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Ectogenesis: the next generation

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A thesis submitted to the Faculty of Graduate Studies and Research in partial
fulfillment of the requirements of the degree of Master's in Biomedical Ethics
(LL.M.)

October 2008
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Your file *Votre référence*
ISBN: 978-0-494-66881-8
Our file *Notre référence*
ISBN: 978-0-494-66881-8

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Abstract

Ectogenesis – literally creation outside the womb – is a word coined by British geneticist J.B.S. Haldane in 1923 as he provocatively predicted future scientific frontiers. Fast-moving assisted reproductive technologies assure us that ectogenesis is no longer the fantastical creation of futuristic writers. Instead, it is likely to manifest in one of three ways. It may be a quiet byproduct of the lessening gap between *in vitro* procedures and the use of sophisticated neonatal environments. It may arise from endometrial tissue ladders grown into artificial wombs. Or, it may be as bizarre as that envisioned in *Brave New World* where there is an intentional effort to create an artificial womb from which the development of a human being may be scrutinized and monitored from start to finish.

The morass of hasty and reckless legislation passed in various countries to deal with the creation and termination of embryonic life shows that few are prepared to deal with exigencies of ectogenesis when it arrives insidiously or abruptly. Moreover, Eastern thought and traditions will conflict with Western ideology with respect to the beginning and maintenance of human life. This thesis suggests that the language, structure and philosophy of the United Kingdom's Human Fertilisation and Embryology Act is well crafted and should be considered as a world-wide paradigm. This thesis also suggests that ectogenesis will mandate that the interests of the developing fetus override notions of reproductive autonomy.

Résumé

Le terme « ectogénèse » (littéralement, création hors matrice) a été inventé en 1923 par le généticien britannique J.B.S. Haldane dans sa prédiction provocatrice des futures frontières scientifiques. Les technologies reproductives qui avancent aujourd'hui à grands pas viennent nous prouver que l'ectogénèse n'est plus la création fantastique d'auteurs futuristes. Elle s'exprime plutôt sous l'une de trois formes : il peut s'agir d'un sous-produit tranquille de la collaboration de plus en plus étroite entre les procédures *in vitro* et l'utilisation d'environnements néonataux sophistiqués ; elle peut naître des échelles de tissu endométrial qui se développent dans des matrices artificielles ; ou, elle peut être aussi étrange que la vision du *Meilleur des mondes* avec un effort intentionnel de création d'une matrice artificielle à partir de laquelle il est possible d'examiner en profondeur et de surveiller du début à la fin le développement d'un être humain.

L'imbroglia de législations hâtives et imprudentes passées dans différents pays pour gérer la création et l'interruption de la vie embryonnaire met en exergue la rareté de ceux qui sont prêts à faire face aux exigences de l'ectogénèse dès qu'elles sont soulevées, que ce soit de manière insidieuse ou soudaine. En outre, la philosophie et les traditions orientales entrent en conflit avec l'idéologie occidentale quant au commencement et à la continuation de la vie humaine. Cette thèse suggère que de par son langage, sa structure et sa philosophie, l'acte britannique sur la fertilisation et l'embryologie humaine (Human Fertilisation and Embryology Act) a été bien réfléchi et formulé et devrait être considéré comme paradigme à l'échelle mondiale. Cette thèse suggère également que l'ectogénèse imposera la priorité de l'intérêt du fœtus en cours de développement sur les notions d'autonomie reproductive.

Acknowledgements

I wish to thank my McGill supervisor Professor Ronald Sklar who was persuaded to let me take on this odd topic, who waded through the scientific jargon without complaint, and who offered me his wonderful humor, observations and kindness throughout my time at McGill. I also wish to thank Linda McDonald Glenn, J.D. (LL.M., bioethics, McGill 2002) for her tireless and unwavering support throughout the many months this thesis was researched and written. I thank McGill Professor Mark Antaki for his time and attention to the first draft of this thesis. I also thank William Sims Bainbridge, Ph.D. for his inestimable moral support. I especially want to recognize my fellow bioethics enthusiasts Jessica Merkel-Keller (M.Sc., bioethics, McGill 2006, M.D. Robert Woods Johnson, degree to be awarded in 2009) and Brenda Chomey, LL.B. (M.Sc., bioethics, McGill 2006) who were always available to talk about new ideas. Two recent graduates of the University of Denver School of Law, Ted Gleason, J.D. and Bryan Lange, J.D. assisted me with the painstaking task of cite-checking my thesis. Suzanne Nix, a dear friend of many years, helped with the final formatting. Finally, I thank those who assisted me on my treks to and from Canada and New York: Kreg Hamburger, Dale Jennings and William Cooper. I dedicate this thesis to the late Geoffrey Alan Ross, Ph.D., who first introduced me to philosophy at Stanford University, and who kept my interest in philosophy alive for thirty years, despite my becoming a lawyer. Without him, I may not have had the interest in the burgeoning field of bioethics which propelled me from the comfort of Colorado to the vast unknown of Montreal and McGill University which has forever changed me.

Introduction

'Ectogenesis' is used in this thesis to mean an artificial womb designed to bring forth new human life; the word itself is a derivative of the Greek word 'ecto' [outside] and the word 'genesis' [to come into existence].¹ Once thought unworthy of discussion as science fiction even a few years ago, ectogenesis is becoming a subject of serious legal and ethical exploration in anticipation of its eventuality.² Questions concerning the nature and rights of an embryo and its developmental cousin, the fetus, are being modified and fixed by court decisions and laws. Ectogenesis may become a reality in five years or it may be as far away as sixty years. It will change assisted reproductive technologies as surely as Louise Brown³ changed the world forever for infertile couples. Ectogenesis also harbingers major social changes and upheaval if it is possible to gestate an embryo to maturation entirely outside of a woman's body.

Although ectogenesis is a technology that may soon be in the arsenal of physicians specializing in assisted reproduction for infertile couples, most countries are not well equipped to deal with impending scientific advances in this field. Nevertheless, laws can and must be molded to fit these looming scientific changes, but such changes will need to be implemented on a global scale. A well-crafted decisional algorithm needs to be created in order to meet the challenges

¹ Ectogenesis. The production of structures or bodies outside the organism... Ectogenetic, ectogenic, ectogenous, adjs., pertaining to ectogenesis, producing or produced from without. Online: <<http://www.dictionary.oed.com>>.

² As well-known bioethicist Art Caplan noted when asked about his thoughts on ectogenesis: "The future looks rosy for bioethicists." Online: [www the triplehelix.org/documents/issues/Berkeley_Spring_06.pdf](http://www.triplehelix.org/documents/issues/Berkeley_Spring_06.pdf).

³ The world's first 'test tube baby' in 1978.

that are sure to arise if and as childbearing can be accomplished without a human womb.

This thesis argues that the United Kingdom's Human Fertilisation and Embryology Act of 1990,⁴ along with its proposed amendments,⁵ is the most thoughtful and comprehensive legislation in existence and should be the basis for any worldwide legal framework related to ectogenesis. As a corollary, as the science of ectogenesis develops, the law will also need to revisit unworkable notions of reproductive autonomy to place the well-being of the developing conceptus⁶ ahead of the desires of its genetic parents.

Chapter One of this thesis dissects some of the terminology related to embryology and reviews the current status of ectogenesis from a scientific perspective. It is vital to use a common language in embryology and assisted reproductive technology. The use of certain non-scientific language, such as conception and pre-embryo, should be discarded in favor of medically accurate terminology.

Chapter Two exposes the myriad social ramifications of artificial wombs. As with any technological change of this magnitude, it holds enormous promise and it presages serious threats to the *status quo*. It is not difficult to envisage benign and/or malevolent uses of this technology. Ignoring the scientific advances that are inexorably marching in this direction is foolhardy; the wiser

⁴ Human Fertilisation and Embryology Act 1990 (U.K.), 1990 c. 37. [1990 HFEA].

⁵ Human Tissue and Embryos (Draft) Bill, 200602007 Sess., 2007 (Joint Committee on the Human Tissue and Embryos (Draft) Bill. [2007 HFEA].

⁶ A 'conceptus' is a comprehensive word to describe all stages of human development from embryo to viable fetus. Online: <http://www.oed.com>: Conceptus: the product of conception, *i.e.* the union of sperm and egg, an embryo or fetus together with the placenta, and amniotic fluid.

approach will be to engage in an historical analysis of the various reasons that ectogenesis has been alternately eagerly anticipated and feared, especially from a feminist perspective.

Chapter Three illustrates the wild divergence in opinions - ideologically, sociologically, theologically, and bioethically - of the metaphysical status of embryos. An international dialogue about a comprehensive worldwide structure to address developments in the field of creating human beings, which simply and boldly brackets irresolvable metaphysical considerations, should be commenced. Even now, the world is seeing “reproductive tourism.” Individuals from a more restrictive country travel to other less restrictive countries to obtain assisted reproductive technologies that are forbidden at home. Reproductive tourism destabilizes any kind of orderly decision-making by policymakers for foreseeable technological advances such as ectogenesis. This Chapter undertakes a review of significant and sadly inconsistent *in vitro* legislation in various countries.

Chapter Four exposes dramatically conflicting case law on the subject of frozen embryos and termination of fetal life. In the spring of 2007, the European Court of Human Rights in *Evans v. United Kingdom*⁷ decided an important “frozen embryo” case, concluding that the frozen embryos were not “persons.” By contrast, in the spring of 2007, the United States Supreme Court in *Gonzales v. Carhart*⁸ upheld Congressional criminalization of a specific type of abortion procedure, revealing in *dictum* that the highest Court it is poised to declare that fetuses and even embryos are “persons” with attendant rights and interests.

⁷ Grand Chamber of the European Court of Human Rights: Application No. 6339/05, Judgment of 10 April 2007.

⁸ 550 U.S.____(2007); 2007 U.S. Lexis 4338; 75 U.S.L.W. 4210.

These differing notions are on such a collision course that the next United States President may be elected or rejected based upon “personhood” considerations of the unborn and his support or rejection of *Roe v. Wade*.⁹

Chapter Five takes the provocative abortion issue one step further. There is no adequate or coherent legal structure with respect to termination of fetal life if the maternal/fetal conflict inherent in abortion law is rendered moot by ectogenesis. In particular, cherished notions of reproductive autonomy and privacy may have to be revisited and give way to considerations of giving the fetus the ‘right’ to be born healthy and without significant impairments.

⁹ 410 U.S. 133 (1973).

Chapter One: Ectogenesis: Language and Science

In 1923, J.B.S. Haldane read his paper encaptioned *Daedalus of Science and the Future* to a group called the Heretics at Cambridge University.¹ The paper was prophetic, provocative and inflammatory. He foresaw that Einstein's work would challenge the role and respectability of contemporary metaphysicians.² He noted that Darwin's results were just "beginning to be appreciated" and that those, along with Mendel's findings, would "affect political and philosophical theories almost equally profoundly."³

He predicted that biology would invade the provinces of physics and life; developments in that direction would bring mankind more and more together, would render life more and more complex, artificial, and rich in possibilities - and would tend to increase infinitely man's powers for good and evil. That scientific advances would be assailed on moral and religious fronts was predictable:

One may remark that it is impossible to keep religion out of any discussion of the practices which they popularized... there is no invention, from fire to flying, which has not been hailed as an insult to some god. [I]f every physical and chemical invention is a blasphemy, every biological invention is a perversion. There is hardly one which, on first being brought to the notice of any

¹ J.B.S. Haldane, "Daedalus of Science and the Future" (Paper read to the Heretics, Cambridge, February 1923) [2nd ed. (London: Kegan Paul, Trench & Co., 1928)], online: <<http://www.cscs.umich.edu/~crshalizi/Daedalus.html>>; Haldane chose Daedalus for the title of his talk for the following reason: "The sentimental interest attaching to Prometheus has unduly distracted our attention from the far more interesting figure of Daedalus....[His interest in sculpting] inevitably turned to biological problems, and it is safe to say [had other more pressing concerns not occupied him, i.e. the Minotaur] Daedalus would have anticipated Mendel... Thus he was forced to invent the art of flying... He was the first to demonstrate that the scientific worker is not concerned with the gods..."

² *Ibid.* at 2: "It has been customary for the majority of metaphysicians to proclaim the ideality of Time or Space or both. Einstein, so far from deducing a new Decalogue, has contented himself with deducing the consequences of space and time themselves."

³ *Ibid.* at 8.

observer from any nation which has not previously heard of their existence, would not appear to him as indecent and unnatural.”⁴

Haldane foresaw the application of biology to politics with all of its human nobility and savagery – from eugenics to the “separation of reproduction from sexual love” to ectogenesis. He is credited with being the first modern person to articulate the word “ectogenesis” to mean an artificial chamber in which babies could grow and used it in his *Daedalus* talk as a thought experiment.⁵ He posited that man’s increasing power over nature would force him to form the nucleus of an international government.⁶ I posit that mankind’s increasing power over reproduction should be viewed as the ethical canary’s⁷ plaintive plea for a revisitation and clarification of metaphysical and legal views on the status of embryos and fetuses.

As did Haldane, I am using ectogenesis in this thesis as a vehicle - metaphorically, provocatively, and futuristically - to examine a number of issues which are raised by any technological leap which was previously unthinkable and which, predictably, foments dissension and mandates an examination of contemporary ethics, religious thought, philosophy and law. In the words of Haldane, “I would ask you to excuse what at first sight might appear improbable or indecent in the speculations which appear below.”⁸ The first part of this

⁴ *Ibid.* at 7. He mentions that milking and drinking cow’s milk and allowing it to rot into cheese and creating wine by corrupting perfectly good grapes were probably first thought offensive and unnatural. These would be good ancient examples of the Yuk factor, see *infra*, Chapter Two, part (B).

⁵ *Ibid.*

⁶ *Ibid.*

⁷ Great term borrowed from Margaret Somerville. See, Margaret A. Somerville, *The Ethical Canary: Science, Society and the Human Spirit* (Toronto: Penguin Canada, 2000).

⁸ Haldane, *supra* note 1 at 5.

Chapter explores the language used in embryology that will be implicated in the development of ectogenic alternatives to the human womb, and the second part will discuss scientific efforts to create full or partial artificial wombs.

(A) The Language

However theoretical at this stage, some serious scientific progress has been made toward ectogenesis. These scientific advances are sometimes difficult to grasp as the lingo surrounding these advances is complex and has sometimes been badly mangled or politically misused by those with vehement positions, pro or con. From A.R.T.⁹ to zygote, this first Chapter will endeavor to clarify and simplify some of the language which will appear in this thesis. Without a common agreement on language, it is impossible to craft any consensus about methodology to address impending difficult issues surrounding ectogenesis. Moreover that language must be scientifically accurate; otherwise, a mishmash of inconsistent laws, regulations, and judicial decisions will effectively eliminate any effort to deal preemptively with the upcoming revolution in assisted reproductive technology.

The language in the 1990 Human Fertilisation and Embryology Act¹⁰ and its 2007 amendments as embodied in The Draft Embryo and Tissue Bill¹¹ are ripe to be considered as the “universal legal language of embryology,” at least insofar

⁹ Assisted Reproductive Technology.

¹⁰ Human Fertilisation and Embryology Act 1990 (U.K.), 1990 c. 37. [1990 HFEA].

¹¹ *Human Tissue and Embryos (Draft) Bill*, 2006-2007 Sess., 2007 (Joint Committee on the Human Tissue and Embryos (Draft) Bill). [2007 HFEA].

as lawmakers, politicians and courts are concerned.¹² The reason for this is simple. The U.K., perhaps because of Louise Brown, the world's first "test-tube baby," has had the most time legislatively to ruminate upon, dissect, send to committee for comment, revise, and reenvision the most comprehensive and thoughtful schema to date on the beginning of life. One of the stated purposes of the 2007 HFEA is to "promote public confidence in the development and use of human reproductive technologies through efficient regulatory controls applicable to them."¹³ It has the foresight to address, regulate and define the creation of hybrids, cybrids and chimeras.¹⁴ The 2007 HFEA complies with Directive 2004/23/EC of the European Parliament and of the Council on "setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells." As stated by the Directive of that Council: "as tissue and cell therapy is a field in which an intensive worldwide exchange is taking place, it is desirable to have worldwide standards." However, one cannot have worldwide standards without a common legal language. The 2007 HFEA provides this.

¹² Medicine of course has a need for language describing some of the processes more exquisitely, but for "lay science" purposes, which suit regulatory and legal purposes, consensus on a term and a point in time when a legally significant event "occurs" is more important.

¹³ 2007 HFEA, *supra* note 11 at 9.

¹⁴ "A human hybrid that is one formed by fertilisation of a human egg by an animal sperm. [We have used the term chimera to include] the formation of a chimera by taking a human embryo and adding animal cells. A human cybrid is created by placing a human cell into an empty animal egg." United Kingdom, House of Commons, *Minutes of Evidence Taken Before Science and Technology Committee*, Session 2006-07, HC 272-iii (28 February 2007), online: <<http://www.publications.parliament.uk/pa/cm200607/cmselect/cmsctech/uc272-iii/uc27202.htm>>.

The older 1990 Act provided that an embryo “is a live human embryo where fertilisation is complete.”¹⁵ “Fertilisation” was not deemed “complete” by that Act until the appearance of a two cell zygote although a zygote is a single-celled organism immediately after egg and sperm fusion.¹⁶ In the 2007 HFEA, the word “embryo” is redefined to include an egg that is in the process of fertilisation *or is undergoing any other process capable of resulting in an embryo* thus pushing back the date an embryo “exists” legally and unequivocally.¹⁷ The 2007 HFEA also establishes another important date: it provides that an embryo develops the “primitive streak” on or around day 14.¹⁸

The ‘primitive streak’ is the first observable change in the cells as they engage in their elaborate tango that will develop into the neural system.¹⁹ This primitive streak is legally important as it corresponds to the time limits already established for embryonic experimentation in the U.K. as well as in many other countries.²⁰ It is a “bright-line” cut-off point which corresponds exactly with the commencement of development of any neural system in the embryo and with the end of the twinning capacities of the pluripotent cells. Neurulation is a process which includes the formation of the neural plate around day 18-19, the neural folds around days 20-21 and the neural tube around days 22-26.²¹ The neural tube

¹⁵ 1990 HFEA, *supra* note 10 at Art. 1.(1)(a).

¹⁶ *Ibid.*

¹⁷ 2007 HFEA, *supra* note 11. Italics indicate new statutory language. This reference is to address cloning.

¹⁸ 2007 HFEA, *supra* note 11.

¹⁹ For a full discussion of the medical processes, see, Human Embryo Research Panel, http://ospp.od.nih.gov/pdf/VOLUME1_REVISED.PDF and http://ospp.od.nih.gov/pdf/VOLUME2_REVISED.PDF. [HERP] Vol. 1 at 8-10.

²⁰ *Ibid.*

²¹ *Ibid.*

will later develop into the brain and spinal cord.²² The 14 day Rule provides a rational basis for an international dialogue about the point at which some increment of "respect" for the embryo-as-an-individual inures.

(B) Contra-conception

Conception is a word and idea which must go the way of "consumption," "dropsy" and "lunacy." It is an incomplete and overbroad notion defying medical verity, despite the law in Missouri.²³ That "conception" occurs at a fixed point in time is based upon the scientifically inaccurate and anthropomorphic notion that the manly hunter sperm swims upstream to penetrate the passively awaiting egg and when the sperm actually penetrates the egg, voila, the "moment of conception."²⁴ This idea can be traced back to Aristotle who thought the ejaculate itself emitted the principle of soul.²⁵ Sperm by itself is infertile until it is exposed to the female reproductive tract or the *in vitro* facsimile thereof and the sperm becomes "capacitated."²⁶ The sperm does not exactly penetrate the passive egg, either. The egg engages in contractile movements to draw the sperm inside which is also a complex process and is not an exact point in time.²⁷

²² *Ibid.*

²³ *Webster v. Reproductive Services*, 492 U.S. 490 (1989); The Missouri statute defines "conception" as "the fertilisation of the ovum of a female by a sperm of a male" even though standard medical texts equate "conception" with implantation in the uterus, occurring about six days after fertilisation; See Mo. Rev. Stat. 188.015(3) (1986); Apparently there is also some confusion in Missouri as to which sex possesses the ovum and which possesses the sperm.

²⁴ The inherently sexist notions of conception are playfully – but pointedly – impugned in *Mis-Conceptions, the Moment of Conception in Religion*; Elizabeth Spahn & Barbara Andrade, "Mis-conceptions: The Moment of Conception in Religion, Science, and Law" (1998) 32 U.S.F. L. Rev. 261.

²⁵ *Ibid.* at 288.

²⁶ *Ibid.*

²⁷ *Ibid.*

Sperm and egg fusion constitutes fertilisation.²⁸ Fertilisation is not an instantaneous process either; it can take from seventeen hours after ejaculate to a week.²⁹ Conception does not occur until the fertilised egg implants into the uterine wall approximately one week after ejaculation.³⁰ Thus, fertilisation occurs at an earlier stage than conception. Moreover, a large number of fertilised eggs fail to implant at all, thus “conception” never occurs.³¹ For these reasons, undoubtedly, the 2007 HFEA does away with “conception” language as well as inaccurate “fertilisation is complete” language and defines an embryo as an egg in the process of fertilisation which is incontrovertible legally and religiously by any standard.³²

Adopting the language of the HFEA as a universal legal language would also eliminate the confusing terminology of “pre-embryo” which has been used to designate the period, which is post-zygote and pre-blastocyst.³³ It would enable juridical segmentation of human life into time frames which acknowledge the scientific verity that human development is a process.³⁴ And, it eliminates the seeming requirement that Courts – wherever they may be located - become

²⁸ *Ibid.* at 264.

²⁹ *Ibid.* at 278.

³⁰ *Ibid.* at 264.

³¹ *Ibid.*

³² Individual states within the United States have been passing legislation which is scientifically inaccurate and problematic. For example, in Illinois, conception is equated with fertilisation and in Louisiana, conception and fertilization are the same when the “sperm contacts” the egg, raising the possibility that all birth control is criminal and that a sperm touching an unfertilised egg is still “conception.” *Ibid.* at 329.

³³ See, e.g. confusing discussion of the so-called pre-embryo dispute in *Davis v. Davis*, 842 S.W.2d 588 (Tenn. Sup. Ct. 1992).

³⁴ Jessica Berg, “Of Elephants and Embryos: A Proposed Framework for Legal Personhood” (2007) [unpublished archived at <http://works.bepress.com>], online: Selected Works <http://works.bepress.com/jessica_berg/1/>. See also discussion *infra*, Chapter Four.

medical clairvoyants in each case to sort out what the legislature must have truly intended in enacting laws which make no sense.

Some political ideologies have crept into legislation intentionally or unintentionally contributing to embryonic confusion. Diane Irving of the American Bioethics Advisory Commission has this to say: “during the process of gametogenesis and fertilization – [there is a] change from two simple PARTS of a human being, i.e. a sperm and an oocyte which simply possess ‘human life’ and [there is created then] a new genetically unique, newly existing, individual, live human BEING, an embryonic single-cell human zygote.” [Irving’s emphasis in original]³⁵ It is questionable whether it is at all helpful to legislation to revere an egg and sperm as “human life” inasmuch as sloughed off human skin cells are also “human life.” Further, it seems academically irresponsible to capitalize the word BEING as if that somehow conveyed legal personhood status.³⁶ Or, consider this statement: “it seems indisputable that at syngamy³⁷ a new human being exists.³⁸ Again, the implication is that a “human being” is something that does or should possess the full complement of “legal personhood” rights as and against all others. Conflation of medical terms with wished-for political agendas

³⁵ Diane N. Irving, “When Do Human Beings Begin? ‘Scientific’ Myths and Scientific Facts” (1999) 19:3/4 Int’l J. Soc. & Social Pol’y 22.

³⁶ Her emphasis on BEING is in her article. Capitalizing BEING is not particularly explanatory or helpful.

³⁷ Synagmy is the point at which a one-celled zygote is formed, approximately twenty hours after fertilisation; See John A. Robertson, “Assisted Reproduction in Germany and the United States: An Essay in Comparative Law and Bioethics” (2004) 43 Colum. J. Transnat’l. L. 189. [Roberts I].

³⁸ Francis J. Beckwith, “Defending Abortion Philosophically: A Review of David Boonin’s *A Defense of Abortion*” (2006) 31 J. Med. & Philosophy 177.

is not uncommon in a field which is rife with emotion, anti-religious and religious convictions.³⁹

(C) Other embryology terms

Certain terms and words arise specifically in the context of stem-cell issues. Stem cell issues overlap with and are implicated in ectogenesis. Embryonic cells are “totipotent” up to approximately four days after fertilization, meaning that each cell has the capacity to form into a new human entity.⁴⁰ At approximately four days after the fertilisation of the egg, the cells become restricted and are deemed to be “pluripotent” which means that they may form many types of cells but they cannot become a zygote (or so it was thought until November 21, 2007).⁴¹ Up to approximately 14 days, twinning may still occur because of the pluripotent cells, i.e. identical twins may result from a cell splitting.⁴²

Ectogenesis will of course involve embryos which are created outside of the mother. “I.V.F.” is the abbreviation for *in-vitro* fertilization which means that

³⁹ Irving, *supra* note 35 at 64. For example, Irving accuses certain bioethicists of creating the term “pre-embryo” to denote lesser moral status. But the counterclaim that a fertilised egg is a “human being” in order to endow it *sub silentio* with full moral status is hardly more helpful.

