DEFINING A NEW ETHICAL STANDARD FOR HUMAN *IN VITRO* EMBRYOS IN THE CONTEXT OF STEM CELL RESEARCH

This iBrief discusses some of the social, ethical and legal considerations surrounding the use of unimplanted, in vitro embryos in stem cell research. It proposes that a new ethical standard be elucidated for these embryos. The iBrief gives an overview of two proposals for such a standard at opposite ends of the spectrum: treating the in vitro embryo as a legal person versus treating it as mere property. It argues against both approaches. The former can have undesirable social implications including undue interference with female reproductive autonomy, while the latter would objectify potential human life and reproductive potential. The iBrief proposes an intermediate approach that treats the embryo as a special entity. It warns against a model whereby the respect accorded to embryos is made dependent on the attainment of various qualitative or developmental criteria. The complexities surrounding human life, it argues, are too uncertain. What is certain is the embryo's unique potential for human life, at any developmental stage. This, the iBrief proposes, should be the sole criterion for an embryo's special status, a status that should be confined within constitutional limits.

I. INTRODUCTION

Research on embryonic stem cells has generated passionate social debate. Many in the scientific community believe that stem cell-based therapies can one day treat many physical human ailments. The extraction of embryonic stem cells for research, however, involves the destruction of the human embryo. This has led to many debates about if and when this research can be ethically justified. Many countries are now struggling to establish principles to guide research in this sensitive field.

In developing these principles, it is important to elucidate a new ethical standard regarding the status of the human embryo. Previous judicial and legal debates have generated rules and principles that relate to unborn children. This is contextually different from the situation of laboratory-generated *in vitro* embryos that have an independent physical existence. Different views regarding the status of the embryo in this context range from regarding it as a person to regarding it as mere property. This paper examines these views and proposes an intermediate approach that treats the embryo as a special entity. This approach is meant to incorporate various considerations, including the medical benefits of stem cell research, the sanctity of potential human life, and the need to respect female reproductive autonomy.

II. DIFFERENT ETHICAL STANDARDS FOR DEFINING THE HUMAN EMBRYO

The embryo as a person

At one extreme of the spectrum of possible legal protections for the embryo lies the view that the embryo constitutes a legal person from the moment of conception. Proponents of this view rely on various scientific and philosophical explanations to reinforce their position. Scientifically, it is at conception that a biological entity is created with a genome distinct from that of either parent. That genome encodes all the genetic information necessary to create a new, unique, adult human individual. Conception is also what initiates the complex and mysterious series of biological events that characterize embryonic development and that culminate in the creation of a living, human individual.

It is both infeasible and inappropriate, the argument continues, for opponents of this view to try to gauge the different stages of embryonic development in terms of some order of importance. Instead, life is more appropriately viewed as a continuum that exists from conception until death. "At every stage, it is, and remains from beginning to end, the same life, by whatever name it may be described–whether a zygote, an embryo, a fetus, a baby, a child, an infant, a toddler, a teenager, an adult or a geriatric."[1] It would be morally unjustifiable to deny legal personhood to any of these stages or, indeed, to any category of human life. To do so is analogous to the historical denials of personhood to slaves and women, acts that are now accepted to have been both unacceptable and immoral.

As legal persons, it follows that human embryos ought not to be the subjects of scientific research that is aimed at benefiting anyone other than the embryos themselves. Just as it is immoral to experiment on adult human subjects for the advancement of medicine, so too is experimenting on embryos. It is true that most of the embryos that will be used in this research will likely come from the surplus that is created during fertility treatments and so are destined for destruction anyway. However, an imminent death does not create a license to subject one to lethal experimentation.[2] The organs of U.S. death-row inmates, for example, cannot be harvested without their consent.

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[1] Revised Factum of the Appellant Joseph Borowski in *Borowski* v. *Canada (Attorney General)* 33 C.C.C. (3d) 402 (1987).

