feb. 15/07). Argentina now ranks in the top 4 (with Canada, China and the US) in number of GM acres planted: National Association of State Departments of Agriculture, "Biotechnology – A Key to Agriculture's Future" (2002), at www.nasda.org/policies/three.htm (Feb. 14/07).

investigating regenerative medicine possibilities,¹¹ and is taking steps to build a competitive domestic SCR market. Indeed, although its overall R&D spending is low by international standards, it is nonetheless a leading SCR spender.¹² It is undertaking a variety of research and has already moved to human trials for somatic stem cell-based cerebral infarction treatments and diabetes treatments. Additionally, multi-centre international somatic stem cell treatment collaborations are being pursued with respect to congestive heart failure.¹³ There is little evidence and so it remains unclear how much ESCR is being conducted.

1.2. The Moral Background

In addition to technical hurdles, there are also ethical hurdles to the widespread application of ESC-based solutions to (ill)health.¹⁴ In particular, concerns over the wellbeing of the embryo (currently destroyed in the ESC extraction process) and the wellbeing of society represent substantial obstacles to the widespread acceptance of ESCR and cloning. Concerns over embryo wellbeing turn on questions about the commencement of human life, the moral status of the embryo, and the meaning of personhood. Concerns over societal wellbeing turn on interpretations of the limits of our duty to alleviate the social damage caused by injury and disease (ie: the limitations we must respect so as to avoid destruction of existing social relationships, structures and rights).

In the ESCR and cloning context, the bioethical discourse has coalesced into four divergent positions, which are functionally (as opposed to philosophically) characterised as “prohibitive”, “restrictive”, “permissive” and “facilitative”. Explored in greater detail elsewhere,¹⁵ they can be summarised as follows:

- Prohibitive Position: Proponents of this position, who often though not necessarily

¹¹ H. Greenwood *et al.*, *supra*, note 10, elucidate 4 categories of conduct – (1) academic, (2) corporate, (3) publication, and (4) consumer goods/products – noting that Argentina is active in each.

¹² In 2004, R&D spending represented 0.44% of GDP, and of that, 14% related to health research: K. Thorn, *supra*, note x, at 6. Argentina is now listed as a world leader in SCR (see Biocrawler, “Stem Cell” (2006) at www.biocrawler.com/encyclopedia/stem_cell (Oct. 12/06)), in stark contrast to the dismal state of science funding during Argentina’s 2001/02 crisis: C. Marzuola, “Argentina’s Crisis Heralds Time of Torment for Scientists” (2002) 415 *Nature* 104.

¹³ See H. Greenwood *et al.*, *supra*, note 10, at 68, M. Valente, *supra*, note 14, H. Pilcher, “Bone Marrow Stem Cells Help Mend Broken Hearts” (2004) at www.bioedonline.org/news/news.cfm?art=936 (Oct. 30/06), and Medical News Today, “Stem Cells Implanted in Brain of Patient Who Suffered a Cerebral Infarction: Argentina”, June 2005, at www.medicalnewstoday.com/medicalnews.php?newsid=25613 (Oct. 3/06), and Medical News Today, “Stem Cell Breakthrough Helps 85% of Type II Diabetes Patients”, February 2006, at www.medicalnewstoday.com/medicalnews.php?newsid=37226 (Oct. 3/06). Indeed, there are now Biology of Reproduction Summer Fellowships: see www.ivf.net/content/index.php?page=out&id=2452 (Feb. 15/07).

¹⁴ See the debates examined in J. Kitzinger & C. Williams, “Forecasting Science Futures: Legitimizing Hope and Calming Fears in the Embryo Stem Cell Debate” (2005) 61 *Soc. Sci. & Med.* 731-740, C. Ganchoff, “Regenerative Movements: Embryonic Stem Cells and the Politics of Potentiality” (2004) 26 *Soc. Of Health & Illness* 757-774, B. Nerlich & D. Clarke, “Anatomy of a Media Event: How Arguments Clashed in the 2001 Human Cloning Debate” (2003) 22 *New Gen. & Soc.* 43-59, and S. Parry, “The Politics of Cloning: Mapping the Rhetorical Convergence of Embryos and Stem Cells in Parliamentary Debates” (2003) 22 *New. Gen. & Soc.* 145-168. In the US, ethical concerns have led to serious funding restraints: Economist, “Hype Over Experience” (2005) at http://www.economist.com/business/displayStory.cfm?story_id=4427625 (Oct. 12/06).