⁴⁰ See U.S., National Institutes of Health, *NIH Statement Before the Senate Appropriations Subcommittee* (26 April 2000), online: <<http://stemcells.nih.gov/policy/statements/State.asp>>.

⁴¹ See Rose Koch-Hershenov, “Totipotency, Twinning, and Ensoulment at Fertilisation” (2006) 31 *J. Med. & Philosophy* 139. As of November 20, 2007, Japanese researcher Shinya Yamanaka and American researcher James A. Thomson simultaneously announced that they were able to create pluripotent stem cell lines from human skin. Takashi et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, (*Cell*) 207, doi: 10.1016/j.cell.2007.11.019; Thomson, et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells*, found at <http://www.scienceexpress.org/> 20 November 2007. Shortly thereafter, in an interview with *New Scientist*, Dr. Yamanaka confided that he could make eggs as well as sperm from his own male cells, *New Scientist* December 15, 2007 at 44. Dr. Yamanaka is very concerned that a resulting embryo would be defective and he is urging a global ban on such technology. See, Rob Waters & John Lauerma, “Human Stem Cells Created Without Destroying Embryos” *Bloomberg.com* (20 November 2007), online: http://www.bloomberg.com/apps/news?pid=email_en&refer=home&sid=a3kuMHhfbG.g.

⁴² Patrick Lee and Robert P. George, “The First Fourteen Days of Human Life” *The New Atlantis*, (Summer 2006) 61, online: <<http://www.thenewatlantis.com/archive/13/leegeorge.htm>>

fertilisation occurs outside of the mother. Ectogenesis also encompasses the possibility that humans would use this process to create certain types of embryos or to repair faulty embryos with certain kinds of diagnostic tests. This winnowing process already exists in the form of “P.G.D.” or “PGD” which stands for Preimplantation Genetic Diagnosis; it allows for the screening of embryos prior to transfer to the uterus to assess their viability and their genetic makeup.⁴³ At this time, PGD is utilized to determine whether the chromosomes have an improper number and are thus unlikely to implant and/or to determine whether the embryo has an X-linked or autosomal recessive genetic disease.⁴⁴ PGD involves the practice of removing a cell from an embryo at around day three to detect whether it has any genetic abnormalities. The purpose of PGD is to identify and refrain from implanting embryos that are diseased or carry the risk of genetic abnormalities.⁴⁵

The “Warnock Rule” – another term which is familiar in embryology – is the source of the “14 day Rule.” It arose in the United Kingdom in 1984 when the Warnock Report was issued, recommending the limitation of embryo research to 14 days based upon the primitive streak and upon the end of the period in which twinning is possible.⁴⁶ The 14 day Rule continues to be cited and is used as an important cut-off line for experimentation with embryos in those parts of the world that permit embryonic research at all, including the United Kingdom, Australia, and Canada. The leading IVF medical association in the United States,

⁴³ Robertson I, *supra* note 37 at 193.

⁴⁴ *Ibid.*

⁴⁵ Rachel Anne Fenton, “Time For Change” (2007) 157 New L.J. 954 at 955.

⁴⁶ William Saletan, “The Organ Factory” *Slate* (27 July 2005), online: *Slate* <<http://www.slate.com/id/2123269/entry/2123273>>.

the American Fertility Society, observes this cut-off although it is nowhere regulated in the United States.⁴⁷ The next stage of development for legal purposes is then the fetus which is the label given to the human entity from eight weeks after fertilisation until birth.⁴⁸

The terms that I will use by abbreviation repeatedly throughout this thesis will be “IVF” (in-vitro fertilization), “ART” (Assisted Reproductive Technologies which by definition include IVF as well as other procedures); “PGD” (Preimplantation Genetic Diagnosis which analyses embryos for genetic disorders before they are implanted); and the “14 day Rule” which is the bright-line cutoff point for embryonic experimentation in all countries at this point including stem-cell research and PGD. No country has been able to keep human embryos alive outside of a woman longer than about nine days even if they were so inclined. Therefore, the 14 day Rule correlates with numerous developmental milestones and is set well beyond the current date that a live embryo which has not been destroyed, died, or been implanted, could survive.

(D) The Science of Ectogenesis

(1) Time shrinks

Although the phrase “artificial womb” conjures *Brave New World* technology and commodification of humans, the likelihood is that ectogenesis will arrive in far more benign ways. The age at which fetuses may survive is receding. Literature regarding infants born in tertiary centers in the United States in the 1990's shows a reported aggregate survival rate of 10% at 22 completed weeks,

⁴⁷ *Ibid.*

⁴⁸ HERP report, *supra* note 19 at 8-10.

28% at 23 weeks, and 51% at 24 weeks.⁴⁹ In the 1960's, fetuses born around 30 weeks and weighing over three pounds often died because their lungs were too immature to sustain them.⁵⁰ In February 2007, a 21 week old fetus survived to the surprise of the obstetrician who assumed he was delivering a 24 week old fetus.⁵¹ At the other end, the length of time that an embryo may be created and maintained *ex utero* grows. In 1975, Robert Edwards⁵² was able to grow a human embryo for nine days without implantation; mouse and rat embryos have been kept alive for two weeks.⁵³ The inability to extend embryonic development *in vitro* beyond two weeks is an engineering problem related to establishing a feto-placental exchange under culture conditions that would meet the nutritional demands of the embryo.⁵⁴

On July 26, 2007, it was announced that Teruo Fujii of the University of Japan in Tokyo is in the process of building a microfluidic chip to nurture the first stages of pregnancy. NewScientist.com reported that he hoped to create a “fully automated artificial uterus in which egg and sperm are fed in at one end and an early embryo comes out the other, ready for implanting in a real mother.”⁵⁵ The newest process is predicted to create healthier embryos that have not been moved

⁴⁹ J.M. Lorenz, “The Outcome of Extreme Prematurity” (2001) 25 Sem. Perinatol. 348.

⁵⁰ *Ibid.*

⁵¹ See Pat Wingert, “The Baby Who’s Not Supposed to Be Alive” *Newsweek* (5 March 2007) at 60.

⁵² Robert Edwards is the same embryologist who created the test-tube baby Louise Brown; Liza Mundy, *Everything Conceivable: How Assisted Reproduction is Changing Men, Women, and the World*, 1st ed. (New York: Random House, 2007) at 8.

⁵³ Singer, Peter & Wells, Deane. *Reproduction Revolution: New Ways of Making Babies* (Oxford: Oxford University Press, 1984) at 118.

⁵⁴ See Patrick P. L. Tam, “Post-Implantation Mouse Development: Whole Embryo Culture and Micro-Manipulation” (1998) 42 Int. J. Dev. Biol. 895.

⁵⁵ Linda Geddes, “Womb-on-a-chip May Boost IVF Successes” *New Scientist* (26 July 2007), online: NewScientist.com <<http://www.newscientist.com/article.ns?id=mg19526146.200>>.

or washed with culture fluid, which causes changes in temperature and pH.⁵⁶ The tiny “lab on a chip” can take up to 20 eggs, which can then be fertilised and grown on endometrial cells.⁵⁷ As the length of time between *in vitro* development lengthens and the length of time a premature infant may be kept alive and developing shortens, ectogenesis may occur “almost by accident.”⁵⁸

(2) Organ transplants

The “accident of ectogenesis” may also arise as a byproduct of technology whereby replacement organs are being developed. Already, scientists have found ways to grow skin and cartilage and two Harvard researchers have grown animal tissue from a variety of organs including heart, kidneys and bladder.⁵⁹ On January 14, 2008, the New York Times announced that a rat heart had been grown on tissue ladders from cells of baby rats.⁶⁰ Dr. Anthony Atala is currently the director of Tissue Engineering and Cellular Therapeutics at Children’s Hospital and Harvard Medical School in Boston, Mass. His work focuses on growing new human tissues and organs to repair those that are defective at birth or destroyed by disease.⁶¹ Atala has created bioengineered urethras and cartilage cells, which are

⁵⁶ *Ibid.*

⁵⁷ *Ibid.*

⁵⁸ Scott Gelfand & John R. Shook, eds., *Ectogenesis: Artificial Womb Technology and the Future of Human Reproduction* (New York: Editions Rodopi BV, 2006), Peter Singer and Deanne Wells, “Ectogenesis” at 10. [Ectogenesis].

⁵⁹ Richard Schroepfel, “Growing Organs” *The Associated Press* (22 July 1997).

⁶⁰ Lawrence K. Altman, “Team Creates Rat Heart Using Cells of Baby Rats” *The New York Times* (14 January 2008), online: The New York Times <http://www.nytimes.com/2008/01/14/health/14heart.html?_r=1&oref=slogin>.

⁶¹ Wake Forest University Baptist Medical Center, News Release, “Internationally Recognized Tissue Engineering Program To Join Wake Forest University Baptist Medical Center” (8 November 2003), online: <<http://www1.wfubmc.edu/News/NewsArticle.htm?ArticleID=30>>.

currently being tested in the bladder neck and in ureters.⁶²

Reportedly, Dr. Atala has also successfully created blood vessels, muscle, bladders, wombs, and vaginas that have been tested in large animals and are close to being ready to test in humans.⁶³ To repair or replace parts, he seeds a biodegradable scaffold with cells and inserts it into the body, where the cells have an opportunity to mature into functioning tissue.⁶⁴ Dr. Atala and eighty of his colleagues are working on tissue replacement projects for many body parts — blood vessels and nerves, muscles, cartilage and bones, esophagus and trachea, pancreas, kidneys, liver, heart and even uterus.⁶⁵ As an outgrowth of this thinking and technology, Dr. Hung-Ching Liu of Cornell University announced in 2001 that her team had successfully grown a sample of cells from the lining of a human uterus and used tissue engineering theories and technologies to shape them into a womb.⁶⁶

In a lively interview at a conference in late 2001, Dr. Liu excitedly explained what she was doing and what problems she had encountered.⁶⁷ Her earlier efforts at creating an artificial uterus had encountered difficulties with the implantation of the embryo, so she decided to construct a three-dimensional human endometrial tissue for co-culture with which she could then simulate

⁶² *Ibid.*

⁶³ *Ibid.*

⁶⁴ *Ibid.*

⁶⁵ Ann Parson, "A Tissue Engineer Sows Cells and Grows Organs" *The New York Times* (11 July 2006), online: The New York Times <<http://www.nytimes.com/2006/07/11/health/11prof.html?ex=1310270400&en=799360eaae879b1c&ei=5088&partner=rssnyt&emc=rss>>.

⁶⁶ Peter Singer, "Where the President's Ethics Lecture Went Wrong" *Free Inquiry* 22:1 (Winter 2002) 23.

⁶⁷ Interview of Helen Liu by Hans van der Slikke (October 2001) found at *OBGYN.net* Conference Coverage From the American Society of Reproductive Medicine, Orlando, Florida, October 22-24, 2001, online: OBGYN.net <http://www.obgyn.net/displaytranscript.asp?page=/avtranscripts/asrm2001-liu>.

implantation into a woman.⁶⁸ Accordingly, she used a matrix made of a copolymer composed of chondroitin and collagen. When the co-polymer grows, she explained, “it forms a three dimensional platform so that a cell can grow to be a three dimensional tissue.”⁶⁹ Also, this tissue platform was designed to be biodegradable so that it would just dissolve or be absorbed when transplanted into a woman.⁷⁰ She described successfully engineering the endometrial tissue that was composed of the glands and the stromal⁷¹ cells. She noted that the glands mimicked the *in vivo* structure and that, after five days, they reached the hatch stage, and after six days, they attached to the epithelium itself, simulating early implantation *in vivo*.⁷²

Dr. Liu’s hope was to culture the 3-D tissue and transplant it to women with a variety of reproductive issues.⁷³ One vision was to transplant the tissue to women who have only a partial uterus which would then expand to absorb the tissue; another idea was to transplant it into women who have been born with T-shaped uterus that tend to reject implantation of an embryo.⁷⁴ With the new technology, women with severely damaged or missing uteruses might well be capable of bringing a baby to full term.⁷⁵

⁶⁸ *Ibid.*

⁶⁹ *Ibid.*

⁷⁰ *Ibid.*

⁷¹ Stromal cells are connective tissue cells of an organ found in the loose connective tissue. These are most often associated with the uterine mucosa and the ovary; “Stromal Cells” *Biology Online*, online: <http://www.biologyonline.org/dictionary/Stromal_cells>.

⁷² *In vivo* is within a living organism as opposed to *in vitro* which is a laboratory.

⁷³ See Interview *supra* note 68.

⁷⁴ See *ibid.*

⁷⁵ *Ibid.*

(3) Complete Ectogenesis

The more deliberate leap to ectogenesis also evolves from Dr. Liu's work. In response to an interviewer's question whether she could create a real breathing embryo and have a child in the laboratory, Dr. Liu dropped a bombshell:

That's my final goal, I call it an 'artificial uterus.' I want to see whether I can develop an actual external device with this endometrium cell and then probably with a computer system simulate the feed-in medium, feed-out medium, ... and also have a chip controlling the hormonal level.... I want to use a computer to help me do this, and I believe if this can be achieved, we could possibly have an artificial uterus so then you could grow a baby to term."⁷⁶

At present, the gap between the second and twenty-second gestational week is insurmountable because of problems with the developing lungs.⁷⁷ The lungs of very premature infants collapse and their blood vessels hemorrhage readily causing brain damage, infection and death.⁷⁸ One possible remedy for this problem would be to create an artificial placenta. As stated by Jack Sills from the Intensive Care Nursery at the University of California, "it would be ideal to continue the *in utero* environment, keeping the premature infant in a warm water bath attached to...an artificial placenta."⁷⁹ Experimentation with an artificial placenta is already underway at Temple University with Dr. Thomas Shaffer.⁸⁰ He is attempting to save premature infants by using a synthetic amniotic fluid. He has developed a breathable liquid made of perfluorocarbons, which are liquid and

⁷⁶ Interview, *supra* note 67.

⁷⁷ Simonstein, Frida. "Artificial Reproduction Technologies (RTs): All the Way to the Artificial Womb?" (2006) 9 Med. Health Care & Philosophy 359 at 361.

⁷⁸ *Ibid.*

⁷⁹ *Ibid* at 360.

⁸⁰ Jonathan Knight. "An out of body experience." (2002) 419 Nature 106.

carry more oxygen than air.⁸¹

Dr. Shaffer has tested the breathable fluid with premature lamb fetuses, which cannot yet breathe air, and he believes that the technique he has developed is ripe for application to otherwise unsaveable human infants.⁸² He cites a lack of funding as the reason his research and technique has not yet been tested on infants.⁸³

Meanwhile, in Japan, Dr. Yoshinori Kuwabara has created an artificial womb, using an acrylic tank filled with a breathable fluid similar to that developed by Dr. Shaffer.⁸⁴ Dr. Kuwabara's fluid acts as a placenta to bring not only oxygen but also nutrients to the fetus.⁸⁵ Using this technology, Dr. Kuwabara has delivered goats after just three weeks of gestation, which is the human equivalent of the first trimester.⁸⁶ This technology is called EUFI – extrauterine fetal incubation.⁸⁷ With the goat fetuses, he has threaded catheters through the large vessels in the umbilical cord and supplied the fetuses with oxygenated blood.⁸⁸ The goats are then suspended in incubators that contain the body-temperature artificial amniotic fluid.⁸⁹

Dr. Nobuya Unno of the University of Toyko is also working with goat

⁸¹ *Ibid.*

⁸² *Ibid* at 107.

⁸³ *Ibid.*

⁸⁴ *Ibid.*

⁸⁵ *Ibid.*

⁸⁶ *Ibid.* The goats although they are “delivered” have not survived according to any published reports.

⁸⁷ I will consistently use the term EUFI to mean full ectogenesis from conception to delivery outside of the body of a woman.

⁸⁸ Perri Klass, “The Artificial Womb is Born” *The New York Times* (29 September 1996), online: *The New York Times* <<http://query.nytimes.com/gst/fullpage.html?res=9A02E4D9173CF93AA1575AC0A960958260>>.

⁸⁹ *Ibid.*

fetuses. He cites his interest in ectogenesis as providing a response to the demand for fertility treatments and better babies. In particular, there is a problem with multiple births arising out of fertility treatments and “it is not so rare for five, six or even more fetuses to be jammed together in a berth that was really designed for just one.”⁹⁰ These premature births of multiple babies result in “iatrogenic injuries”⁹¹ which include brain damage, blindness and mental retardation. Dr. Unno too is utilizing EUFI. His is a double-walled vertical acrylic box filled with artificial amniotic fluid warmed to 40 degrees Celsius or to 104 degrees Fahrenheit.⁹² The challenge is to engineer an artificial placenta that will do the work of a natural placenta. A biological placenta adds oxygen and removes carbon dioxide from the fetus’s circulating blood, just as lungs will do when they are fully developed.⁹³ In order to build a successful artificial human womb, scientists must create an artificial placenta that will “build a detour into the fetus’s circulatory system so that blood passes from the umbilical artery to the umbilical vein, changing gases as it goes.”⁹⁴ This would, of necessity, be an apparatus *ex utero* given the complexity of the process.

Currently, Dr. Liu’s studies and experiments continue with lesser visibility and fanfare – perhaps because she wishes to avoid the publicity. According to an article in Popular Science Magazine published in August 2005, Liu grew a mouse embryo almost to full term: “It moved. It breathed. It bubbled.” “And not just

⁹⁰ Tabitha M. Powledge, “The Ultimate Baby Bottle” *Scientific American* (Fall 1999) 96.

⁹¹ Medically induced.

⁹² Powledge *supra* note 90 at 96.

⁹³ *Ibid.*

⁹⁴ *Ibid.*

one bubble,” the article claims Liu said: “We saw bubble, bubble, bubble.”⁹⁵ Then it died, probably as a result of the failure of blood vessels to develop.⁹⁶ These results reportedly have not been published because of Dr. Liu’s qualms about how those results might be received.⁹⁷ This same article declares that the goat experiments in Tokyo are presently inactive, leaving Dr. Liu to pick up where Dr. Kuwabara left off, if indeed he did leave off.⁹⁸ One of Dr. Liu’s colleagues, Weidong Wang, has been studying the expression of a gene that seems to stimulate blood-vessel formation with the womb.⁹⁹ If that gene is blocked, the embryo cannot implant and grow, thus possibly accounting for miscarriages; if that gene is stimulated, however, then a “clot of veins” may develop which may be an important factor in allowing the mouse embryo to continue to develop to a healthy conclusion.¹⁰⁰ Based upon mouse problems, Dr. Liu has pushed back her estimate of a viable human artificial womb to ten years, but she continues to be very hopeful: “It will be helping a life, a baby, helping parents. Those are good things, and that’s all I can be thinking about right now.”¹⁰¹

The science of ectogenesis must also take into account new developments in cognitive neuroscience relating to the psychological health and functioning of the infant. A significant unknown is whether early time spent in an EUFI without the wash of maternal hormones including oxytocin, as well as the absence of

⁹⁵ Reynolds, Gretchen. “Artificial Wombs” *Popular Science* (August 2005), online: Popular Science <<http://www.popsci.com/popsci/futurebody/dc8d9371b1d75010vgnvcm1000004eecbccdr crd.html>>.

⁹⁶ *Ibid.*

⁹⁷ *Ibid.*

⁹⁸ Perhaps he too is continuing to experiment without publishing results.

⁹⁹ *Ibid.*

¹⁰⁰ *Ibid.*

¹⁰¹ *Ibid.*

maternal/fetal interaction with feeding, breathing, and sleeping in utero, may affect the infant's ability to bond with its mother or others later in life.

There is perhaps no relationship more profound yet enigmatic than the first one. The bond between mother and fetus has been extolled throughout history and literature, with supposition on its nature ranging from the material to the metaphysical.¹⁰²

One study has shown that the fetus may stimulate maternal sympathetic activation to prepare the mother for late night feedings while the mother dampens her own physiological activation to certain stressors that might jeopardize the pregnancy.¹⁰³ Parasympathetic surges, which are generated by the fetus, may cause the mother to develop a strong maternal protective response.¹⁰⁴

Importantly for ectogenesis, current studies show that the relationship between mothers and children is bidirectional. Using rat models, researchers have discovered that rat fetuses have an impact upon the development of the maternal nervous system.¹⁰⁵ An open question left by the foregoing study is whether success at fetal stimulation of a maternal response translates to an infant's later success at eliciting superior caregiving from his mother or others.¹⁰⁶

Such concerns, however, do not perforce demand that total or partial EUFI be foreclosed but the scientific community must address them before significant ectogenesis developments appear in some part of the world. Writer Gregory

¹⁰² Janet A. DiPietro, *et. al.* "The Psychophysiology of the Maternal-Fetal Relationship" (2004) 41 *Psychophysiology* 510 at 510.

¹⁰³ *Ibid.* at 518.

¹⁰⁴ *Ibid.*

¹⁰⁵ *Ibid.* at 518-519.

¹⁰⁶ *Ibid.*

Pence points out that once primate studies show that EUFIs are safe¹⁰⁷ – including bonding issues – then perhaps the burden of proof should be on the critics who would deny their use, “especially as potentially therapeutic last-ditch efforts for dying, premature babies.”¹⁰⁸

The importance of bonding cannot be underestimated or overlooked. We know that a lack of bonding causes epigenetic changes in the brain that will present with a lifetime of problems, including, among things, reactive attachment disorder.¹⁰⁹ Already, some mothers are using their own experiences with neonatal intensive care units (“NICU”) to demand “womb rooms” which would replicate the qualities of the womb: its darkness, relative quiet and “full entanglement with the mother’s biological rhythms.”¹¹⁰ One tiny neonate, born after 24 weeks, had a head the size of a kiwi fruit and legs the size of index fingers. She was then thrust

¹⁰⁷ The famous rhesus monkey experiments show what happens to a young monkey deprived of its real mother and who was given a wire monkey mother. The baby monkey suffers very badly from a lack of bonding to its wire mother, but does better when the wire mother is “softened” with cloth, etc. See, e.g. Bylinski, Gene. “New Clues to the Causes of Violence” *Fortune* (January 1973) 134, online: Violence.de <http://www.violence.de/bylinsky/article.html>>. To assure that such angst is not unintentionally visited upon a human baby, researchers would need to experiment extensively with primate babies in a full EUFI. IVF in humans was not attempted until there had been significant experience with farm animals, particularly cattle. Such notables as Leon Kass and Paul Ramsey initially condemned IVF in humans. Peter Singer & Deane Wells, “Ectogenesis” in Scott Gelfand & John R. Shook, eds. *Ectogenesis: Artificial Womb Technology and the Future of Human Reproduction* (New York: Editions Rodopi BV, 2006) 21. Contrary to Peter Singer’s contention that we could never know the psychological effects of full EUFI upon a human infant and thus a Catch-22 is created, extensive studies upon primates would be very helpful. Perhaps he fails to mention this because such experimentation may violate sentient animal rights, a separate issue.

¹⁰⁸ Gregory Pence. What’s so Good about Natural Motherhood?(In Praise of Unnatural Gestation) in Scott Gelfand & John R. Shook, eds. *Ectogenesis: Artificial Womb Technology and the Future of Human Reproduction* (New York: Editions Rodopi BV, 2006) 77.

¹⁰⁹ Jeri A Doane, et al. ,”A Development View of Therapeutic Bonding in the Family: The Treatment of the Disconnected Family (1991) 30 *Family Process*, Issue 2, 155.

¹¹⁰ Christine Hauser, “For the Tiniest Babies, the Closest Thing to a Cocoon” *The New York Times* (29 May 2007), online: The New York Times <<http://www.nytimes.com/2007/05/29/health/29baby.html?scp=1&sq=tiniest+babies&st=nyt>>.

in the whirring, beeping, glaring world of the NICU.¹¹¹ Her mother and other mothers of extremely premature infants are demanding the overhaul of the NICU to restore some of the womb-like qualities these infants would otherwise have enjoyed including parent's voices, listening to mother's heartbeat, and intestinal gurgling. Supporters of NICU overhaul assume that these interactions may assist the neural connections in the extremely premature neonate's developing brain.¹¹² More research on these issues should be demanded by the scientific community as the technological leaps - from Baby Louise Brown to Dolly the cloned sheep to regressing skin cells to a pluripotent state to full ectogenesis of a baby - no longer seems to be the stuff of science fiction.

¹¹¹ *Ibid.*

¹¹² *Ibid.*

Chapter Two: Ectogenesis: Societal and feminist considerations

Ectogenesis is a technology that inspires curiosity, suspicion and revulsion. As discussed in Chapter One, ectogenesis may manifest in many ways including in the form of a full extrauterine fetal incubator (EUFI), or as a human womb grown on tissue ladders that may then be implanted in a woman (Dr. Liu) or as a quiet development of extending life in a petri dish forward and extending life in a neonatal unit backwards (Peter Singer). Of course, there could be some combination of all of the above at various points of fetal development. An embryo could be created by IVF, placed in a Dr. Liu-type human womb in a woman born without a womb, extracted because of fetal difficulties, repaired and grown in a EUFI for a period of time, then transferred to an advanced neonatal unit. Clearly the “full EUFI” is the one that should concern us the most and about which most has been written. This Chapter ponders the good, bad and ugly uses of ectogenesis, and focuses on slippery slope arguments that are often associated with the field. It then explores feminist issues associated with ectogenesis.