[2] Scott Klusendorf, *Fetal Tissue and Embryo Stem Cell Research: The March of Dimes, NIH, and Alleged Moral Neutrality* (2000), *available at* http://www.str.org/free/bioethics/stemcell.pdf (last visited Nov. 24, 2002).

Some jurisdictions appear to be adopting a legal model that views the embryo as a person. In Louisiana, for example, laws have been passed declaring that non-implanted embryos are juridical persons that cannot be intentionally destroyed and that have full civil rights to sue or be sued.[3]

However, there can be a number of problems with such a legal model. Biologically, a young embryo can, at a very young age, split into two or more twins (a process known as "twinning"). This is possible because the stem cells it is comprised of at this age are extremely unspecialized, therefore having unlimited developmental potential. Is it sensible to argue, therefore, that every one of these early stem cells ought to be considered a person?

There are also numerous social implications to treating embryos as persons. Their termination or disposal, even for fertility treatments, would become tantamount to homicide. Moreover, it might be difficult to limit the application of legal personhood of the embryo to the *in vitro* context. Once this line is crossed, there may be pressure to treat all embryos according to the "best interests of the child" rule in all contexts.[4] This could have profound consequences for women's reproductive autonomy. It is therefore important to examine other legal models for application to *in vitro* embryos.

The embryo as property

At the opposite extreme is the view that the young *in vitro* embryo is a form of biological property. Such a position would include embryos within some or all of the bundle of property rights (e.g. alienability rights) that society already recognizes in certain biological products, including blood, hair, urine, semen, ova and certain tissues.[5] Essentially, this view holds that the embryo is little more than a collection of cells that can be freely donated for research or other purposes. In the prenatal context, such embryos (or fetuses) are seen as mere appendages of the mother, no different from any other body part. As such, prenatal remains need not be given any special treatment following therapeutic or elective abortions, for example, and can be discarded like any other surgical by-product.[6]

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[3] LA. REV. STAT. TIT. 9, §§ 123, 129 (West 2000). For the implications of such legislation, *see* Mona S. Amer, *Breaking the Mold: Human Embryo Cloning and its Implications for a Right to Individuality,* 43 U.C.L.A. L. REV. 1659 (1996).

[4] Judith D. Fischer, *Misappropriation of Human Eggs and Embryos and the Tort of Conversion: A Relational View*, 32 LOY. L.A. L. REV. 381 (1999).

[5] William Boulier, Note, *Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts*, 23 HOFSTRA L. REV. 693, 731 (1995).

[6] Steven Maynard-Moody, THE DILEMMA OF THE FETUS 83 (1995).

To view the *in vitro* embryo as property likely means that it will be the parents-donors of those gametes that gave rise to the embryo in whom the property rights will be vested. This gives rise to a host of complex legal issues, including which of the two parents can claim custody over the *in vitro* embryo, or the legal effect of any transfer of decisional authority over the embryo (e.g. upon donation). Such issues have been the topic of much litigation, particularly in the United States, and are largely beyond the scope of this paper.

What remain relevant, however, are the many social considerations that influence whether or not it is desirable to view the embryo as property. As mentioned earlier, there is concern that any step beyond the property model towards ascribing any rights to the embryo/fetus, in whatever context, will unduly interfere with female reproductive rights. Access to abortion could become strongly limited, pregnant women may become more restricted in the lifestyle choices they make and pregnancy might be transformed into a contest of competing rights.[7]

Those who maintain that it is legitimate to treat the embryo as property also dismiss the analogy that is frequently drawn between their position and slavery. They note that there is an important distinction between ownership rights in one's own body or products of one's own body and those in the body of another. Moreover, it could be argued that an absolute protection of the right of women to control their own bodies (in the same way that men can) actually helps affirm the value of personhood as a concept by providing people with the fullest personal autonomy.[8]

At the same time, critics of this view warn strongly against the dangers of treating any aspect of human life as property. Many argue, again, that there is a fine line between outright ownership of adult human beings (i.e. slavery), and granting property rights in any other form of human life, or even potential human life. The fact that gametes and embryos implicate very personal concerns, given their roles in human reproduction, should also make their commodification questionable.[9]