¹⁵ See S. Harmon, “X”.

come from a religious perspective, generally consider human life and personhood to occur simultaneously at the moment of conception.¹⁶ The embryo's unique potential to develop into a human endows it with a right to "special protection". Interfering with that potential is tantamount to permitting the formation of an instrumentalised underclass.¹⁷ With respect to broader concerns for societal wellbeing, proponents of this position attach much greater weight to the risks of ESCR and cloning than to their benefits, and they question the moral fabric of a society that routinely destroys human life for inquisitive purposes. They deplore cloning and claim that ESCR is too closely tied to it; advances in therapeutic cloning (intended to increase the number of SCs available) eliminate important obstacles to the acceptability of reproductive cloning (eg: lack of safety) with the result that ESCR constitutes a "slippery slope" to the eventual application of cloning as a means of reproduction, a potentially disastrous practice. As such, proponents of this position would prohibit cloning and procuring or using ESCs, or indeed conducting embryonic research for any purpose other than assisting reproduction.

¹⁶ Pontifical Academy for Life, "Declaration on the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells" (2000) at www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20000824_cellule-staminali_en.html (Oct. 18/06). See also R. Doerflinger, "Destructive Stem-Cell Research on Human Embryos" (1999) 28 *Origins* 769-773.

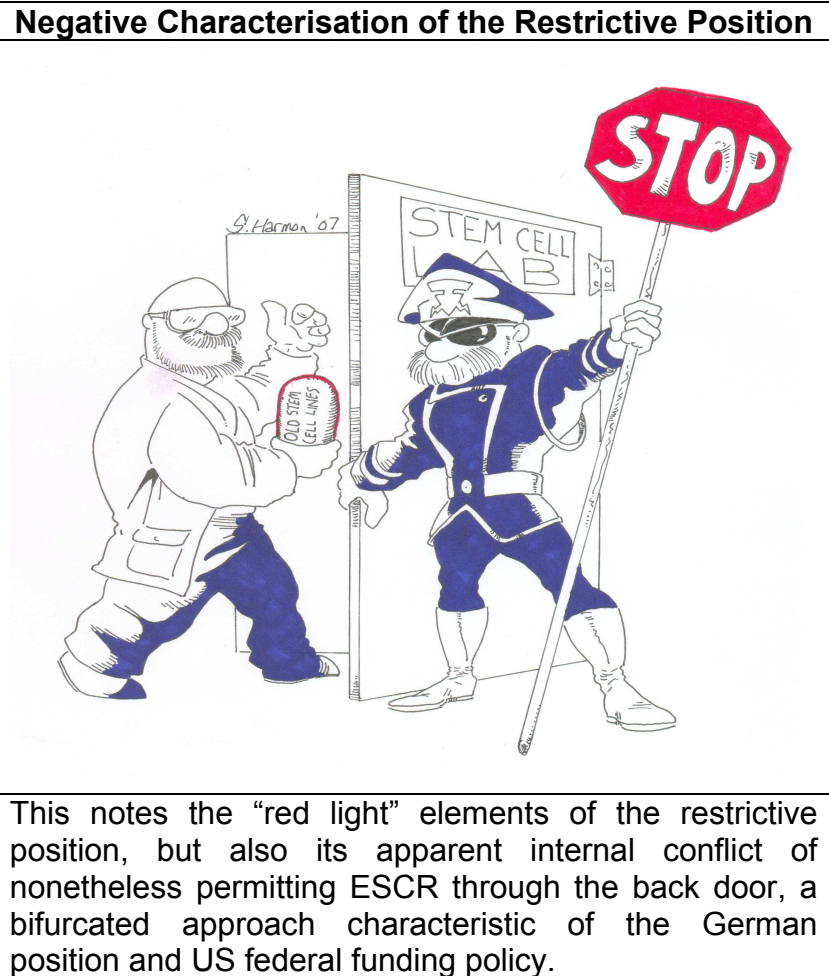
¹⁷ For a potentiality argument, see J. Deckers, "Why Current UK Legislation on Embryo Research is Immoral: How the Argument from Lack of Qualities and the Argument from Potentiality Have Been Applied and Why They Should be Rejected" (2005) 19 *Bioethics* 251-271.

Negative Characterisation of the Prohibitive Position



This emphasises the “red light” nature of the prohibitive position, which imposes limits via some central authority which is (often) heavily influenced by religion which itself shuts its eyes to the terrible suffering of humans living with injury and disease.

- **Restrictive Position:** Proponents of this position advance interpretations of the commencement of human life and personhood comparable to prohibitive proponents, though they adopt a slightly looser (and less internally consistent) approach to using ESCs. They would prohibit cloning and would prohibit *procuring* ESCs, but would allow research to continue on those cell lines already in existence, viewing the unethical damage to have already been done.