(A) The Good. A number of writers have written about the potential beneficial uses of ectogenesis. Women who have problems in pregnancy such as preeclampsia or gestational diabetes could transfer a fetus that started out in their body to an EUFI.¹ The remainder of gestation would be healthier for both the infant and the mother. Preimplantation diagnoses could immediately identify chromosomal abnormalities that could be repaired. An “embryo-becoming-fetus”

¹ Peter Singer and Deanne Wells, “Ectogenesis” in Scott Gelfand and John R. Shook, eds. *Ectogenesis: Artificial Womb Technology and the Future of Reproduction* (Amsterdam: Rodopi B.V. 2006) 9 at 11, cited previously Chapter One at note 58.

could then be monitored in an EUFI and could be implanted into its mother when indicated medically.² A fetus with abnormalities that would otherwise be born prematurely or die would not have to face a life of disability.³ A fetus in full EUFI ectogenesis would not be impacted by smoking, caffeine, car accidents, falls, spicy pizza, drugs or alcohol if ectogenesis were used *ab initio*.⁴

Ectogenesis would also save the lives of women. Around the world, an estimated 529,000 women per year die during pregnancy or childbirth. Ten million suffer injuries, infection or disability.⁵

Pregnancy is absolutely central to reproduction, and yet pregnancy doesn't seem to work very well. If you think about the heart or the kidney, they're wonderful bits of engineering that work day in and day out for years and years. But pregnancy is associated with all sorts of medical problems...The difference is that the heart and the kidney belong to a single individual while pregnancy is a two person operation. And this operation does not run in perfect harmony. Instead, a mother and her unborn child engage in an unconscious struggle over the nutrients she will provide it...A fetus does not sit passively in its mother's womb and wait to be fed. Its placenta aggressively sprouts blood vessels that invade its mother's tissues to extract nutrients...⁶

The next generation of fetal surgeons is excited about the possibility of prenatal surgery where interventions could be made before the immune system has matured and for advances that could be used in everything from organ

² Jacqueline Stenson, "The Future Of Babymaking: Scientists Explore New Techniques for Tackling Infertility Problems" *MSNBC.com* (22 July 2003), online: <<http://msnbc.msn.com/id/3076784/>>.

³ "Abortion Access: Ectogenesis (The Use of an Artificial Womb): Will It Make Abortion Illegal, Or Not Needed?," online: Religious Tolerance <<http://www.religioustolerance.org/abowomb.htm>>.

⁴ *Ibid.* See also Robin McKie, "Men Redundant? Now We Don't Need Women Either" *The Observer* (12 February 2002), online: The Observer <<http://observer.guardian.co.uk/print/0,3858,4353368-102275,00.html>>.

⁵ Carl Zimmer, "Silent Struggle: A New Theory of Pregnancy" *The New York Times* (14 March 2006), online: The New York Times <<http://www.nytimes.com/2006/03/14/health/14preg.html?scp=1&sq=%22Silent+Struggle%22&st=nyt>>.

⁶ *Ibid.*

transplantation to repair or replacement of genetic deficiencies.⁷ Impaired fetal growth leads to increased cardiovascular mortality, high blood pressure in childhood and adult life, and impaired glucose tolerance.⁸ Studies at Southampton University are showing that the first 266 days from conception are the time when much of what will happen during the decades to come is determined.⁹ Among other things, the time and quality of time spent in the womb (as opposed to being born severely prematurely) influences the likelihood that a person will develop cancer, asthma, osteoporosis and even depression and schizophrenia.¹⁰ And the addition of hormonal surges *in utero* can affect soccer ability, navigational skills, personality and even the likely number of sexual partners a person may have.¹¹ Hormonal surges can have unexpected endophenotypical results which can result in an “extreme male brain” which may cause disorders on the autism spectrum.¹²

The demand for “uterine transplants” - a probable first step in ectogenesis - is already here. In New York in January, 2007, in a “shot heard round the world” thanks to the internet, the phone calls and emails started streaming into New York Downtown Hospital upon erroneous information that uterine transplants from cadavers might be in the works. As reported, one caller was a

⁷ Perri Klass, “The Artificial Womb is Born” *The New York Times* (29 September 1996), online: *The New York Times* <<http://query.nytimes.com/gst/fullpage.html?res=9A02E4D9173CF93AA1575AC0A960958260>>.

⁸ Roger Robinson, “The Fetal Origins of Adult Disease” (2001) 322 *British Med. J.* 375, online: *BMJ* <<http://bmj.bmjournals.com/cgi/content/full/322/7283/375>>.

⁹ Roger Dobson, “The 266 Days That Determine Your Future Health” *Times Online* (11 March 2006), online: *Times Online* <<http://www.timesonline.co.uk/article/02682-2078125,00.html>>.

¹⁰ *Ibid.*

¹¹ *Ibid.*

¹² Simon Baron-Cohen, *The Essential Difference: Male and Female Brains and the Truth About Autism* (Jackson, TN: Basic Books, 2003) at 97-109; 149-151.

25-year-old woman born without a uterus and another was a 33-year-old who had undergone a hysterectomy at age 24.¹³ One caller offered to donate her uterus as she was finished with childbearing. The calls poured in as a result of a news report of an article in the January issue of *Obstetrics and Gynecology* discussing uterine harvesting, a technique being researched by Giuseppe Del Priore and others interested in assisting young women whose cancer treatments rendered them unable to bear children. It is evident from the IVF demand that ectogenesis – at least in the incarnation of a uterine transplant – will continue to be in demand and have aspects to it that unquestionably contribute to the mother and her fetus' well-being and future quality of life.

(B) The Bad, the Slippery Slope and the Yuk factor

The prospect of full EUFI ectogenesis is shocking. There is a temptation to invoke the slippery slope argument to ban it prospectively because it does not take a great leap of imagination (or any evidence whatsoever) to suggest that it could be used to mass produce babies as warriors or it could be used to grow sentient babies for spare parts.¹⁴ It also could be used eugenically to engineer genetics that may eliminate diversity.¹⁵ Some feminists fear that it could be used to eliminate women altogether.¹⁶

At the outset, it is important to distinguish a logical form of the slippery slope argument from a causal one. Neither are valid arguments as explained presently. The logical form simply consists of pointing out that if everyone

¹³ Roni Rabin, "Hospital Swamped With Calls After Report of Pending Uterine Transplant" *The New York Times* (30 January 2007).

¹⁴ *Ectogenesis, supra* at note 58, Singer and Welles 9 at 18.

¹⁵ *Ibid.* Julien S. Murphy, "Is Pregnancy Necessary" 27 at 40.

¹⁶ *Ibid* at 36.

accepts that (N) is rational, logical and the only morally acceptable action, we are logically committed to accepting its precedent steps including (A). In that case, goes this slippery slope argument; those who embrace (N) also must agree logically that (A) is the only rational, logical and moral choice.¹⁷ An example of this “logical form” of slippery slope argument in ethics would be the following: Pro-choice and anti-abortion individuals completely agree that the termination of a healthy thirty-six week pregnancy is “wrong.” (N). The anti-abortion proponent will argue, logically, that if terminating a thirty six week pregnancy is wrong, terminating a thirty five week pregnancy is wrong (M), terminating a thirty-four week pregnancy is wrong (L), etc. because no “moral change” can happen within a week. As a matter of “logical connection” if you accept the apparently reasonable proposition (N) (i.e. it is morally wrong to terminate a thirty six week healthy pregnancy), logically you must commit to the fact that it is morally wrong to terminate a fertilised egg, via, for example the “morning after pill” (A).

However interesting this “logical” form of the slippery slope argument may be to philosophers in pure formal logic, it is rather difficult to follow in ethics as the factual assumptions contain an infinite number of variables. Obviously, *contra* the “logical slippery slope argument,” the pro-choice individual might argue that the justifications for terminating a pregnancy may well change from fertilisation to 36 weeks. The “weight of justification” changes and to

¹⁷ Govert Den Hartogh, “The slippery slope argument,” in Helga Kuhse & Peter Singer, eds., *A Companion to Bioethics* (Malden, MA: Blackwell Publishing Ltd., 1998) 280 at 280-290.

oversimplify it by simply contending that because (N) contains serious moral considerations, so does (A), is unwarranted.¹⁸

Worse, this form of argument tends to insidiously transmogrify into a “causal slippery slope argument” in ethics which states that if we allow (X) it *will cause* us to allow (X +1) which we all agree is unacceptable. While this is seen less in the abortion field, it abounds in discussions of euthanasia. For example, if we permit (X) (rational, informed decision to end one’s life by selecting euthanasia) it *will cause us* to institute non-voluntary euthanasia on rational non-consenting human beings (X+1).¹⁹ Thus, goes the argument, because (X) will cause us to institute non-voluntary euthanasia (X+1), (X) should not be permitted as a matter of policy. However, the real issue is to examine how compelling is the evidence for such assumptions, and perhaps instead of banning (X) the better practice would be to institute “bright line” policies to avoid the possibility of such feared “causal slips.”

For purposes of ectogenesis, both forms of “slippery slope arguments” are likely to surface and be commingled. However, the slippery slope arguments should be carefully examined before ectogenesis is discarded outright as an unacceptable method of providing an environment in which to grow a baby. One way to do so is to compare the change from (N) (let us assume *arguendo* that it is good that childless couples would be able to have healthy genetically related babies) and all arguably causal or intermediate steps (O), (P), etc. which may occur, and to analyze whether they lead inexorably to (X+1) (creating conscious

¹⁸ Tony Hope *et al.* *Medical Ethics and the Law: The Core Curriculum*, 1st ed. (New York: Churchill Livingstone, 2003) 26.

¹⁹ *Ibid.* at 27.

babies consigned to a life of drudgery or slavery). The question is thus whether (X+1) is in fact causally related or logically required by any antecedent or related step.

Restated, the argument may be viewed this way. It is a good thing that a childless man and woman may still have a genetic child of their own through ectogenesis (N). A causal byproduct of ectogenesis is that it will allow women without uteruses to have an equal reproductive life span with men (O). Ectogenesis will allow physicians to repair defects as soon as possible (P). However, there is no causal link between (N) and (X+1), even if there is a causal link between (N) and (O) or (N) and (P). Moreover, there is no causal or logical link between (O) and (P). Even if (O) is not as highly valued as (N) or (P), there is no causal link between (O) and (X+1). Permitting (N) or its causal cousins (O) or (P) does not lead logically, causally, or perniciously to (X+1) without some additional “wrong” assumptions, *e.g.*, slavery is widely accepted and acceptable.

The slippery slope argument is especially unpersuasive (or should be deemed so) when the argument is advanced that people are somehow helpless to control unacceptable outcomes because ideas themselves are dangerous.

When a substantial taboo crashes, the prohibition it once protected suffers the elimination of a condition of its prohibition. . . [A]t each stage downwards, the weakened prohibition meets with public acquiescence or not. **If not, the process stops.** If so, it is likely to continue, collecting in its wake new waves of public acquiescence. Public acquiescence is important.²⁰

The author contends that the success of a “slippery slope” requires that the public have “dialectical impotence,” that is, “the inability to stop the acceptance of

²⁰ John Woods, “Slippery Slopes and Collapsing Taboos” (2000) 14 *Argumentation* 107 at 109.

apparently small deviations from a heretofore secure policy or practice from leading to apparently large and unacceptable deviation.”²¹ Because dialectical argument is used successfully to harness the power of many technologies, it is error to assume that for some reason, this ability would be somehow rendered impotent in connection with ectogenesis.²²

As we have seen, one of the potent responses of the public to delay innovation or change in the biotechnology arena is the “Yuk” factor.²³ Leon Kass, head of the President’s bioethics council thinks that the Yuk factor is a good gauge of moral wisdom as part and parcel of his theory of the “Wisdom of Moral Repugnance.”²⁴ Others disagree: “Disgust is not a particularly discerning, reflective reaction. Disgust is visceral, immediate, and remarkably powerful . . . I still remember the first time someone invited me to try sushi. Yuk!”²⁵ The “Yuk” factor may be a vital public temperature-taking gauge used to reveal a temporary or irrevocable barrier to further uses of a given technology provided it is not used to condemn behaviors that are not actually harmful except in the eye of the beholder.

²¹ *Ibid.*

²² For example, nuclear power can be used for beneficial or horrible purposes. No doubt the public dialectic has had an important say in world policies governing the use and misuse of nuclear power. Just because the atom can be split to create nuclear fission does not require the slippery slope conclusion that it must or will be used to annihilate the world because no one has the power to say no. The public does have the power to say ‘no’ and to demand that its leaders sit down with each other and discuss the terrible possibilities.

²³ Leon Kass, “Welcome and Opening Remarks” (President’s Council on Bioethics, 7th Meeting, 18 January 2002).

²⁴ *Ibid.*

²⁵ Leigh Turner, “Is Repugnance Wise? Visceral Responses to Biotechnology” (2004) 22 *Nature Biotechnology* 269 at 269.

Steve Pinker, in *The Blank Slate*, discusses the Yuk factor:

The difference between a defensible moral position and an atavistic gut feeling [Yuk] is that with the former we can give *reasons* why our conviction is valid. We can explain why torture and murder and rape are wrong, or why we should oppose discrimination and injustice. On the other hand, no good reasons can be produced to show why homosexuality should be suppressed or why the races should be segregated. And the good reasons for a moral position are not pulled out of thin air: they always have to do with what makes people feel better off or worse off, and are grounded in the logic that we have to treat other people in the way that we demand they treat us.²⁶

In short, Yuk is the start, but not the end, of the discussion. “We should be wary about equating visceral reactions of revulsion with moral wisdom . . . there are instances where initial reactions of uncertainty, fear and disgust deserve to be heeded . . . but labeling particular biotechnologies as intuitively “Yukky” or “repugnant” does not make a particularly useful contribution to public ethical debate.”²⁷ Ectogenesis could of course be “Yukky” and “slippery” and could be used to imagine all sorts of bizarre scenarios that are alarming. However, we can do nothing in the unfounded belief that it will go away quietly, or we may anticipate that there will be a worldwide demand for ectogenesis, analyze it, and regulate it before it manifests in its various incarnations.

(C) The Ugly and the Weird

The prospect of porcine pregnancies with human embryos has been used as a scare tactic to repulse people instead of engaging in the more probing ethical challenges that are presented by the possibility of removing baby-bearing from

²⁶ Steven Pinker, *The Blank Slate: The Modern Denial of Human Nature* (New York: Viking Press, 2002) at 274.

²⁷ Turner, *supra* note 25.

women.²⁸ For example, theoretically, bovine and equine uteruses could be used to gestate human embryos.²⁹ These cross-species gestations are unlikely to occur without worldwide disapprobation and are probably not only ‘Yukky’ (in terms of causing us to think about an ethical yellow light) but are also unnecessary unless one accepts the proposition that all embryos in existence have a right to life and are going to perish, otherwise unwanted, in a deep freeze somewhere.

Another ectogenic prospect that is shocking at this time is male pregnancy. There is no actual physical barrier to men becoming pregnant; some ectopic pregnancies in women have resulted in live births.³⁰

Again, perhaps, a “Yuk” signal is warranted. Ectogenesis in the form of surrogate mother where an embryo of an unrelated couple is placed in a woman having no biological relationship to either of the parents is now not uncommon although it was once considered to be Yukky. There are websites devoted to locating surrogate mothers and providing legal and medical counseling to all concerned without nearly as much ethical debate as once surrounded surrogate motherhood.³¹

Initially, it will be “weird” and unusual to be a child borne of ectogenesis. No doubt, ectogenic children would have the curiosity of children now born of sperm donors or egg donors who are not surprisingly asking the question, “Where did I come from?” Even now, this question is no longer susceptible to the

²⁸ Stellan Welin, “Reproductive Ectogenesis: The Third Era of Human Reproduction and Some Moral Consequences” (2004) 10 *Science & Engineering Ethics* 615 at 626.

²⁹ Christine Rosen, “Why Not Artificial Wombs” *The New Atlantis* (Fall 2003) 67, online: *The New Atlantis* <<http://www.thenewatlantis.com/archive/3/rosen.htm>>.

³⁰ Graves, Jen. “Getting Patrick Pregnant” *The Stranger* (11 July 2007), online: *The Stranger* <<http://www.thestranger.com/seattle/Content?oid=262568>>.

³¹ See, e.g. Surrogate Mothers Online, online: <<http://www.surromomsonline.com>>.

standard Dr. Spock or Dr. Suess answer.³² A recent article in the *New York Times* talked about the sperm father gathering up the courage to contact his genetic children. He decided to contact them after reading that two teenagers were looking for him via a sperm-donor registry started by a woman in Colorado.³³ He was concerned about disappointing these two teenagers who believed him to be 6 feet tall, and blue eyed with interests in philosophy, music and drama.³⁴ Although he was making a meager living doing odd jobs while living with his four dogs in a recreational vehicle, he did feel that he could tell them that their grandfather was an Ivy-League educated financial executive and their grandmother had been the volunteer president for the Prevention of Cruelty to Animals.³⁵ Accordingly, he logged onto the website and found a total of six people had signed in to find Donor number 150, the number he'd used to make twice-weekly donations in California during the late 1980s. One curious byproduct of the newfound family was the discovery by all of the half-siblings of each other's existence and their common love of animals.³⁶

Similarly, a poignant article entitled "Your Gamete, Myself," published in the *New York Times Magazine* on July 15, 2007 describes a young daughter working on a middle school project casually asking: "Mom, what was the year

³² See Eastman, P.D. *Are You My Mother* (New York: Random House, 1960).

³³ Harmon, Amy. "Sperm Donor Father Ends His Anonymity" *The New York Times* (February 14, 2007), online: New York Times <<http://www.nytimes.com/2007/02/14/us/14donor.html?scp=1&sq=Sperm+Donor%2C+Harmon&st=nyt>>.

³⁴ *Ibid.*

³⁵ *Ibid.*

³⁶ *Ibid.*

that you and Dad met our donor?"³⁷ Suddenly, the mother realized that she was going to be "outed" on the wall of the middle school for all to see that her daughter had been the product of an egg donor. In short, people will pay a great deal of money, tolerate a great deal of inconvenience, and endure the puzzlement and curiosity of others, just to have a genetic child or at least a child genetically related to their spouse. This is one of the driving forces, ultimately, for ectogenesis.

(D) The Feminist Issues

In some ways, no issue could be more of a feminist issue than ectogenesis.

Motherhood also symbolizes all that is comforting and safe and personal, the opposite of what is dangerous, foreign, state controlled, and harmful... Changes in gestation may seem to be especially dangerous to conventional notions of family and female nurturing...³⁸

Many feminist writers³⁹ have explored the societal and symbolic ramifications of removing childbearing from females. The greatest fear perhaps amongst these writers is that ectogenesis will contribute to the oppression of women. These writers argue that pregnancy, birth and motherhood are inherently empowering for women and that removal of them from women would contribute

³⁷ Peggy Orenstein, "Your Gamete, Myself" *The New York Times* (15 July 2007), online: The New York Times <<http://www.nytimes.com/2007/07/15/magazine/15egg-t.html>>.

³⁸ Gregory Pence, "What's so good about natural motherhood?" in *Ectogenesis*, *supra* note 58, Chapter One at 78.

³⁹ Although ectogenic fears are not necessarily "feminist" in nature, many writers have self-identified as being feminist writers or bioethicists and the issues of ectogenesis of course impact females and their role in society.

to men's omnipresent efforts to control women's reproductive capacities.⁴⁰ Writer Maureen Sander-Staudt states that ectogenesis "demeans women's biology" and may be construed as a campaign against nature.⁴¹ Andrea Dworkin argues that infertility experts, gynecologists and obstetricians are seizing control of a woman's reproductive powers and that if an artificial womb is developed, women may lose their social status as mothers and their primary source of leverage in patriarchal societies.⁴² Mary O'Brien contends that men are jealous of women's reproductive powers and are alienated from a woman's "reproductive consciousness."⁴³

From these perspectives, ectogenesis is a loss of control for women. It takes away their one source of power, a power which men have envied and have attempted to control bit by bit, by replacing midwives with male obstetricians and otherwise intruding in the birthing process.⁴⁴ The feminist argument that female control will be irrevocably damaged by ectogenesis is dramatically summed up by Robyn Rowland:

What may be happening is the last battle in the long war of men against women. Women's position is the most precarious.... We may find ourselves without a product of any kind with which to bargain. For the history of "mankind" women have been seen in terms of their value as childbearers. We have to ask, if that last power is taken and controlled by men, what role is envisaged for women in the new world? Will women become obsolete? Will we

⁴⁰ Maureen Sander-Staudt, "Of Machine Born" in *Ectogenesis*, *supra* note 58, Chapter One, 109 at 124.

⁴¹ *Ibid.*

⁴² Rosemarie Tong, "Out of Body Gestation: In Whose Best Interests?" in Scott Gelfand & John R. Shook, eds. *Ectogenesis: Artificial Womb Technology and the Future of Human Reproduction* (New York: Editions Rodopi BV, 2006) *supra* note 58 Chapter One, 59 at 65.

⁴³ *Ibid.*

⁴⁴ *Ibid.* at 65-66.

be fighting to retain or reclaim the right to bear children – has patriarchy conned us once again? I urge you sisters to be vigilant.⁴⁵

Malignant patriarchy, which presently seems to include certain so-called pro-life women, seems to be going in the opposite direction, however, to require a woman to gestate and to give birth to her conceptus even if she is raped or the victim of incest.⁴⁶ As recently as the spring of 2007, an all-male majority of justices of the United States Supreme Court curtailed a woman's right to decide with her physician the best and safest method of abortion:

Respect for human life finds an ultimate expression in the bond of love the mother has for her child... While we find no reliable data to measure the phenomenon, it seems unexceptional to conclude some women come to regret their choice.... Severe depression and loss of esteem can follow. It is self-evident that a mother who comes to regret her choice to abort must struggle with grief more anguished and sorrow more profound when she learns after event that [third trimester abortions are gruesome]... We do this because it is a reasonable inference that the woman will elect not to have an abortion....⁴⁷

The composition of this Court might also find that any woman who chose ectogenesis would be “shirking her obligations as a mother and denying her essential identity as a woman.”⁴⁸

Shulamith Firestone was the first contemporary feminist (1970) who suggested that men and women will never be equal in terms of job opportunities or lifestyle choices until women are freed from the “tyranny of their reproductive

⁴⁵ Robyn Rowland, “Reproductive Technologies: The Final Solution to the Woman Question?” in Rita Arditti *et al.* eds., *Test Tube Women: What Future for Motherhood?* (Boston: Pandora Press, 1984), cited in Peter Singer & Deane Wells, *Reproduction Revolution: New Ways of Making Babies* (Oxford: Oxford University Press, 1984) at 17.

⁴⁶ The philosophy that a woman must be a baby bearer regardless of her health or circumstances of conception is the position Gov. Sarah Palin maintains. As of this writing, she is Sen. John McCain's running mate in his candidacy for President of the United States. The November, 2008 election has not taken place.

⁴⁷ *Gonzales v. Carhart et. al.*, 2007 U.S. Lexis 4338 (2007), slip. Op. at 5-6.

⁴⁸ Singer & Wells, *supra* note 45 at 16.

biology.”⁴⁹ While she admitted that a woman having children is “natural,” she also stated:

The “natural” is not necessarily a “human” value. Humanity has begun to outgrow nature: we can no longer justify the maintenance of a discriminatory sex class system on the grounds of its origins in Nature.”⁵⁰

In *Dialectic of Sex*, Firestone curtly pronounced: “Pregnancy is barbaric. It hurts. [A]nd it isn’t good for you.”⁵¹ She cautioned, however, that the power structure in 1970 was still in the hands of the male scientists and that any attempted use of ectogenic technology to “free” anyone should be viewed with suspicion.⁵²

Firestone’s lone voice found a new ally thirty-seven years later in Anna Smajdor.⁵³ In the United Kingdom, where childbearing has been delayed, as in other Western societies, some women who have done so - and compromised their ability to have children because of aging eggs - are being subtly shamed for being selfish and chastised for failing to commence their childbearing career earlier.⁵⁴ Smajdor responds that it is not the woman who is selfish, but rather a system that demands that a woman be the “sole risk taker in reproductive enterprises.”⁵⁵ She also views ectogenesis through the lens of distributive justice:

The fact that women have to gestate and give birth in order to have children, whereas men do not, is a *prima facie* injustice that should be addressed by the development of ectogenesis... [I]f there is a

⁴⁹ *Ectogenesis*, *supra* at note 42, Julien S. Murphy at 38.

⁵⁰ Shulamith Firestone, *The Dialectic of Sex* (New York: Bantam Books, 1970) at 10.

⁵¹ *Ibid.* at 198.

⁵² *Ibid.* at 38.

⁵³ Smajdor, Anna. “The Moral Imperative for Ectogenesis” (2007) 16 *Cambridge Quarterly of Healthcare Ethics* 336.

⁵⁴ *Ibid.* at 336.