Moreover, the potential of embryos to develop into complete human beings distinguishes them fundamentally from other biological products in which property rights have already been ascribed. This is in addition to the fact that courts already show some hesitation in granting property interests in the human body.[10] Hence, many scholars believe that some alternative status

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[7] Martha Shaffer, *Foetal Rights and the Regulation of Abortion* 39 MCGILL L.J. 58 (1994).
[8] Fischer, *supra* note 4.
[9] *Id.*
[10] *See, e.g.*, Moore v. Regents of the University of California, 793 P.2d 479 (Cal. 1990), where the Supreme Court of California refused to find a common law conversion claim for the

is more appropriate for defining the *in vitro* embryo, one that lies between the two extremes of viewing the embryo as either a person, or as mere property.

The embryo as a special entity

An intermediate view would confer a type of legal protection that takes into account the embryo's unique and special quality of being a potential source of human life. Indeed, some courts in the U.S. have explicitly adopted such a position. In *Davis v. Davis*, a divorce case involving a custody battle over young frozen embryos, the Tennessee Supreme Court ruled that frozen embryos are neither persons nor property, "but occupy an interim category that entitles them to special respect because of their potential for human life." [11] Such special respect would be equally warranted in the context of stem cell research.

A possible way of defining the "interim category" that covers *in vitro* embryos is by employing the legal concept of "quasi-property." This concept is already in use. For example, it has helped in defining the rights of treatment over a corpse by the next-of-kin.[12] It has also been used by courts in some jurisdictions to help define a mother's rights over her stillborn fetus.[13] Applied to an *in vitro* embryo, such a concept may help establish a useful compromise: the property rights ascribed need not be so absolute as to constitute complete ownership over the embryo (and its potential for human life), but can be extensive enough to safeguard reproductive freedom concerns.

An important debate arising here is whether the proposed special status that is to be conferred upon the embryo should remain static from conception through further stages of embryonic development. Much of the popular literature in this field either assumes that it should not or recognizes the prevalence of this assumption.[14] The model frequently presented is one

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unauthorized use of Moore's cells, noting the lack of any precedent that held that a patient retains any ownership interest in his cells or genetic material after removal from the body.

[11] Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992).

[12] Fischer, *supra* note 4.

[13] *See, e.g.*, Jackson v. State, 430 S.E.2d 781 (Ga. Ct. App. 1993).

[14] *See, e.g.*, John A. Robertson, *Reproductive Technology and Reproductive Rights: In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437, 445-51 (1990); Heidi Forster, *Recent Development: The Legal and Ethical Debate Surrounding the Storage and Destruction of Frozen Human Embryos: A Reaction to the Mass Disposal in Britain and the Lack of Law in the United States* 76 WASH. U.L.Q. 759, 768-9 (1998); Parsi, *supra* note 8 at 705-16; *see also* Ronald M. Green, *Stopping Embryo Research* 9 HEALTH MATRIX 235, 246-7 (1999), where Mr. Green summarizes many of the arguments of the developmental approach to assessing the status of the embryo; *but see* Kelly Hollowell, *Cloning: Exposing Flaws in the Pre-embryo-Embryo Distinction and Redefining When Life Begins* 11 REGENT U.L. REV. 319, (1998) who argues against one such developmental distinction.

whereby greater protection is ascribed to the embryo as it develops and matures. This literature is also replete with discussions as to what criteria are to be used in determining those fundamental developmental stages that trigger entitlement to greater legal protection.[15] Some of these criteria are quantitative, based on physical changes including, *inter alia*, such major biological developments as differentiation, nervous system development and brain wave generation.[16] Others are qualitative, based on more subjective characteristics that are somewhat difficult to define, including sentience, consciousness and self-consciousness, self-motivated activity and the ability to reason.[17]

