USING EXCESS IVF BLASTOCYSTS FOR EMBRYONIC STEM CELL RESEARCH: DEVELOPING ETHICAL DOCTRINE, SECULAR AND RELIGIOUS

*Gerard Magill, Ph.D.**

I. INTRODUCTION

Ethics can be an uncomfortable field when faced with astounding breakthroughs in scientific research that could change the face of medicine. The sequencing of the human genome in the Human Genome Project that started in 1990 was effectively completed at the turn of this millennium.[1] Subsequent discoveries about many gene traits have substantively ensconced values discourse into the molecular landscape of the human condition. Closely related to the importance of gene discoveries was the achievement in 1998 of isolating and cultivating human embryonic stem cells ("hESCs").[2] The discovery of this technique occurred over twenty-five years ago in mice and over ten years ago in primates.[3] These marvels raise complex ethical dilemmas for scientists who seek to develop a multitude of treatments and therapies for a plethora of diseases and debilities. Many examples of the high hopes for hESC research could be provided, such as hESCs possibly soon becoming a resource of hematopoietic cells whose transplantation today provides the most likely pathway to cure many diseases.[4] This Article focuses upon a particularly complex debate around the ethical legitimacy of hESC research. The timeliness of this debate is manifested by the Executive Order of President Barack Obama on March 9, 2009 to permit federal funding for embryonic stem cell

* Vernon F. Gallagher Chair, Center for Healthcare Ethics, Duquesne University.

1. Eric S. Lander et al., Int'l Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE 860, 862-63 (2001); J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304, 1305-06 (2001).

2. *See* Michael J. Shamblott et al., *Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells*, 95 PROC. NAT'L ACAD. SCI. U.S.A. 13726, 13729-30 (1998); James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145, 1145 (1998).

3. Anthony C.F. Perry, *Progress in Human Somatic-Cell Nuclear Transfer*, 353 NEW ENG. J. MED. 87, 88 (2005).

4. *See* Edward A. Copelan, *Hematopoietic Stem-Cell Transplantation*, 354 NEW ENG. J. MED. 1813, 1820 (2006).

("ESC") research, revoking the prior Executive Order of President George W. Bush on August 9, 2001 that limited such funding.[5]

The focus of this analysis is to apply the ethical imagination to overcome a specific roadblock against a particular aspect of this research that significantly curtails scientific progress in this fast-moving field. The roadblock pertains to a conservative doctrine upheld by both secular and religious policy to prevent the use of excess embryos created by in vitro fertilization ("IVF") at fertility clinics.[6] There are approximately 400,000 excess IVF frozen embryos in the United States.[7] The problem presented by this roadblock is increased in light of the large number of fertility clinics, a number that has mushroomed over the years.[8] Excess IVF embryos in fertility clinics are a much desired source for hESC research.[9] This Article focuses upon using these unwanted and frozen embryos, often referred to as "excess embryos."[10] And the word "use" or "using" is not meant to convey a merely utilitarian calculation; rather, it is adopted to convey the meaning of "making available" conditional upon appropriate ethical justification. This specific discussion, including the moral status of the human embryo,[11] fits into a much larger debate on the ethics of embryo use.[12]

To comprehend the trajectory of this Article, it is helpful to grasp a threefold connection: how this doctrine arises from a traditional ethical

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5. Exec. Order No. 13,505, 74 Fed. Reg. 46 (Mar. 9, 2009).

6. *See, e.g.*, Susan Okie, *Stem-Cell Research—Signposts and Roadblocks*, 353 NEW ENG. J. MED. 1, 1, 5 (2005) (discussing President George W. Bush's veto of federal funding for expanded stem cell research); Michael J. Sandel, *Embryo Ethics—The Moral Logic of Stem Cell Research*, 351 NEW ENG. J. MED. 207, 207 (2004) (summarizing the debate against stem cell research and noting that some base their opposition to stem cell research on religious beliefs).

7. David I. Hoffman et al., *Cyropreserved Embryos in the United States and Their Availability for Research*, 79 FERTILITY & STERILITY 1063, 1066 (2003); Okie, *supra* note 6, at 3.

8. Franco Furger & Francis Fukuyama, *A Proposal for Modernizing the Regulation of Human Biotechnologies*, HASTINGS CTR. REP., July-Aug. 2007, at 16, 16.

9. *See* Okie, *supra* note 6, at 3.

10. *See, e.g.*, Ger P.A. Bongaerts & René S.V.M. Severijnen, *Stem Cells from Residual IVF-Embryos—Continuation of Life Justifies Isolation*, 69 MED. HYPOTHESES 478, 478 (2007) (describing the most common source of hESCs as "excess human embryos from IVF treatments"); Debora Spar, *The Business of Stem Cells*, 351 NEW ENG. J. MED. 211, 211 (2004) (using the term "excess embryos" in reference to the type of embryos permitted for use in stem cell research in Canada).

11. *See* Bonnie Steinbock, *Moral Status, Moral Value, and Human Embryos: Implications for Stem Cell Research*, *in* THE OXFORD HANDBOOK OF BIOETHICS 416, 417, 420-32 (Bonnie Steinbock ed., 2007) (describing various views of the moral status of an embryo based on biological humanity, personhood, possession of interest, and the view that an embryo has a "future-like-ours"). *See generally* Glenn C. Graber, *The Moral Status of Gametes and Embryos: Storage and Surrogacy*, *in* HEALTH CARE ETHICS: CRITICAL ISSUES FOR THE 21ST CENTURY 61 (Eileen E. Morrison ed., 2d ed. 2009) (discussing different theories behind affording moral status to reproductive materials).

12. *See generally* LOUIS M. GUENIN, THE MORALITY OF EMBRYO USE (2008) (thoroughly discussing the ESC debate, including arguments centered on the moral rights of an embryo).

principle and entails a prudential assumption. The analysis seeks to develop this doctrine in a cautious manner by acceding to the prudential assumption and engaging complementary traditional ethical principles. The conservative doctrine being considered here is the opposition to using spare IVF embryos for hESC research. The traditional ethical principle is respect for human life that upholds human dignity from the secular perspective of having personal status and from the religious perspective of having a soul.[13] And the difficulty of maintaining society's ethical integrity should not be underestimated given the pace of development in biotechnology today.[14] The prudential assumption here is that human life should be treated as personal—hence, being inviolable in secular terms—or as having a soul from its inception, with ensoulment being a religious connotation. That is, insofar as the presence of personal life or a soul cannot be demonstrated at an embryo's inception, that presence should be asserted out of maximum caution—as a prudential assumption. And it is important to note that the secular debate about defending the early cellular development of human life as personal is akin to the religious debate about recognizing the early cellular development of human life as having a soul. Hence, for the purpose of consistency, this Article engages the secular and religious debate by rhetorically referring to the personal soul.

However, dispute over this prudential assumption continues unabated in bioethics discourse.[15] In other words, applying this ethical principle and prudential assumption supports the conservative doctrine: To respect the embryo as a subject with a personal soul, as an end in itself, the embryo should not be treated merely as a means or as an object. Hence, the embryo should be protected from intentional killing or destruction,[16] even when pursuing noble goals in medical research.[17]

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13. *See* Adam Schulman, *Bioethics and the Question of Human Dignity*, *in* HUMAN DIGNITY AND BIOETHICS: ESSAYS COMMISSIONED BY THE PRESIDENT'S COUNCIL ON BIOETHICS 3, 6-15 (2008) (describing the concept of human dignity as arising from several different sources, including the Bible, philosophical theories, constitutions, and international declarations).

14. *See* MICHAEL HAUSKELLER, BIOTECHNOLOGY AND THE INTEGRITY OF LIFE: TAKING PUBLIC FEARS SERIOUSLY 19-27 (2007) (discussing the need to maintain ethical integrity and respect for life in the face of advances in the field of genetic engineering).

15. *See, e.g.*, CYNTHIA B. COHEN, RENEWING THE STUFF OF LIFE: STEM CELLS, ETHICS, AND PUBLIC POLICY 59-109 (2007) (describing the stem cell research debate from the secular and religious perspectives); David DeGrazia, *Must We Have Full Moral Status Throughout Our Existence? A Reply to Alfonso Gómez-Lobo*, 17 KENNEDY INST. ETHICS J. 297, 301-06 (2007) (exploring different rationales for affording a fetus moral status); Katrien Devolder & John Harris, *The Ambiguity of the Embryo: Ethical Inconsistency in the Human Embryonic Stem Cell Debate*, *in* STEM CELL RESEARCH: THE ETHICAL ISSUES 16, 26 (Lori Gruen et al. eds., 2007) (discussing the debate between those who believe embryos should be used for "morally important purposes" and those who feel embryos should be protected as human life).

16. *See* TED PETERS, THE STEM CELL DEBATE 29-38 (2007); Sandel, *supra* note 6, at 207.

The purpose of this Article is to explain how a cautious development of this doctrine can shift the outcome from opposing to supporting the use of excess IVF embryos for hESC research. The analysis develops the doctrine in a cautious manner by acceding to the prudential assumption and supporting the traditional ethical principle, thereby respecting life from its inception, and also by applying two complementary traditional ethical principles.

From the outset the problem should be delineated clearly. When IVF embryos are created in fertility clinics, typically the result is creating more embryos than required by a prospective mother for reproduction. The excess IVF embryos could be used for hESC research, and many laboratories would like to do so.[18] But substantive opposition is encountered due to the unavoidable destruction of the ex utero embryo when harvesting the hESCs. The technique of harvesting these cells is now well established: The cells are derived from the inner cell mass ("ICM") of an embryo that has developed into the blastocyst stage, typically around five days after fertilization, and the process destroys the embryo.[19]

Despite the robust opposition to using IVF embryos for hESC research, plausible arguments have been offered to justify the practice. One rationale might be described as a practical usefulness argument. The excess frozen embryos are destined to die because they are unwanted for procreative purposes and cannot survive endlessly in cryopreservation. Hence, perhaps some good use to benefit humankind should accrue from these embryos that are otherwise destined to perish. This perspective is similar to what some call the "nothing is lost" principle.[20] A related rationale might be construed as a compassionate argument. There are vast populations of diseased, debilitated, or terminally ill patients who could benefit or survive from the future development of ESC treatments.

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17. ROBERT P. GEORGE & CHRISTOPHER TOLLEFSEN, EMBRYO: A DEFENSE OF HUMAN LIFE 17 (2008); *see* Paul R. McHugh, *Zygote and "Clonote"—The Ethical Use of Embryonic Stem Cells*, 351 NEW ENG. J. MED. 209, 209 (2004).

18. *See* Xin Zhang et al., *Derivation of Human Embryonic Stem Cells from Developing and Arrested Embryos*, 24 STEM CELLS 2669, 2669 (2006).

19. For discussion of these concepts, see RUSSELL KOROBKIN WITH STEPHEN R. MUNZER, STEM CELL CENTURY: LAW AND POLICY FOR A BREAKTHROUGH TECHNOLOGY 34 (2007) (describing a five-day-old embryo as a blastocyst); Michal Amit & Joseph Itskovitz-Eldor, *Isolation, Characterization, and Maintenance of Primate ES Cells*, *in* ESSENTIALS OF STEM CELL BIOLOGY 275, 275 (Robert Lanza et al. eds., 2006) (explaining that ESCs can be "isolated from the inner cell mass (ICM) of the blastocyst"); Donald W. Landry & Howard A. Zucker, *Embryonic Death and the Creation of Human Embryonic Stem Cells*, 114 J. CLINICAL INVESTIGATION 1184, 1184 ("[L]ive human embryos must be destroyed in the process of creating stem cells.").