- Permissive Position: Proponents of this position generally believe that, while embryos may be genetically human, they have none of the characteristics of personhood by which human life is given meaning (eg: consciousness, reason, self-awareness).¹⁸ Drawing support from religion,¹⁹ biology,²⁰ and law,²¹ they argue that, although embryos are deserving of some special status, they are not sacrosanct, and

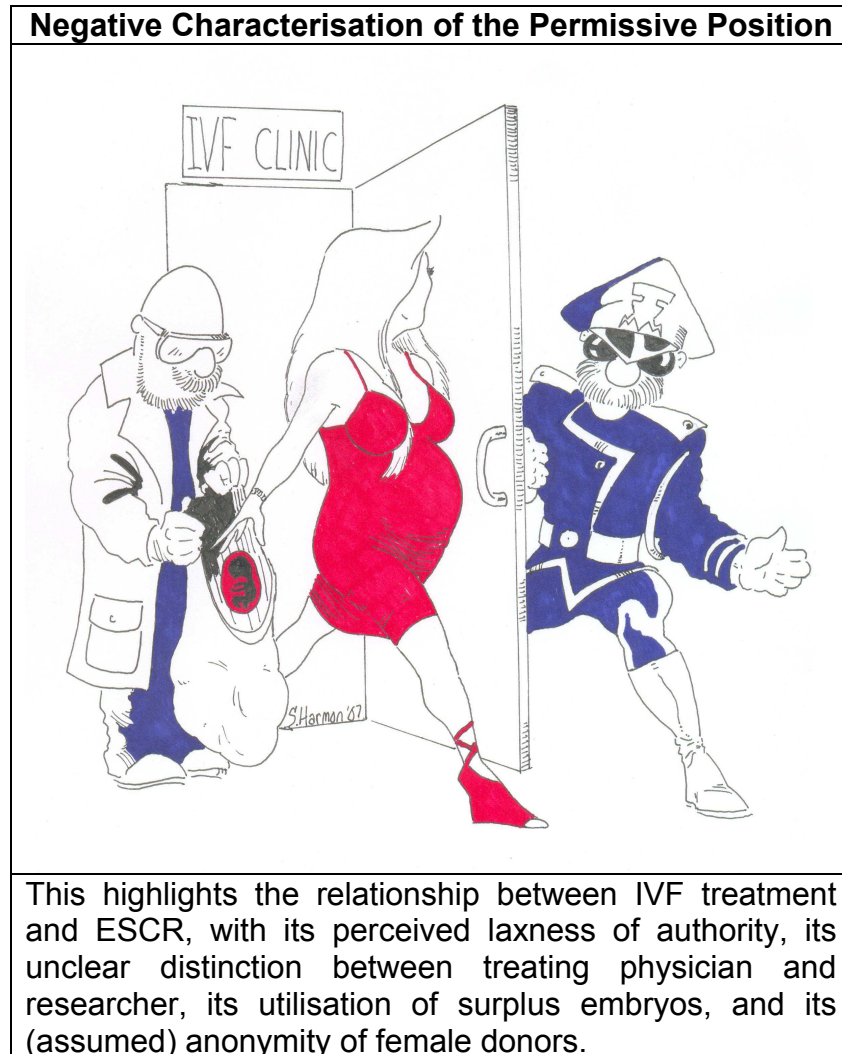
¹⁸ For an interesting discussion on the status of the embryo, see H. McLachlan, “Persons and Their Bodies: How We Should Think About Human Embryos” (2002) 10 H.C.A. 155-164.

¹⁹ In Judaic and Protestant traditions, personhood is believed to develop gradually as opposed to the instance of conception: see S. Siegel, “Fetal Experimentation” in M. Kellner (ed.), *Contemporary Jewish Ethics* (NY: Hebrew Publishing Co., 1978) 289, L. Cahill, “The Embryo and the Fetus: New Moral Contexts” (1993) 54 *Theo. Studies* 124-142, and T. Peters, *For the Love of Children* (Louisville: John Knox Press, 1996). In Islamic tradition, personhood is achieved after “ensoulment”, which takes place no earlier than 40 days post-fertilisation: C. Dabu, “Stem-Cell Science Stirs Debate in Muslim World Too” (2005) at www.csmonitor.com/2005/0622/p15s02-wogi.html (Sep. 29/06).