The idea of using such criteria is popular and may even appear to have a basis in logic. It seems reasonable, after all, that the more the fetus matures and resembles a fully developed human being, the more capable it is of becoming a subject of legal protection. This approach has also found judicial acceptance, most notably in *Roe* v. *Wade*,[18] the U.S. Supreme Court decision that partially legalized non-therapeutic abortions. Justice Blackmun in *Roe*, writing for the Court, identified *viability* to be the "compelling" point after which a state would be permitted to legislate in the interest of protecting fetal life, even to the extent of proscribing abortion altogether (except where necessary to protect the mother's health).[19] Viability can be defined as the point after which a fetus will be able to exist on its own. The Court noted that such legislation would have "both logical and biological justifications."[20]

However, an adoption of an "incrementalist" approach to determining an embryo's entitlement to state protection can be replete with difficulties. In terms of legal practice, it essentially means that the embryo would, with development, become less and less like property and more and more like a person. Stated as such, it seems that what is really being applied here is not a separate legal model for the embryo; rather, it is a blend of the two extreme positions described earlier, with all the social and legal difficulties they entailed. This may hardly be a satisfactory course to help in determining the embryo's legal status.

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[15] *Id.*
[16] *See e.g.*, Donald Hope, *The Hand as Emblem of Human Identity: A Solution to the Abortion Controversy Based on Science and Reason* 32 U. TOL. L. REV. 205 (2001), who argues the significance of factors marking the embryo-fetus divide, such as brain activity.
[17] *See e.g.*, Rachel E. Fishman, *Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?* 15 AM. J.L. & MED. 461 (1989), who includes among the qualitative criteria the ability to reason, the ability to evaluate principles and observations to arrive at reasoned decisions, the ability to formulate speech and communicate, and the demonstration of awareness of self as a unique and separate being.
[18] Roe v. Wade, 410 U.S. 113 (1973).
[19] *Id.* at 164.
[20] *Id.*

The proposed criteria to be used in such an analysis are also far from being reliable. For example, how can such qualitative characteristics as self-consciousness or reasoning be measured? What about cases of anaesthetized or comatose patients, who do not sense pain and lack self-awareness, but are still considered persons? Will it be possible to clearly define the limits of application for such criteria?

Other criteria are almost entirely dependent on technology. This includes the U.S. approach of determining viability, as put forth by the Court in *Roe*, *supra*. The point of viability is constantly being pushed back by technological developments such that if artificial wombs are ever created, an embryo may theoretically be able to survive *in vitro* from the moment of its conception. Clearly, many of the criteria proposed for measuring the embryo's moral worth are ill defined and devoid of certainty at least.

That which *is* certain is the embryo's potential for human life. That fact alone can serve as a sound basis for the embryo's proposed special status. To otherwise determine that status on the basis of vague, intangible criteria is problematic. It will essentially result in an exercise of defining *human life* according to those factors (given that it is the respect for human life that will have prompted society to seek a special status for the embryo). The problem is that such an exercise is, in all likelihood, beyond human capability. Put differently, it is inaccurate and perhaps even hubristic to suggest that the concept of *life* is, at least at present, within our realm of understanding. To try to compartmentalize it according to a hierarchical system that relies on qualitative criteria that are themselves vague and difficult to characterize is unhelpful.

Moreover, such a simplification can lead to undesired social consequences. It makes the value of human life dependent upon the possession of certain mental or physical qualities. This can have significant implications for those members of society who lack or have a diminished possession of those qualities. This would include, *inter alia*, the terminally ill, the mentally handicapped, and the elderly. The potential harm that may arise from these implications may be mitigated by the fact that such people are already recognized as legal persons. Still, any suggestion that their lives may be less worthy of protection than the lives of those with full possession of purportedly "life-defining" qualities is worrisome and repugnant to our society.[21]

There are also no clear ethical reasons why the absence of certain developmental criteria should make some embryos less morally relevant than others. After all, the value of the human entity can be said to be greater than the sum of its parts. That entity as a whole may mature to develop such properties as sentience or certain physical structures with time. However, its

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[21] Christine L. Feiler, Note, *Human Embryo Experimentation: Regulation and Relative Rights*, 66 FORDHAM L. REV. 2435 (1998).

intrinsic worth remains unchanged.[22] Thus, a better legal model for the *in vitro* embryo may be one that operates on the basic premise that the intrinsic value of potential human life is to be respected, and is deserving of legal protection. Such an approach would also avoid many of the pitfalls and social dangers outlined above.