⁵⁵ *Ibid.* at 337.

prima facie injustice involved in reproduction, then it would seem that there could indeed be a *prima facie* moral duty to consider the possibility of alleviating it.⁵⁶

She then proceeds to examine the issue of ectogenesis from the “veil of ignorance”⁵⁷ perspective and suggests that a condition which affects 50% of the population and in which there is considerable pain and suffering involved might dictate that ectogenesis – if actually feasible – be chosen as the moral alternative to pregnancy.⁵⁸

Smajdor suggest that the principle of autonomy is implicated too:

[T]he fact of encompassing another life in their bodies often takes a serious toll on their (women’s) autonomy. Pregnant women are routinely expected to subsume their appetites and desires into those that would be in keeping with the well being of the fetus.⁵⁹

She compares a woman’s lack of autonomy with respect to the conditions of childbearing and childbirth, as well as the inequality of forced sterilizations, caesarians and abortions, with a man’s almost unlimited autonomy over his own bodily integrity in support of her “moral imperative of ectogenesis” theory.⁶⁰ She counters the argument - that in this day of contraception, childbearing is voluntary and thus not subject to a distributive justice rationale - by revisiting the

⁵⁶ *Ibid.* at 338.

⁵⁷ John Rawls’ “original position,” a philosophical thought experiment designed to set up a fair procedure so that ‘any actions or principles will be just,’ situates the actors behind a ‘veil of ignorance.’ This means that they do not know how various alternatives - including stations in life - will affect them personally because they are ignorant of their own sex, social status, abilities, strength, and the like. The ‘veil of ignorance’ assumes that since the differences amongst the actors are unknown, and everyone is equally rational and similarly situated, they can form an ideal stasis and perspective on any given proposition. An example used most often is slavery – a condition that, from a ‘veil of ignorance,’ could not be chosen by any rational person. John Rawls, *A Theory of Justice* (Cambridge: The Belknap Press of Harvard University Press, 1971) at 136-142, 167.

⁵⁸ Smajdor, *supra* at note 53, at 339.

⁵⁹ *Ibid.* at 340.

⁶⁰ *Ibid.* at 341.

fact that a man's "voluntary" jump into parenthood carries none of the attendant physical risks it does for a woman.⁶¹

There are realistic concerns about what ectogenesis might do for the status of women and how it might be used – properly or improperly - in derogation of a woman's right to autonomy.⁶² For example, there is the possibility that women who wanted to get pregnant the "old fashioned way" would be considered second-class citizens.⁶³ This concern, while slippery-slope in nature, gains more credibility if one views it from the angle that ectogenesis might be urged upon mothers by employers, subtly or otherwise, who wish to keep their workstaff working despite a woman's autonomous desire to become pregnant.⁶⁴ On the other hand, extant labor and anti-discrimination laws could make short shrift of employers' endeavors to do so.⁶⁵ This slippery slope argument, as do most others surrounding ectogenesis, fails logically and causally.

⁶¹ *Ibid.*

⁶² Including perhaps forcibly removing a fetus in danger of being seriously harmed by the activities of its mother. In *Winnipeg Child & Family Services (Northwest Area) v. G. (D.F.)* 3 S.C.R. 925, 930, the Court was faced with an application by Child and Family Services to incarcerate a glue-sniffing pregnant mother for the duration of her pregnancy who had previously given birth to two babies born seriously disabled who were permanent wards of the State. Although the majority denied the application, a vigorous dissent recognized that "when a woman chooses to carry a fetus to term (and is actively harming it), the State has an interest in trying to ensure the child's health."

⁶³ See Sander-Staudt *supra* note 41 at 126.

⁶⁴ *Ectogenesis*, *supra* at note 42, Julien S. Murphy at 40.

⁶⁵ For example, family and medical leave policies could be uniformly expanded to accommodate "old fashioned pregnancies." Any injuries therefrom should be treated no differently than any other medical problem arising from lifestyle choices.

Chapter Three: Ectogenesis: Divergence of Opinion and Moving toward Consensus

Ectogenesis shakes the very foundation of our worldview. It makes real the possibility that women's bodies will no longer be the only vessels available that may create and sustain new human life. It is important to identify the divergent metaphysical viewpoints that may attach to ectogenesis and to contemplate a preliminary, workable legal framework to deal with them consonant with a 2008 view of human rights.

This first part of this Chapter briefly reviews the current writings and thoughts from the lay public, the bioethical experts, and the theologians who have had occasion to contemplate the question of the moral status of embryos. The second part of this Chapter will review different IVF schemes already in place in various countries and will highlight the differences and similarities between them and the problems of "reproductive tourism." It will also review the solutions recommended or devised by some countries to accommodate divergent opinions regarding the moral status of embryos. The third part of this Chapter will discuss the desirability of adopting fluid worldwide standards for addressing new developments in reproductive technologies that are ontologically¹ neutral in

¹ Here I am using "ontology" in the Aristotelian sense, as interpreted by Hilary Putnam, to mean metaphysics or *a priori* Forms of Good or Justice or Morality. "When one thinks that one has explained *why* some persons, traits of character, activities, and states of affairs are good by postulating something "non-natural," something mysterious and sublime standing invisibly behind the goodness of the persons, actions, situations, etc., in question, one thereby commits oneself to a form of *monism* in the sense that one reduces or imagines one has reduced all ethical phenomena, all ethical problems, and all ethical questions, indeed all value problems, to just one issue, the presence of absence of this single super-thing, i.e. *Good (or Justice or Morality)*." Hilary Putnam, *Ethics Without Ontology* (Harvard University Press, 2005) 18-19. In the place of "ontology" with metaphysical attributes, one may very reasonably defend an ethical structure derived from pragmatic pluralism and the most reasoned legislative schemes do just that.

anticipation of further advances in neuroscience, thereby encouraging pragmatic pluralism to flourish and inform these developments.

(A) Bioethical field study

The confusion described in Chapter One surrounding the futile effort to define “a moment of conception,” which is then repeated in poorly drafted legislation, would be somewhat repaired by adopting HFEA definitions that can then be incorporated into sensible legislation and less tortured case law. However, the moral and/or emotional content a man or woman may ascribe to a human embryo, especially since the advent of assisted reproductive technology and the concomitant viewability via ultrasound of early humanhood, is something quite different.

In a German bioethical field study, researchers compared the views of experts, patients, and the general public on the beginning of human life and the status of the preimplantation embryo in Germany.² They used a qualitative and quantitative multi-method approach. In the study, they divided experts from lay individuals. Within the expert population, they included human geneticists, ethicists, midwives, obstetricians and pediatricians. In the lay population, they included IVF couples, high genetic risk couples and the general population.³

The researchers undertook this study because: “beliefs about conception are inseparable from questions about what it is to be human, how a human comes

² Tanja Krones *et al.* “What is the Preimplantation Embryo?” (2006) 63 Soc. Sci. & Med. 1 at 5, also *supra*, Chapter Two at note 52.

³ *Ibid.* at 7.

into being and the ‘miracle’ of this creation.”⁴ They felt that the predominant bioethical discourse on the subject was out of kilter with the actual feelings of the “expert” and “lay populations.”⁵ The researchers observed that the bioethical thinking and debate about the status of embryos tends to split radically along deontological versus utilitarian lines *viz.*, the writings to date tend to be unimaginatively black or white. While deontologists and Christian ethicists believe that embryos are homunculi ready for full personhood rights, the utilitarians and secular bioethicists are prepared to manipulate and use the cluster of cells without moral qualm.⁶

The study self-identified as a context sensitive, critical bioethics perspective of the views of the German public.⁷ With respect to the “beginning of life,” 69% of IVF couples did not believe that life had begun until implantation where 65% of ethicists believed that life had begun at conception.⁸ 24% of IVF women did not believe that life began until the fourth month, whereas only 2.3% of women ethicists held this view.⁹ IVF men reported in the highest percentile as believing that the preimplantation embryo is nothing more than a cluster of cells (11%) while a similar percentage of male ethicists believed that a pre-implantation embryo was a person with full dignity (10.5%).¹⁰

⁴ *Ibid.* at 2. See also, Sarah Franklin, *Embodied Progress: A Cultural Account of Assisted Conception* (London: Routledge, 1997).

⁵ *Ibid.* at 14.

⁶ *Ibid.* at 2.

⁷ *Ibid.* at 6.

⁸ *Ibid.* at 9.

⁹ *Ibid.*

¹⁰ *Ibid.* at 10.

The ability to view one's own embryo affected the results: fully 62% of IVF women said the embryo was "clearly my child" versus 37% who said it was "more a cluster of cells." High-risk IVF females were even more adamant (80%) that the preimplantation embryo was "clearly more my child than a mere cluster of cells."¹¹ The study concluded that the unique genome - the point at which the conceptus bears a full complement of genes - is considered by an average of the lay and expert population as the decisive point in time when human life begins and human value should be ascribed.¹² The study also concluded that the moral view on the status of the embryo is pluralistic and contradictory in some regard although the moral caliber of the embryo is valued very highly, it is not defined in terms of human dignity or right to life definitions contained in the German EPA and Constitution.¹³

The German Constitution contains the highest possible protection for a human entity – to wit, a "right to life" for every totipotent cell derived from an embryo.¹⁴ To the contrary, the English embryo is an embryo with legal status – but not personhood - as soon as the egg is fertilised.¹⁵ Thus, some international schemes governing embryos are becoming more stringent with almost unworkable notions (a right to life for skin cells which may be regressed to pluripotency and theoretically to totipotency which means they could be regressed to gametes of either sex) while the views of the lay population are tending to ascribe value to the

¹¹ *Ibid.* at 11.

¹² *Ibid.* at 14.

¹³ *Ibid.* at 18.

¹⁴ Germany, *Basic Law for the Federal Republic of Germany* (1949) (as Amended by the Unification Treaty of 31 August 1990 and Federal Statute of 23 September 1990), Arts. II § 2.

¹⁵ United Kingdom, Human Fertilisation and Embryology Act 1990 (U.K.), 1990 c. 37 first cited in Chapter One, *supra*, at note 10.

embryo because of ultrasound technology and because of its personal meaning to the woman attempting to become pregnant.

(B) Theological views of the embryo

Most major religions and many religious scholars have tackled the intricacies of embryology.¹⁶ Important questions can be distilled from the world's major religions: when and whether a "right to life" inheres in an embryo, when "ensoulment" occurs in an embryo, and when respect is due to the embryo. Each religion answers these questions differently.

(1) Catholic doctrine

A sacred "right to life" from the moment of conception is the current Catholic doctrine. The basis for this belief is that an embryo is ensouled from the moment of conception. The idea of "ensoulment from the moment of conception" is sorely tested with the facts of embryology, to wit, that twinning can still occur up to 14 days (what happened to the original soul?), totipotency (what happened to all of the souls of each embryonic stem cell that didn't go on to become a zygote?) and now pluripotency (human skin cells can become embryonic stem cells, or gametes of either sex although they derive from a single sex, according to the new research from Wisconsin and Japan in late December, 2007).¹⁷ An impressive effort to address all of these issues (except the last one because it is so

¹⁶ These efforts are sometimes as difficult as attempting to grab and hold mercury as daily advances and discoveries in embryology render yesterday's theological constructs obsolete.

¹⁷ Inasmuch as these same sex derived gametes of either sex could be combined to form a new embryo, there would never be "conception" of a sperm from a man and an ovum from a woman; the resulting embryo would be derived from one human. See Dr. Yamanaka's concerns described in Chapter One, note 41.

new) is made by Catholic bioethicist Rose Koch-Hershenov in her article *Totipotency, Twinning and Ensoulment at Fertilization*.¹⁸

Her answer is that human beings are “hylomorphic composites”¹⁹ of form and matter. She recounts that some Catholic philosophers have contended that the mini-souls “fission out of existence” following a Thomistic “succession of souls” theory.²⁰ Koch-Hershenov dislikes this approach and argues, instead, “the current biological data on the human embryo does not provide sufficient evidence for...totipotency.”²¹ She adopts her own notion of Aquinas’ hylomorphic metaphysics which holds that plants, animals and human beings are “animated beings” that is, composites of matter and substantial Form.²² According to her revisioning of Aquinas’ doctrine, only humans have rational souls and, unlike the

¹⁸ Rose Koch-Hershenov, “Totipotency, Twinning, and Ensoulment at Fertilization” (2006) 31 J. Med. & Philosophy 139, see also at Chapter One note 41.

¹⁹ Hylomorphism derives from Aristotle’s metaphysics; his concern was to define the soul and his theory—known as hylomorphism—holds that the relation of soul to body is that of form to matter. S. Marc Cohen, “Hylomorphism and Functionalism” in Martha C. Nussbaum & Amelie Rorty, eds., *Essays on Aristotle’s De Anima* (London: Oxford University Press, 1995) at 58. According to Aristotle the soul is the “first actuality of a natural organic body,” that it is a “substance as form of a natural body which has life in potentiality,” and that it is a first actuality of a natural body which has life in potentiality.” Aristotle, *De Anima II*, trans. by D.W. Hamlyn (London: Oxford University Press, 1995) 1, 412b5-6, 1, 412a20-1, and 412a27-8) Aristotle believed that the claims applied to plants, animals and humans alike. See Christopher Shields, “Aristotle” *The Stanford Encyclopedia of Philosophy* Spring 2003 ed., online: <<http://plato.stanford.edu/entries/aristotle-psychology/>>, for a brief overview of Aristotle’s hylomorphism. Aristotle’s hylomorphism accounts for the composition of substances as well as the metaphysics of change. See Thomas F. Glick et. al., eds. *Medieval Science, Technology, and Medicine: An Encyclopedia*, 1st ed. (London: Routledge 2005) at 234.

²⁰ Koch-Hershenov *supra* note 18 at 143.

²¹ *Ibid.*

²² *Ibid.* at 150. The word ‘Form’ is capitalized because this concept derives from Plato who believed that there was an essence of Form, a higher world of Ideas or Forms which are unchanging, absolute and universal. This idea of Form is an ontology which presumes *a priori* truths which leads to monism which the philosophical principle that there is only one truth. Its opposite is pluralism, as in pluralistic morality—the notion that there may be different concepts of morality. See, e.g. Leigh Turner “Zones of Consensus and Zones of Conflict: Questioning the ‘Common Morality’ Presumption in Bioethics, 13 Kennedy Institute of Ethics Journal 193. See also note 1 of this Chapter Three.

vegetative and sensible souls found in plants and animals, the rational human soul “transcends” matter and is not confined within the limits of corporal nature.²³

“Aquinas’ metaphysics withstands his scientific errors...the forms of all other animated beings are wholly encompassed by and merged in matter, so it is possible that these forms can be divided when the body is divided. But this is not the case for the transcendental human form because there is no evidence for the artificial division of human embryos (induced twinning) and the reason for this may be that these embryos are ensouled human beings.”²⁴ She conceded that even if embryos may be divided to form several new humans via induced twinning, ensoulments would happen seriatim.²⁵ Although she agrees that natural twinning poses a problem for hylomorphism, she solves this by arguing that, “they are only ‘apparently’ single embryos that divide.”²⁶

Ronald Dworkin, in *Life’s Dominion*,²⁷ notes that 13th century philosopher/saint Aquinas did not believe that a fetus had an intellectual or rational soul until forty days, contrary to Koch-Hershnov’s revisioning of Aquinas’s beliefs. He disputes that modern embryology would have changed his view to immediate ensoulment and agrees with Joseph Donceel, S.J., that Aquinas’s doctrine of hylomorphism in fact requires the organs necessary for

²³ *Ibid.* at 152, at citing Thomas Aquinas *Summa Theologica*, trans. by Fathers of the English Dominican Province, New Ed. ed. (Christian Classics, 1981) [ST] Iq.76a.2.

²⁴ *Ibid.* at 155. Or, more likely, this has not been accomplished or reported, because it is widely considered to be unethical to divide a human embryo for purposes of “seeing whether” you can grow more than one human. She notes that this has been done with primates, so, scientifically, there truly is no reason to assume that the same could not be done with human embryos.

²⁵ *Ibid.* at 155.

²⁶ *Ibid.* at 157.

²⁷ Ronald M. Dworkin. *Life’s Dominion: An Argument About Abortion, Euthanasia, and Individual Freedom*, 1st ed. (New York: Vintage Books, 1994).

spiritual activities including the brain and cortex.²⁸ The Catholic account proffered by Koch-Hershnov also fails to take into account human chimeras.²⁹

(2) Judaic and Islamic doctrine

Other traditions, including most sects of Judaism and Islam, do not consider the early embryo exactly “human.”³⁰ Talmudic scholars believe that ensoulment takes place 40 days or more into pregnancy and prior to that time, the embryo is “as if it were simply water.”³¹ Rabbi Moshe David Tender of Yeshiva University advised the National Bioethics Advisory Commission in the United States that the Judeo-biblical tradition does not grant moral status to an embryo before 40 days gestation and destruction prior to quickening has the same moral import as the wasting of human seed.³²

Islamic traditions, both Shiite and Sunni, believe that there is a difference between a biological and a moral person because of the Koran’s silence with respect to any particular point at which ensoulment occurs.³³ The majority of

²⁸ *Ibid.* at 42.

²⁹ On November 15, 2003, NewScientist.com reported a case of a human chimera who only discovered she was a chimera when she was told that two of her three sons whom she had borne “could not be hers.” It was not a case of switched babies; instead, they discovered that she was a mixture of two individuals, non-identical sisters who fused in the womb and grew into a single body. Parts of her were derived from one twin and parts of her were derived from the other. The story reported perhaps 30 other living “chimeras.”; Claire Ainsworth, “The Stranger Within” *New Scientist* (15 November 2003), online: NewScientist.com <<http://www.newscientist.com/article.ns?id=mg18024215.100>>.

³⁰ Ethical Issues In Human Stem Cell Research: Volume III, Religious Perspectives” (Testimony presented by various doctors to the National Bioethics Advisory Committee, Rockville, Maryland, June 2000) C-4. Online: https://idea.iupui.edu/dspace/bitstream/1805/756/1/nbac_stemcell3.pdf.

³¹ *Ibid.*

³² Ethical Issues, *supra* note 30 at H-3.

³³ *Ibid.* at G-4 (Islamic Perspectives on Research by Abdulazia Sachedina).

Sunni scholars believe that ensoulment takes place by the end of the fourth month.³⁴

(3) Church of England doctrine

The Church of England was invited to provide input to the HFEA upon the 2007 Draft of the Human Tissues and Embryo Bill, having already provided similar input at various stages of the creation of the HFEA.³⁵ The Church of England traced its theological understandings and provided the following information in its 2007 Synod:

It should be noted that, historically, Christian writers refer to embryonic and fetal life only when they are dealing with punishments for killing life in the womb. Where distinctions are made between different stages of development of the embryo and fetus, this is in order to grade the seriousness of the crime. Even when distinctions are drawn, destruction of the embryo or fetus remains a serious crime at all stages of development. Because developments are so recent, the countervailing good of using embryos for medical treatment does not figure at all.³⁶

The Synod proceeds to discuss the Septuagint translation of Exodus 21.22, the Epistle to Barnabas (19,5, and 14, 11) and Didache (2,2), by Gregory of Nyssa (372 A.D.), Augustine (254-430 A.D.) and St Thomas Aquinas (1212-1274 A.D.) who “favoured later ensoulment.”³⁷ He said that the soul did not enter the male fetus until it was 40 days old and the female fetus until it was 90 days old.³⁸ After tracing this history, the Synod noted that the theological reflections illuminate

³⁴ *Ibid.*

³⁵ See, “Science, Medicine, Technology & Environment – Human Fertilisation” *The Church of England*, online: The Church of England <http://www.cofe.anglican.org/info/socialpublic/snte.html#humanfertilisation>; *The fetus in the Christian tradition, Embryo Research: Some Christian Perspectives*, A report from the Mission and Public Affairs Council, paragraph 10. This is an HTML link from the online site: embryos_research_-mpa_council.doc.

³⁶ *Ibid.*

³⁷ *Ibid.*, Gregory of Nyssa (On the Holy Spirit against Macedonius); Augustine (Quaestionum in Hept I II n 80), paragraphs 13-15.

³⁸ *Ibid.* at paragraphs 15-30.

what a human embryo is: "They have evoked an attitude of profound respect, love and wonder at the sheer mystery and intelligence of creation and life."³⁹ But, concluded the Synod, there is no one reflection "which tells us what we ought to do."⁴⁰

Christians who hold that the (current HFEA) legislation is largely correct will regard the early embryo as having developmental status. This stance accords the embryo a profound moral respect on the basis of its potential to develop into a human being, but it sees that ethical status of human personhood as being something that develops with increasing complexity of being.

The stance is based on the fact that there is no clear continuity of individual identity from fertilisation to the fetus in the womb. The undifferentiated cells of the fertilised egg in its first few days form not only the fetus but also the placenta and umbilical cord. Furthermore embryos can divide to form identical twins. Seventy percent of them will be washed away.

The actual individual emerges with the primitive streak at about 14 days. After that twinning is no longer possible and the outer cells of the early embryo have established themselves as umbilical cord and placenta. With the formation of the primitive streak there is the basis of the nervous system and all that makes for a particular individual.

From that point it is possible to say that there is a continuity of identity with the later child and adult and therefore it is right to talk about an individual human being. Before that there is only the potential for an individual human life.

It should be noted that an absolutist view of the embryo does not accord with actual practice. Funeral services are not held for embryos that fail to implant and are lost. Few would suggest that heaven is peopled - by a large majority - by embryos of fewer than 14 days' gestation.⁴¹

In conclusion the Synod stated:

³⁹ *Ibid.*

⁴⁰ *Ibid.*

⁴¹ *Ibid.*

In reflecting on these issues all Christians will seek to frame their views in the light of the fundamental convictions about God and humankind which shaped the teaching of the early Church. Whatever particular policy conclusions Christians may come to, they will agree that it is vital that scientific and medical developments be celebrated and encouraged, but they must also be carefully and critically assessed to ensure that such developments are compatible with the dignity and vocation of human kind as created by God to which the Christian faith witnesses.⁴²

(4) Eastern thought

Within China, there are different words for the “spirit” of an embryo/fetus and for the soul of an adult, the arrival of “spirit” is neither automatic nor time-constricted, with the becoming-adult spirit arriving into the child at about four months.⁴³

Chinese theories were based on the belief that the fetus is formed by the harmony of the yin and yang elements of the parents and sustained by different circuits of acupuncture points during its development. ... Each of these circuits...supplie[d] the foetus with a different need. A foetus that is delivered before full term or very near full term, would be incomplete ... Although a human foetus is always a human life, the cosmological forces do not confer a rational soul that turns a beast into a human being, rather they complete the organic unit of human life that is neither spiritualistic nor materialistic. Unlike the Western dichotomy where the only choice is between one human life (animated, viable) and zero, the Chinese duality allows much variation in between.⁴⁴

In Chinese law, human life is not constant in its legal, moral or ethical qualities.⁴⁵ Many factors, social, political and familial, enter into the Chinese attribution of moral value. The Chinese are neither pro-life, nor pro-choice: “birth affects the welfare of the family unit...The idea of valuing an unborn life in and

⁴² *Ibid.*

⁴³ Susan M. Rigdon, “Abortion Law and Practice in China: An Overview With Comparisons to the United States” (1996) 42 Soc. Sci. & Med. 543 at 543.

⁴⁴ Bernard H.K. Luk, “Abortion in Chinese Law” (1977) 25 Am J. Comp. L. 372 at 374.

⁴⁵ Rigdon *supra* note 42 at 547.

of itself, without regard for its social significance, is alien in Chinese social thinking.”⁴⁶ The notion of a fetus, much less an embryo, as a person with a moral hold on the family or as a legal or spiritual entity with a right to be born is an unfamiliar concept in Chinese thought.⁴⁷

Similar thinking arises in Japan. The Buddhist notion of rebirth gives an added dimension to any discussion of embryonic or fetal spirit. The concern with an incompleated being is that it may still be an active agent, requiring intervention so that spirit might return to limbo.⁴⁸ In the Japanese context of abortion, the focus is upon the pregnant woman and her desires and the fetus-as-spirit, not fetus-as-person.⁴⁹

It seems that the Church of England and the Judeo-biblical traditions are most in accord with the lay population studies which accord respect to embryos. Distilling the above, it appears that ensoulment at fertilisation versus respect at fertilisation will be the primary value conflicts which will need to be addressed in any legal structure attempting to regulate ectogenesis.

(C) Potentiality

Although not specifically religious in nature, an argument heard especially in the United States against embryonic stem cell research or the destruction of embryos is their potential to become individual human beings, especially after syngamy, when they have a unique human genome. Baroness Ruth Deech, the

⁴⁶ S.H. Potter & J.M. Potter, *China's Peasants: The Anthropology of a Revolution* (Cambridge: Cambridge University Press 1990) 235.

⁴⁷ Luk *supra* note 44.

⁴⁸ Oaks, Laury. "Fetal Spirithood and Fetal Personhood: The Cultural Construction of Abortion in Japan" (1994) 17 Women's Studies Int'l Forum 511, 518.