²⁰ Biologically, human uniqueness and the ability to feel occurs gradually – only after the embryo can no longer split into identical twins and after it has developed a functional nervous system. However, the timeframe is very much contested: see H. Greely, “Moving Human Embryonic Stem Cells from Legislature to Lab: Remaining Legal and Ethical Questions” (2006) 3 *PLOS Medicine* e143, M. Mulkay, *The Embryo Research Debate: Science and the Politics of Reproduction* (Cambridge: CUP, 1997), and P. Spallone, *Beyond Conception: The New Politics of Reproduction* (London: MacMillan Education, 1989).

²¹ Legally, it has been held that an embryo is not a human life and has no right to life. In the UK, see *Evans v. Amicus Healthcare Ltd.*, [2003] 4 All E.R. 903 (H.C.), which cites *Re F (in utero)*, [1988] 2 All E.R. 193 (C.A.) and *Paton v. B.P.A.S.T.*, [1978] 2 All E.R. 987 (Q.B.).

can therefore be utilised for worthy/virtuous ends before they are in a position to experience loss. Thus, they would permit the use of embryos left over from *in vitro* fertilisation (“IVF”). Using surplus IVF embryos affords respect to individuals by recognising their autonomous choice to donate and their right to make moral judgments (about research), and affords respect to embryos by investing them with a moral status greater than if they were simply discarded/destroyed.²² They stipulate, however, that embryos must never be *created* for the sole purpose of destruction/research; to do so would be to legally create an underclass of beings with a purely instrumental role.²³



- **Facilitative Position:** Proponents of this position attach minimal moral status to embryos, classifying them as collections of cells little different from any other bodily tissue. Personhood is gained gradually over time and the embryo’s moral status is

²² R. Isasi & B. Knoppers, “Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards” (2006) 21 H. Reproduction 2474-2481, at 2477.

²³ W. Cheshire Jr., “Small Things Considered: The Ethical Significance of Human Embryonic Stem Cell Research” (2005) 39 New Eng. L.R. 573-582.

similarly elevated.^{24, 25} If it is morally acceptable to create embryos to help the infertile (or to conduct pre-implantation genetic diagnoses), they argue, it can be no less moral to create them to help the ill or injured (or for research that will benefit the ill/injured). With respect to societal wellbeing, they generally emphasise the obligation to do everything possible to alleviate the suffering of existing and future human beings; intergenerational justice demands that we enhance the life chances of emerging and future generations.²⁶ The consequence of this position is that the broadest approach to acquiring ESCs is supported, from using surplus IVF embryos, to creating research-bound embryos through IVF or cloning. Similarly, only frivolous uses (eg: for the creation of cosmetics) which diminish the moral respect shown to embryos are unacceptable. Ultimately, if ESCR and cloning has the potential to achieve virtuous social ends, then, despite its costs and risks, there is a moral duty to pursue it, and the limitations imposed on its pursuit must be minimal and narrow.²⁷ This, it is argued, is the most ethically and practically defensible position for a diverse, pluralistic society (which should not be held hostage to the restrictive beliefs of a minority).²⁸

²⁴ A. McCall-Smith & M. Revel, *supra*, note 36, at 11. See also Resolution in Support of Stem Cell Research and Education, Rabbinical Assembly Convention, April 2003, at www.rabbinicalassembly.org/docs/2003resolutions2.pdf (Oct. 3/06).

²⁵ K. Devolder, *supra*, note 8, at 182-183. In Japan, respect is shown to research embryos by treating them carefully and offering prayers for them at the time of their use: M. Sleeboom-Faulkner, "Regulating 'Respect' for the Embryo in Japan: Steering Scientific Explorations in hESCR" presented at EGENIS Conference, "Governing Genomics: Interdisciplinary Perspectives on the Regulation of Biosciences", January 25-27, 2007.

²⁶ It is a curious juxtaposition that sees proponents of this position invoking the wellbeing of future individuals to justify use of embryos to which they attach no significant moral value.

²⁷ O. Corrigan *et al.*, "Ethical, Legal and Social Issues in Stem Cell Research and Therapy" (2005) at www.eeescn.org.uk/pdfs/elsi_paper.pdf (Oct. 3/06), at 6.

²⁸ J. Childress, "An Ethical Defence of Federal Funding for Human Embryonic Stem Cell Research" (2001) 2 Yale J.H.P.L.E. 157-165, and K. Devolder, "What's in a Name? Embryos, Entities and ANTitles in the Stem Cell Debate" (2006) 32 J.M.E. 43-48.