A legal focus on protecting human life per se would mean, by extension, that such protection ought to be conferred upon any form that either embodies, or at least has the potential to embody human life. Included would be *in vitro* embryos, regardless of their age or any another developmental criteria. Of course, the extent of such protection would still need to be confined to within constitutional limits.

Challenging the embryo/pre-embryo distinction

One moral distinction that is frequently drawn is between embryos that are younger and older than fourteen days. Recall that this is the age marking the development of the primitive streak, along which the major tissues and organs of the body differentiate. The term *pre-embryo* is now commonly used to refer to the young, pre-fourteen day old embryo. Certain governments have sanctioned this embryo/pre-embryo distinction. In the United Kingdom, for example, the embryonic age of fourteen days has been set as the upper limit for which government funds for embryo research are available.[23] In Canada, some influential organizations and a Royal Commission have recommended that the federal government introduce legislation that does the same.[24]

In the United States, some courts have cited the pre-embryo/embryo distinction. In *Davis*, *supra*, for example, the Tennessee Supreme Court accepted the testimony of scientific experts who outlined the distinction: "…[A]t the [pre-embryo] stage, the developmental singleness of one person has not been established…The first cellular differentiation…relates to physiologic interaction with the mother, rather than to the establishment of the embryo itself. It is for this reason that it is appropriate to refer to the developing entity up to this point as a pre-embryo, rather than an embryo."[25] Indeed, it is

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[22] Klusendorf, *supra* note 2.
[23] *See* Human Fertilisation and Embryology Act, 1990, c. 37 (U.K.), which allows the creation of embryos for research for specified purposes up to the age of 14 days, and is administered by the Human Fertilisation and Embryology Authority.
[24] *See, e.g.*, Canadian Minister of Government Services, FINAL REPORT OF THE ROYAL COMMISSION ON NEW REPRODUCTIVE TECHNOLOGY: PROCEED WITH CARE 632 (1990).
[25] *Davis*, 842 S.W.2d at 594.

widely accepted in scientific circles that there is no possibility that *feeling*, *experience* or any of the other proposed criteria for evaluating the embryo's moral status could exist in the pre-embryo.

As was explained earlier, however, these criteria are relevant only insofar as such values as sentience or consciousness are considered to be of special moral significance. This consensus does not exist. It is also somewhat misleading to suggest that individuality takes hold only at the onset of differentiation. It is at conception, after all, when all the genetic information necessary to create a distinct human individual is attained. This genetic code remains fixed and unchanged throughout the development of the embryo. Also, the creation of twins, triplets, etc. at the *pre-embryo* stage can be characterized as little more than a resetting of the embryo's biological clock, such that it repeats cleavages that it had previously underwent.[26]

There are also practical difficulties associated with adopting the fourteen-day distinction. For example, a certain level of uncertainty is associated with attempts to establish the age of an embryo in days. Measurements are often inaccurate to within a few days.[27] This means that the fourteen-day measure is, at least at present, ambiguous and therefore an unreliable standard to assist in determining the embryo's legal status. Much safer, again, is an approach that protects an embryo simply because of its potential for human life. Such an approach would not discriminate between any *in vitro* embryos, all of which are endued with that same potential from the moment of their conception and are therefore entitled to some legal protection on that basis alone.

"Spare" versus "research" embryos

While some distinctions have been drawn between embryos based on different developmental criteria, another important distinction is based on the underlying purpose behind the creation of an embryo. Many hold the view that experimenting on embryos that have been created specifically for purposes of research is more morally problematic than research on embryos created for other, less objectionable purposes, including fertility treatments.