20. Gene Outka, *The Ethics of Human Stem Cell Research*, 12 KENNEDY INST. ETHICS J. 175, 193 (2002).

Hence, perhaps there is a duty to use this extraordinarily limited but significantly promising resource of excess frozen embryos to make an immensely valuable contribution to assist so many needy in society.[21] And finally, there is a related rationale that might be construed as a noble cause argument. Immense hope is offered for medical treatments, therapies, and cures through ESC research.[22] Indeed, despite charges of hype over realism, the accomplishments of research in this fledgling field in its first decade are astounding, recognizing of course that a lot more time is needed for these endeavors to offer reliable interventions.[23] Hence, this argument suggests that perhaps research on excess IVF embryos should be permitted for the noble cause of human flourishing, which appears to be a broader argument than assisting sick patients.[24] These rationales elicit expansive support from different and overlapping constituencies. Yet, conservative secular and religious doctrine is not persuaded by these arguments and continues to oppose the destruction of excess IVF embryos for hESC research.[25] There are several ways to engage such opposition in a scholarly manner: to agree with it, to disagree with it, or to further develop it in a constructive manner while retaining its central insight. This Article follows the latter trajectory, adopting a hermeneutical or interpretative approach.

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21. *See* COHEN, *supra* note 15, at 4; *see also* KOROBKIN WITH MUNZER, *supra* note 19, at 232-42 (telling the story of a young girl whose parents conceived her brother through in vitro fertilization so that stem cells from his umbilical cord could be given to his sister, who was suffering from a genetic disorder, and examining the ethical concerns involved in the intentional creation of stem cell donors).

22. *See, e.g.*, David M. Panchision, *Repairing the Nervous System with Stem Cells*, *in* REGENERATIVE MEDICINE 35, 40-42 (2006) (describing how stem cells have the potential to treat spinal cord injuries, brain trauma, and neurodegenerative diseases such as Alzheimer's and Huntington's); Philip H. Schwartz & Peter J. Bryant, *Therapeutic Uses of Stem Cells*, *in* FUNDAMENTALS OF THE STEM CELL DEBATE 37, 38-46 (Kristen Renwick Monroe et al. eds., 2008) (an overview of the current application of stem cell therapy towards blood and immune disorders, retinal degeneration, diabetes, and cardiovascular disease).

23. Panchision, *supra* note 22, at 42.

24. *See* Gerard Magill, *Science, Ethics, and Policy: Relating Human Genomics to Embryonic Stem-Cell Research and Therapeutic Cloning*, *in* GENETICS AND ETHICS: AN INTERDISCIPLINARY STUDY 253, 260 (Gerard Magill ed., 2004).

25. *See, e.g.*, CONGREGATION FOR THE DOCTRINE OF THE FAITH, INSTRUCTION *DIGNITAS PERSONAE* ON CERTAIN BIOETHICAL QUESTIONS §§ 31-32 (2008), *available at* http://www.usccb.org/comm/Dignitaspersonae/Dignitas_Personae.pdf [hereinafter CONGREGATION, *DIGNITAS PERSONAE*] (stating that in vitro fertilization and the intentional destruction of embryos is against the Catholic faith); GEORGE & TOLLEFSEN, *supra* note 17, at 194-99 (arguing that the destruction of excess embryos constitutes the destruction of potential life, despite any benefits such research may provide).

II. HERMENEUTICS AND ETHICS

The specifics of this doctrine can be illustrated by the opposition of former President George W. Bush (the secular dimension),[26] as well as the opposition of some influential faith traditions (the religious dimension).[27] The term "doctrine" is adopted in this Article to convey a policy stance, both secular and religious. The policy stance can be construed as a "doctrine" in the sense that its assertion requires belief in its truth claim insofar as it can be explained coherently, although not in a probative manner. It is important to emphasize that by adopting the term "doctrine," the analysis intends to critique this policy stance in a constructive manner and not in a deprecatory way. In other words, many secular and religious policies that govern daily life are coherent, plausible, and constructive but cannot be logically demonstrated or proven. Such doctrines are based on deeper assumptions—secular belief assumptions or religious faith assumptions—that have a pervasive and persuasive influence even though they may turn out to be capable of subsequently developing. And this critical relation between truth claims and deeper assumptions has fostered the exciting enterprise of hermeneutics in many different fields—for example, from legal interpretation and literary criticism to philosophy, psychology, and religion.[28]

This observation on hermeneutics leads to another reason for adopting the word "doctrine" in this Article. Religious doctrine is commonly understood as presenting substantive truth claims that are justifiably interpreted in different ways over time in a manner that actually changes their meaning. This cautious process of justified change in traditional religious faith is referred to as the development of doctrine or doctrinal development.[29] This crucially important interpretative or hermeneutical approach to doctrine permits its meaning to develop

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26. *See* President George W. Bush, Address on Federal Funding of Embryonic Stem-Cell Research (Aug. 9, 2001), *in* 31 ORIGINS 213, 214 (2001); *see also* Gerard Magill, *The Ethics Weave in Human Genomics, Embryonic Stem Cell Research, and Therapeutic Cloning: Promoting and Protecting Society's Interests*, 65 ALB. L. REV. 701, 720-21 (2002) (summarizing President Bush's policy banning federal funding of research that involved the future destruction of human embryos).

27. *See* CONGREGATION, *DIGNITAS PERSONAE*, *supra* note 25, §§ 31-32.

28. On the tension between secular reason and religious faith in hermeneutics, see generally Gerard Magill & Marie D. Hoff, *Introduction: Public Conversation on Values*, *in* VALUES AND PUBLIC LIFE: AN INTERDISCIPLINARY STUDY 1 (Gerard Magill & Marie D. Hoff eds., 1995). For an exploration of the reason-faith hermeneutics to stem cell research, see Ralph Charbonnier, *The Contribution of the Protestant Church in Germany to the Pluralist Discourse in Bioethics: The Case of Stem Cell Research*, 14 CHRISTIAN BIOETHICS 95, 100-04 (2008).

29. For a thorough discussion of the creation of religious doctrine, see generally JOHN HENRY CARDINAL NEWMAN, AN ESSAY ON THE DEVELOPMENT OF CHRISTIAN DOCTRINE (1960).

across generations and cultures. Moreover, this hermeneutical approach can shed significant light on whether and how the conservative doctrine opposing hESC research might be open to such development.

This Article's argument pursues this approach of hermeneutics by applying the ethical imagination. Ethical imagination means an intellectual process that tries to infer conclusions from converging data rather than from merely deductive logic.[30] For example, when couples fall in love and marry, the discernment process tends not to result merely from deductive logic—though that has a place—but appears to be a function of their imagination that constructively interprets the entire range of relevant data in an integrative manner cumulating to a conclusion.

The cumulative character of converging argument in this Article, applying the ethical imagination, occurs by combining two traditional ethical principles to support using excess IVF embryos for hESC research in constructive tension with the traditional ethical principle of respecting human life that opposes this research. And the outcome is to conclude that the shift from opposing to supporting the research can be construed as a development rather than a mere rejection of the conservative doctrine. The purpose of appealing to converging arguments using the ethical imagination here is to justify a cautious development of this conservative doctrine. The analysis confirms the traditional ethical principle that underlies this doctrine and also considers complementary traditional ethical principles to explain how the conservative doctrine might properly develop. So, the hermeneutical endeavor here is not to submit a progressive or liberal argument against the traditional ethical principle underlying this conservative doctrine. Rather, the hermeneutical enterprise is to appeal to complementary conservative ethical principles that have widespread secular and religious acceptance in our society to explain how this conservative doctrine can develop legitimately.

The quest of this hermeneutical endeavor is to explain that the doctrine of President Bush—that is, the secular perspective—and some influential faith traditions—the religious perspective—can be developed constructively and cautiously. The development entails a move from vigorously opposing to strenuously supporting hESC research using excess IVF embryos. While this shift appears dramatic in the sense of seeming to adopt a polar opposite position, in fact the change is indeed developmental, as the acorn to the oak tree. The nuance is to explain

30. *See* Brian Devlin & Gerard Magill, *The Process of Ethical Decision Making*, 20 BEST PRAC. & RES. CLINICAL ANAESTHESIOLOGY 493, 497-98 (2006).

how to safeguard the fundamental insight in the doctrine that opposes this research while also embracing a contrasting position by applying complementary ethical principles that are likewise traditional. So, the outcome is to justify the use of excess IVF embryos for hESC research by applying complementary ethical principles, thereby generating a contrasting development of doctrine. And it is fascinating to ascertain how the traditional doctrine of opposition need not be discarded in the process of justifying a developed doctrine that offers support for using excess IVF embryos for hESC research.

Finally, the significance of this outcome may be far-reaching, not only in permitting the identified research to occur with all of its promise for medical breakthroughs but also in placing the influence and plausibility of conservative secular and religious doctrine behind the research. The potential for a myriad of treatments, therapies, and cures arising from hESC research is worthy of uniting a nation in a common pursuit with widespread support. This posture can avoid the entrenched tension between progressive and conservative perspectives that all too often hamstring policy debates and thereby delay the much sought relief that medical science can bring to so many suffering patients. This optimistic quest seeks to overcome the unfortunate delay in progress that became ensconced so quickly in both secular and religious policy after the initial discovery of how to harvest and cultivate ESCs.

III. DISCOVERY AND DELAY

The amazing discovery of how to isolate and harvest ESCs occurred just a decade ago, in 1998.[31] But by 2001, secular and religious doctrine had asserted their ethical reservations to effectively delay the fast-paced research in this fascinating new field. After discovering how to manipulate ESCs, vigorous opposition was voiced by some religious traditions.[32] And in the secular domain, President Bill Clinton initially adopted the recommendations of his National Bioethics Advisory

31. Junying Yu & James A. Thomson, *Embryonic Stem Cells*, *in* REGENERATIVE MEDICINE, *supra* note 22, at 1, 3.

32. *See generally* Richard M. Doerflinger, *The Ethics of Funding Embryonic Stem Cell Research: A Catholic Viewpoint*, 9 KENNEDY INST. ETHICS J. 137 (1999) (describing the Catholic perspective of stem cell research); Margaret A. Farley, *Roman Catholic Views on Research Involving Human Embryonic Stem Cells*, *in* 3 ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH D-3 (2000) (discussing the Catholic position on ESC research); INT'L ASS'N OF CATHOLIC BIOETHICISTS, STATEMENT ON REGENERATIVE MEDICINE AND STEM CELL RESEARCH, *in* 8 NAT'L CATH. BIOETHICS Q. 328, 334-38 (2008) (explaining the Catholic belief that every embryo is a "potential human being" and thus should not be used in stem cell research).

Commission.[33] In August 2001, President Bush restricted the use of federal funding for hESC research to a specific number of previously developed hESC lines.[34] This meant that if researchers had funding from other sources to undertake hESC research, they could not conduct their studies using labs or equipment paid for by federal funding, such as by the National Institutes of Health.[35] Naturally, this policy placed significant constraints on the business success of United States stem cell laboratories in the globalized context of this research.[36] Congress attempted to reverse President Bush's policy,[37] but it remained in effect until March 9, 2009, when President Obama issued an Executive Order to permit federal funding of ESC research, revoking the previous Executive Order of President Bush in 2001.[38] And similar debates have been occurring internationally.[39]

These circumstances depict the common tension between science and ethics: the tension between the vigorous progress of scientific research that seeks new discoveries and the cautious concern of traditional doctrine, secular and religious alike, that defends long-standing traditional ethical perspectives. While the tension between science and ethics need not be confrontational and controversial, often it is, and the debate over hESC research certainly exemplifies the latter.[40] The hope of this analysis is to explain that the tension between science and ethics on hESC research can be constructive and conciliatory. To accomplish this outcome, the coherence and plausibility of the prudential assumption underlying the conservative doctrine needs to be considered.