Given the concerns and positions articulated above, one would hope that legislation in this field would adopt a framework which explicitly addresses: (1) oversight of ESCR and cloning; (2) ESC sourcing; (3) the purposes to which ESCR and cloning can be applied; (4) safeguards for participants; (5) commercialisation of research outputs; and (6) sanctions for breaches of norms established. Such a framework has the potential to deliver clear and flexible guidance that translates the moral into the legal and therefore positively influences the direction of research so as to facilitate outputs that are socially useful and acceptable; it has the greatest potential to ensure our most virtuous dreams are realised and our nightmares are avoided.

2. Lost in translation: legal rules, moral values and Argentina's position

Part II uses the above framework to examine Argentina's ESCR and cloning governance regimes with a view to assessing the moral approach adopted by the law, the moral values that inform the law, the moral approach best characterised by the law, and the effectiveness of the translation of those values into enforceable, action-guiding rules.

2.1. Legal Content of ESCR and Cloning Governance

Argentina's sci-tech framework has been described as complex, fragmented and uncoordinated, with unclear lines of responsibility and underperformance of innovation-promoting functions.³⁰ In fact, Argentina has largely permitted market forces to determine research direction and there is no regulation of the related fields of IVF or embryonic research.³¹ However, with respect to cloning, Argentina has enacted the *Prohibition on Human Cloning Research*³² ("1997 Decree"), a curt Presidential Decree which contains seven recitals and four operative provisions. Having reference to the six criteria of the framework offered above, the 1997 Decree can be assessed as follows:

- **ESCR/Cloning Oversight:** It has been claimed that licensing, with its imposition of quality control, reporting procedures and ethics approval, is the most effective means of influencing the conduct of research.³³ However, the 1997 Decree contains no element of research oversight with the result that it has no means of monitoring researcher compliance with its substantive provisions. In October 2006, the Science and Technology Promotion Agency created an Advisory Commission on Stem Cells to produce an opinion on this science, but it is not a monitoring agency.

- **ESCR Sourcing:** The 1997 Decree is directed at cloning, not ESCR, and, as such, is silent on all matters relating to ESCR, including, importantly, the definition of an

³⁰ K. Thorn, *supra*, note 59, and D. Chudnovsky, "Science and Technology Policy and the National Innovation System in Argentina" (1999) at www.cepal.org/publicaciones/xml/3/20113/chudnovsky.pdf (Oct. 30/06).

³¹ R. Isasi & B. Knoppers, *supra*, note 40, at 2475, E. Rivera-Lopez, "Ethics and Genetics in Latin America" (2002) 2 *Developing World Bioethics* 11-20.

³² Prohíbase los Experimentos de Clonación Relacionados con Seres Humanos, Decreto No. 200/1997.

³³ R. Isasi & B. Knoppers, *supra*, note 40, at 2478.

embryo.³⁴ Although Recital 4 articulates the need to control all activities associated with cloning (and ESCR is clearly and directly associated with cloning),³⁵ and although Article 2 directs the writing of a bill related to “this matter” (cloning and associated activities) within 60 days of passage of the 1997 Decree,³⁶ the Argentine legislature has yet to adopt a law on SCR, ESCR or cloning.

- **ESCR/Cloning Purposes:** The only truly substantive provision of the 1997 Decree is Article 1, which states that all cloning experiments relating to human beings are prohibited.³⁷ The precise meaning of cloning (ie: the technical process the drafters had in mind) is left undefined, and there is no indication in the 1997 Decree as to why cloning has been banned other than a passing reference in Recital 1 to the state’s duty to defend the dignity of the human being. Of course, there is no reference to ESC sourcing.

- **Participant Safeguards:** Given the nature and scope of the 1997 Decree, it is not surprising that it contains no legal protections for the individual. However, the consequence of its failure to anticipate that prohibited conduct may be undertaken or that research material may be imported which has been cloned from human tissue is that participants/donors have no legal recourse where some might be warranted. Nor does any other law offer explicit protection to individuals, for Argentina has no enforceable regulatory instrument with respect to human subject research.³⁸ The Argentine Ministry of Health has commenced work on human subject research guidelines, but no results have yet been published.³⁹

- **Commercialisation:** The 1997 Decree makes no reference to commercial interests or activities in relation to cloned material or ESCR. Though it is not research regulation *per se* (non-patentability does not bar pursuit of research), the *Patent Law*⁴⁰ is relevant. It defines patentable inventions as anything created by man which allows the transformation of matter or energy for exploitation by man,⁴¹ but excludes cells that could lead to whole animals, including embryonic cells, unless they are isolated, purified and modified from their natural state (ie: not identical to a

³⁴ The importance of such a definition and its absence in Argentina is noted in R. Isasi *et al.*, “Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia and Africa” (2004) 32 J.L. Med. & Ethics 626-638.