⁴⁹ *Ibid.* at 518, 521.

former Chair of the UK Human Fertilisation and Embryology Authority

["HFEA"], makes relatively short shrift of this idea:

Up to 70% of natural embryos in the body never succeed in implanting in any case and are lost. The *reductio ad absurdum* of protection of the embryo is that natural intercourse should be avoided because that is bound to lead to the loss of some fertilised embryos. Alternatively and equally unrealistic, if each embryo is a possible life and should not be wasted, then because all fertile adults are capable of combining to produce embryos at every moment of the day, we should do so incessantly in order to avoid any possibility of wasted potential.⁵⁰

(D) *In vitro* technology legislation

Baroness Deech also writes about some of the issues she foresees with respect to regulation of human reproduction and the inconsistencies from country to country:

There will soon be a patchwork of regulation...[T]his will lead to scientific tourism, a reflection of the world situation ... My experience on the HFEA (has) convinced me that to mix the pragmatic with the philosophical is the best way of going forward. ... [O]n the basis of examination of the inconsistencies and weakness of various national situations, what may be concluded about the ideal regulatory framework?⁵¹

What may be said about the ideal regulatory framework for ectogenesis, is that it should be contemplated soon before "reproductive tourism" worsens and that it is desirable to have worldwide standards now pertaining to embryos and the creation and/or destruction thereof.⁵²

⁵⁰ Baroness Ruth Deech, "Playing God: Who Should Regulate Embryo Research?" (2007) 32 Brooklyn J. Int'l L. 321 at 323; See also U.S., Congressional Research Service, *Human Embryo Research* (95-910 STM)(Irene Smith-Coleman, CRS Report for Congress (29 January 1998)). "Approximately 60% of embryos are believed to fail to implant or miscarry after implantation probably because of chromosomal and single-gene deformities."

⁵¹ *Ibid.* at 330.

⁵² EC, *Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*, [2004] O.J. L 102/48.

The ethical positions are muddled ... If patients, researchers, and gametes may move from country to country in search of the desired facilities that may be legally available to them as is permitted to Europeans by the Treaty of Rome, there is little point in restriction in a few countries, other than to send a signal. The ethics of the entire continent of Europe have to sink to the lowest point because the scientist who is unable to carry out ... research in Italy may move to United Kingdom; the would-be patient who prefers to have a [certain procedure] may leave United Kingdom or Sweden and go to Belgium; and so on.⁵³

It is evident that the treatment of embryos, regulations pertaining to embryos, and the issue of destruction of embryos for any reason will become important components for ectogenesis. The second part of this Chapter is devoted to reviewing the current conflict of laws and regulations that exist now with respect to Assisted Reproductive Technology, including embryo creation, storage, consent, and manipulation of embryos. There is special emphasis on the laws and regulations of Italy, the United Kingdom, Canada, the United States and Germany.⁵⁴ This Chapter will conclude by handpicking the more forward thinking and arguably better reasoned laws and regulatory structures which should be bulwarks for any international treatment of full ectogenesis when it arrives.

(1) Italy

Italy has attempted to enact bright-line legislation and in doing so has criminalized various practices. This has had unfortunate results.⁵⁵ In 2004, Italy enacted a comprehensive law attempting to deal with Italy's unregulated IVF

⁵³ Deech, *supra* note 50 at 333.

⁵⁴ Important abortion and frozen embryo cases that may affect ectogenesis when it arrives will be discussed in Chapter Four. The purpose of the upcoming extensive review of conflicting *in vitro* technology legislation is to highlight what happens when worldwide standards are not utilized.

⁵⁵ See "Italy: Abortion Blunder Rekindles Debate" *New York Times* (28 August 2007), online: The New York Times <<http://query.nytimes.com/gst/fullpage.html?res=9A0CE2DC1E3CF93BA1575BC0A9619C8B63>>.

industry.⁵⁶ Baroness Deech said of Italy's IVF laws: "The law amounts to a set of prohibitions rather than the construction of a general regulatory framework for the conduct of assisted reproduction."⁵⁷ For example, only three embryos may be created during IVF and all three must be transferred to the uterus.⁵⁸ As a result, the risk of a woman having twins or triplets increases dramatically and women may feel compelled to abort to obtain the desired number of children. On August 28, 2007, The New York Times reported a botched abortion in Italy occurred when a twin healthy fetus was aborted instead of its sibling whom had Down's Syndrome, which could have been detected by preimplantation genetic diagnosis had it been legal in Italy.⁵⁹ In another case, a woman forced to have three embryos implanted had to appeal to the courts to have a fetal reduction to save her life.⁶⁰ In Italy, abortions are permitted up to 90 days from conception and later if the fetus is malformed. While this procedure is being decried as eugenics by Senator Paola Binette, a member of Italy's national bioethics committee, the result of having Italy's bright-line legislation on the number of embryos which may be created at any one time and the requirement that all of them be implanted rules out

⁵⁶ Italy, *Medically Assisted Reproduction Law* (2004) Law 40/2004, Feb. 19, 2004, Gazz. Uff. No. 45.

⁵⁷ Deech, *supra* note 50.

⁵⁸ John A. Robertson, "Protecting Embryos and Burdening Women: Assisted Reproduction in Italy" (2004) 19 Hum. Reprod. 1693, online: <<http://humrep.oxfordjournals.org/cgi/content/full/19/8/1693>>. [Robertson II].

⁵⁹ New York Times, Abortion Blunder, *supra* note 55.

⁶⁰ Sophie Arie, "Woman Forced to Have Three Embryos Implanted Is Allowed Fetal Reduction To Save Her Life" (2004) 329 British Medical Journal 71, online: BMJ <<http://www.bmj.com/cgi/content/full/329/7457/71-c?etoc>>.

preimplantation genetic diagnosis and creates an atmosphere in which the woman is more likely to utilize the abortion permissions of the Italian law.⁶¹

Law Professor John A. Robertson suggests that a resolution to Italy's dilemma would be to use a different definition of embryo that imputes moral status at a certain stage, and that it occur at "syngamy" which happens approximately 20 hours after fertilisation. He believes that syngamy should be the key for persons who believe that the moral duty to protect embryos rests on their possessing a unique genome with the potential to become an adult.⁶² He points out that Germany uses the "syngamy" standard for protected embryos which allows the removal of multiple eggs, which can then be frozen.⁶³ However, this still poses the multiple embryo implantation problem, although it would alleviate requiring a woman to undergo additional stimulation and retrieval cycles if her first effort at IVF fails.⁶⁴ While the embryo biopsy required for preimplantation genetic diagnosis is not outright banned in Italy, it is virtually impossible as all embryos must be implanted, even those that are defective.⁶⁵ Reproductive tourism is already an active itinerary for Italian citizens, with Italian infertility doctors setting up clinics across the border in Croatia.⁶⁶ Changing the definition of embryo – from the HFEA definition discussed in Chapter One – to syngamy - permits of a tiny allowance for moral pluralism, but it does not permit

⁶¹ *Ibid.*

⁶² Robertson *supra* note 58 at 1694.

⁶³ *Ibid.* However, egg freezing has been largely unsuccessful to date except for short periods of time; See Maria Cheng, "Young Cancer Patients' Eggs Matured in Lab, Frozen" *The Denver Post* (3 July 2007).

⁶⁴ *Ibid.*

⁶⁵ *Ibid.* See also discussion of PGD in Chapter One.

⁶⁶ *Ibid.*

preimplantation genetic diagnosis, which is one of the primary reasons for the 14 day rule. It seems obvious that it is better to define an embryo as a fertilised egg per the HFEA and proceed from there.

(2) Germany

Germany has a strong aversion to eugenics possibilities given its dismal propensities during World War II.⁶⁷ The first two Articles of the German Constitution articulate the principles that the protection of human dignity and the right to life of every human being are paramount.⁶⁸ The German high court, in a case decided in 1975 held that, under the German Constitution, “unborn life possesses human dignity and has a right to life of its own from approximately day 14.”⁶⁹

The current law pertaining to embryos, the Embryo Protection Act of 1991, attempts to track the Basic Law of the Federal Republic of Germany enacted in 1945. “The Act’s primary purpose was to exclude even the slightest chance for programmes aimed at so-called improvement of humans through genetic tampering.”⁷⁰ While early efforts were to stave off legislation regarding IVF, a coalition of radical Greens, feminists and conservatives “rallied behind the call for the state to protect embryos from abuse, instrumentalization and destruction.”⁷¹ The Embryo Protection Act defines “embryo” as occurring after syngamy and apparently, *sub silentio*, also renders obsolete the earlier Court

⁶⁷ See Kara L. Belew, “Stem Cell Division: Abortion Law and Its Influence on the Adoption of Radically Different Embryonic Stem Cell Legislation in the United States, the United Kingdom, and Germany” (2004) 39 Tex. Int’l L. J. 479 at 507.

⁶⁸ Germany, *Basic Law* *supra* note 14 at Arts. I, II.

⁶⁹ See *Ibid.*

⁷⁰ Belew *supra* note 67 at 512 citing Hans Engelhard, Minister of Justice.

⁷¹ *Ibid.*

ruling that life did not exist until the fourteenth day. The Act does not address the moral status of the embryo.⁷² Because of the wording of this Act, every single totipotent cell derived from the embryo is an embryo possessing a “right to life.”⁷³ The Act criminalized transferring more than three embryos to the uterus, an offense punishable by three years in prison. It also prohibited sex selection, embryo freezing, and posthumous IVF.

At present, the German restrictiveness on what may be done with embryos has all but eliminated embryonic stem cell research and would also eliminate any possibility of ectogenesis. It also means that no preimplantation genetic diagnosis may be performed that might assist in eliminating serious genetic handicaps.

(3) The United States

The United States is perhaps the biggest international embarrassment with respect to its inconsistent approaches. There is no federal regulation of IVF or embryo research. The U.S. apparently prefers to leave this to the individual states:⁷⁴

The regulation which has been attempted by professional bodies in the United States has proved ineffective because no consensus has been reached on the main issues and guidelines are unenforceable at law. These issues are all bound up with the very sensitive American position on abortion and the tension over childbearing issues between religious forces and constitutional rights to privacy and liberty.... Much as the United States needs federal regulation of embryo research, it is particularly difficult to achieve because of the Constitution, guarantees of state and personal autonomy, and the political/religious lobby.⁷⁵

⁷² Bundesrepublik Deutschland, “Embryonenschutzgesetz” (1992) 43 Int’l Digest Health Legs. 740.

⁷³ *Ibid.* at 744.

⁷⁴ See Belew, *supra* note 67 at 10.

⁷⁵ Deech, *supra* note 50 at 5.

Embryo creation – without regulation – is performed in private IVF clinics, which are only loosely regulated in the United States via reporting requirements.⁷⁶ Under the Fertility Clinic Success Rate and Certification Act (FCSRA), IVF centers must report success rates.⁷⁷ The Food and Drug Administration claims that it has authority over human cloning procedures and possibly other genetics practices, but these claims remain untested in the courts.⁷⁸ The American Society for Reproductive medicine, a voluntary organization, has issued guidelines covering assisted reproductive technologies and the guidelines themselves do cover safety issues and at least raise some ethical concerns.⁷⁹

The Human Embryo Research Panel (HERP) was an advisory panel appointed by the Director of the National Institute of Health in 1994.⁸⁰ HERP attempted to formulate regulations and recommendations but was stymied completely by the change from the Clinton administration to the George W. Bush administration.⁸¹ HERP utilized much of the Warnock Commission's work⁸² and anticipated all of the major scientific developments that eventuated in the ten

⁷⁶ See Margaret Foster Riley & Richard A. Merrill, "Regulating Reproductive Genetics: A Review of American Bioethics Commissions and Comparison to the British Human Fertilisation and Embryology Authority" (2005) 6 Colum. Sci. & Tech. L. Rev. 1, 4.

⁷⁷ *Ibid.*

⁷⁸ *Ibid.*

⁷⁹ *Ibid.* at 6. These concerns include compensation of egg donors (permitted), access to fertility treatment by gays, lesbians, and unmarried persons (permitted); child-rearing ability (a reason for withholding fertility treatments); informing offspring of their conception by gamete donation (recommended); preconception gender selection for non-medical reasons (permissible with counseling); See "Ethical Considerations of Assisted Reproductive Technologies: ASRM Ethics Committee Reports & Statements" *American Society of Reproductive Medicine*, online: ASRM <http://www.asrm.org/Media/Ethics/ethicsmain.html>.

⁸⁰ *Ibid.* at 22-26.

⁸¹ *Ibid.* at 22.

⁸² *Ibid.*

years after its inception.⁸³ HERP embraced a pluralistic and segmented approach toward respect for the embryo and refused to be drawn into the moral personhood battle.⁸⁴ It envisioned a continuum where “the aggregate of several factors, e.g. genetic uniqueness, potential, the onset of a heartbeat, sentience, brain activity” all require increasing respect.⁸⁵ HERP’s report was far-reaching and well researched.

It found the following procedures unacceptable: induced twinning, nuclear cloning, research on the embryo after closure of the neural tube, preimplantation genetic diagnosis [PGD] for sex-selection unless related to a sex-linked genetic disease, development of chimeras,⁸⁶ transfer of human embryos into non-human animals, and, interestingly, transfer of human embryos for extrauterine or abdominal pregnancy (ectogenesis).⁸⁷ This blue-ribbon Panel met a tragic end, though, with its recommendation that embryos could be created for research. The American press reacted swiftly, stirred up the alarmist anti-abortion forces, and then President Clinton issued a statement that the administration would bar funding for the creation of embryos for research purposes.⁸⁸

The entire HERP report became political poison and, in August 1995, two Republican House Representatives pushed an amendment to the appropriations bill that forbade any federal funding for the creation of human embryos for

⁸³ *Ibid.* at 23.

⁸⁴ *Ibid.* at 24.

⁸⁵ *Ibid.* at 23-26.

⁸⁶ Roman Catholic bishops approve of transferring chimeras to the human woman who provided the ovum. See Simon Rabinovitch, “Animal-Human Embryos Need Human Rights, Bishops Say” *Reuters* (27 June 2007), online: <<http://www.reuters.com/article/topNews/idUSL2740483620070627>>.

⁸⁷ See Riley & Merrill *supra* note 78 at 24.

⁸⁸ *Ibid.* at 26.

research purposes. Worse, it also forbade federal funding for research upon any human embryo where the embryo is destroyed, discarded or knowingly subjected to death which would encompass any preimplantation genetic diagnosis.⁸⁹

By Executive Order of November 28, 2001, President George Bush created the President's Council on Bioethics. Its head is Leon Kass, a well-known conservative who opposes birth control and believes that a woman's destiny is motherhood.⁹⁰ Diane Irving, a Catholic bioethicist on the American Bioethics Advisory Commission believes that there are scientific "myths" and scientific "facts."⁹¹ She counts as a myth the notion that a fertilised egg is a potential human being and insists in capital letters that it is a human being and criticizes using the 14-day criterion as "scientific myth". She discounts the end of the twinning period as "scientific myth" pointing out that twinning may happen after 14 days with Siamese twins, thus "raising questions about the adequacy of using the landmark of segmentation in development as the determinant of moral status."⁹² She conflates the science of embryology with the philosophy of moral personhood. While other members of the Council on Bioethics have called for

⁸⁹ *Ibid.*

⁹⁰ Leon Kass's conservatism is quite dramatic as evidenced by these quotes from his essay, "The End of Courtship," found at <http://www.boundless.org/2005/articles/a0001161.cfm>:

"The change most immediately devastating for wooing is probably the sexual revolution. For why would a man court a woman for marriage when she may be sexually enjoyed, and regularly, without it?" " Her menstrual cycle, since puberty a regular reminder of her natural maternal destiny, is now anovulatory and directed instead by her will and her medications, serving goals only of pleasure and convenience."... "On the one side, there is a rise in female assertiveness and efforts at empowerment, with a consequent need to deny all womanly dependence and the kind of vulnerability that calls for the protection of strong and loving men. ...Not by mistake did God create a woman — rather than a dialectic partner — to cure Adam's aloneness."

⁹¹ Irving, Diane N. "When Do Human Beings Begin?: 'Scientific' Myths and Scientific Facts" (1999) 19:3/4 *Int'l J. Soc. & Social Pol'y* 22, online: <<http://www.l4l.org/library/mythfact.html>>.

⁹² Query: This would seem to cut in favor of the 14 day rule instead of against it, as any twinning after 14 days would be "protected" under all legislative schemes which use this cutoff point.

regulation of assisted reproductive technologies that would be patterned upon the HFEA in United Kingdom, until there is a change in political complexion in Washington, all such efforts are premature.⁹³ American bioethicist George Annas laments the American position that the “USA is failing not only to lead, but even to contribute to, the reinforcement of bioethical values in legal, international and political areas and is currently a force of reaction especially in the way it reverts to religiosity to define acceptable conduct.”⁹⁴

(4) The United Kingdom

The United Kingdom is in the throes of parliamentary hearings upon the proposed 2007 Amendments to the 1990 Human Fertilisation and Embryology Act. These Amendments expand upon the 1990 HFEA which in turn was based upon The Warnock Committee Report. The 1990 HFEA does not define the “moral status” of embryos, nor does it attempt to do so. Instead, it allows the creation of embryos purely for research purposes and permits research until day 14.⁹⁵ The 2007 Amendments maintain the extensive framework of the 1990 HFEA, primarily updating and homogenizing the law in this area, which needed updating as a result of piecemeal changes brought about by legal challenges to the 1990 HFEA.⁹⁶ The 2007 proposed Amendments initially called for a new Regulatory Authority for Tissues and Embryos (called RATE), which would combine the functions of the Human Fertilisation and Embryology Authority with

⁹³ Alicia Ouellette *et. al.* “Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States” (2005) 31 Am. J. L. & Med. 419, 421.

⁹⁴ George J. Annas. *American Bioethics: Crossing Human Rights and Health Law Boundaries* (New York: Oxford University Press, 2005) 244.

⁹⁵ Rachel Anne Fenton, “Time for Change” (2007) 157 New L.J. 848; later article, same author, same title, same journal at 157 New L. J. 964. (Both accessible only via Reid Elsevier (UK) 2007).

⁹⁶ See later article at 2.

the Human Tissue Authority.⁹⁷ However, in October 2007, this idea was abandoned.⁹⁸ Other items that raised contention in the 2007 draft bill include the elimination of a need for a father from the welfare of the child provision and the creation of interspecies and chimera embryos for research purposes.⁹⁹ It expands “legitimate purposes” for preimplantation genetic diagnosis.¹⁰⁰

In the United Kingdom, the embryo is given special status but not absolute protection.¹⁰¹ Instead, the embryo is treated as an entity deserving due attention which means that it is to be used only if there is no alternative and its use or destruction is ruled by the informed consent of both donors. Moreover, there are significant restrictions upon mixing them with non-human material, and there is detailed recordkeeping to ensure that every single embryo is accounted for.¹⁰² Baroness Deech, former Chair of the HFEA, Former Principal of St Anne’s College at Oxford, and Member of the House of Lords recently had occasion to address some of the difficult issues which the United States and others refuse to ask:

It is often asked by what moral right do the members of the HFEA pronounce on these issues. It is because it embodies the democratic compromise between strongly held views in society.... The Authority works within the Act to reconcile opposing views and point a way forward, with public accountability.¹⁰³

⁹⁷ *Ibid.*

⁹⁸ See U.K., Secretary of State for Health, “Government Response to the Report from the Joint Committee on the Human Tissue and Embryos (Draft) Bill”, Cm 7209 (2007).

⁹⁹ Fenton, *supra* at note 97.

¹⁰⁰ *Ibid.*

¹⁰¹ U.K., H.L., “Select Committee Report on Stem Cell Research”, H.L. 83-1, B 4.21 (2002).

¹⁰² Deech *supra* note 50 at 2.

¹⁰³ *Ibid.* at 7.

At present, the HFEA licenses and monitors clinics that carry out IVF treatments, donor insemination and embryo research. In speaking for the practical value of regulation, Baroness Deech notes that regulation in Britain serves to protect clinicians and scientists not only from legal action for malpractice, but also gives them a shield against accusations of ethical malpractice provided they are acting within the parameters agreed by Parliament, the HFEA, and the Code of Practice. The Code of Practice is an important element of regulation missing from all other regulatory schemes worldwide.¹⁰⁴

She contends that international regulation of these issues is important because regulations can be far more responsive to developing issues; it is more responsible to attempt regulation beforehand rather than leaving many profound issues to be decided slowly by individual court cases.¹⁰⁵ The HFEA developed five ethical principles derived from legislation and real cases: (1) Assurance of human dignity, worth and autonomy, especially consent; (2) The welfare of the potential child; (3) Safety, including safety checks of preimplantation genetic diagnosis; (4) Respect for the status of embryos, prohibiting any research upon embryos over fourteen days old; and (5) Acknowledging that the saving of life is a good use to which new advances in embryology may be put.¹⁰⁶ Her understandable pride in the work done by the HFEA is lauded by others and is highly regarded throughout the world.¹⁰⁷

¹⁰⁴ *Ibid.*

¹⁰⁵ *Ibid.* at 8.

¹⁰⁶ *Ibid.* at 9.

¹⁰⁷ Belew *supra* note 67 at 8.

(5) Canada

Canada appointed the Royal Commission on New Reproductive Technologies in 1989.¹⁰⁸ The government's response to 293 Commission recommendations was ultimately to pass "An Act Respecting Assisted Human Reproduction and Regulated Research in 2004."¹⁰⁹ The Government of Canada's biostrategy statement articulates the overall scheme:

The primary objectives of the legislation are to ensure the health and safety of those using AHR (Assisted Human Reproduction) by regulating acceptable practices, to ban certain unacceptable practices based on health and safety, and moral and ethical concerns; and to ensure that AHR research involving the *in vitro* embryo is conducted with a regulated environment.¹¹⁰

The Act contains a number of specifically prohibited activities including cloning, sex-selection for non-medical reasons, commercial surrogacy, and purchase of embryos. It also regulates the storage of embryos. The Parliament of Canada passed the Act itself on March 11, 2004 and it received Royal Assent on March 29, 2004.

(E) International recommendations

The Hinxton Group is an International Consortium on stem cells, ethics and law.¹¹¹ Having thoroughly reviewed the welter of laws which have been enacted in Europe, Russia, the Baltic States, and Scandinavian countries, the Hinxton Group observed that a "patchwork of laws and ethics rules governing human

¹⁰⁸ Canada, Canadian Biotechnology Advisory Committee, *Canadian Biotechnology Strategy (Reports)*, online: http://www.biostrategy.gc.ca/HumanRights/HumanRightsE/ch2_2_e.html#comparative.

¹⁰⁹ Canada, *Assisted Human Reproduction Act*, S.C. 2004, c. 2.

¹¹⁰ See "About Health Canada," online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/media/contact/index_e.html>.

¹¹¹ See, <http://www.hinxtongroup.org>.

embryonic stem cell research is sowing confusion” and encouraging research tourism.¹¹² On February 24, 2006, the Group issued a consensus statement with the admonition: “Societies have the authority to regulate science and scientists have a responsibility to obey the law. However the policymakers should refrain from interfering with the freedom of the citizens unless good and sufficient justifications can be produced for so doing.”¹¹³ That statement came from the Hinxton Group which consisted of 60 scientists, doctors, philosophers, lawyers, scientific journal editors, federal regulators and others from 14 countries who met in Hinxton, United Kingdom, to consider "ethically acceptable norms" of stem cell research.¹¹⁴ The Hinxton Group refused to engage in the no-win dialogue regarding the issue of the moral status of embryos and issued a Consensus Statement of 15 overriding principles which should be used worldwide.¹¹⁵

The United Nations Educational Scientific and Cultural Organization (UNESCO) issued a Universal Declaration on Bioethics and Human Rights in 2005.¹¹⁶ In its Preamble it states: “Resolved: that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity’s response to the ever-increasing dilemmas and

¹¹² See Rick Weiss, “Universal Stem Cell Principles Proposed” *The Washington Post* (2 March, 2006).

¹¹³ *Ibid.*

¹¹⁴ *Ibid.*

¹¹⁵ The 15 principles may be found at <http://www.hopkinsmedicine.org/bioethics/finalsc.doc> and are reproduced in Appendix A hereto.

¹¹⁶ *Universal Declaration on Bioethics and Human Rights*, 19 October 2005, UNESCO, online: <http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html>.

controversies that science and technology present.”¹¹⁷ Article 18 promotes “informed pluralistic public debate.”¹¹⁸

(F) Moving toward consensus

Fortunately, a number of academic and legal writers have concentrated their analytical efforts upon comparing the best of these legislative schemes using Canada and United Kingdom (and by comparison for its lack of regulation) the United States. One Canadian writer, now a Superior Court Judge in Ontario, faults Canada with being overly preoccupied with setting boundaries. In an extensive article entitled *Let's Try Again...this Time with Feeling: Bill C-6 and the New Reproductive Technologies*,¹¹⁹ she follows the labyrinthine process Bill C-6 followed to arrive at its present configuration.¹²⁰ Specifically, she notes that Bill C-47, a predecessor bill, took over 10 years to gestate and set forth only prohibitions and no regulatory scheme. Bill C-47 died on the Order Paper in April 1997.¹²¹ Bill C-6 then took another seven years to become law. “Bill C-6 does not have the paternalistic, at times sanctimonious tone that characterized Bill C-47.”¹²² She applauds the new regulatory provisions of C-6 which are “founded upon a recognition of the rapid pace of technological development and that views may change quickly.”¹²³ However, she faults C-6 for containing a number of criminal provisions which she thinks reflect a disturbing and inaccurate view that

¹¹⁷ *Ibid.* at Preamble.