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33. *See* National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,977 (Aug. 25, 2000); *see also* NAT'L BIOETHICS ADVISORY COMM'N, 1 ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH 68-81 (1999) (listing the National Bioethics Advisory Commission's thirteen recommendations for federal funding of ESCs that were adopted by President Clinton).

34. Bush, *supra* note 26, at 214.

35. Elizabeth G. Phimister, *A Tetraploid Twist on the Embryonic Stem Cell*, 353 NEW ENG. J. MED. 1646, 1647 (2005).

36. *See* Spar, *supra* note 10, at 211-12.

37. *See* Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong. (2005).

38. Exec. Order No. 13,505, 74 Fed. Reg. 46 (Mar. 9, 2009).

39. *See generally* LeRoy Walters, *Human Embryonic Stem Cell Research: An Intercultural Perspective*, 14 KENNEDY INST. ETHICS J. 3 (2004) (summarizing views of ESC research in a variety of cultures).

40. *See, e.g.*, PATRICK LEE & ROBERT P. GEORGE, BODY-SELF DUALISM IN CONTEMPORARY ETHICS AND POLITICS 122-40 (2008).

IV. THE PRUDENTIAL ASSUMPTION

The basic ethical conundrum being engaged here is trying to square the amazing promise of hESC research for medical science with the necessity of having to destroy a human embryo, a blastocyst, in the process of harvesting the stem cells. The profound ethical concern that arises with hESC research deals with protecting the human blastocyst from its inception as personal human life. That is, the concern is that we should not destroy personal human life even for the most promising medical research.[41] While this stance prima facie is appealing, it encounters significant challenges. The analysis begins by considering what it means to claim that the very early cellular development of human life is unambiguously personal. Then the analysis will explain that even if we can assume or accede to the claim that human life is personal from its inception, it does not necessarily follow that early cellular development, of which destruction is unavoidable in harvesting stem cells, in absolutely no circumstances can be used for hESC research. These two issues demarcate the foundation and the substance of the ethical argument presented in this Article.

The prudential assumption and the traditional ethical principle of respecting life encompasses a long-standing debate about the ethical obligation to protect the early cellular development of human life from its inception. The long-standing debate includes several contested issues that need to be considered. The prudential assumption deals with a question that merging secular and religious terminology might be phrased in this way: Is it warranted to construe early cellular human life as having a personal soul?

There is widespread recognition that no one can demonstrate when a personal soul enters the early cellular development of human life. Philosophy, theology, and science are at a loss for demonstrative proof about this highly significant claim. For example, traditional religious doctrine recognizes that "no experimental datum can be in itself sufficient to bring us to the recognition of a spiritual soul" and hence Roman Catholic official teaching "has not expressly committed itself to an affirmation of a philosophical nature" about the presence of a personal soul in early human life even though that teaching protects human life as personal from its inception.[42] Hence, asserting the claim

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41. *See generally* COHEN, *supra* note 15, at 59-109 (discussing the secular and religious reasons to protect human embryos).

42. CONGREGATION FOR THE DOCTRINE OF THE FAITH, RESPECT FOR HUMAN LIFE (*DONUM VITAE*) § I.1 (1987), *available at* http://helpersbrooklynny.org/Donum%20Vitae.pdf [hereinafter CONGREGATION, *DONUM VITAE*]; *see also* JOHN PAUL II, ENCYCLICAL LETTER: *EVANGELIUM VITAE*

appears to be based on the following assumption as a function of prudence. Given the importance of the generally agreed upon stance that early human life with a personal soul should not be readily destroyed, and given the apparent impossibility of adequately demonstrating when early human life develops or receives a personal soul,[43] then it seems prudent to assume that early human life has a personal soul from the earliest or safest point which is its inception. This prudential discernment results from recognizing that while empirical data cannot prove the existence of a personal soul, there is sufficient scientific research that seems to provide "a valuable indication"—though short of demonstrative proof—"for discerning by the use of reason a personal presence at the moment of this first appearance of a human life."[44] This prudential assumption basically construes the early cellular development of human life as personal and hence worthy of protection from its inception. However, the long-standing debate over this prudential assumption has been met with substantive skepticism that can be articulated in the following points.

The first point addresses the question of a personal soul in the process of embryo division and embryo combination.[45] In natural human reproduction, a single embryo, after developing to the blastocyst stage, can divide, thereby becoming identical twins.[46] This division presents a conundrum for the position that upholds conception as the point for construing the presence of a personal soul. The obvious question is how one embryo with a personal soul can lead to the emergence of another in the twin—with the unambiguous corollary that the emergence of the twin's personal soul occurs after conception, at the point of twinning. Moreover, science also indicates that two independently conceived blastocysts—fraternal rather than identical twins—can fuse before the formation of the primitive streak (around fourteen days) and implantation in the womb.[47] This fusion creates one embryo that is a sort of chimera of the cells with the different genomes of the original twins.[48] The obvious question here is how two embryos, each construed as having a personal soul from conception, can recombine into one embryo

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¶ 60 (1995), *available at* http://www.catholic-pages.com/documents/evangelium_vitae.pdf (stating that a new life begins at the moment an egg is fertilized).

43. *See, e.g.*, JOHN PAUL II, *supra* note 42, ¶ 60 ("[T]he presence of a spiritual soul cannot be ascertained by empirical data . . . .").

44. CONGREGATION, *DONUM VITAE*, *supra* note 42, § I.1.

45. For a discussion of embryotic combination, see generally Kurt Benirschke, *Spontaneous Chimerism in Mammals: A Critical Review*, 51 CURRENT TOPICS PATHOLOGY 1 (1970).

46. *See* Okie, *supra* note 6, at 3.

47. *Id.*

48. *See* Benirschke, *supra* note 45, at 3.

with presumably one personal soul as evidently appears to be so after birth. It seems appropriate to inquire about what happens to the other personal soul of the no-longer-existing twin after the fusion of their different "bodies" (as blastocysts). The second point addresses the meaning of the low ratio of conception to birth for construing the presence of personal souls. Science indicates that more than half of fertilized eggs are lost, thereby not resulting in birth,[49] and some estimate the percentage of loss could be as high as two-thirds.[50]

Perhaps the third point is the most important one to bear in mind. The meaning of the prudential assumption about the personal soul is that the assumption is indeed only prudential in the sense that it can change based on new data. Given insufficient data to identify when a personal soul begins, the earliest point for such protection being the inception of human life can make sense. Yet that prudential assumption is open to change if new scientific information emerges. Indeed, such data was discovered in late 2007, using a new process called direct nuclear reprogramming to create induced pluripotent stem cells ("iPSCs").[51] Scientists discovered this process in the wake of successful mouse experiments,[52] and found that direct reprogramming enabled human skin cells to be turned into iPSCs, which resemble and behave like ESCs, though the two are genetically different from each other.[53]

An immediate reaction from conservative voices was to applaud the breakthrough as possibly side-stepping the need to harvest ESCs in a manner that destroys the human embryo.[54] However, very quickly an implication emerged that could cause consternation for these voices. Another laboratory used the technique in mouse experiments to develop a mouse fetus from the iPSCs.[55] That experiment demonstrated that by using the new technique it may be possible to develop a human fetus

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49. Sandel, *supra* note 6, at 208.

50. *See* HENRI LERIDON, HUMAN FERTILITY: THE BASIC COMPONENTS 79 (Judith F. Helzner trans., Univ. of Chi. Press 1977) (1973); D. Keith Edmonds, *Early Embryonic Mortality in Women*, 38 FERTILITY & STERILITY 447, 451 (1982).

51. *See* Kazutoshi Takahashi et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861, 861-63, 868 (2007); Junying Yu et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells*, 318 SCIENCE 1917, 1917 (2007).

52. *See* Marius Wernig et al., In vitro *Reprogramming of Fibroblasts into a Pluripotent ES-cell-like State*, 448 NATURE 318, 322-23 (2007) (discussing the results of a study in which mouse cells were reprogrammed into pluripotent cells).

53. *See* Takahashi et al., *supra* note 51, at 862-63.

54. *See* W. Malcolm Byrnes, *Direct Reprogramming and Ethics in Stem Cell Research*, 8 NAT'L CATH. BIOETHICS Q. 277, 285 (2008); Maureen L. Condic & Edward J. Furton, *Harvesting Embryonic Stem Cells from Deceased Human Embryos*, 7 NAT'L CATH. BIOETHICS Q. 507, 513-14 (2007).

55. Wernig et al., *supra* note 52, at 322.

from human iPSCs. The critical point was the apparent discovery that any human cell through direct nuclear reprogramming as an iPSC, with the provision of a placenta and a womb, could become a human fetus, akin to the natural process of fertilization and conception.[56]

This dramatic new biological information raises a crucial question about the prudential assumption over the presence of a personal soul. Two clear options are apparent. First, if the prudential assumption is adopted, protecting human life as having a personal soul from its inception, it could be argued that iPSCs, given the capability of developing into a fetus, should be protected as potentially having a personal soul. The prudential assumption requires that human life should be protected as having a personal soul from its inception. Second, consistency would require applying that assumption now to include iPSCs. But that stance, though consistent, may stretch the plausibility of the assumption a step too far by inferring that every cell in the human body through direct reprogramming could have a personal soul. So perhaps this new data provides sufficient biological information to challenge the coherence of the prudential assumption. In other words, that challenge would be premised upon the improbability that every human cell could be manipulated using this technique in a manner that entailed having a personal soul. So, this new data may suggest that the inception of cellular development in human life may not be an appropriate point to construe the presence of a personal soul—though the data do not indicate when such a point might be.[57]

This discovery of iPSCs provides further reason to be skeptical about the prudential assumption stated above. In other words, the prudential assumption must be responsive to the discovery of new scientific knowledge about the early cellular development of human life. Nonetheless, the argument in this Article accedes to the prudential assumption to cautiously present an ethically conservative but alternative position. This analysis simply documents the skepticism about the prudential assumption but does not embrace that skepticism to make the critical argument herein. Rather, by acceding to the prudential assumption, this Article explains how to develop conservative doctrine from opposing to supporting the use of spare IVF embryos for hESC research.

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56. Gerard Magill & William B. Neaves, *Ontological and Ethical Implications of Direct Nuclear Reprogramming*, 19 KENNEDY INST. ETHICS J. 23, 25 (2009).

57. *See id.* at 26-30.

V. DEVELOPING DOCTRINE

After addressing the foundational question about a personal soul, the substantive argument in this Article can be pursued in the following way. If the human blastocyst should be safeguarded from its inception as personal human life, as acceded to here, does it follow that using excess IVF embryos for hESC research should be forbidden? The secular and religious doctrine, aligned with President Bush and some faith traditions, indicates that such a proscription is ethically appropriate.[58] However, a different approach can be pursued by arguing that complementary ethical principles can be deployed to actually provide support for this research. Here, complementary principles refer to other traditional principles that are consistent with but distinct from the traditional ethical principle of respecting human life from its inception. This alternative approach seeks to move from proscribing this practice to permitting this practice. Such a shift from proscription to permission might appear as a rejection of the conservative doctrine with its prudential assumption. But the analysis suggests that supporting this practice can occur while acceding to the prudential assumption. Hence, this Article talks of developing doctrine, not of rejecting it.