Fertility treatment procedures typically involve the creation of extra embryos to increase the chances of a successful pregnancy. The "surplus" embryos, if not used for other purposes, are typically discarded. However, the broader intention of such practices is the creation of a viable, healthy child. Hence, it has been argued that research on those "spare" embryos left over from fertility treatments is more morally acceptable than research on embryos that have been created with the prior intention of destroying them via research practices. To create embryos for research, the argument goes, would be to treat the embryo as a mere instrument in the quest for

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[26] Hollowell, *supra* note 14.
[27] *Id.* at 337.

knowledge. This would be inconsistent with the respect to which an embryo is entitled as a source of human life.

Many do not accept that even research on spare embryos is morally permissible.[28] They question the validity of the distinction between spare and research embryos. Both, after all, are equally capable of human life, and no difference exists in their moral status *qua* embryo, or in their ultimate fate. Thus, if research is not permissible for one, it should similarly be prohibited for the other. Such thinkers also feel that it is inaccurate to suggest that spare embryos will be discarded anyway, even if not experimented on. They note that these embryos can potentially be adopted and implanted into women who either desire pregnancy, or wish to act on the embryo's behalf.[29]

Others, however, maintain that it is simply deceptive to believe that the many thousands of embryos that are currently stored in a cryopreserved state will ever be implanted.[30] To bar potentially beneficial medical research from being conducted on them would, they argue, be an enormous waste. Indeed, the medical potential of embryonic stem cell research, with its potential to save lives, is seen by many as sufficient justification for research on not only spare embryos, but also embryos that are created specifically for research purposes.

Research embryos may also provide many additional research benefits compared to spare embryos. For example, the eggs and sperm selected to create them can be young and viable, as opposed to those embryos from fertility centers that tend to originate from older, infertile couples.[31] Certain aspects of stem cell research may also require the use of research embryos as a practical necessity. For example, some studies in cell maturation processes require the deliberate fertilization of eggs as part of the experimentation.[32]

In 2001, researchers at the Jones Institute for Reproductive Medicine at the Eastern Virginia Medical School became the first to create human embryos for the specific purpose of harvesting their stem cells.[33] Now that this line has been crossed, all that is left is for legislators to decide whether or not this practice should be legal on ethical and public policy grounds.

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[28] *See e.g.*, Ben Mitchell, *NIH, Stem Cells, and Moral Guilt* (August 2000), *available at* http://www.cbhd.org/resources/aps/cbmcomment7.htm (last visited Dec. 3, 2002).
[29] *Id.*
[30] Michael J. McDaniel, *Legal Perspectives on Cloning: Regulation of Human Cloning: Implications for Biotechnological Advancement*, 32 VAL. U.L. REV. 543, 553 (1998).
[31] Christy Oglesby, *Donors Give Eggs, Sperm for Stem Cells*, *at* http://www.cnn.com/2001/HEALTH/07/11/stem.cells/ (July 12, 2001).
[32] Feiler, *supra* note 21.
[33] Oglesby, *supra* note 31.

III. CONCLUSION

Embryonic stem cell research holds both the promise of medical benefits, and the dilemma of embryo research and destruction. Capitalizing on the benefits will require a clarification of the legal status of the embryo, and the adoption of clear ethical standards and guidelines for embryo research. One possible legal model is to treat the embryo as a person. This, however, can have significant implications for female reproductive autonomy. Adopting a legal model that treats the human embryo as mere property assuages such concerns. But this fails to accord the embryo any respect as a source of human life. An intermediate position would hold that the embryo is a special entity entitled to special respect.

Some argue that the measure of this respect should be varied depending on the attainment of certain biological characteristics or other abstract criteria of "personhood." Assessing such criteria, however, will be difficult and runs the risk of compartmentalizing certain aspects of human life in an overly simplistic fashion. To base this special status in the embryo's unique potential for human life appears to be a preferable approach. Given the important ethical, health and social issues that embryonic stem cell research implicates, it is essential that countries establish an effective policy with respect to this technology. Outlining a new legal standard for the human *in vitro* embryo would be one step toward achieving this.

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