¹¹⁸ *Ibid.* at Art. 18.

¹¹⁹ Alison Harvison Young, “Let’s Try Again...This Time With Feeling: Bill C-6 and New Reproductive Technologies” (2005) 38 U.B.C. L. Rev. 123.

¹²⁰ *Ibid.*

¹²¹ *Ibid.* at 124.

¹²² *Ibid.* at 124.

¹²³ *Ibid.* at 125.

the views of Canadians are unchanging and monolithic.¹²⁴ Among the things that are criminalized in Canada is ectogenesis.¹²⁵ She believes, as does Tim Caulfield, that instead of criminalizing practices, a moratorium on certain practices would be more effective to allow flexibility in dealing with changing and unforeseen developments.¹²⁶ She concludes that criminalizing various practices is a poor idea as “the criminal law is a heavy and blunt instrument” and a “practice that is controversial one year may not be the next.”¹²⁷

Writer Erin Nelson faults Canada’s Assisted Human Reproduction Act for “breathing new life into the debate around issues relating to the moral status of the embryo” and for failing to enact, as has the United Kingdom, a “Code of Practice” for policy-making.¹²⁸ Instead, the policy-making role is given to Health Canada, rather than to an expert body similar to the HFEA as it is in United Kingdom. She calls the “regulatory components” of Canada’s Act “disappointing” because the policy-making role is granted to Health Canada rather than to the AHRA (Assisted Human Reproduction Agency), a regulatory agency similar to the HFEA in United Kingdom, and the Act itself contains no legislative charge to the Agency to create a Code of Practice.¹²⁹ In addition to this problem, she sees an

¹²⁴ *Ibid.* at 126.

¹²⁵ *Ibid.* This is a probable carryover from *Proceed with Care*, a preliminary working document in Canada, prior to the adoption of the Assisted Human Reproduction Act, in which there was recommendation for a prohibition with “any experimentation which may lead to ectogenesis.”; See also, Frida Simonstein, “Artificial Reproduction Technologies (RTs): All the Way to the Artificial Womb?” (2006) 9 *Med. Health Care & Philosophy* 359.

¹²⁶ *Ibid.* at 133. See also Timothy Caulfield, “Cones, Controversy, and Criminal Law: A Comment on the Proposal for Legislation Governing Assisted Human Reproduction” (2001) 39 *Alta L. Rev.* 335.

¹²⁷ *Ibid.*

¹²⁸ Nelson, Erin L. “Comparative Perspectives on the Regulation of Assisted Reproductive Technologies in the United Kingdom and Canada” (2006) 43 *Alta. L. Rev.* 1023, 1025.[Nelson I].

¹²⁹ *Ibid.* at 1031.

unwieldy amount of oversight left to Parliament itself.¹³⁰ While acknowledging that administrative agencies lack the same amount of democratic accountability to the public as is borne by Members of Parliament, she also maintains that an independent agency is able to be flexible and responsive to new scientific developments.¹³¹

As an example of a technique that needs quick regulatory responsiveness, she talks about preimplantation genetic diagnosis.¹³² PGD is controversial and is already critical to the diagnosis of certain genetically related defects which, if discovered later, often result in elective abortions. PGD is a vital tool yet it is controversial as it is feared that PGD will be used to create “designer babies.”¹³³ In the United Kingdom, the HFEA is responsible for maintaining a “Code of Practice” for the proper conduct of licensed activities. This includes the performance of PGD. The section of the Code on licensing PGD is very clear; a centre that does such testing must be licensed to do so and may only perform tests for conditions which are indicated in its license, or are specifically approved by the license committee of the HFEA.¹³⁴ If there is a desire to test for a specific condition that is not covered by its license, the centre must apply to the HFEA for each new condition it wishes to test.¹³⁵ There is no list of excluded conditions; instead a number of facts must be taken into consideration including the welfare

¹³⁰ *Ibid.* at 1032.

¹³¹ *Ibid.* at 1033.

¹³² *Ibid.* at 1034, see also discussion of PGD in Chapter One, *supra*.

¹³³ Nelson I *supra* note 130 at 1042, fn. 122.

¹³⁴ *Ibid.* at 1040.

¹³⁵ *Ibid.*

of any child who may be born as a result of treatment and of any other child who might be affected by the birth.¹³⁶

A fascinating reversal of position on the uses of PGD arose in the U.K. with respect to tissue typing for a saviour sibling. In early 2002, the HFEA granted a license to a Nottingham hospital to perform PGD and tissue typing for the parents of a child suffering a rare and usually fatal genetic blood disorder.¹³⁷ They hoped that they could have a child whose umbilical cord blood could provide a tissue- matched source of stem cells as a cure for their ill son.¹³⁸ The grant of this license was opposed by the Committee on Reproductive Ethics [CORE], a “pro-life” organization which challenged the license in court on the basis that embryo selection (and discarding of some embryos which had the same genetic disorder as the ill child) raised such contentious ethical issues that this use of reproductive technology demanded parliamentary oversight.¹³⁹

The case was encapsioned *Quintavalle v. HFEA*,¹⁴⁰ and the lower court agreed with CORE that such a proposal was not “necessary or desirable for the purpose of assisting a woman to carry a child.” The Court of Appeal and the House of Lords disagreed, concluding that the underlying Act authorized the HFEA to license new forms of PGD. “The fact that these decisions might raise difficult ethical questions is no objection.... The membership of the HFEA and

¹³⁶ *Ibid.* at 1041.

¹³⁷ *Ibid.* at 1042.

¹³⁸ *Ibid.*

¹³⁹ Nelson I, *supra* note 130 at 1043.

¹⁴⁰ *Quintavalle v. HFEA* (2002) EWHC 2785, [2003] 2 All ER 105.

the proposals of the Warnock Committee...make it clear that it was intended to grapple with such issues.”¹⁴¹

Nelson criticizes Canada’s failure to give authority to the AHRA to respond to new developments such as PGD and its failure to instruct that Agency to develop something along the lines of the Code of Conduct promulgated by the HFEA to regulate new issues. “There is a real chance that all of the controversial political issues around PGD (or other new developments) will do nothing more than provide an opportunity for revisiting ground already answered in the debate and passage of the [Assisted Human Reproduction Act] itself.”¹⁴²

American scholars and bioethicists also hail the U.K.’s regulatory system, but contend that such a system is unworkable in the U.S.¹⁴³ In an article *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*,¹⁴⁴ several leading American bioethicists faulted the United States for its failure to enact any comprehensive regulatory scheme. The Center for Disease Control compiles statistics upon the annual ART (Assisted Reproductive Technology) success rate, but the submission of such data is strictly voluntary.¹⁴⁵ Data collection in the US from 1992-2004 rested largely upon the Society for Assisted Reproductive Technology, a private organization that requires a yearly membership fee, a registry fee for data collection services, and a

¹⁴¹ Nelson I *supra* note 130 at 1043

¹⁴² *Ibid.* at 1047.

¹⁴³ See Riley & Merrill *supra* note 78.

¹⁴⁴ Alicia Ouellette et al. “Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States” (2005) 31 Am. J. L. & Med. 419.

¹⁴⁵ *Ibid.* at 420.

fee for every Assisted Reproductive Technology cycle performed.¹⁴⁶ The Center for Disease Control does not keep an accurate system of which clinics fail to report at all.¹⁴⁷ No U.S. law requires licensing or accreditation of Assisted Reproductive Technology programs or embryo laboratories or storage units, unlike the U.K.¹⁴⁸ Oddly, “debate rages in Congress about appropriate regulation of stem cell research for therapeutic purposes, but almost no debate exists about regulating assisted reproduction.”¹⁴⁹

Unfortunately, the authors of this article claim that the “wholesale importation of the U.K. model to the U.S. is neither possible nor wise given the American values partly because it does not “accommodate the moral diversity in the U.S.” where “profound disagreement over the moral status of the embryo exists.”¹⁵⁰ Yet, the reasoning is specious: “Any attempt to impose national uniformity in the absence of moral consensus ... will monopolize precious time on the national docket and is unlikely to resolve the ethical dilemmas.”¹⁵¹

However, this lack of moral consensus problem is unlikely ever to be resolved in the United States, which is precisely the reason that an ontologically neutral legislative scheme needs to be implemented regarding Assisted Reproductive Technology.

The concern in the U.S. has been less about *in vitro* fertilisation, as noted by the authors, and much more about abortions, especially late term or so-called

¹⁴⁶ *Ibid.*

¹⁴⁷ See *ibid.* at 425.

¹⁴⁸ *Ibid.* at 429.

¹⁴⁹ *Ibid.* at 432.

¹⁵⁰ *Ibid.* at 435.

¹⁵¹ *Ibid.*

“partial birth abortions” and the creation of embryos specifically for research. The authors are correct in asserting that imposing a legislative scheme pertaining to Assisted Reproductive Technology may be more difficult in the U.S. because of a privatized health care system, but hand-wringing over the United States’ inability to agree on the moral status of the embryo as an insurmountable problem is pointless and short-sighted when the international mandate is to have workable world-wide standards.

Dame Mary Warnock – of the famous 1984 Warnock Committee - still has the last word on this subject. In the November 29, 2007 issue of *Nature*, she talks about the ethical regulation of science. “That science develops too fast for morality has become the cliché of the twentieth century.”¹⁵² The “Warnock Committee,” as it came to be known, was established to look at the problem of regulating assisted reproductive technology, spurred of course by the birth of Louise Brown.¹⁵³ She states that her committee of sixteen, comprised of theologians, social workers and attorneys, quickly concluded that there was little possibility of moral consensus.¹⁵⁴ Just as her committee’s proposed legislation was about to be introduced, the Catholic Church claimed a right to regulate science in the area of *in vitro* technology because of its superior knowledge of morality.¹⁵⁵

¹⁵² Dame Mary Warnock, “Science & Politics: The Ethical Regulation of Science” (2007) 450 *Nature* 615.

¹⁵³ The world’s first “test-tube” baby produced via *in vitro* fertilisation.

¹⁵⁴ *Ibid.*

¹⁵⁵ *Ibid.*

“In sharp contrast, the committee’s entitlement to issue moral advice to ministers derived from its having been set up to do so, and from its having a wide and non-partisan membership.”¹⁵⁶ She continued:

The moral decisions that such committees have to make are essentially matters of public not private morality. We had to consider our own moral or religious scruples (which would obviously influence our thinking) alongside what the consequences might be for the decisions for society as a whole. This was the reason we could not allow ourselves to be swayed by arguments derived from a particular religious dogma. ... To set up a standard, we had to weigh the possible goods against possible harms. The legislation would govern everyone – believers and atheists – and had to take into account wider considerations, such as the relief of suffering ... Above all, the harm that the legislation should seek to minimize was the exploitation of the vulnerable and ignorant [men and women desperate to create a family].¹⁵⁷

The reasons so ably articulated by Dame Warnock urging international standards for reproductive technologies – and the reasons for ensuring that it is ontologically neutral – are ever more important as a global economy continues to evolve and tomorrow’s new reproductive technologies are on the horizon.

¹⁵⁶ *Ibid.*

¹⁵⁷ *Ibid.*

Chapter Four: Looking ahead

If ectogenesis appears in the near future, legal relationships are sure to change in myriad ways. It will remove the maternal/fetal conflict, which is the touchstone of all abortion law, if ectogenesis is sought from the beginning.¹ It will give the father an equal say with the mother, a trend we are beginning to see in frozen embryo cases.² It will change the State's obligation to the growing citizen and will require us to focus upon what exactly the State's interest is in this citizen-to-be.³ Personhood considerations will become paramount in determining whether a fetus-in-ectogenesis is entitled to some measure of legal personhood.⁴

It will require a revisitation of wrongful birth and wrongful life case law and reasoning. Termination of fetal life will implicate philosophical issues of the Repugnant Conclusion and non-identity in addition to the moral instinct that will

¹ The maternal/fetal conflict is still present in ectogenesis, however, when authors discuss the forcible removal of the fetus from the mother or incarceration of the mother because of harmful maternal behavior such as drug or alcohol use. See discussion of the dissent in *Winnipeg Child Services v. DFG*. Forcibly removing an early fetus the mother who wishes to abort and requiring her to expel it instead into an ectogenic chamber implicates "extinction versus extraction" issues (desire not to have any child of hers in the world) and informed consent issues as discussed by Christine Overall in *Human Reproduction: Principles, Practices and Policies* at 69-70. *Cf.*, Judith Jarvis Thomson and Peter Singer who, while supporting abortion, do not support extinction if the fetus is capable of existing elsewhere: "Freedom to choose what is to happen to one's body is one thing; freedom to insist on the death of a being that is capable of living outside one's body is another." *Ectogenesis*, *supra* note 58 Chapter 1 at 12. The autonomy and informed consent issues implicated by such forcible removal will be bracketed for the remainder of this Chapter Four and Five. These Chapters will assume that those availing themselves of ectogenesis do want a child, that their only option is full EUFI ectogenesis, and that it is sought *ab initio*.

² See discussion *infra* Chapter Five.

³ Too facile judicial pronouncements that the State has a compelling 'interest in promoting fetal life', for example, will need to be rationally refined and examined. *Cf.*, *Gonzales v. Carhart*, 2007 U.S. Lexis 4338 (2007).

⁴ Jessica Berg, "Of Elephants and Embryos: A Proposed Framework for Legal Personhood" (2007) [unpublished archived at <http://works.bepress.com>], online: Selected Works <http://works.bepress.com/jessica_berg/1/>. Although 'viability' would seem to be present throughout ectogenesis, true viability (i.e. the ability to exist independently of all significant life-sustaining apparatus) may still be the touchstone for natural and full legal personhood. See Michael Tooley, *Personhood*, in *A Companion to Bioethics* 117 (Helga Kuhse & Peter Singer eds., 1998). An entire second thesis could be written on this issue alone.

be tested by our empathic hardwiring and the complete visibility of the developing fetus. It will require us to rethink reproductive autonomy in ectogenesis. All of these legal issues are sure to be extremely contentious and should be the subject of intensive debate even now. This Chapter first examines relevant case law that may serve as the basis for deciding future disputes that arise as a result of ectogenesis. It then discusses unique causes of action that foreseeably may arise out of ectogenesis.

(A) Case law

(1) Deconstructing abortion law: issues for ectogenesis

The case law that may assist in identifying the issues which will surround the beginning and termination of fetal life still commences with abortion law. It is instructive to witness and analyze the transformation of abortion law especially in the United States. The pendulum counter swing on the United States Supreme Court post *Roe v. Wade*⁵ reflects a fascination with the increasing visibility of the embryo and early fetus via ultrasound and a willingness of lawmakers and courts to publicly discuss and reflect upon the exact nature of medical procedures. There is also a palpable trend in cases after *Roe* to assert governmental interests in promoting fetal life.⁶ Recent judicial refinements of abortion law are predictive of a welter of conflicting concepts infused with theological tinctures that surround the duties arguably owed by the State to a conceptus.⁷

⁵ 410 U.S. 133 (1973).

⁶ The change in abortion thinking from *Roe v. Wade*, *supra* at note 5 to *Gonzales v. Carhart*, *supra*, at note 3, reflects increasing governmental oversight and interest in the fetus. This may be somewhat unique to the United States given its contentious abortion politics.

⁷ It is fair to use the term "State" to mean any supervening governmental authority which could regulate the beginning and end of human life.

Abortion cases were truly the first contemporary efforts judicially to articulate the competing interests involved in intentionally procuring the end of fetal life.⁸ The United States Supreme Court in *Roe v. Wade* made an impressive effort to review the history of the fetus and its legal and theological status before rendering its decision.⁹ At early common law, abortion performed before “quickening”¹⁰ was not an indictable offense.¹¹ Importantly, the point of quickening was the first time that the mother could actually feel the fetus moving; quickening also coincided with the time when the fetus became recognizably human.¹²

In 1929, the Infant Life Preservation Act in England was enacted and fastened criminal repercussions upon anyone procuring the death “of a child capable of being born alive,” but allowed an affirmative defense to any criminal charge that an abortion might have been procured in good faith to preserve the life of the mother.¹³ The idea that an abortion carried less moral impact if it was done to “save the life of the mother” carried forward in England with the Abortion Act of 1967.¹⁴ That Act also permitted a pregnancy to be terminated if “there is a

⁸ Physician proscriptions upon providing abortive remedies may be found in the Hippocratic Oath and other similar Codes for physicians. The Hippocratic Oath provided that a physician will not give a woman a “pessary to produce abortion.” *Roe v. Wade*, 410 U.S. 113, 131 (1973). The Seventeen Rules of Enjuin are a code of conduct developed for students of the Japanese *Ri-shu* school of medicine in the 16th century and it too provides that physicians should not give “abortives” to the people. “Seventeen Rules of Enjuin” *Wikipedia*, online: *Wikipedia* <http://en.wikipedia.org/wiki/Seventeen_Rules_of_Enjuin>. Since physicians were men, it is unclear that these same proscriptions applied to midwives or to the women themselves. Some of these early proscriptions were based in property law and the “wrongness” of the acts was tied to the deprivation of property of the father. *Roe v. Wade*, 410 U.S. 113, 130 (1973).

⁹ *Roe, supra*, note 5 at 130-147.

¹⁰ When movement of the fetus may be felt by the woman. *Roe, supra* note 5 at 132.

¹¹ *Ibid.*

¹² *Ibid.* at 132-133.

¹³ *Infant Life (Preservation) Act, 1929* (U.K.), 19 & 20 Geo. V., c. 34., cited in *ibid.* at 136.

¹⁴ *Abortion Act 1967* (U.K.), 1968, 15&16 Eliz. II., c. 87.

substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped.”¹⁵ The Court in *Roe v. Wade* undertook a painstaking review of medical opinions of the American Medical Association on the issue of abortion. Starting as early as 1857, the AMA was concerned with the health and safety of the child and in 1967, the Committee on Human Reproduction grudgingly approved abortion when the child “may be born with incapacitating physical deformity or mental deficiency.”¹⁶

Thus, *Roe’s* historical analysis of abortion thinking lends some considerable insight into growing appreciation of the fetus as an independent juridical being:¹⁷(1) When the fetus appears recognizably human; (2) When the fetus reaches the point of viability, that is, an ability to live independently of the mother; and (3) Whether the resulting child will have physical or mental abnormalities so as to be seriously handicapped.

(2) Identifying Preliminary Personhood Issues

Not unlike the United States Human Embryo Research Panel (HERP) and the U.K.’s Human Embryology and Fertilisation Authority (the HFEA), the United States Supreme Court in *Roe v. Wade* refused to grant “personhood” to the unborn – moral or natural:

Texas urges that, apart from the 14th Amendment, life begins at conception and is present throughout pregnancy and that, therefore the State has a compelling interest in protecting that life from and

¹⁵ *Ibid.*

¹⁶ *Roe, supra* note 5 at 142.

¹⁷ “There are no legal guidelines for addressing relations involving entities that are neither persons nor property.” Jessica Berg, *Owning Persons: The Application of the Property Theory to Embryos and Fetuses*, 40 Wake Forest L. Rev. (Spring, 2005). The one exception to this is a concept of juridical personhood which the State of Louisiana has conferred upon embryos. See, La Rev. Stat. Sections 9:121, 123.

after conception. We need not resolve the difficult question of when life begins. When those trained in the respective disciplines of medicine, philosophy, and theology are unable to arrive at any consensus, the judiciary...is not in a position to speculate as to the answer.¹⁸

Probably unbeknownst to most who have not read *Roe v. Wade* lately, the Court even considered the development of artificial wombs in declining to declare that a fetus had the status of being a “person.” The majority discussed the argument of ensoulment from conception, noting that new developments in embryology indicated that conception is a process, not an event, and presciently predicted that newer advances in “morning after pill,” “implantation of embryos,” “artificial insemination,” and “even artificial wombs,” would foreclose the Court from holding that a fetus is a person for purposes of the 14th Amendment including the due process clause and equal protection clauses thereof.¹⁹

Not only does the United States deny legal personhood to the fetus, but Canada, Australia, and the United Kingdom also deny that status to the fetus, although those same jurisdictions do confer some juridical status. For example, an unborn child (but thereafter born) may have inheritance rights, some rights to damages in motor vehicle collisions (again, after birth), and the killing of an unborn child coincident to the assault or murder of a pregnant woman may result in criminal charges.²⁰ Other than criminal law ramifications, the rights of the unborn appear to be inchoate and the juridical interest is not and cannot be perfected or acted upon until live birth.

¹⁸ *Ibid.* at 160.

¹⁹ *Roe*, *supra* note 5 at 157.

²⁰ See e.g. *Unborn Victims of Violence Act*, 18 U.S.C. 1841 (2004); See also Erin Lynne Nelson, *Reproductive Autonomy and the Regulation of Reproduction: Issues in Law and Policy* (dissertation for Doctor of Science of Law, Columbia University 2007) [unpublished].

(3) State's interest in promoting fetal life

The *Roe* court also started to articulate what will continue to be a huge issue in ectogenesis: the State's interest in potential life. One of the issues that will need further exploration as ectogenesis nears reality is what exactly is the State's interest in potential life. Surely governments have an interest in having new persons - healthy, functional, tax-paying productive citizens - capable of replacing its old, tired, worn-out natural persons to whom it has a moral and legal commitment to maintain. It is much less clear what might be the government's interest in embryos *qua* embryos or fetuses *qua* fetuses without any specific articulation of the presumed State interest therein.

Although the Court in *Roe v. Wade* rejected Texas' criminalizing all abortion except to save the life of the mother, it did acknowledge that the State has a "legitimate interest" in the "potentiality of human life" which "grows in substantiality as the woman approaches term" and, at "a" point in pregnancy becomes "compelling."²¹ The *Roe* court clearly left open the point at which the State's interest could become compelling and fixed that point at the end of the first trimester, given current medical practice in 1973, but acknowledged that the real issue was not the trimester framework but viability.^{22,23}

²¹ *Roe*, *supra* note 7 at 162-164.

²² *Ibid.* at 163.

²³ Although in Germany the Embryo Protection Act of 1990 provides that all implanted fetuses and embryos have a "right to life" and possess the same dignity that all persons have, abortion, while illegal, is not criminalized. The rhetoric of protection was belied by the reality of permitting abortions which conflicted with a woman's 'right of personalty.' Among other considerations in German law – important to ectogenesis – is the reality that "fetal defects" continue to be valid reasons to terminate a pregnancy. John A. Robertson, "Assisted Reproduction in Germany and the United States: An Essay in Comparative Law and Bioethics" (2004), online: Bepress Legal Series <http://law.bepress.com/expresso/eps/226/>.

*Planned Parenthood v. Casey*²⁴ is also an important U.S. case refining the State's interest in fetal life. *Casey* started a trend to acknowledge a "state's interest in life" – versus a federal interest – which would allow circumstances under which a woman's right to terminate a pregnancy could be restricted.²⁵ The *Casey* court abandoned the trimester framework but reaffirmed that 'viability' is the gravamen for an individual state's interest in fetal life.²⁶ Without much helpful analysis, the *Casey* court gave its imprimatur to the "State's profound interest in the unborn."²⁸ The *Casey* court also reaffirmed *Roe's* holding that, subsequent to viability, an individual state may prohibit abortion altogether except where necessary for the preservation of the life or health of the mother.³⁰

Abortion cases are not, of course, wholly apropos to considerations in ectogenesis because so much of it addresses a maternal/fetal conflict. However, the State's profound interest in the unborn – and the exact nature of that interest – is sure to become more problematic with ectogenesis. The failure of the justices in *Casey* to articulate more specifically the nature of the State's interest in the unborn troubled Justice Stevens.

Stevens perceived a contradiction between acknowledging a state's "legitimate interest in potential human life," and, at the same time, its conclusion that the interest did not justify regulation of abortion before viability.³¹ He foresaw that the State's interest would need to be more than mere rhetoric: "it is

²⁴ *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

²⁵ *Casey*, supra note 26 at 869.

²⁶ *Ibid.* at 871-874.

²⁸ *Ibid.* at 877-878.

³⁰ *Ibid.* at 878.

³¹ *Ibid.* at 914.

clear that, in order to be legitimate, the State's interest must be secular; consistent with the First Amendment, the State may not promote a theological or sectarian interest.³² Moreover, he iterated, "the State's interest in potential human life is not an interest *in loco parentis*, for the fetus is not a person."³³ Stevens had expressed this exact concern in *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 US 747 (1986) where he cautioned his brethren in that case:

Justice (Byron) White is surely wrong in suggesting that the governmental interest in protecting fetal life is equally compelling during the entire period from the moment of conception until the moment of birth ... I recognize that a powerful theological argument can be made for that position, but I believe that our jurisdiction is limited to the evaluation of secular state interests. I should think it obvious that the State's interest in the protection of an embryo – even if that interest is defined as protecting those who will be citizens – increases progressively and dramatically as the organism's capacity to feel pain, to experience pleasure, to survive, and to react to its surroundings increases day by day. ... For unless the religious view that a fetus is a 'person' is adopted, there is a fundamental and well-recognized difference between a fetus and human being...³⁴

The most recent U.S. Supreme Court case pertaining to abortion is the case of *Gonzales v. Carhart*.³⁵ Without any explication, the Supreme Court stated that the government "has a legitimate and substantial interest in preserving and promoting fetal life," claiming that this language was central to the holding in *Casey*.³⁶ *Gonzales v. Carhart* is important for ectogenesis because it focuses on the "viewability" of the fetus, which has already assumed the "recognizable

³² *Ibid.*

³³ *Ibid.*

³⁴ *Thornburgh v. American College of Obstetricians & Gynecologists*, 476 U.S. 747, 778-779 (1986).