There are two conservative ethical principles involved in this alternative approach: the ethical principle of letting some patients die when struggling with a terminal condition, hereafter referred to as the ethical principle of letting die; and the ethical principle of harvesting organs and tissues from deceased individuals for transplant purposes, hereafter referred to as the ethical principle of harvesting after death. For example, on the principle of letting die, the Jewish bioethicist Aaron L. Mackler notes that Catholic and Jewish traditions permit refusal of medical interventions in end of life care when they "are excessively burdensome or lacking benefit."[59] And on the principle of harvesting after death, the Catholic bioethicist Kevin D. O'Rourke notes that harvesting for transplanting after death in itself "presents no ethical problem."[60] An explanation of each of these principles is provided in the subsequent two Parts. The argument that is pursued seeks to combine both ethical principles to reach a point of convergence that enables them, by working together, to justify the practice of using IVF embryos for hESC research. But there are significant hurdles to be crossed in

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58. *See* CONGREGATION, *DIGNITAS PERSONAE*, *supra* note 25, § 32; GEORGE & TOLLEFSEN, *supra* note 17, at 194-99.

59. AARON L. MACKLER, INTRODUCTION TO JEWISH AND CATHOLIC BIOETHICS: A COMPARATIVE ANALYSIS 109 (2003).

60. BENEDICT M. ASHLEY & KEVIN D. O'ROURKE, HEALTH CARE ETHICS: A THEOLOGICAL ANALYSIS 331 (4th ed. 1997).

justifying such an approach, which are discussed in relation to the argument's framework.

Briefly, the argument follows this framework. On the one hand, the principle of letting patients die from a terminal condition can be adopted to justify letting excess IVF embryos thaw from cryopreservation. This principle accedes to the prudential assumption that human life from its inception should be protected from destruction. This prudential principle does not contradict the ethical justification of letting patients die from a terminal condition, such as by withdrawing life-sustaining measures. Likewise, the principle of letting die can justify letting frozen embryos thaw to die, thereby making them accessible to researchers as they thaw. On the other hand, as they thaw, the frozen embryos can be useful for hESC research by harvesting their ESCs in the dying process, akin to adopting the ethical principle of harvesting from deceased individuals.

However, there are two substantive hurdles in this proposed convergence of complementary traditional ethical principles. One hurdle is that previously when embryos were frozen early in their development, the ESCs had not yet developed.[61] The other hurdle is that the frozen embryo does not have a brain, so the brain death criterion that is crucial for harvesting tissues and organs from deceased children and adults does not pertain.[62] The analysis that follows seeks not only to scrutinize the relevance of these two complementary traditional ethical principles that elicit widespread support but also to overcome the hurdles identified if the argument is to be persuasive.

VI. ETHICAL PRINCIPLE OF LETTING DIE

The multitude of medical technologies that typify the delivery of healthcare today has had a major impact on enabling patients to die well. These technologies are especially important not only for secular perspectives but also for perspectives in conservative faith traditions. In religiously affiliated healthcare, these technologies include the practice of pain management, palliative care, hospice care, and indeed the last resort practice of terminal or palliative sedation, whereby unmanageable pain justifies sedating a patient with a terminal condition into unconsciousness until death.[63] The shared ethical principle that underlies

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61. *See infra* notes 105-08 and accompanying text.

62. *See* Ronald B. Miller, *Ethical Issues in Stem Cell Research, Therapy, and Public Policy*, 26 WHITTIER L. REV. 845, 848 (2005).

63. DAVID F. KELLY, CONTEMPORARY CATHOLIC HEALTH CARE ETHICS 139-42 (2004) [hereinafter KELLY, CONTEMPORARY CATHOLIC]; DAVID F. KELLY, MEDICAL CARE AT THE END OF LIFE 19 (2006) [hereinafter KELLY, MEDICAL CARE]. *See generally* James J. Walter, *Terminal Sedation: A Catholic Perspective*, *in* CONTEMPORARY ISSUES IN BIOETHICS: A CATHOLIC

all of these practices is that of justifiably letting patients die in appropriate circumstances without eliciting the charge of killing or murder.[64] This principle reflects a traditional stance in ethics that seeks to respect human life as having a personal soul until the end of life. And part of that respect is to avoid pain and suffering when feasible.[65]

The ethical principle of letting die is widely adopted in traditional religious teaching and practice. The premise underlying this principle is that "the life of the body in its earthly state is not an absolute good" that would demand protection in every circumstance.[66] Although euthanasia is never permitted (understood as an "action or omission which of itself and by intention causes death, with the purpose of eliminating all suffering"), it is important to emphasize that "[e]uthanasia must be distinguished from the decision to forego . . . medical procedures . . . either because they are by now disproportionate to any expected results or because they impose an excessive burden on the patient and his family."[67] That is, "when death is clearly imminent and inevitable, one can in conscience 'refuse forms of treatment that would only secure a precarious and burdensome prolongation of life.'"[68] In other words, in end of life care, "[t]o forego extraordinary or disproportionate means is not the equivalent of suicide or euthanasia."[69]

This ethical principle of letting die is also widely adopted in secular policy and practice.[70] A substantive focus of court decisions over the past decades has been on end of life care, in particular addressing whether and when patients can be allowed to die from their underlying terminal condition. And this history unveils the emergence and prominence of ethics committees in healthcare facilities across the United States.[71]

PERSPECTIVE 225 (James J. Walter & Thomas A. Shannon eds., 2005) (discussing Roman Catholic beliefs with regard to terminal sedation and distinguishing between terminal and palliative sedation).

64. *See, e.g.*, JOHN PAUL II, *supra* note 42, ¶ 65 ("To forego extraordinary or disproportionate means is not the equivalent of suicide or euthanasia . . . .").

65. *See id.*

66. *Id.* ¶ 47.

67. *Id.* ¶ 65.

68. *Id.* (quoting CONGREGATION FOR THE DOCTRINE OF THE FAITH, DECLARATION ON EUTHANASIA (*IURA ET BONA*) § IV (1980)).

69. *Id.*; *see also* U.S. CONFERENCE OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH CARE SERVICES 13 (4th ed. 2001) (stating that a person can reject medical treatment that is not beneficial or extremely burdensome, but that suicide and euthanasia are not "morally acceptable options").

70. *See* JERRY MENIKOFF, LAW AND BIOETHICS: AN INTRODUCTION 241-373 (2001) (discussing United States Supreme Court and state court cases which establish the right of terminally ill patients to refuse medical care).

71. *See id.* at 258.

A brief review of this history can illustrate the widespread acceptance of letting patients die from their terminal conditions.[72] Initially, this principle engendered significant dispute and caused many cases to be presented for court resolution. At regular intervals from 1975, the courts built upon precedent decisions, establishing a consistent outlook by applying the principle of letting die that has become such an accepted ethical practice.[73] Nonetheless, specific details in particular cases continue to require the sophisticated analysis of case consultations by ethics committee professionals.

The contentious debate over letting patients die assumed national prominence in 1975 when Karen Ann Quinlan's case required legal review over the question of withdrawing life-sustaining measures from a patient in a persistent vegetative state.[74] In 1976, the New Jersey Supreme Court upheld the patient's right to refuse medical treatment as a function of the right to privacy, as asserted by her father who was her legal guardian.[75] The case highlighted the substituted judgment standard that has in part shaped this debate, leading to these conclusions: that an individual's right could override state's interest in preserving life; and that ethics committees should be used to address these dilemmas rather than the courts.[76] In the following year, in the case of Joseph Saikewicz, the Supreme Court of Massachusetts confirmed the patient's interest over the State's interest to preserve life, focusing on informed consent and the right to privacy.[77] The case highlighted the "best interests" standard that has also, in part, shaped the national debate since.[78] In 1980, in the case of *Eichner v. Dillon*, the New York Supreme Court Appellate Division supported removal of life-sustaining treatment based on clear and convincing evidence of the patient's previously stated preferences.[79] Then in the 1985 case of Claire Conroy, the Supreme Court of New Jersey justified removal of life-sustaining measures based on both the substituted judgment standard as a subjective standard and the best interests standard as an objective standard, giving priority to the former subjective standard when feasible insofar as it better reflected the

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72. *See generally* Dan W. Brock, *Patient Competence and Surrogate Decision-Making*, *in* THE BLACKWELL GUIDE TO MEDICAL ETHICS 128 (Rosamond Rhodes et al. eds., 2007) (discussing informed consent and patient decisionmaking in medical care).

73. *See infra* notes 74-80 and accompanying text.

74. *See* MENIKOFF, *supra* note 70, at 241-42.

75. *In re* Quinlan, 355 A.2d 647, 664 (N.J. 1976).

76. *Id.* at 664, 668-69.

77. Superintendent of Belchertown State Sch. v. Saikewicz, 370 N.E.2d 417, 427-28 (Mass. 1977).

78. *Id.*

79. Eichner v. Dillon, 426 N.Y.S.2d 517, 545-46 (App. Div. 1980).

patient's previously indicated preferences.[80] In the following year, the case of Elizabeth Bouvia was adjudicated by the California Court of Appeal to uphold a competent patient's right to request the removal of life-sustaining measures.[81] And in 1990, in the famous case of Nancy Beth Cruzan, the United States Supreme Court upheld the State's interest in requiring clear and convincing evidence of the patient's prior stated preference to remove life-sustaining measures, evidence that was provided subsequently to a lower court.[82] And conservative faith traditions adopted a similar posture that effectively followed the lead of these secular court decisions,[83] while at the same time upholding the prudential assumption about respecting human life from inception as having a personal soul.[84]

This recent history of the traditional ethical principle of letting die as pertains to the withdrawal of life-sustaining measures, an arena that continues to elicit significant dispute,[85] sets the stage for applying the principle of letting die to spare IVF embryos. What, then, is the significance for hESC research of this ethical principle of letting patients die? It is a principle that is so widely accepted as to be legitimately construed as being a cautious principle, cautious in the sense of not eliciting much dispute,[86] and a complementary principle, complementary in the sense of being consistent with the traditional ethical principle of respecting and protecting human life from its inception.[87] The principle of letting patients die involves several value-laden perspectives that require scrutiny, as follows.

First, the principle affirms the respect due to each individual, as having what has been discussed above as a personal soul, in the sense of warranting protection from destruction, even for the noble cause of

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80. *In re* Conroy, 486 A.2d 1209, 1227-33 (N.J. 1985).

81. Bouvia v. Superior Court, 225 Cal. Rptr. 297, 305 (Ct. App. 1986).

82. Cruzan v. Director, 497 U.S. 261, 286-87 (1990).

83. *See* U.S. CONFERENCE OF CATHOLIC BISHOPS, *supra* note 69, at 14. Specifically, Directive 59 states that "[t]he free and informed judgment made by a competent adult patient concerning the use or withdrawal of life-sustaining procedures should always be respected and normally complied with, unless it is contrary to Catholic moral teaching." *Id.* Thus, Directive 60 states that "Catholic health care institutions may never condone or participate in euthanasia or assisted suicide in any way." *Id.*

84. *See id.*

85. *See, e.g.*, THE CAMBRIDGE TEXTBOOK OF BIOETHICS 51-91 (Peter A. Singer & A.M. Viens eds., 2008).

86. This caution is indicated in U.S. CONFERENCE OF CATHOLIC BISHOPS, *supra* note 69, at 13: "Only in this way are two extremes avoided: on the one hand, an insistence on useless or burdensome technology even when a patient may legitimately wish to forgo it and, on the other hand, the withdrawal of technology with the intention of causing death."