³⁵ Recital 4 states, “Que, por ello, resulta de urgente necesidad reglamentar, controlar y fiscalizar todas las actividades relacionadas con los experimentos de clonación, en particular con seres humanos”.

³⁶ Article 2 states, “Encomiéndase al Ministerio De Salud y Accion Social que, en un plazo no mayor de sesenta (60) días, elabore el proyecto de ley respectivo.

³⁷ Article 1 states, “El Presidente de la Nación Argentina en Acuerdo General de Ministros Decreta: Prohíbense los experimentos de clonación relacionados con seres humanos”. The remaining 3 provisions of the 1997 Decree merely direct further action in the field and stipulate that the 1997 Decree is to be inscribed as the law of the land.

³⁸ L. Baranao, President, National Agency for the Promotion of Science & Technology, representations made at informal meeting in Edinburgh on October 26, 2006.

³⁹ F. Arzuaga, *supra*, note 70.

⁴⁰ Law 24.481, September 1995, amended by Law 24.572, October 1995, and Law 25.859, January 2004, as implemented and consolidated by Decree No. 260/1996, March 1996, and Annex II thereof. Note that, in December 2003, the Argentine Patent Office issued Guidelines for Patentability which arguably narrows the patentability criteria.

⁴¹ See Article 4.

natural element).⁴² Importantly, inventions that are contrary to public order or morality are unpatentable, though “morality” is not defined and no particular moral approach is apparent.⁴³

- **Sanctions:** By virtue of the 1997 Decree, Argentina has implied that morally grounded health research is important, but that health research which implicates human cloning cannot, for some reason which is not made clear, be considered moral, and therefore cannot be pursued. However, the 1997 Decree fails to erect any sanctions for breach of its single prohibition, and, of course, it says nothing about boundaries or consequences of boundary-breach for ESCR.

The practical consequences of the cloning prohibition combined with silence on other cloning-related matters (ie: ESCR) is that (1) ESCR is permitted, (2) the use of surplus IVF embryos for obtaining ESCs is permitted, and (3) the importation and use of SC lines derived from both surplus IVF embryos and/or from therapeutic cloning is permitted.⁴⁴ On balance, then, despite the carving out of cloning, Argentina’s overall approach to ESCR would appear to fall within the permissive position outlined above. That being the case, one would hope for some guidance – either in the 1997 Decree or some related instrument as called for in Recital 4 – on Argentina’s position relating to:

- the status of the embryo and a definition of same;⁴⁵
- when (or whether) the embryo can be used to derive SCs for research purposes;
- the status of and protections for individuals participating in SCR; and
- the consequences of importing SC lines derived from cloning.

However, no guidance is offered; presumably, limits on personal actions are left to personal morality, non-governmental instruments or individual ethics review boards.

2.2. Moral Foundation of ESCR and Cloning Governance

In this section, Argentine’s governance structure generally and the 1997 Decree more specifically is assessed to determine which moral values are operative through or deployed by the legal text. Such an assessment is important because, historically, laws have evolved out of and/or been influenced by moral thought, and some argue that laws without moral foundations can be ignored as non-binding. This being so, it is difficult to deny the importance to the validity and robustness of law of some identifiable moral basis. Morally-grounded legal boundaries are particularly important for biotechnology, which increasingly represents a fusion of science and health, of organic and inorganic, of human and non-human, of capability and identity. The

⁴² See Article 6, and the discussion in Association of Patent Law Firms, “Protection of Biotechnological Inventions in Argentina” (2007) 15 APLF Newsletter, at www.aplf.org/mailler-private/issue2007-15.html (Jul. 10/07).

⁴³ Article 7.

⁴⁴ And on the importation issue, note that the *Importation of Scientific-Technological Investigation Inputs Law*, Law 25613, July 2002, generally states that the importation of goods for scientific research is exempt from import duties and other taxes.

⁴⁵ The importance of such a definition and its absence in Argentina is noted in R. Isasi *et al.*, “Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia and Africa” (2004) 32 J.L. Med. & Ethics 626-638.

importance of some moral foundation for regulation in this field is conceded in Recital 3 of the 1997 Decree, which states that certain scientific advances (eg: cloning) create ethical and moral problems that run contrary to the values and customs of the people (which “values and customs” are left undefined and unarticulated).⁴⁶

Argentina appears to have adopted an extremely *laissez faire* approach toward sci-tech innovation and research governance. One might argue that this approach is motivated by and enhances the moral value of “autonomy”. Autonomy, which encompasses physical and psychological liberty and the right to be free from coercion within the reasonable limitations, manifests respect for others by empowering them to make decisions for themselves; the individual, exercising moral agency, must determine a course of action that is right/moral for them.⁴⁷ One might further argue that the 1997 Decree, assessed within this relatively open regulatory environment, represents a narrowly defined and therefore minimally restrictive limitation on scientific freedom. Considered within this light, it might appear to represent only a minute narrowing of autonomy, which remains the overriding value behind Argentina’s sci-tech “regime”.