³⁵ *Gonzales v. Carhart*, 2007 U.S. LEXIS 4338 at 38 (Lexis).550 U.S. ____ (2007); 75 U.S.LW. 4210

³⁶ *Ibid.*

human form,” which engenders an instinct to protect it, which is readily understandable from any perspective.³⁷

Thus, three things may be surmised from *Roe* and its progeny, including *Gonzales*, which will be important for ectogenesis: 1) Medical procedures upon the now highly viewable conceptus are sure to be exquisitely scrutinized;³⁸ 2) The United States is on a collision course with most of the rest of the world based upon its interest in “promoting and preserving fetal life” without regard to any consideration of fetal anomalies;³⁹ and 3) State regulation of the enterprise of having a child is appropriate.

(B) Severely impaired nonviable fetuses post ectogenesis: Wrongful Birth and Wrongful Life cases

Sadly, some infants are born with defects that develop during gestation and it is doubtful that ectogenesis will completely eliminate some of these problems. Some of these defects are very serious and mean a short and non-sentient life - such as anencephaly.⁴⁰ Other newborns suffer a variety of genetic

³⁷ “Today, a new field is using illusions to unmask a sixth sense, the moral sense. Moral intuitions are being drawn out of people in the lab, on Web sites and in brain scanners and are being explained with tools from game theory, neuroscience and evolutionary biology.” Using the classic runaway trolley example (where to save five persons, one must flip a switch which will kill one, or personally throw someone into the path of the runaway trolley), neuroscience shows that cross culturally, people will chose the first option. Although they are unable to explain the reason for this ‘moral decision making’, Pinker and cognitive neuroscientist Joshua Greene suggest that there is an ‘instinctive revulsion to manhandling an innocent person’ which can be demonstrated by three different areas of the brain which ‘light up’ on MRI imaging. However, when that person is ‘at a distance’ only one rational, cognitive part of the brain is implicated. Steven Pinker “The Moral Instinct” *The New York Times* (13 January 2008). See also Joshua Greene, *The Terrible, Horrible, No Good, Very Bad Truth about Morality and What to do about it* (Doctor of Philosophy, Princeton University, 2002) [unpublished].

³⁸ Sentience is the capacity to feel pleasure or pain. One may be sentient without being conscious, but one cannot be sentient without a nervous system or other sense organs indicative of perceptual ability. Mary Anne Warren, *Moral Status: Obligations to Persons and Other Living Things*, (New York: Oxford University Press, 1997) at 52-60.

³⁹ The Partial Birth Abortion Act does not provide for an exception for fetal anomalies.

⁴⁰ Anencephaly is a disorder that results from a neural tube defect that occurs when the cephalic

problems.⁴¹ Preimplantation genetic diagnosis would aid immensely in avoiding these problems, but still other birth defects are not genetic and manifest during the first three months of pregnancy. These include conjoined twins, missing limbs, failure of neural tube to close, etc. Predictably, there will be lawsuits by and on behalf of infants born with serious medical defects post-ectogenesis.

Wrongful birth actions are widely recognized, essentially as medical malpractice action by a parent against the medical provider, for the costs involved with caring for a child with disabilities.⁴² One of the interesting issues in wrongful birth cases – which is sure to continue into ectogenesis – is the causation factor, to wit, whether a “reasonable person” in the position of the plaintiff parent (had she not been negligently informed or negligently uninformed of possible birth defects) would have chosen to continue the pregnancy or terminate it.⁴³ The second issue widely discussed in wrongful birth cases is the measure of damages with most courts holding that the measure of damages is simply the additional cost of raising a disabled child.⁴⁴

England’s Congenital Disabilities (Civil Liability) Act,⁴⁵ read in conjunction with the HFEA, provides a window into the future of wrongful birth

(head) end of the neural tube fails to close, usually between the 23rd and 26th day of pregnancy, resulting in the absence of a major portion of the brain, skull, and scalp. “Anencephaly” *Wikipedia*, online: *Wikipedia* <<http://en.wikipedia.org/wiki/Anencephaly>>.

⁴¹ Common hereditary birth defects include Tay-Sachs Disease, Muscular Dystrophy, Sickle Cell Anemia, Fragile X Syndrome, and Down’ Syndrome. See “Hereditary Birth Defects” *Pregnancy info.net*, online: *Pregnancy info.net* <http://www.pregnancy-info.net/complications_hereditary.html>..

⁴² See Erin Lynne Nelson, *Reproductive Autonomy and the Regulation of Reproduction: Issues in Law and Policy* (Doctor of The Science of Law, Columbia University, 2007) [unpublished dissertation ProQuest] (Nelson II) at 49.

⁴³ See Nelson II, *ibid.* at 52.

⁴⁴ *Ibid.* at 51.

⁴⁵ *Congenital Disabilities (Civil Liability) Act 1976* (U.K.), 1976, Eliz. II, c. 28.

claims in regard to ectogenesis. Section 1A of England's Civil Liability Act provides that where a person fails to exercise due care in the course of the selection of the embryo, and a child is born with disabilities, "the child's disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child."^{46,47} As this cause of action starts to merge into the concept of "wrongful life" cases, it will be necessary to address the existential difficulties most courts have with wrongful life cases.

In comparison to wrongful birth cases, wrongful life cases are actions brought by the child itself, through a guardian *ad litem*, typically alleging a failure by physicians to inform the child's mother of a genetic or heritable defect thus giving the mother a chance to abort the defective fetus. A handful of courts have started to address the issue of the child's bringing a cause of action against the parent for "wrongful life," that is, for failing to abort it despite knowledge that it would be born with serious defects.⁴⁸ Because the essence of the Plaintiff's claim is that he or she should not have been born at all - hence wrongful "life" - these actions are disallowed in England and Canada as there is an assumption that some

⁴⁶ *Nelson*, *supra* note 37 at 46.

⁴⁷ On January 22, 2008, The Sydney Morning Herald reported that a couple is suing a Melbourne fertility clinic because pre-implantation genetic testing failed to pick up that their son was carrying an inherited cancer gene. They are seeking extraordinary medical expenses as well as "wrongful life" damages.

⁴⁸ See *Curlender v. Bio-Science Laboratories*, 106 Cal. App. 3d 811 (1988). In *Curlender*, the Court said, "we see no sound public policy which should protect those parents from being answerable for the pain, suffering and misery which they have wrought upon their offspring." (*ibid.* at 829).

life is better than no life at all and a recognition that such a claim “against life itself” is against public policy.⁴⁹

In the United States, California, Washington and New Jersey permit wrongful life claims whereas ten states have statutorily precluded such claims.⁵⁰ The states that do permit wrongful life actions have limited these claims to special damages not general damages. In other words, the guardian *ad litem* may recover on behalf of the child the damages relating to the extraordinary costs that the child will incur in having to live with a significant impairment, but the Courts have uniformly disallowed general damages for the pain and suffering of having a less-than-normal life.⁵¹ Author T. Brendan Kennedy asserts:

The greatest obstacle to recognizing a cause of action for wrongful life lies in the great weight accorded public policy ...The weight of public policy is perhaps most forceful in those jurisdictions rejecting wrongful life due to the impossibility of calculating damages; an inability often addressed in metaphysical terms. ...The essence of the wrongful life claim touches sacrosanct tenets of human existence embodied in the common law as the preciousness of human life....Yet, this policy also bears weakness. The notion that mere existence carries with it an indeterminate benefit is individually inspired. For there is no benefit when one cannot conceive, cannot process, cannot comprehend or cannot act to enjoy one's own existence.⁵²

Courts which presently refuse to countenance “wrongful life” claims incorrectly assume *sub silentio* that there is no extant medical intervention which

⁴⁹ See *McKay v. Essex Area Health Authority*, [1982] 2 W.L.R 890 (C.A.).

⁵⁰ See *Gleitman v. Cosgrove*, 227 A.2d 689 (N.J. 1967); *Becker v. Schwartz*, 386 N.E.2d 807 (N.Y. 1978), both of which disallowed wrongful life actions, and were widely followed in other US jurisdictions. Only three U.S. states permit recovery for wrongful life: California (*Turpin v. Sortini*, 643 P.2d 954 (Cal. 1982) (*Turpin*), which allowed special, but not general, damages for wrongful life); New Jersey (*Procanik v. Cillo*, 478 A.2d 755 (N.J. 1984), which followed *Turpin*); and Washington (*Harbeson v Parke-Davis Inc*, 656 P.2d 483 (Wash. 1983), which also followed *Turpin*).

⁵¹ See T. Brendan Kennedy, “Comment: The Cost of Living: Maryland’s Refusal to Recognize the Wrongful Life Cause of Action Short-Changes Plaintiffs” (2002) 32 U. Balt. L. Rev. 97.

⁵² *Ibid.*

could prevent or minimize the pre-existing genetic defects.⁵³ This is untrue. For ectogenesis, preimplantation genetic diagnosis, if required, may well eliminate some of the more obvious genetic impairments by eliminating embryos that contain those genetic impairments. However, a problem would still arise if the embryos are not required to be pre-screened, or are negligently prescreened and/or a fetus develops identifiable and serious defects while in ectogenesis regardless of prescreening. These issues will give rise to the same existential problems as they do now: The Repugnant Conclusion and the Non-Identity problem.

(C) Dealing with the Repugnant Conclusion and the Problem of Non-identity

Although Courts have been loathe to drop into the abyss of speculating that non-existence might be better than a life of suffering or severe handicap – and having the difficult task of calculating reasonable damages therefor – philosophers have willingly jumped into this vacuum. Derek Parfit is the one most often cited as the father of the non-identity problem which logically arrives at the philosophically interesting “Repugnant Conclusion.” In short, the non-identity problem postulates that if any human existence at all is better than non-existence, then there is nothing morally wrong with intentionally overpopulating the earth and depleting resources causing a worse existence for the next generation of humans *ad nauseum* – a conclusion that Parfit terms the “Repugnant Conclusion.”⁵⁵

Parfit arrived at the Repugnant Conclusion reluctantly and unhappily by

⁵³ See Deana Pollard, “Wrongful Analysis in Wrongful Life Jurisprudence” (2004) 55 Ala. L. Rev. 327.

⁵⁵ Derek Parfit, *Reasons and Persons* (New York: Oxford University Press, 1984) at 388.

attempting to identify a moral theory of how we ought to act in cases where our decisions have an impact upon those who will exist in the future. In so doing, he considered two medical scenarios where healthy children will be born, but, by virtue of a medical test, one whole set of certain children will never exist because a medical test will be used to inform the mother-they-will-never-have not to conceive in a particular month because of a condition that would result in that specific child being handicapped.⁵⁶ Thus, the egg of the month that would have been one gamete contributor will never meet the other gamete contributor's sperm and that child will not exist. Thus, the issue of non-identity brings up the moral problem of whether some existence is better than no existence even if handicapped, and if the answer to that query is in the affirmative, thus arises the related Repugnant Conclusion that, morally, some life is better than no life even if it means a very low quality of life for everyone.⁵⁷

Melinda A. Roberts and others have tackled the Repugnant Conclusion and non-identity problem. These existential issues directly impinge upon wrongful life suits, assisted reproductive technologies, and the Courts' general unwillingness to discuss the issue of non-life. Roberts argues that Courts' refusals to tackle this issue of intolerable life head-on intimates that it is perfectly reasonable to negligently cause an individual to be handicapped based on a "no harm done" theory of non-identity.⁵⁸

⁵⁶ *Ibid.*

⁵⁷ *Parfit, supra* note 61 at 367.

⁵⁸ Most courts, however, have rejected claims for wrongful life on the grounds that, as a matter of law, it cannot be established that the child has been harmed or has suffered damages. After all, the

The "no harm done" wrongful life model may not even be applicable to all instances of wrongful life. Where the child who is negligently brought into existence foreseeably experiences so much pain and misery and so little of whatever it is that we think makes life worth living, it is plausible to say that the child would have been better off never having been born at all and thus is harmed when he or she is brought into existence.⁵⁹

As an example, Roberts talks about a real instance involving octuplets born to a couple (the Chukwus) in Houston, Texas. The Chukwu octuplet tragedy illustrates the defects in the non-identity argument. Fertility drugs were used with consent of both parents without any effort to avoid a "supernumerary" pregnancy. One octuplet died and the remaining seven were so impaired at birth that it was clear that they would all suffer serious life-long physical, emotional and intellectual impairments.⁶⁰ Roberts argues that without the high doses of fertility drugs, none of the octuplets would have existed at all. She argues that the factual question of actual harm must turn on whether the agents involved (i.e. the doctors and parents) physically could have done more to avoid harm.

She aptly points out that lower doses of fertility drugs might have been given, fewer embryos could have been transferred, and selective reduction of fetal life could have taken place.⁶¹ Opting not to bring octuplets 4-8 into existence would have been a better outcome for octuplets 1-3. "The fact that creating a

child's flawed existence is the child's only alternative to never having been born at all; and courts are reluctant to admit the possibility that in egregious cases nonexistence is better for the child than a flawed existence. Since the only way to avoid the genetic or chromosomal abnormality is to produce some distinct child, "nonidentical" to the original, or no child at all, the wrongful life model in effect presents us with a first version of the nonidentity problem. Melinda A. Roberts, "Can it Ever Be Better Never to Have Existed At All? Person-based Consequentialism and a New Repugnant Conclusion" (2003) 20:2 *Journal of Applied Philosophy* 159. [Roberts I].

⁵⁹ *Ibid.* at 160.

⁶⁰ Melinda A. Roberts, "Supernumerary Pregnancies, the Harm Issues and the Limits of Constitutional Privacy" (2005) 32 *Journal of Philosophical Research* 105. [Roberts II].

⁶¹ Roberts II, *ibid.* at 111.

better outcome for some of the octuplets – any arbitrary group of three – requires never existing at all for the other five does not let the agents off the hook for declining to create a better outcome for the three.”⁶² Roberts submits that the Chukwu facts suggest that the non-identity no-harm concept must be corrected and that some reproductive choices impose harm on offspring that are morally and legally significant.⁶³ Thus, she concludes, a properly formulated non-identity analysis must be viewed on a technology-by-technology basis; those that cause harm may mandate that the state prohibit certain otherwise autonomous or religious choices. She further suggests that the usual tort law principles governing medical malpractice certainly can and should apply to wrongful life cases.⁶⁴

One solution to the “wrongful life” problem is to impose strict liability upon providers “who disseminate avoidably inaccurate genetic information.” Inasmuch as strict liability entails liability without fault, the benefits of this approach would be to reduce the child’s burden of proving that his life is an injury and would “prevent courts from tripping over the metaphysical paradox.”⁶⁵ On the other hand, this still leaves open an interesting problem especially in ectogenesis - parental liability and responsibility to their offspring for negligently causing a wrongful life.

To date, there have been only a handful of wrongful life lawsuits against a parent, but if embryos and fetuses are successfully declared to be legal persons, these suits are sure to ensue and increase. This then gives rise to the next

⁶² *Ibid.* at 112.

⁶³ *Ibid.* at 113.

⁶⁴ *Ibid.*

⁶⁵ See Thomas A. Burns, “Note: When Life Is an Injury: An Economic Approach to Wrongful Life Lawsuits” (2003) 52 Duke L.J. 807 at 819.

foreseeable issue: whether in ectogenesis there can or should be limits upon the right of reproductive autonomy. Surely if an embryo or fetus is a legal person, reproductive autonomy clashes with an arguable right to be born healthy.

Chapter Five: Rethinking reproductive autonomy in ectogenesis

Ectogenesis will surely force us to re-examine our beliefs about our right to bring new lives into being without restrictions. One author, Carter J. Dillard, has undertaken an extensive review of that right, insisting that it is important to understand what the procreative right consists of in the first place by differentiating a ‘legal procreative right’ from a ‘moral procreative right’ based upon its intrinsic value(s) and relationships to other rights. His article, in main, disputes “the illusion of procreation as a private act.”¹ This Chapter explores these imminent challenges to our beliefs by examining the way prominent thinkers have analyzed similar scenarios, both philosophically and judicially.

(A) The illusion of reproductive autonomy in ectogenesis

In the United States, the right to procreate has been said to be grounded in privacy considerations.² Other places the right to procreate is said to be grounded is in substantive due process,³ the equal protection clause of the Fourteenth Amendment, or in some sort of “umbrella-like fundamental right.”⁴ Dillard submits that virtually all abortion and conception cases discuss reproductive freedoms but not the right to procreate *per se*, noting that it is important to realize that the act of creating an entity distinct from its procreator - which is a *sui generis* activity - is unlike the exercise of any other fundamental right. “Unlike

¹ Carter J. Dillard, “Rethinking the Procreative Right” (2007), 10 Yale Human Rts. & Dev. L.J. 1 at 6 [Dillard].

² See *Griswold v. Connecticut*, 381 U.S. 479 (1965). But, *Griswold*, a contraception case, involved the right to avoid procreation, not the right to procreate. This is also true of the case of *Eisenstadt v. Baird*, holding that a state law that prohibited distribution of contraceptives to unmarried couples was a violation of the equal protection law. See *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

³ See *Carey v. Population Services International*, 431 U.S. 678 (1977).

⁴ Laura Shanner, “The Right to Procreate: When Rights Claims have Gone Wrong” (1995) 40 McGill L.J. 823 at 826.

the decision to prevent it, the decision to accomplish procreation substantially affects the prospective child and the society in which it is born.”⁵ Commentators in the United States cite *Skinner v. Oklahoma* as the primary case in which procreation was deemed a fundamental right, but this is in fact a misreading of the case.⁶ In *Skinner*, the United States Supreme Court held unconstitutional a state scheme, which provided for forced sterilization of convicts with three or more felonies involving moral turpitude.⁷ The Court struck down the statute as a violation of the equal protection clause – and did not cite the 8th Amendment involving cruel and unusual punishment - because the alleged morally turpitudinous acts and those deemed non-morally turpitudinous were arbitrary. The expansive language about procreation being a fundamental right was *dicta*. The *Skinner* Court discussed and did not overrule *Buck v. Bell*⁸, a mandatory sterilization case in which Justice Holmes notoriously stated, “three generations of imbeciles are enough.”⁹

Dillard’s main premise is as follows: “Because procreation is inherently interpersonal, and without limitation becomes injurious to others, it involves limiting duties and thus countervailing state interests. It does not fit into a framework based on privacy and autonomy....”¹⁰ He points out that state courts have been willing to curtail procreative liberty. In 1998, the Oregon Court of Appeals determined that there was no violation of a right to procreate when a

⁵ Dillard, *supra*, note 1 at 9.

⁶ *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

⁷ *Ibid.*

⁸ *Buck v. Bell*, 274 U.S. 200 (1927).

⁹ *Ibid.* at 208.

¹⁰ Dillard, *supra* note 1 at 20.

lower court required a defendant, as a condition of probation, to participate in a drug and anger management program before having any more children. The defendant had abused his infant daughter and had broken her leg.¹¹ In *State v. Oakley*, the Supreme Court of Wisconsin concluded that a defendant who had victimized his nine children was properly precluded by a parole condition from having more children until he could show the means to support them.¹²

Dillard also reviews international sources that may be cited on the ‘right to procreate.’ The International Covenant on Civil and Political Rights¹³, the International Covenant on Economic, Social and Cultural Rights,¹⁴ and the Universal Declaration of Human Rights,¹⁵ which together comprise the International Bill of Rights.

All of these documents recognize a ‘right to found a family,’ a right which Dillard contends is the same basic right as that pronounced by John Locke.¹⁶ He analyzes this right, however, and argues that Locke’s concept of a ‘right to found a family’ is limited to a right to live together, copulate, and attempt to procreate.¹⁷ This ‘right,’ claims Dillard, is inflated by commentators who move from this fundamental right to an assumption that all people are entitled to an “unfettered procreative choice,” thus leading to angry and hot criticism of the People’s Republic of China (which allows only one child per family) as an incursion upon

¹¹ *State v. Kline*, 963 P.2d 697 (Or. Ct. App. 1998).

¹² *State v. Oakley*, 629 N.W.2d 200 (Wis. 2001).

¹³ Dec. 19, 1966, S. Exec. Doc. E, 95-2 (1978), 1999 U.N.T.S. 171.

¹⁴ Dec. 16, 1966, S. Exec. Doc. D, 95-2 (1978), 993 U.N.T.S. 3.

¹⁵ G.A. Res.217 A (III), U.N. Doc. A/810 (Dec. 10, 1948), online:
<http://www.un.org/Overview/rights.html>.

¹⁶ Dillard, *supra* note 1 at 28.

¹⁷ *Ibid.* at 28.

the 'right to found a family.'¹⁸ Dillard disagrees with these commentators, and contends that there are competing rights and correlative duties that go along with procreation.¹⁹

The Convention on the Rights of the Child²⁰ creates enormous State obligations: "The states are the final obligors and must ensure development, expression, an environment that is in the best interests of the child including state custody when necessary, special assistance for disabled children, health care, pre and post natal health care for mothers, social security, an adequate standard of living, education and protection from exploitation."²¹ Obviously, these rights compete with an unfettered 'procreative right.'²²

Dillard reviews several checks upon the 'procreative rights' with incentive and disincentive programs in Indonesia, Vietnam and Bangladesh.²³ China sees no conflict between its one child per family planning policy and a broad procreative right.²⁴ It has been forced, perhaps ahead of the rest of the world, to contemplate the notions of competing rights and the obligations to protect children and society as a whole from unjustified and destructive behavior.²⁵

¹⁸ *Ibid.* at 29.

¹⁹ *Ibid.*

²⁰ *Convention on the Rights of the Child*, GA Res. 25(XLIV), UN GAOR, 44th Sess., Supp. No. 49, UN Doc. A/44/25 (1989).

²¹ Dillard, *supra* note 1 at 30.

²² *Ibid.*

²³ *Ibid.* at 35.

²⁴ See *Ibid.* at 36. Same issues as its inability to grasp the concept of an embryo as a person with rights against the family..

²⁵ See 1991 White Paper of 1991, Information Office of the State Council of The PRC, Human Rights in China. Online: <http://english.people.cn/whitepaper/4.html>. "China has only two alternatives in handling its population problem: to implement the family planning policy or to allow blind growth in births...Which of the two pays more attention to human rights and is more humane?" Dillard, *supra* note 1 at 3.

(B) Rights and Procreation

Dillard returns to John Locke and his Two Treatises of Government²⁶ inasmuch as Locke's model of 'rights' provides the foundation for today's domestic and international conceptions of fundamental 'rights' and the oft-cited proposition that procreation is "one of the basic civil rights of man."²⁷ In the Second Treatise of Government, Locke's concern is not procreation *per se*, but a continuation of the Species.²⁸ Locke places man in a state of nature and identifies natural, negative rights to life, health, liberty and property based in reason or the 'law of nature' that furthers the peace and preservation of mankind.²⁹ According to A. John Simmons, a leading scholar on the Lockean Theory of Rights,³⁰ 'rights' correlate to 'duties' to protect ourselves and others and to the 'duties' of non-interference others owe us in some act.³¹

According to Lockean theory, parents are by the law of nature under an obligation to preserve, nourish and educate children for their own good, and the power that the parents have over their children arises from that duty.³² A parent who procreates at maximum possible biological capacity, and then fails to observe the 'duties' prescribed by Locke, compels the State or others to use resources to

²⁶ *Ibid.* at 37.

²⁷ *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942) cited in *Dillard*, *supra* note 1, at 37.

²⁸ John Locke, *The Second Treatise on Government* (1690), cited in *Dillard*, *supra* note 1 at 38.

²⁹ John Locke, *The Second Treatise on Government* (1690), cited in *Dillard*, *supra* note 1 at 39.

³⁰ A. John Simmons, *The Lockean Theory of Rights* 6 (Princeton: Princeton University Press 1994).

³¹ *Ibid.* at 68-79.

³² John Locke, *The Second Treatise on Government* (1690) ¶¶ 56, 58, cited in *Dillard*, *supra* note 1 at 40.

provide for their progeny's care, thereby impinging upon the property rights and liberty of others.³³

Although Dillard's article is specifically concerned with population ethics, his thoughtful article is applicable to concerns that need to be addressed now given the expansion of assisted reproductive technologies. "Despite common rhetoric, procreation is not protected by privacy or autonomy interests because it is not a personal and private act. Indeed, it is difficult to think of something less personal than creating another person. It is the antithesis of the personal, changing and creating essential legal relations, perhaps more than any other act, most certainly for the person or persons created."³⁴ As such, he contends that "not procreating is personal; procreating is interpersonal."³⁵

Recent frozen embryo cases are illustrative of the fact that the State is beginning to acknowledge that procreating is interpersonal and that State controls can and should be implemented. The most important frozen embryo case was decided within days of *Gonzales v. Carhart*.³⁶ Unlike the *Gonzales* court, which finds some sort of metaphysical need for the state to promote fetal life *qua* fetal life,³⁷ the European Court of Human Rights found that the structure of the HFEA, which unequivocally terminates fetal life in frozen embryo disputes, was dispositive in the case before it.³⁸ Once again, England is in the forefront of contemplating and regulating conflicts in assisted reproductive technologies.