87. For example, "the duty to preserve life is not absolute, for we may reject life-prolonging procedures that are insufficiently beneficial or excessively burdensome." *Id.*

medical research. Simply, this principle does not permit science to prey upon dying patients even though their deceased bodies could be immensely useful for medical research.[88] Both secular and religious perspectives share this stance. For example, in secular ethics, one of the basic tenets of the ethical movement called principlism is that of respect for the individual patient.[89] And in religious discourse, respect for each individual permeates all forms of care.[90] In particular, religious discourse aligns respect for each person with being made in the image of God. Yet that religious alignment does not stand against letting patients die in appropriate circumstances. That religious perspective recognizes that there is no duty to keep each patient alive at any cost in all circumstances: "[T]he duty to preserve life is not absolute, for we may reject life-prolonging procedures that are insufficiently beneficial or excessively burdensome."[91]

Second, the principle of letting die also acknowledges that the way patients with a terminal condition end their lives is an important reflection of the basic respect that is their due. Hence, the emergence of movements for pain management, palliative care, hospice care, and the practice of terminal or palliative sedation are mainstream fixtures in healthcare facilities that care for dying patients.[92] For example, the acceptance of the practice of sedating a patient whose pain is unmanageable into unconsciousness until death, known as terminal or palliative sedation, is justifiable from secular and religious perspectives alike.[93] That acceptance is based upon applying the principle of double effect to explain that terminal or palliative sedation is legitimate insofar as intending its use is warranted when there is no other way to manage the pain of a dying patient, even recognizing that death is the inevitable result—foreseen but not intended.[94]

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88. Additionally, medical standards are in place to regulate how bodies and organs may be obtained and used after termination of life by withdrawal of life-sustaining procedures. *See* Gail A. Van Norman, *Another Matter of Life and Death: What Every Anesthesiologist Should Know About the Ethical, Legal, and Policy Implications of the Non-Heart-Beating Cadaver Organ Donor*, 98 ANESTHESIOLOGY 763, 764 (2003).

89. *See* TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 120-28 (4th ed. 1994).

90. *See* U.S. CONFERENCE OF CATHOLIC BISHOPS, *supra* note 69, at 13-14.

91. *Id.* at 13.

92. *See id.* at 14. Directive 61 states that: "Medicines capable of alleviating or suppressing pain may be given to a dying person, even if this therapy may indirectly shorten the person's life so long as the intent is not to hasten death." *Id.*

93. *See* KELLY, MEDICAL CARE, *supra* note 63, at 15-20; MENIKOFF, *supra* note 70, at 241-303.

94. *See* KELLY, MEDICAL CARE, *supra* note 63, at 16, 19. The principle of double effect holds that an action that has both good and bad effects is right if: (1) the act is not in itself morally wrong;

Without doubt, the history of court decisions that permit the withdrawal of life-sustaining interventions from dying patients adds additional credibility to the widespread acceptance of the ethical principle of letting die.[95] Hence, the legitimacy of letting patients die from their terminal condition in specific circumstances can be construed as a function of the conservative ethical principle of respect for human life that eschews killing. And the principle of letting die, also construed as a traditional ethical principle, highlights that there is no ethical duty from either secular or religious perspectives to keep patients alive at any cost or as long as technically feasible. That is, both traditional religious discourse and secular legal precedents support this ethical principle of letting die when understood as freely and competently deciding to forego end of life care in appropriate circumstances as described above.[96]

This ethical principle of letting die is important for dealing with excess IVF embryos in the debate over hESC research. Even acceding to the prudential assumption that a personal soul exists from the inception of human life, thereby including IVF embryos, the principle of letting die can be applied to excess IVF embryos. Insofar as embryos may not remain viable forever in the state of cryopreservation, and do not have donor consent for subsequent procreative use, the unwanted embryos will not be used for procreative purpose.[97] Their state of cryopreservation can be construed reasonably as involving a medical circumstance that is truly terminal. Hence, the ethical principle permits withdrawal of their life-sustaining measures, that is, cryopreservation—a process that results in the frozen embryos thawing until they die. The ethical principle of letting die justifies allowing these embryos to die. Just as there is no ethical duty to keep dying patients alive at any cost or as long as technically feasible, there is no ethical duty to maintain frozen embryos forever in a state of cryopreservation.[98] And establishing the

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(2) the good effect is not the result of the bad effect; (3) the bad effect was not intended; and (4) the good effect is not outweighed by the bad effect. *Id.* at 16.

95. *See id.* at 14.

96. For a discussion on the religious perspective of refusing life-saving medical care, see JOHN PAUL II, *supra* note 42, ¶ 65; U.S. CONFERENCE OF CATHOLIC BISHOPS, *supra* note 69, at 13. For a summary of the legal precedents supporting this principle, see MENIKOFF, *supra* note 70, at 241-303.

97. *Cf.* NAT'L INSTS. OF HEALTH, 1 REPORT OF THE HUMAN EMBRYO RESEARCH PANEL 53-54 (1994) (discussing informed consent and the use of couples' excess reproductive materials for research purposes as well as fertility treatments for others).

98. The exact length of time that cryopreserved embryos remain viable is unknown. While theoretically the embryos may be stored forever, there is some evidence that after a certain amount of time, the embryos could no longer result in a healthy pregnancy. *See* Tenn. Reproductive Med., In Vitro Fertilization: Embryo Freezing, http://www.trmbaby.com/in_vitro/embryo_freezing.shtml (last visited Mar. 22, 2009).

ethical legitimacy of allowing frozen embryos to die sets the stage for what interventions may be justified in the dying process—adopting another traditional ethical principle, as follows.

VII. ETHICAL PRINCIPLE OF HARVESTING FROM DECEASED PATIENTS

There is crucial relevance for combining the ethical principle of letting die with the ethical principle of allowing organs and tissues to be harvested from deceased patients. The relevance is that harvesting ESCs from the thawing embryo might be feasible. If organs and tissues can be harvested legitimately from deceased patients to accomplish substantive good for others, such as transplantation or research, there is no reason why a similar practice cannot be justified for thawing embryos as they die.

The ethical debate over harvesting and transplantation continues apace in the United States.[99] A settled aspect of the practice of harvesting organs and tissues from deceased individuals is the use of brain death criteria to determine the definition of death,[100] developing from the earlier heart-lung criteria.[101] The shift from the cessation of cardiopulmonary function up to the 1960s to legally adopting brain death criteria for organ transplantation occurred over two decades: from the Harvard Medical School focusing on the state of irreversible coma in 1968, to focusing on irreversible brain function in 1972, to the recognition of brain death as the legal equivalent of death in the 1981 Uniform Determination of Death Act ("UDDA"), to the Omnibus Reconciliation Act in 1986 to connect brain death with organ donation, to the American Academy of Neurology in 1995 confirming the use of brain death criteria being appropriate to ethically and legally harvest organs for transplantation.[102] The outcome was to confirm a fully

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99. *See, e.g.*, MENIKOFF, *supra* note 70, at 443-94 (describing the debate over the definition of death and ethical issues involved in death and organ transplantation).

100. Stuart J. Youngner, *The Definition of Death*, *in* THE OXFORD HANDBOOK OF BIOETHICS, *supra* note 11, at 285, 289.

101. *See* MENIKOFF, *supra* note 70, at 462-64; Sam D. Shemie et al., *Brain Death*, *in* THE CAMBRIDGE TEXTBOOK OF BIOETHICS, *supra* note 85, at 85, 86.

102. Landry & Zucker, *supra* note 19, at 1184-85. In documenting the various stages of the shift from cardiopulmonary to brain death criteria, Landry and Zucker cite the following: Omnibus Reconciliation Act of 1986, 42 U.S.C. § 1320b-8 (2000); PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMED. & BEHAVIORAL RESEARCH, DEFINING DEATH: MEDICAL, LEGAL AND ETHICAL ISSUES IN THE DETERMINATION OF DEATH (1981); Ad Hoc Comm. of the Harvard Med. Sch. to Examine the Definition of Brain Death, *A Definition of Irreversible Coma*, 205 JAMA 337 (1968); Alexander Morgan Capron & Leon R. Kass, *A Statutory Definition of the Standards for Determining Human Death: An Appraisal and a Proposal*, 121 U. PA. L. REV. 87 (1973); and Quality Standards Subcomm. of the Am. Acad. of Neurology, *Practice Parameters for Determining Brain Death in Adults (Summary Statement)*, 45 NEUROLOGY 1012 (1995).

developed human being is organismically dead when brain function is irretrievably lost—brain death criteria.[103] The President's Council on Bioethics is currently preparing two new reports, one on organ transplantation and one on brain death, to update the 1981 report by the President's Commission.[104]

Combining these two ethical principles, letting die and harvesting from deceased patients, provides a persuasive argument to permit equivalent harvesting of ESCs from excess IVF embryos. However, the ethics argument is relevant only if there is sufficient scientific data to make the practice feasible. And it is the scientific perspective that raises hurdles to be traversed if this ethical argument is to succeed. There are two scientific hurdles that need to be engaged: the developmental status of the frozen embryo when applying the principle of letting die; and the lack of brain development in the thawing embryo that seems crucial for ascertaining brain death to apply the principle of harvesting upon death.

VIII. DEVELOPMENTAL STATUS OF THE FROZEN EMBRYO

Important research studies have been published recently on the advantages of five-day over three-day IVF embryos for pregnancy and delivery.[105] Until recently, excess embryos in IVF clinics were frozen at the three-day stage of cellular growth (the single cleavage-stage embryo) prior to the embryo becoming a blastocyst containing ESCs.[106] This scientific practice seems to present an insurmountable problem for subsequently harvesting the stem cells in the thawing process. The three-

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103. Landry & Zucker, *supra* note 19, at 1185.

104. Diane M. Gianelli & F. Daniel Davis, *News from the President's Council on Bioethics*, 17 KENNEDY INST. ETHICS J. 397, 397-98 (2007). The white paper on the issue of determination of death is currently available online. *See* PRESIDENT'S COUNCIL ON BIOETHICS, CONTROVERSIES IN THE DETERMINATION OF DEATH (2008), *available at* http://www.bioethics.gov/reports/death/determination_of_death_report.pdf.

105. *See, e.g.*, E.M. Kolibianakis et al., *Should We Advise Patients Undergoing IVF to Start a Cycle Leading to a Day 3 or a Day 5 Transfer?*, 19 HUMAN REPROD. 2550, 2553 (2004) (asserting that blastocysts at the five-day stage have a greater chance of implantation than an embryo at the three-day cleavage stage); Evangelos G. Papanikolaou et al., *In Vitro Fertilization with Single Blastocyst-Stage Versus Single Cleavage-Stage Embryos*, 354 NEW ENG. J. MED. 1139, 1142 (2006) (finding that transferring embryos at the blastocyst stage resulted in a higher likelihood of pregnancy); Laura A. Schieve, *The Promise of Single-Embryo Transfer*, 354 NEW ENG. J. MED. 1190, 1191 (2006) ("Culturing embryos for five days, to the blastocyst stage, may allow for more accurate assessment of embryo quality and thus for enhanced selection of a high-quality embryo.").