However, this interpretation is not without its difficulties. One might argue that Argentina’s apparent *laissez faire* attitude is not so much intended as it is a consequence of its fragmented and complex regime, and of another shortcoming common to developing countries, namely lack of legislative and regulatory capacity. In this light, the researcher liberty inferred above – which emerges from inactivity rather than proactive creation of opportunity to do a particular thing – looks less like an autonomy-founded or autonomy-promoting condition. Moreover, there are other value characteristics of Argentine law which lead one to question the autonomy foundation of the 1997 Decree and other sci-tech governance structures. For example:

- Argentina has ratified of the American Convention on Human Rights (1969),⁴⁸ which states that every person has the right to have his life protected by law from the moment of conception;⁴⁹ and

- Argentina has constitutionally entrenched Catholic dogma,⁵⁰ which views the creation of embryos for research purposes as the creation of “sacrificial victims predestined to be immolated on the alter of scientific progress”.⁵¹

⁴⁶ Recital 3 states, “Que los avances científicos que son de conocimiento público posibilitan la realización de experimentos de clonación humana que plantean problemas éticos y morales que se contraponen a las pautas y valores culturales propios de nuestro pueblo”.

⁴⁷ S. Harmon, *supra*, note 19, T. Beauchamp & J. Childress, *Principles of Biomedical Ethics*, 4th ed. (Oxford: OUP, 1994), R. Scott, *Rights, Duties and the Body* (Oxford: Hart Publishing, 2002), S. Aksoy & A. Elmali, “The Core Concepts of the ‘Four Principles’ of Bioethics as Found in Islamic Tradition” (2002) 21 *Med. Law* 211-224. R. Gillon, “Ethics Needs Principles - Four Can Encompass the Rest - and Respect for Autonomy Should be ‘First Among Equals’” (2003) 29 *J.M.E.* 307-312, argues that autonomy must be respected if morality is to exist.

⁴⁸ American Convention on Human Rights, 1969, OAS Treaty Series, No. 36.

⁴⁹ See Article 4.

⁵⁰ See s. 2, *Argentinean Constitution 1853*, available at www.oefre.unibe.ch/law/icl/ar00000_.html, which obliges the federal government to “support the Roman Catholic Apostolic religion”.

⁵¹ Pontifical Academy for Life, “The Dignity of Human Procreation and Reproductive Technologies: Anthropological and Ethical Aspects” (2004) at www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pont-

As such, a strong argument can be made that “human dignity” and “sanctity of life” are core values of Argentine society and therefore defining values of the 1997 Decree.

Dignity generally encapsulates the idea that individuals must be afforded honour and respect, and that the human species has a unique value which must be maintained through enhanced protection.⁵² In the present circumstances, it is interpreted as a constraining value, a violation of which occurs whenever an act directed toward another is viewed, on an objective basis by some external authority, as humiliating, insulting, shameful, contemptuous or damaging to the whole of humanity. Sanctity generally connotes an interpretation of human life as intrinsically valuable or sacred and deserving of priority over all other forms of life or considerations, including comfort, health and actualisation.⁵³

For evidence of their philosophical support of and containment in the 1997 Decree, note Recital 1, which states, *inter alia*, that it is the inviolable duty of the state to defend the dignity of the human being.⁵⁴ Although human dignity is not defined, its deployment is consistent with its interpretation as a constraining value (for it is being used to constrain cloning research and therefore scientific freedom). One can assume that the legislators felt that cloning would diminish human dignity in some way, though it is wildly speculative to offer any insight as to how they may have thought it did so. Also note Recital 6, which states that the government has taken account of the opinions of religious groups, scientific institutions and other countries (that have adopted a view on cloning).⁵⁵ One can assume from this that the American Convention on Human Rights and Catholic interpretations were operative, though this is speculation as the Recital gives no hint as to which groups/institutions/states it considered or found compelling.