³³ See Dillard, *supra* note 1 at 41.

³⁴ *Ibid.* at 50.

³⁵ *Ibid.* at 51.

³⁶ See *Gonzales v. Carhart et al.*, 2007 U.S. Lexis 4338 (2007), slip. Op. 500 U.S. ____ (2007), 75 U.S.L.W. 4210.

³⁷ *Ibid.*

³⁸ *Evans v. United Kingdom*, *supra* at note _52_.

(C) *Evans v. United Kingdom*

The facts in *Evans v. United Kingdom*.³⁹ are compelling and if ever a “right to procreate” could be argued more forcefully, it would be hard to imagine it. On July 12, 2000, Natalie Evans and Mr. Johnson, her long-term partner, commenced fertility treatments. On October 10, 2000, she was told that she had tumors in both ovaries and the ovaries would have to be removed. She was also told that eggs could be extracted for IVF but that this would have to be done quickly.⁴⁰ The lower court found that Mr. Johnson reassured her that they were not going to split up, that she did not need to consider the freezing of her eggs, that she should not be ‘negative,’ and that he wanted to be the father of her child. This all occurred in a one hour period on October 10. Ms. Evans signed the HFEA mandatory consent form that provided that either party could withdraw consent prior to the time they were implanted per the licensing and storage provisions of the HFEA. Six embryos were created and consigned to storage.

Within a month, Ms. Evans’ ovaries were removed and she was told to wait two years before attempting implantation because the tumors were malignant. Within that two year period, the couple broke up and Johnson demanded the destruction of the embryos. Ms. Evans wanted them implanted because she had no other way to have a genetic child. There issues were several fold and attacked the 1990 HFEA. Specifically, Ms. Evans argued that the HFEA

³⁹ *Evans v. Amicus Healthcare Ltd. et. al.; Hadley v. Midland Fertility Services Ltd. et. al.* [2003] EWHC 2161 (Fam) [*Evans*] was the initial name, the final court to pronounce on this case was the Grand Chamber of the European Court of Human Rights and the case name by then was *Evans v. United Kingdom*.

⁴⁰ Egg freezing was not mentioned, nor is it as yet a successful strategy to preserve viable eggs, unlike the freezing of sperm which is uncomplicated. See discussion at: <http://www.scienceblog.com/community/older/2001/B/200111960.html>

structure for the destruction of embryos was incompatible with the Human Rights Act of 1998⁴¹ to the effect that section 12 thereof (licensing requirements for IVF clinics) and Schedule 3 thereof (consent by partner required) breached her rights under Articles 2, 8, and 14 of the Convention for the Protection of Human Rights and Fundamental Freedoms⁴², as Amended by Protocol No. 11. Article 2 provides for a ‘right to life.’ Article 8 provides for respect for private and family life with no interference by a public authority. Article 14 prohibits discrimination on the basis of sex.

The original case was encaptioned *Evans v. Amicus Healthcare Ltd. and others*.⁴³ In that case Justice Wall issued detailed findings of fact, which were adopted in their entirety without comment by subsequent courts. Justice Wall found, among other things, that estoppel was inconsistent with and excluded by the policy considerations of the HFEA.⁴⁴ He also found that Johnson could not have given unequivocal consent to the use of the embryos even had he wanted to do so as unequivocal consent would violate public policy.⁴⁵ He found that the foundation for the 1990 HFEA was based upon the “twin pillars of consent” and “the interests of the unborn child.”⁴⁶ One of the significant interests of the “unborn child” is that it will have two parents.⁴⁷ He found that an embryo is not a

⁴¹ *Human Rights Act 1998* (U.K.), 1998, c.42.

⁴² *Convention for the Protection of Human Rights and Fundamental Freedoms*, 4 November 1950, 213 U.N.T.S. 221 at 223, Eur. T.S. 5.

⁴³ *Evans v. Amicus Healthcare Ltd.*, [2003] EWHC 2161 (Fam). This was appealed to the Court of Appeal, [2004] EWCA Civ. 727 and then to the Queen’s Bench Division [2005] EWHC 1092 (QB). At the Queen’s Bench level, the case was encaptioned *Human Fertilisation and Embryology Authority v. Amicus Healthcare Ltd. and others*.

⁴⁴ *Evans*, *supra* note 42 *Ibid.* at ¶ 280 of Justice Wall’s opinion

⁴⁵ *Evans*, *supra* note 42 at ¶ 37 of the opinion .

⁴⁶ *Ibid.* at ¶ 280 of Justice Wall’s opinion.

⁴⁷ *Ibid.*

person and did not itself have any 'right to life' pursuant to Article 2.⁴⁸ He found that the legislative scheme treated men and women equally in that either could withdraw their consent to implantation; thus, there was no violation of Article 14.⁴⁹ Justice Wall found no property rights of Ms. Evans to 'her' embryo: "The law must strive to avoid sex discrimination...if this embryo is seen as her embryo, then she would have sole power to determine its future and that would be a very serious form of sex discrimination."⁵⁰

The Court of Appeal found that the 1990 HFEA did indeed interfere with the private lives of the parties but that it is "justified and proportionate."⁵¹ It found that the purpose of the 1990 Act was to promote the welfare of the child, including its need for a father. The Court went further to say that a fetus, prior to the moment of birth, does not have independent rights or interests, and that Ms. Evans' case was not about a 'right to life' but about an alleged 'right to bring life into being.' A concurring opinion by Lady Arden noted that the policy of the 1990 HFEA is that children should not be brought into the world simply to satisfy the wishes of their genetic parents or other human beings.⁵² A third Court, the European Court of Human Rights, Strasbourg, March 7, 2006⁵³ elaborated that it is not contrary for a State to adopt legislation governing important aspects of private life which also does not permit the weighing of competing interests as Ms. Evans was urging.⁵⁴

⁴⁸ *Ibid.* at ¶ 178.

⁴⁹ *Ibid.*

⁵⁰ *Ibid.* at ¶ 43

⁵¹ [2004] EWCA Civ. 727.

⁵² *Ibid.*

⁵³ Case of Evans v. The United Kingdom (Application no. 6339/05).

⁵⁴ *Evans v. The United Kingdom* [GC], no. 6339/05 [2006] (E.C.H.R.)

The final decision in the *Evans* case, by now called *Evans v. United Kingdom*, issued from the Grand Chamber of the European Court of Human Rights of Strasbourg on April 10, 2007.⁵⁵ It reviewed the conflicting ways various countries handle frozen embryo disputes. The majority of cases it reviewed were from the United States. In *Davis v. Davis*, the Tennessee Supreme Court attempted a balancing test, viewing the relative interests of the parties in using or not using the embryos.⁵⁶ On this analysis, Ms. Evans would clearly have the more compelling interests to have one or more of the embryos implanted given her inability to bear genetic children of her own in any other way.

In *Kass v. Kass*, the couple had entered into a contractual agreement that in the event of a dispute over the frozen embryos, they would be used for research.⁵⁷ When Ms. Kass wanted to overturn this agreement and have the embryos implanted, the New York Court of Appeals decided that the contractual agreement was clear and should be honored. In *AZ v. BZ*, there was a previous written agreement that in the event of a separation, the frozen embryos would be given to the wife.⁵⁸ The Supreme Court of Massachusetts invalidated this agreement, finding that “forced procreation is not an area amenable to judicial enforcement.”⁵⁹

In *JB v. MB*, the wife sought destruction of the embryos while the husband wanted to donate them or preserve them for use with a future partner.⁶⁰ Inasmuch as the father was not infertile and could, presumably, still have his own genetic

⁵⁵ *Evans v. The United Kingdom* [GC], no. 6339/05, [2007] (E.C.H.R., unreported).

⁵⁶ *Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1992).

⁵⁷ *Kass v. Kass*, 98 N.Y. Int. 0049 (1998).

⁵⁸ *AZ v. BZ*, 431 Mass. 150; 725 N.E.2d 1051 (2000).

⁵⁹ *Ibid.*

⁶⁰ *J.B. v. M.B.*, 2001 WL 909294.

child with a new partner, the Court held that forced procreation would be against public policy. In *Litowitz v. Litowitz*, the embryos had been created with donor eggs and the husband's sperm.⁶¹ The woman – who had undergone a hysterectomy but also had prior children – wanted the embryos implanted in a surrogate. The Washington Supreme Court adopted a contractual analysis and honored the couple's agreement with the clinic not to store the embryos for more than five years.

In *Nachmani v. Nachmani*, a very split court awarded the embryos to the woman because she had no other way to have a genetic child.⁶² However, a strong dissent disfavored this approach, emphasizing the 'right not to procreate.' After reviewing these major frozen embryo cases, the Grand Chamber of the European Court of Human Rights quickly dispensed with Ms. Evans Article 2 and Article 14 claims, reasoning that England had made it clear in its elaborate HFEA scheme that embryos do not have independent rights, cannot claim a 'right to life,' and that the scheme applied equally to men and women.⁶³

However the Grand Chamber of the ECHR took great pains to analyze her Article 8 claim. In analyzing her Article 8 Claim⁶⁴ the Court noted that, as in two other cases⁶⁵, strong policy considerations underlie the decision of the legislature to favour a clear or bright line rule which would serve to produce legal certainty

⁶¹ *Litowitz v. Litowitz*, 48 P.3d 261 (Wash. 2002).

⁶² *Nachmani v. Nachmani*, (50(4) PD 661 (Israel).

⁶³ Grand Chamber of the ECHR, *supra* note 55.

⁶⁴ "Everyone has the right to respect for his private and family life and there shall be no interference by a public authority with the exercise of this right except as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country...and for the protection of the rights and freedoms of others." *Convention for the Protection of Human Rights and Fundamental Freedoms*, 4 November 1950, 213 U.N.T.S. 221 at 223, Eur. T.S. 5, Art. 8.

⁶⁵ See *Pretty v. the United Kingdom*, ECHR 2002-III; *Odievre v. France*, ECHR 2003-III.

and to maintain public confidence in the law in a sensitive field.⁶⁶ In denying Ms. Evans' Article 8 claim, the Court made some interesting inroads upon the notion of reproductive autonomy, saying that "[i]t must be noted that the applicant does not complain that she is in any way prevented from becoming a mother in a social, legal or physical sense since she may adopt a child or give birth to a child created in vitro from donated gametes."⁶⁷ In discussing State involvement in her inability to use her own gametes, the Court noted there may be "positive obligations" inherent in an effective respect for private life. The issue thus becomes whether the legislative provisions under consideration strike a "fair balance between the competing public and private interests involved."⁶⁸

In concluding that the HFEA scheme did strike a fair balance, the ECHR noted that it is now technically possible to keep embryos frozen in storage indefinitely. As such, a state structure which dictates what will happen to those embryos if a couple dissolves their relationship, sometime between the creation of the embryos and the implantation of the embryos, is fair and reasonable. "The absolute nature of the rule serves to promote legal certainty and to avoid the problems of arbitrariness and inconsistency inherent in weighing, on a case by case basis, 'entirely incommensurable' interests."⁶⁹

These considerations have important ramifications for ectogenesis as a tentative and preliminary acknowledgement that a 'right to procreate' is not unlimited and does affect other persons, including the unborn. It is not so far-

⁶⁶ Grand Chamber of the ECHR, *supra* at note 55 at ¶ 60.

⁶⁷ *Ibid.* at ¶ 72.

⁶⁸ *Ibid.* at ¶ 76.

⁶⁹ *Ibid.* at ¶¶ 84, 89.

fetched to suggest that parents do not have the ‘right’ to create a child without a consideration of the impact upon the child, including its need for a father. Surely, it is not a great leap from there to suggest that parents do not have the ‘right’ to create a child – especially in ectogenesis where defects can be eliminated via PGD or can be visibly observed as they develop – without consideration of the impact upon the child and its need for good health.

In *Park v. Chessin*, a lower New York court boldly found that a child had the "fundamental right...to be born as a whole, functional human being."⁷⁰ Although this court’s ruling was never followed and is primarily of interest to those writing law review articles, it is foreseeable that ectogenesis will mandate that the right of that child to have qualities of good health will become paramount to the procreative interests of the genetic parents.

Dillard examines the myths that serve to bolster the notion that there is an unfettered ‘procreative right’ to create defective children. He points out that there are universal laws prohibiting consanguineous marriages which obviously are designed to avoid the genetic ill effects of inbreeding.⁷¹ “As a social policy matter, why would the state recognize interests of existing children, but not of prospective children? If we no longer presume the overriding interest or intrinsic value of the procreative right, we may grant that the State may seek to protect the competing interest before it has grown into an actuality.”⁷² The only retreat from this cogent argument is into the philosophical issue of non-identity of the specific

⁷⁰ *Park v. Chessin*, 46 N.Y.2d 401 (1978).

⁷¹ *Dillard, supra* note 1 at 52.

⁷² *Ibid.*

child.⁷³ We can expect to see growing case law in the wrongful life area which reflects a grudging judicial acknowledgement that wrongfully creating life can be actionable, not only against a negligent IVF provider, but against a negligent parent. The countries who address these issues prospectively, preferably collectively with world-wide standards, rather than reactively, really are the brave ones in this new world.

Post Script:

We've come a long way since Baby Louise. Continuing advancements in assisted reproductive technologies are occurring daily. While this thesis was in gestation, two major cases were decided: *Gonzales v. Carhart* and *Evans v. United Kingdom*.⁷⁴ In October 2007, researchers Yamanaka and Tomson separately announced that they could take skin cells and regress them to a pluripotent state.⁷⁵ This research was published – and was prematurely announced by major newspapers – as “ending the stem cell debate.” But a new moral problem was announced in the December 2007 issue of *New Scientist*: the induced pluripotent stem cells could be regressed to gametes of either sex from a single individual. And as this thesis is being put to bed, a news article appeared out of Australia where a couple is suing the providers of IVF for failing to identify a cancer gene in their child despite pre-implantation diagnosis and are suing for its wrongful life.⁷⁶

⁷³ See Elizabeth Harman whose “person-affecting” theory of harm to future persons provides compelling reasons to consider the interests of prospective children when procreating. Elizabeth Harman, “Can We Harm and Benefit in Creating” (2004) 18 *Phil. Persp.* 89.

⁷⁴ Chapter Two at note 46; Chapter Five at note 55.

⁷⁵ Chapter One at note 41.

⁷⁶ Chapter Four at note 47.

Conclusion and summary

It is vital to use a common language in embryology and assisted reproductive technology. The use of certain non-scientific language, such as conception and pre-embryo, should be discarded in favor of more accurate terminology. The United Kingdom has already crafted a beautifully detailed and accurate scheme in its Human Embryology and Fertilisation Act, with its 2007 proposed Amendments, which uses exactly correct scientific language. It dispenses with imprecise and politically inspired language. It also classifies even an ova in the process of fertilization as an 'embryo,' thus pushing back the date an embryo 'exists' legally to its earliest possible manifestation. This should be unassailable by any country, regardless of its religious or political persuasion. There can be no worldwide regulation of assisted reproductive technologies without a common language and the HFEA's exquisite and scientifically accurate detailed scheme is the only reasonable place to start.

Although ectogenesis does not exist, it seems logically certain that it will soon exist somewhere in the world as technological advances in this area seem to occur on an hourly basis. It is important to consider, in advance of this eventual technology, what arguments may be advanced in favor of and against ectogenesis. There are benign and compassionate reasons not to ban ectogenesis altogether. Any such outright ban is necessarily based upon a slippery slope argument which is intellectually dishonest and inaccurate. Instead, a compassionate understanding of the purposes for which the ectogenesis is sought should be paramount.

Religious and metaphysical views of conception, personhood, 'right to life,' soul, spirit, or life force, spiritually enhance and inform our own lives and

cultures in important ways. When they clash with a need to regulate overnight changes in embryology and assisted reproductive technologies, they unfortunately contribute to 'scientific tourism,' a result which is only growing more real as globalization advances. Attempting to use cast-in-iron theological beliefs from ancient days to regulate assisted reproduction is like insisting that those working on space research confine themselves to a set of working instructions which presumes that the sun revolves around the earth. This is dangerous and encourages reproductive pilgrimages to other countries where unscrupulous individuals may prey upon desperate people. It also results in rather horrific results and bad medicine as is evident in Italy. The United Kingdom solution - to bracket these views and to declare them unresolvable - is wise and the HFEA's rational, pragmatic scheme has worked well. Other countries, especially the United States, would be well advised to follow suit.

The same religious and metaphysical issues will surround ectogenesis when it finally does arrive and there are significant anomalies during fetal development. We can only borrow from abortion law to know what has been deemed historically significant in the ending of human life before it has been born. Certain patterns emerge: increasing respect for the fetus as it assumes human-like characteristics, respectful termination of fetal life for life-impairing fetal anomalies, and significant State protection when the fetus reaches viability. These concepts do not disappear with ectogenesis; it is foreseeable that the visibility of the developing human will oddly obfuscate the real human rights issue which, arguably and quite reasonably, is the 'right to be born healthy.'

Failure to consider this issue in advance will likely result in an increase in wrongful birth and wrongful life suits, a result no one would desire.

In order to begin to address the ending of life issues that will arise in ectogenesis, it is necessary to re-examine the underpinnings of reproductive autonomy and privacy. These very important tenets of most legal systems may have to be refined to identify what is more important – the health of the child to be introduced into the world versus the right of the parent to autonomous reproductive decision-making. By definition, a great deal of autonomy and privacy would be lost with the introduction of an advanced technology such as ectogenesis. States are involving themselves ever more deeply in the side-effects of assisted reproductive technology already, including the disposition of frozen embryos, and the assertion of State interests in pre-viable fetuses. We can anticipate that termination of fetal life issues in ectogenesis will be no less contentious than they are at present and that State involvement is sure to increase. Where and how that State interest is articulated is better reposed in highly specialized authorities and agencies, such as the HFEA, than on a case-by-case basis.

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The Hinxton Group

An International Consortium on Stem Cells, Ethics and Law

Consensus Statement

February 24, 2006

Stem cell and related research holds out immense promise for good. This research has the potential to dramatically increase our understanding of human biology from which may come new treatments for many serious diseases and injuries. The moral reason to conduct stem cell and nuclear reprogramming research thus comes from both the possibility of advancing knowledge and the values of relieving suffering and promoting human welfare. Furthermore, intra- and international scientific collaboration are vital to the success and advancement of science.

While we strive for consensus on a fundamental ethical framework for embryonic stem cell research, we acknowledge the reality of cultural diversity and moral disagreement about some elements of the research. Inconsistent and conflicting laws prevent some scientists from engaging in this research and hinder global collaboration. Societies have the authority to regulate science, and scientists have a responsibility to obey the law. However, policy makers should refrain from interfering with the freedom of citizens unless good and sufficient justification can be produced for so doing. As scientists, philosophers, bioethicists, lawyers, clinicians, journal editors and regulators involved in this field, we have reached consensus that if humankind is to have the very best chance of realizing the benefits of stem cell research in an ethically acceptable manner, the following principles should govern the ethical and legal regulation and oversight of embryonic stem cell and related research and its clinical applications. This is by no means a comprehensive list of principles, but rather a declaration of those discussed and agreed upon by our group:

1. Stem cell research should seek to minimize harm, and any risk of harm should be commensurate with expected overall benefit. Scientists and clinicians should conduct research according to ethically acceptable norms. For example, research should be conducted so as to protect the well-being, liberty and rights of cell and tissue donors as well as research participants. Research participants and donors of human materials must provide valid informed consent, and conflicts of interest should be appropriately addressed.
2. The law carries great power to facilitate or restrict scientific exploration in the area of human embryonic stem cell (hESC) research. Law makers should be circumspect when regulating science. When enacted, laws or regulations governing science nationally and internationally ought to be flexible, so as to accommodate rapid scientific advance.
3. Scientists and clinicians have a responsibility to obey the law. However, they also have the right to know through clear and explicit laws, what is and is not permitted with respect to their research, the jurisdiction of any prohibitions, and related penalties, so that they can regulate their behavior accordingly.
4. In countries with laws that restrict elements of hESC research but that do not expressly prohibit international collaborations, research institutions should neither discriminate against nor restrict the freedom of their investigators who want to travel to do work that is undertaken with scientific and ethical integrity.
5. Law makers should be similarly circumspect in restricting citizens' conduct extraterritorially with regard to stem cell research. So long as scientifically and ethically defensible hESC research is undertaken in a country in which it is legally permissible, scientists should be free to participate

in that research without fear of being liable to prosecution, restriction, or discrimination in another jurisdiction.

6. It is essential that scientists and policy makers consult each other and the public in the attempt to develop regulatory regimes for stem cell research that strike the best possible balance between free scientific inquiry and social values.

7. Journal editors should encourage authors to include in manuscripts explicit descriptions of their roles in the published research so as to clarify the appropriateness of their participation, in particular for researchers residing in countries with more restrictive laws and collaborating with researchers residing in countries with more permissive laws.

In addition, we reached consensus on the following forward-looking strategies to foster the scientific and ethical integrity of research in a global context:

8. Insofar as hESC lines are a precious resource and replication and scientific collaboration are vital to scientific advancement, we encourage scientists conducting stem cell research to submit any stem cell lines they derive to national or international depositories that subscribe to internationally accepted standards of quality and make cell lines and data (e.g. DNA fingerprinting and microsatellite data) publicly available.

9. Journal editors should support and promote high standards for scientific peer review. For studies generating new hESC lines described in manuscripts submitted for publication, we encourage journal editors to require that authors submit data verifying the authenticity of the hESC line(s), and an explanation of how the authors have complied with accepted standards of good cell culture practiceⁱ. We further urge journal editors to require that the source of the cells used in the research be clearly specified.

10. Journal editors should also support and promote high standards for ethical integrity in stem cell science. Journal editors should require a statement from scientists that their research conforms to local laws and policies, and that, where applicable, it has been approved by all appropriate oversight committees. Authors should provide statements of all conflicts of interest that affect their research. On request from editors, authors should provide protocols approved by ethics review committees, consent forms, information provided to potential human subjects and tissue donors, and other related documents or information that may bear on the ethics of the research.

11. For the purposes of oversight, regulations and applications to ethics review boards and funding agencies, etc., human materials donors in the context of hESC research ought to be treated as human research subjects.

12. We encourage the creation of a public database for the deposition of statements of ethical conduct and guidance, research protocols, consent forms, information provided to potential human subjects and tissue donors and other related documents that bear on the ethics of hESC research.

13. As the science evolves, academies of science and relevant professional organizations, in consultation with the public, should continue to develop guidelines for the ethical conduct of hESC research and clinical trials. Insofar as possible, these guidelines should be applicable to stem cell research internationally and should continue to address the challenges of international collaboration.

14. Funding bodies must take adequate steps to satisfy themselves that those they fund intend to carry out their research ethically and in accordance with relevant national regulations and appropriate international guidance as it emerges.

15. Research institutions and laboratories are encouraged to provide opportunities for scientists and trainees to engage in ethical discussion, review, and education.

While we believe we have accomplished much, we believe there is much work to be done. For example:

16. Insofar as donors of human materials are treated as human subjects, many of the ethical issues raised by hESC research can be adequately addressed through existing international codes of ethics and policy documents governing research involving human subjects. However, new ethical challenges in the conduct of stem cell research that are on the horizon cannot be adequately addressed by existing international ethical codes or practices. Examples are gametes derived from hESCs, and human-nonhuman chimeras. At least one national effort is currently underway to anticipate such challengesⁱⁱ. However, it is imperative that international efforts to address these new issues be initiated as soon as possible in order to ensure that science proceeds in an ethically acceptable fashion and to reduce the likelihood that diversity in international response will result in obstacles to ethical conduct similar to those raised by existing differences in national policies governing hESC research and nuclear transfer.

17. Steps should be taken to develop consensus in ethical standards and practices in hESC research for international collaboration to proceed with confidence and for research from anywhere in the world that adheres to these standards and practices to be accepted as valid and valuable by the scientific community and academic journals.

18. To achieve this goal, it will be necessary to specify what these standards and practices should be through the international efforts of scientists, philosophers, bioethicists, lawyers, clinicians, journal editors and regulators involved in this field, in collaboration and consultation with the public.

19. This process of identification of international ethical standards and practices should include concerted efforts to engage people throughout the world in honest and realistic conversations about the science and ethics of stem cell research and its emerging applications.

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Funded By:

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The Wellcome Trust

The British Embassy, Washington

The Juvenile Diabetes Research Foundation

The Phoebe R. Berman Bioethics Institute, The Johns Hopkins University

The consensus statement from the Hinxton Group is available at www.HinxtonGroup.org

ⁱ Coecke S, et al. Guidance on good cell culture practice: A report of the second ECVAM task force on good cell culture practice. *ATLA*: 2005; 33: 261-287.

ⁱⁱ The Human Fertilization and Embryology Authority (HFEA) is conducting at least one national effort to anticipate to these challenges.