106. *See* James J. Stachecki et al., *Cryopreservation of Biopsied Cleavage Stage Human Embryos*, 11 REPROD. BIOMED. ONLINE 711, 712 (2005) (discussing standard cryopreservation protocols and the freezing of embryos at the three-day stage).

day stage embryo is not yet a blastocyst with ESCs.[107] Hence, a plan to harvest ESCs would require thawing the frozen embryo and further cultivating it to the five-day stage (the single blastocyst-stage embryo) when it becomes a blastocyst with ESCs. This process involves thawing the embryo, further cultivating it albeit for some days, then letting it die to harvest the stem cells.[108]

This process of thawing, growing, and letting die would be inconsistent with an ethical argument that accedes to the prudential assumption of an embryo having a personal soul from its inception—if that is so, it would be unethical to let the embryo thaw, then grow in order to let die once it developed ESCs. The paradigm of the principle of letting patients die of their terminal disease would not pertain in such circumstances. The critical factor in that paradigm is the removal of life-sustaining measures in order to let the patient die. The equivalent action with regard to the frozen embryo would be to withdraw the life-sustaining measure of cryopreservation to let the embryo thaw in a dying process.

Two relevant observations need to be highlighted. On the one hand, an embryo frozen at the three-day stage of its cellular growth has not become a blastocyst with stem cells for harvesting.[109] Hence, the argument for combining the ethical principles in this Article—letting die and harvesting from the deceased—could not be applied because there are no stem cells to harvest. On the other hand, it is contrary to the prudential assumption of the embryo having a personal soul to let the IVF frozen embryo thaw, then develop into the blastocyst stage with stem cells, and then be allowed to die to harvest the stem cells. That is, manipulating the embryo in this way depicts a merely utilitarian perspective that compromises the basic respect due to the embryo as human life with a personal soul, not to be treated merely as a means or as an object. Until recently, the standard of care in IVF clinics of freezing excess embryos at the three-day stage of cellular growth presents scientific data that presents insurmountable difficulties for the ethical argument being sought here—that is, combining the principles of letting die and harvesting from the deceased to justify using excess IVF embryos for hESC research.

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107. *See* Joe Leigh Simpson, *Blastomeres and Stem Cells*, 444 NATURE 432, 433 (2006) (stating that stem cells have been derived from embryos at the preimplantation blastocyst stage, which occurs five to six days after conception).

108. *See* Christopher L. R. Barratt et al., *Clinical Challenges in Providing Embryos for Stem-Cell Initiatives*, 364 LANCET 115, 115 (2004) (describing the process of thawing and further culturing an embryo to the blastocyst stage in order to harvest stem cells).

109. *See* Thomson et al., *supra* note 2, at 1145.

However, recent scientific research has indicated that there is a new standard of care for fertility treatment in IVF clinics. The new practice is to implant the five-day single blastocyst-stage embryo rather than the three-day single cleavage-stage embryo.[110] And the rationale is based upon enhancing the likelihood of successful pregnancy and delivery. A prospective, randomized, controlled trial published in 2006 concluded that "transfer of a single blastocyst-stage embryo significantly increases the likelihood of pregnancy and delivery as compared with transfer of a single cleavage-stage embryo."[111] This study added to earlier results from a different randomized, multicenter trial published in 2004 that addressed the increased risk of premature birth and perinatal death as being related to increased number of embryos transferred. The 2004 study concluded:

> [A] single fresh-embryo transfer, followed (if there was no live birth) by the transfer of one frozen-and-thawed embryo, results in a marked reduction in the rate of multiple gestations but not in a substantial reduction in the rate of pregnancy resulting in one or more live births.[112]

And finally, research has also demonstrated that "human embryonic stem-cell lines may be derived more efficiently from frozen blastocysts than from frozen cleaved embryos."[113]

This new standard of care for IVF patients is significant insofar as the five-day blastocyst-stage embryo has developed stem cells within the inner cell mass. Hence, when freezing excess embryos they will already have developed stem cells. Given this new standard of care, it becomes increasingly plausible to adopt the ethical argument of letting the frozen embryo die and then harvesting its stem cells. In other words, the paradigm of applying the ethical principle of letting die has relevance in the sense that if the principle can justify withdrawing life-sustaining care from living patients, then, *a fortiori*, the principle can be applied to frozen embryos. As a result, the first scientific hurdle is traversed as a condition for the ethical argument to have traction. But there is a second scientific hurdle dealing with brain death criteria that could block the ethics argument on using frozen embryos.

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110. *See* Schieve, *supra* note 105, at 1191.

111. Papanikolaou et al., *supra* note 105, at 1145.

112. Ann Thurin et al., *Elective Single-Embryo Transfer Versus Double-Embryo Transfer in In Vitro Fertilization*, 351 NEW ENG. J. MED. 2392, 2401 (2004).

113. Chad A. Cowan et al., *Derivation of Embryonic Stem-Cell Lines from Human Blastocysts*, 350 NEW ENG. J. MED. 1353, 1353 (2004).

IX. EQUIVALENT POINT OF BRAIN DEATH IN THE THAWING EMBRYO

Insofar as the ethical principle of letting die can be applied cogently to thaw embryos that were frozen at the blastocyst stage in order to harvest their stem cells, the critical question that remains is when to determine the equivalent point of brain death. The ethical principle of harvesting organs and tissues from patients using brain death criteria is widely accepted in our culture.[114] However, there has been a lack of corresponding criteria for human embryos. Obviously the frozen embryo at the blastocyst stage does not yet have brain development to facilitate the application of brain death criteria as a condition for harvesting.[115] So the scientific hurdle here is whether an equivalent point of brain death can be ascertained in the thawing embryo. But before considering this issue, another point needs attention.

A plausible argument can be sustained in favor of permitting harvesting of stem cells at any time in the process of letting the frozen blastocyst die, thereby not needing an equivalent point of brain death as required for patients. When the ethical principle of harvesting uses brain death criteria in patients, the purpose is to ascertain scientifically the point at which recovery of the patient is not feasible yet the cells in organs and tissues remain viable for transplantation. And three important issues arise from this observation.

First, the obvious difference between a thawing five-day blastocyst and a dying patient is that both have cellular viability but only the patient has what we recognize as fully developed human life. This distinction is not made to argue against the blastocyst having a personal soul—that is acceded to in this analysis. The difference between the dying blastocyst and the dying patient as each having a personal soul could be explained in a variety of ways, such as with regard to sentience, consciousness, etc.[116] But more importantly, the similarity between them is that both have viable cells in the dying process. If the viable cells can be harvested from a patient after developed human life has died (using brain death criteria), and if there is no equivalent of developed human life to die in the blastocyst (so brain death criteria do not pertain), then it seems that the blastocyst's cells can be harvested at any time in its thawing/dying process. In contrast to this point of view, the third point below seeks to justify harvesting the blastocyst's stem cells by a more cautious approach, by determining the equivalent of brain death criteria.

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114. Eun-Kyoung Choi et al., *Brain Death Revisited: The Case for a National Standard*, 36 J.L. MED. & ETHICS 824, 825 (2008).

115. Miller, *supra* note 62, at 848.

116. *See* Sandel, *supra* note 6, at 208.

The second issue deals with the relevance of the prudential assumption that human life has a personal soul from its inception. This point suggests that the ethical principle of harvesting (using brain death criteria) appears not to be concerned about having a personal soul at the biological end of life. Recalling the equivalency of the secular understanding of human life as personal and the religious understanding of human life as having a soul, considerable emphasis is given to the prudential assumption that human life is deemed to have a personal soul from the biological start of life. As indicated previously, there is a plausible rationale for this prudential assumption: Because it is not known when human life becomes personal or has a soul, caution accords protecting human life from the earliest possible moment, its inception. Yet, it is interesting that caution over this prudential assumption does not appear to similarly pertain at the end of life.

If the same caution were to prevail, it is likely that harvesting may not be permitted, legally or ethically. When a personal soul enters or leaves human life is not known and cannot be known. If that lack of knowledge justifies the prudential assumption at the start of life, consistency would suggest that it also pertains at the end of human life. And it would not be sufficient to distinguish the start/end of life spectrum by arguing that much life lies ahead from the start and life is petering out at the end. In each case, if human life has a personal soul, the conservative stance about respecting human life should seek to maintain that respect at each end of the spectrum. The argument of consistency is this: Not knowing when life begins to have a personal soul warrants maximum caution by protection from its biological beginning, which is the inception of cellular development. Likewise, not knowing when life stops having a personal soul should warrant maximum caution by protection until its biological demise, which would be the end of cellular development. But if we waited until the end of cellular development, we could not harvest organs and tissues for transplantation.

So, why does our culture so readily accept the ethical principle of harvesting after death using brain death criteria? There is a good explanation, though it does raise an awkward challenge for the prudential assumption at the start of life. From both secular and religious perspectives, harvesting after brain death criteria is deemed ethically legitimate despite not knowing whether a personal soul remains in the body given the continuing cellular activity required for transplantation. The rationale appears to be that of reliance on the probabilities of science to delineate a practical moment of death, even though death is

better understood by science as a process than as a specific moment.[117] Ascertaining that point has become more sophisticated over time as science has progressed. And it may be that we will move from brain death criteria to another standard, such as molecular markers, to determine the moment of death of developed individuals or patients. It appears that using the probabilities of science to determine a legal point of death currently elicits widespread ethical support, both secular and religious.[118] For example, "determination of death should be made . . . in accordance with responsible and commonly accepted scientific criteria."[119]

This common-sense approach at the end of life presents an interesting challenge for adopting a consistent ethical stance at the start of life with regard to respecting and protecting human life as having a personal soul. If the prudential assumption at the start of life is applied to the end of life, as considered above, consistency could require ending the practice of harvesting viable organs and tissues, at least insofar as a plausible case can be made that a personal soul remains in the dying body until cellular activity ends. But such a stance appears to lack prudence, especially given the practical need to determine a so-called moment of death such as by brain death criteria. In contrast, another perspective appears more plausible. Perhaps reliance on the probabilities of science to determine the so-called end of life, or the moment of death, should also pertain to determine the so-called start of life, determinations that would delineate when human life warrants respect and protection as having a soul. If this stance were to prevail, a considerable change in start of life ethical discourse could result.

For example, the probabilities of science may suggest the start of life at the time of the development of the primitive streak, which occurs around day fourteen of embryonic development.[120] The primitive streak is constituted by "a band of cells that establishes the embryo's head-tail and right-left orientations."[121] The primitive streak is construed as a biological threshold point insofar as it indicates when biological individuation occurs and twinning is no longer possible.[122] From this

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117. *See* Youngner, *supra* note 100, at 297-98.

118. For a discussion of the religious perspective, see U.S. CONFERENCE OF CATHOLIC BISHOPS, *supra* note 69, at 14. The ethical acceptance of and need for standard scientific criteria to be used in determining the point of death is discussed in Choi et al., *supra* note 114, at 825.

119. U.S. CONFERENCE OF CATHOLIC BISHOPS, *supra* note 69, at 14.

120. *See* Okie, *supra* note 6, at 3; *see also* Sandel, *supra* note 6, at 209 (discussing possible regulations that could be imposed on stem cell research in order to protect embryos, including prohibiting research embryos from developing beyond fourteen days).

121. Okie, *supra* note 6, at 3.

122. *Id.*; *see also* Mary Warnock, *The Warnock Report*, 291 BRIT. MED. J. 187, 188 (1985).

biological point, the embryo warrants respect and protection of its cellular development, akin to what was described previously as human life with a personal soul.

There is sound rationale for ascertaining the moment of death using brain death criteria, and thereby ethically justifying harvesting. Nonetheless, this common-sense stance raises a consistency challenge about the prudential assumption that is acceded to in this Article with respect to the start of life. The reliance on the probabilities of science to determine the point of death at the end of life is a contrasting prudential assumption. So, ethical discourse on issues about the start and end of life need to more rigorously evaluate these contrasting prudential assumptions. However, for the purpose of this analysis, it suffices to acknowledge that harvesting after brain death criteria is ethically justifiable. Hence, the relevant question here is how such criteria pertain to harvesting stem cells from thawing embryos that have no brain development.