2.3. Conclusion: The Black Box Model and Un-Reified Morality

The regulatory framework proposed above is not exemplified in Argentina. Rather, its approach can be characterised as a “black box” whereby the minimal regulation that exists does nothing more than prohibit a specified activity viewed to be particularly reprehensible. Aside from this legislatively-enclosed conduct, ESCR takes place outwith the regulation. The absence of an oversight mechanism means

acd_life_doc_20040316_x-gen-assembly-final_en.html (Oct. 31/06). It has been noted that Latin American legislators receive mandates from the Vatican and frequently act under Vatican morality rather than their own: F. Zegers-Hochschild, “Attitudes Towards Reproduction in Latin America: Teachings from the Use of Modern Reproductive Technologies” (1999) 5 *Human Reproduction Update* 21-25. This deference to the church goes so far as criminalising abortion in all circumstances and refraining from legislating on IVF: see E. Rivera-Lopez, *supra*, note 65.

⁵² M. Cutter, “Genetic Databases and What the Rat Won’t Do: What is Dignity at Law?” in G. Arnason *et al.* (eds.), *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases* (Reykjavik: UIP, 2004) 217-222, at 219.

⁵³ P. Suber, “Against the Sanctity of Life” (1996) at www.earlham.edu/~peters/writing/sanctity.htm (5 Aug 2005).

⁵⁴ Recital 1 states, “Que es funcion indelegable del Estado la defensa de la dignidad de la persona humana, la preservación de su salud y la calidad de vida de los habitantes”.

⁵⁵ Recital 6 states, “Que, igualmente, ha tomado conocimiento de las opiniones formuladas por representantes de distintos credos religiosos e instituciones cientificos y de las decisiones adoptadas por gobiernos de diversos países fijando posiciones concretas al respecto”.

the ESCR (and indeed cloning) is largely invisible to regulators, and the regulation has little chance of shaping research trajectories; choice of ESCR direction remains a bottom-up process with authorities relying on individual researchers to police themselves and to act both virtuously and with utility.

Lack of detail makes it difficult to identify either the values underlying the 1997 Decree or the effectiveness of their translation into legal rules. On the first point, both the social context and the limited textual evidence suggest that the driving values are dignity and sanctity. On the second point, the 1997 Decree does not effectively translate its motivating values (and those enshrined in other legal instruments) into action-guiding rules. Although Argentina's legal and constitutional character and conservative (church-influenced) social history suggest that it should espouse the prohibitive position, its regulatory environment is not reflective of this position, but rather of the permissive position.⁵⁶ On the whole, one must conclude, as presaged by the title to Part II, that the apparently dominant values are lost in the translation from the moral to the legal.

Conclusion

Argentina has targeted biotech innovation as a means of social and economic development. Because biotech innovation (and SCR as a part thereof) is so new, it represents a real opportunity for Argentina to build scientific capacity alongside developed countries and thereby blur the developing/developed divide in this field.⁵⁷ However, to do so, Argentina needs clear and flexible governance structures with some recognition of the moral and some reification of a socially acceptable moral approach. Concise and comprehensive regulation with clear limitations and sanctions for prohibited conduct doubly important because of the legitimate moral disagreement that endures in this field. A regulatory approach as fallow as Argentina's could be seen as irresponsible in the SCR setting where outputs are translated (very quickly) into medical applications some of which will undoubtedly encounter technical problems (with potentially harmful consequences for individual and group health). Neither lack of public funding nor delicate industry conditions are an excuse for under-regulation; the law must be made to cope with new technologies as it evolves. On the positive side, given the regulatory work that is commencing in this field, Argentina's position should not be viewed as settled. A new and improved regulatory framework to SCR (and related activities such as cloning and IVF) is most welcome.

⁵⁶ One might argue that Argentina's drive toward recovery from its socio-economic crisis, combined with its success in other genomic fields (eg: GM crops) goes some way in explaining its disconnect between apparent values and actual conduct. For example, Argentine farmers support GM crops in large part because it keeps them in business: see Commentary, "Argentine Farmers Embrace Biotech" (2001), at www.biotech-info.net/embrace.html (Feb. 14/07).

⁵⁷ A phenomenon which is already occurring in some sectors, particularly the digital communications sector: see M. Kende & O. Ocholi, "Leap-Frogging the Divide: Next Generation Networks in Developing Countries" (2006) at <http://web.si.umich.edu/tprc/papers/2006/580/Microsoft%20Word%20-%20Leap-frogging%20the%20divide.pdf> (Feb. 15/07), and R. Davison *et al.*, "Technology Leapfrogging in Developing Countries – An Inevitable Luxury?" (2000) at www3.undp.org/istarch/sdnpaf/pdf00000.pdf (Feb. 15/07).