Third, to deploy an ethics argument that would apply the ethical principle of harvesting after death, it would be advantageous to determine in the thawing blastocyst an equivalent point of brain death criteria for a human cadaver. Brain death criteria ascertain the point at which the patient has advanced sufficiently into the dying process as to be irretrievable while the organs and tissues of the patient remain viable.[123] But an embryo has no brain to apply brain death criteria, nor can cardiopulmonary function be tested.[124] By establishing brain death criteria, it is possible to confirm that a fully developed human being is organismically dead. Ideally, it would be helpful if equivalent criteria might be available to determine the organismic death of a thawing embryo prior to the development of its central nervous system. And this is what recent research has been able to accomplish.

This research considers death as being the loss of capacity for continued and integrated cellular division, growth, and differentiation. This capacity can be lost in an embryo even though its individual cells remain alive.[125] That is, in the embryo there is a developing organism with cells directing the gene expression and differentiation thereby growing as a whole, akin to how the central nervous system integrates tissues and organs subsequently. An embryonic cell marker called *Oct4* (Octamer-4) is a protein that is being investigated as an objective criterion for ascertaining the irreversible arrest of cell integration in the

123. *See* Youngner, *supra* note 100, at 288.
124. *See* Miller, *supra* note 62, at 848.
125. Landry & Zucker, *supra* note 19, at 1186.

developing embryo and thereby as the equivalent to brain death criteria.[126] Continued research is likely to refine the predictive reliability of such markers to firmly establish criteria for determining an embryo's death when its cells remain viable for transplantation.[127]

As this quest for a biochemical indicator or cell-surface marker continues, there appears to be a reliable measure to ascertain irreversibility or embryonic death based upon the natural history of embryonic death. For example, in research by Donald Landry and others, several twenty-four-hour periods of frozen embryos failing to divide indicate organismic death, and arrested development at the multicellular stage at a specific time seems to indicate irreversible loss of integrated organic function, thereby presenting an indicator of the embryo's death.[128] In further research, Landry and others concluded: "Criteria for irreversible loss of the capacity for normal embryonic development would provide an operational definition for the diagnosis of embryo death consistent with the concept of death as the irreversible loss of integrated organic function. The issue of irreversibility is a paramount concern for any determination of death."[129] Hence, they proposed that "a natural history study of nonviable IVF embryos might yield a time beyond which an embryo, having failed to divide normally despite best efforts, never returns to the path of normal development."[130] In other words, the criteria dealing with irreversibility adopted for harvesting from deceased persons could be applied cogently to harvesting live cells from dead embryos. It is also worth noting that there is reliable evidence to indicate that the overwhelming majority of hESCs remain viable in the thawing process under standard conditions and also that embryonic cell death can be managed by temperature controls.[131]

This remarkable hypothesis of using similar criteria dealing with natural history indicators, like irreversibility for diagnosing death in

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126. *Id.* at 1185.

127. *Id.* at 1186.

128. *Id.*; Donald W. Landry et al., *Hypocellularity and Absence of Compaction as Criteria for Embryonic Death*, 1 REGENERATIVE MED. 367, 369 (2006); Zhang et al., *supra* note 18, at 2672.

129. Landry et al., *supra* note 128, at 368.

130. *Id.*

131. B.C. Heng et al., *Kinetics of Cell Death of Frozen-Thawed Human Embryonic Stem Cell Colonies Is Reversibly Slowed Down by Exposure to Low Temperature*, 14 ZYGOTE 341, 344 (2006); Boon Chin Heng et al., *Loss of Viability During Freeze-Thaw of Intact and Adherent Human Embryonic Stem Cells with Conventional Slow-Cooling Protocols Is Predominantly Due to Apoptosis Rather than Cellular Necrosis*, 13 J. BIOMED. SCI. 433, 439 (2006); *see also* Bongaerts & Severijnen, *supra* note 10, at 479-80 (describing how microorganisms can exist in a state that is not dead, but instead is both lifeless and still viable, and arguing that embryos are not completely killed when stem cells are harvested).

deceased patients and in embryos, threads the needle, so to speak, to justify using excess IVF embryos for hESC research. And a significant corollary should be noted. The analysis here refers to frozen embryos, specifically justifying harvesting from the five-day blastocyst the ESCs in the inner mass. However, this argument cannot be applied to live embryos created by IVF procedures but not yet frozen. The argument does not apply because the embryo at the point of creation in the IVF process has not developed its ESCs that could be harvested by letting the embryo die if it was unwanted. Typically unused IVF embryos are frozen to be available for subsequent use by the prospective mother in the event that previous embryos do not lead to pregnancy.[132] Moreover, the embryo could not simply be cultivated for five days to develop into a blastocyst in order to harvest its ESCs by letting it die—that process would meet the same ethical opposition as described above in thawing a three-day frozen embryo, cultivating it to become a blastocyst, and then letting it die to harvest its stem cells.

X. ETHICAL JUSTIFICATION OF A RESTRICTED BUT PRODUCTIVE RESEARCH RESOURCE

The ethical justification in this Article is the argument for hESC research on a very restricted yet highly productive resource. The resource refers to excess blastocysts frozen as five-day embryos whose inner cell mass already contains ESCs. This resource is restricted to embryos created in IVF clinics for fertility purposes, so it cannot be applied to the creation of embryos for the specific purpose of research. The resource does not include newly created embryos. However, this highly restrictive resource could be very productive. And researchers need a large number of hESC lines. A number of hESC lines have been developed so far.[133] And a small number of these lines remained eligible for federal funding based on the 2001 decision of President Bush permitting these lines because they had been created prior to the enactment of his policy. Although President Obama revoked the 2001 Executive Order of President Bush that restricted federal funding for ESC research beyond these limited lines,[134] it is important to understand the justification of President Bush's stance. This can be achieved by appealing to another centuries-old conservative ethical principle called

132. *See* Hoffman et al., *supra* note 7, at 1063.

133. Cowan et al., *supra* note 113, at 1353 (stating that fifteen human stem cell lines are available for public research use).

134. Exec. Order No. 13,505, 74 Fed. Reg. 46 (Mar. 9, 2009).

the principle of material cooperation.[135] Both President Bush and his predecessor President Clinton appear to have adopted this ethical principle.[136]

The point of the principle is to ascertain that there is no moral complicity in a perceived wrongdoing, even though there is a material connection, hence the name of the ethical principle.[137] This principle is perhaps one of the most commonly used ethical principles in secular and religious discourse.[138] An illustration can indicate its common coinage. Opponents to nuclear weapons may continue to pay their government taxes even though a small percentage of those taxes can be materially connected to funding for nuclear weapons—research, creation, maintenance, and deployment. That is, when paying government taxes, there is sufficient opposition to and distance from the perceived wrongdoing, and there is sufficient good being accomplished—that is, paying legitimate taxes that otherwise also contribute to the common good of society.

Hence, the principle of material cooperation permits use, including research and medical treatments, of resources that may have been obtained unethically. For example, in religious discourse, when many reliable vaccines were developed from aborted fetal tissue, many pro-life patients and families who opposed abortion worried about their ethical complicity in the perceived wrongdoing of abortion. However, the principle of cooperation permits the use of such vaccines, despite their genesis, conditional upon the following: being opposed to the perceived wrongdoing; being sufficiently distant from the perceived wrongdoing as to be unable to prevent it; and being able to accomplish significant good by using the vaccines.[139] However, the vaccines application of this ethical principle by traditional religious doctrine does raise an awkward

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135. *See* Charles E. Curran, *Cooperation: Toward a Revision of the Concept and its Application*, 41 LINACRE Q. 152, 153-55 (1984); Neil Scolding, *Cooperation Problems in Science: Use of Embryonic/Fetal Material*, *in* COOPERATION, COMPLICITY AND CONSCIENCE: PROBLEMS IN HEALTHCARE, SCIENCE, LAW AND PUBLIC POLICY 105, 111 (Helen Watt ed., 2005).

136. Magill, *supra* note 26, at 720-22.

137. *Id.* at 721-22.

138. *See, e.g.*, Scolding, *supra* note 135, at 111 (applying the principle of cooperation to the stem cell debate). *See generally* Curran, *supra* note 135 (discussing the principle of cooperation from a religious perspective and exploring its applicability in the medical context).

139. *See* Daniel P. Maher, *Vaccines, Abortion, and Moral Coherence*, 2 NAT'L CATH. BIOETHICS Q. 60-62 (2002). *See generally* Edward J. Furton, *Vaccines Originating in Abortion*, 24 ETHICS & MEDICS 3 (1999) (discussing potential controversies over the use of vaccines developed from aborted fetal material and stating that the use of these vaccines by Catholics is not cooperation with the practice of abortion because it is so far removed from the act of abortion and because refusal of the vaccine may pose a fatal risk to the individual); James F. Keenan & Thomas R. Kopfensteiner, *The Principle of Cooperation*, HEALTH PROGRESS, Apr. 1995, at 23-26 (describing the theory of cooperation and its implications).

question: Will there be a similar occurrence in years ahead regarding hESC therapies that may be developed—the recurrence being antecedently opposing hESC research in principle yet subsequently being amenable to using hESC therapies when they are developed? That stance may not be plausible to everyone, thereby inviting a reconsideration of practice at either end of the spectrum in the cause of consistency: to accept hES research now or to reject using hESC therapies later.

Notwithstanding the above difficulty, the principle of material cooperation can present a justification for President Bush permitting federal research funding on the ESC lines that were created prior to his 2001 policy.[140] However, all of these approved lines were developed using mouse cultures. Although these lines are helpful for studies in basic science, the mouse contamination means they should never be used to develop clinical therapies for humans, such as developing lines that model specific diseases to develop human treatments.[141] In addition, a limited number of hESC lines have been developed since 2001 by independent funding.[142] Fortunately, many of these stem cell lines are not contaminated by mouse cultures, and hence can be helpful for research and the future development of treatments and therapies for humans. Nonetheless, this small number of ESC lines is prone to the typical problems of maintaining any cell line over time, and hence need to be replaced by others.[143] And, naturally, a larger diversity of stem cell lines can contribute advantageously to continuing hESC research.

So, there will be an ongoing need for ESCs to develop non-contaminated lines for hESC research.[144] The narrow focus of this Article has been to present a cautious ethical argument that justifies using excess IVF frozen blastocysts as a narrow but potentially very productive research resource. Until 2009, using this resource was opposed by secular doctrine based on the 2001 policy of President Bush—a policy that, as mentioned previously, President Obama revoked

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140. Magill, *supra* note 26, at 720-22.

141. *See generally* George Q. Daley, *Missed Opportunities in Embryonic Stem-Cell Research*, 351 NEW ENG. J. MED. 627 (2004) (arguing that the ban on federal funding for the development of new stem cell lines has severely hindered biomedical research and the development of cures for genetic defects).

142. Seventeen such lines were developed with the approval from a Harvard University institutional review board. Cowan et al., *supra* note 113, at 1353. For a discussion on the private institutions that have provided funding for stem cell research, see Stephen S. Hall, *Stem Cells: A Status Report*, HASTINGS CTR. REP., Jan.-Feb. 2006, at 16, 18.

143. *See* John Gearhart, *New Human Embryonic Stem-Cell Lines—More Is Better*, 350 NEW ENG. J. MED. 1275, 1275 (2004).

144. *Id.* at 1276.

in 2009.[145] Some religious doctrine continues this opposition.[146] There has been hope that ESCs may be obtained by other means than destroying the human blastocyst, such as by using iPSCs.[147] But as discussed previously, human iPSCs have the potential of developing into a human fetus, akin to the developmental capacity of a blastocyst.[148] As a result, the initial wave of hopeful optimism among conservative voices may dissipate with this emerging understanding of the biological capacity of iPSCs.

Another way of obtaining ESCs is that of somatic cell nuclear transfer ("SCNT"),[149] which elicits robust debate on the relation between science and ethics.[150] Substantive progress has been made recently in increasing the efficiency of developing ESC lines from human blastocysts. A recent study reports that such an increase in efficiency means "the line has been crossed between viewing the derivation of human nuclear-transfer ESCs as an experimental system and viewing it as a viable clinical proposition."[151] However, SCNT is unacceptable to many who uphold conservative doctrine, such as President Bush and many faith traditions. They oppose SCNT because they construe the cloned embryo as having a personal soul and hence, it cannot be destroyed for hESC research. And they excoriate any effort to use a human SCNT embryo, because it is a cloned organism, for research or for reproductive purposes.[152] It should be noted that there is a consensus in the scientific community to embrace SCNT exclusively for research, adopting the technology only to create cells and never to create babies.[153] Even though scientists ardently seek to obtain federal funding for using SCNT technology only for hESC research,[154] this Article does not engage this topic because it requires the creation and intentional destruction of a human blastocyst which stands counter to acceding to

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145. *See* Bush, *supra* note 26, at 214; *see also* Exec. Order No. 13,505, 74 Fed. Reg. 46 (Mar. 9, 2009).

146. *See* CONGREGATION, *DIGNITAS PERSONAE*, *supra* note 25, § 32.

147. Magill & Neaves, *supra* note 56, at 24.

148. *Id.* at 26.

149. *See* Woo Suk Hwang et al., *Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts*, 308 SCIENCE 1777, 1778 (2005).

150. *See generally* Rudolf Jaenisch, *Human Cloning—The Science and Ethics of Nuclear Transplantation*, 351 NEW ENG. J. MED. 2787 (2004) (discussing the ethical implications of nuclear transfer and focusing on how the technique is used in the cloning process).

151. Perry, *supra* note 3, at 87-88.

152. *See* CONGREGATION, *DIGNITAS PERSONAE*, *supra* note 25, §§ 28-30; McHugh, *supra* note 17, at 210.

153. *See* McHugh, *supra* note 17, at 210.

154. *See* Phimister, *supra* note 35, at 1647-48.

the prudential assumption mentioned previously. However, this Article does not adopt a position on the ethics of SCNT.

There are other techniques being explored to obtain ESCs and they have been considered by the President's Council on Bioethics, though none have been adopted yet by the Council.[155] One technique is single-blastomere biopsy whereby a single cell, a blastomere, is removed from an eight-cell stage blastocyst.[156] The blastomere is cultured to develop an ESC line and the remaining seven-cell embryo would be implanted for reproduction.[157] And prior experiments with mice indicate the feasibility of this approach.[158] But substantive problems arise when applying this technique to humans, both scientific, due to the complexity involved, and ethical, due to the uncertainty of the remaining seven-cell embryo after implantation always developing into a normal human baby.[159] However, it should be noticed that the procedure is based on the increasingly practiced technique of pre-implantation genetic diagnosis ("PGD"). The practice of PGD removes a human blastomere for testing purposes and implants the blastocyst minus that blastomere, and more than 1000 healthy babies have been born.[160] Also, there have been successful experiments demonstrating that hESCs can be derived from the single blastomere.[161]

Another technique being explored to obtain ESCs is called altered nuclear transfer ("ANT"), such as that proposed by Professor Hurlbut on the President's Council on Bioethics.[162] The technique creates an embryo whose gene for normal development is inactivated from the outset. A similar phenomenon occurs in the natural process of human reproduction. A proof-of-principle study was undertaken successfully in

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155. *See generally* PRESIDENT'S COUNCIL ON BIOETHICS, ALTERNATIVE SOURCES OF HUMAN PLURIPOTENT STEM CELLS (2005) (reporting on a number of different potential sources of stem cells, including organismically dead embryos, somatic cell differentiation, biological artifacts, and blastomere extraction from living embryos); Bonnie Steinbock, *Alternative Sources of Stem Cells*, HASTINGS CTR. REP., July-Aug. 2005, at 24 (discussing the President's Council on Bioethics' report and summarizing the alternative sources of stem cells proposed by the Council).

156. PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 155, at 24-25.

157. *Id.*

158. Young Chung et al., *Embryonic and Extraembryonic Stem Cell Lines Derived from Single Mouse Blastomeres*, 439 NATURE 216, 218 (2006).

159. *See id.*; Nick Strelchenko, *Morula-Derived Human Embryonic Stem Cells*, 9 REPROD. BIOMED. ONLINE 623, 628 (2004).

160. Steinbock, *supra* note 155, at 25.

161. Irina Klimanskaya et al., *Human Embryonic Stem Cell Lines Derived from Single Blastomeres*, 444 NATURE 481, 484 (2006).

162. William B. Hurlbut, *Altered Nuclear Transfer as a Morally Acceptable Means for the Procurement of Human Embryonic Stem Cells*, 48 PERSP. BIOLOGY & MED. 211, 212, 220 (2005).

mice that effectively tested the ANT hypothesis.[163] In the mice experiment, through SCNT, the technique inactivated a developmental gene (*Cdx2*) in the somatic cell nucleus before combining with the enucleated egg.[164] That gene is necessary for trophectoderm development (to form the outer layer of the blastocyst, the trophoblast) that enables the embryo to implant in the uterine wall.[165] As a result of this technique, cloned blastocysts cannot develop beyond the blastocyst stage, although they develop the inner cell mass from which their ESCs can be harvested.[166] Some argue that the alteration fundamentally changes the structural capacity to develop as a human embryo, thereby causing the resulting organism to lack the moral status of a human embryo, even though it can develop hESCs.[167] Again there are substantive problems that arise when applying this technique to humans, both scientific problems, based on the complexities of shifting the research model from mice to human experiments, and ethical problems, as the method could not guarantee that every such entity would be incapable of normal development as a human embryo.[168]

Neither of these two techniques (single-blastomere biopsy or ANT) offers an immediate capacity for developing ESC lines that would readily resolve conservative ethical concerns about safeguarding the human embryo. Hence, this Article focuses upon providing an ethical argument to justify using excess IVF blastocysts for hESC research by adopting a cautious posture of deploying two traditional ethical principles. Each principle would be inadequate on its own to justify the argument. The two ethical principles are: the principle of letting die and the ethical principle of harvesting after death. By combining these principles, this Article has provided a robust justification and strenuous support for the use of IVF frozen blastocysts in hESC research. Moreover, the analysis is submitted as a development of doctrine, secular and religious alike, rather than a rejection of the current doctrine that opposes this use of IVF embryos for hESC research.

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163. Alexander Meissner & Rudolf Jaenisch, *Generation of Nuclear Transfer-Derived Pluripotent ES Cells from Cloned* Cdx2*-Deficient Blastocysts*, 439 NATURE 212, 214-15 (2006).

164. *Id.* at 213.

165. *Id.*; *see also* COHEN, *supra* note 15, at 52 (describing Meissner and Jaenisch's mouse experiment).

166. Meissner & Jaenisch, *supra* note 163, at 212.

167. Hurlbut, *supra* note 162, at 226.

168. *See* W. Malcolm Byrnes, *Partial Trajectory: The Story of the Altered Nuclear Transfer-Oocyte Assisted Reprogramming (ANT-OAR) Proposal*, 74 LINACRE Q. 50, 53 (2007); Carina Dennis & Erika Check, *'Ethical' Routes to Stem Cells Highlight Political Divide*, 437 NATURE 1076, 1077 (2005); Davor Solter, *Politically Correct Human Embryonic Stem Cells?*, 353 NEW ENG. J. MED. 2321, 2323 (2005).

XI. CONCLUSION

An explanation of the difference between developing and rejecting the conservative doctrine on opposing the use of excess IVF frozen embryos for hESC research should sharpen the point of the argument. The analysis clearly accedes to the prudential assumption that human life has a personal soul from its inception, even though serious flaws have been exposed in that assumption. This Article justifies using IVF blastocysts for hESC research in a manner that does not repudiate the rationale underlying the conservative doctrine that opposes the research. The argument could have sought to reject the current doctrine by a more persuasive appeal to other traditional ethical principles. But doing so would needlessly forfeit the central insight of the conservative doctrine: that human life is construed to have a personal soul from its inception and therefore elicits not only respect but also protection from destruction even for the noble cause of medical research.

The central insight of the conservative doctrine is that excess IVF embryos should not be destroyed despite the fact that they will not lead to a pregnancy and will die eventually (the so-called practical usefulness argument of using them for some good), irrespective of the urgent need for treatments by so many sick or diseased or debilitated patients (the so-called compassionate argument of assisting the needy), and notwithstanding the high hopes of medical research (the so-called noble cause argument of human flourishing). This Article has not adopted any of these widely used claims to justify a shift from opposing to supporting the use of excess IVF embryos for hESC research.

Instead, this Article has acceded to the prudential assumption in the conservative doctrine and thereby rejects interventions that intend or seek to destroy the frozen blastocyst for whatever reason, just as medical care refuses to kill any patient no matter how sick or close to death. The analysis adopts the paradigm of a dying patient in a terminal condition to highlight the practice that both letting the patient die and harvesting after death, using brain death criteria, is not only ethically justifiable but a world away from killing or murdering the patient. Similarly, letting frozen embryos thaw to die and then harvesting their ESCs, after adopting the equivalent practice of using brain death criteria, is a world away from killing or destroying the blastocyst. And just as a patient or family can voluntarily permit the withdrawal of life-sustaining treatment and harvesting after death, similarly informed consent should be sought

from the biological parents to use excess IVF frozen blastocysts for hESC research, whether the research is federally funded or not.[169]

In other words, this Article submits an argument based on the development of doctrine rather than being an outright rejection of the conservative doctrine, both secular and religious. The central stance of the conservative doctrine continues to prevail in this new argument: acceding to the prudential assumption that assigns to human life from its inception a personal soul that warrants the embryo being protected from intentional destruction. And the novelty in this analysis is a function of ethical imagination—to combine the traditional ethical principle of respecting human life in the conservative doctrine with complementary traditional ethical principles (justifiably letting die and harvesting after death), adopting the paradigm of a dying patient. The outcome is to propose a developed doctrine that supports using excess IVF frozen blastocysts for hESC research in a process that indeed entails their death, but not by seeking or intending to kill or destroy them—just as letting a patient die and harvesting organs does not involve either seeking or intending the patient's death. This new stance is a genuine development of the previous doctrine, as an oak tree from the acorn, even though there are opposing outcomes. The nuance of the argument is that the shift from opposing to supporting the research in question emerges as a function not of rejection but of development. In today's complex ethical discourse, the gentle winds and hermeneutic of developing doctrine can result in refreshing and invigorating change.

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169. Robert Streiffer, *Informed Consent and Federal Funding for Stem Cell Research*, HASTINGS CTR. REP., May-June 2008, at 40, 42. The development of consent in this field was based on the recommendations of the National Institutes of Health. *See* NAT'L INSTS. OF HEALTH, *supra* note 97, at 53-54.