Embryo Culture and the "Culture of Life": Constitutional Issues in the Embryonic Stem Cell Debate

John A. Robertson[†]

The "culture of life" debate has been a powerful force in recent American law and politics. It influences the choice of Supreme Court justices and inspires sanctions on doctors who legally prescribe drugs for assisted suicide. Like an erupting volcano, it drove the extraordinary attempt by Congress in 2005 to overturn Florida court decisions that allowed Teri Schiavo's husband to remove her feeding tube.[1]

The embryonic stem cell controversy, another battleground in the "culture of life" wars, has potentially even greater significance for people's lives. The ability to culture human embryonic stem cells ("ESCs") in the laboratory has opened the door to cell replacement treatments for a wide range of diseases. The need, however, to destroy embryos to obtain ESCs has mired scientific progress in the trenches of yet another pitched battle between the "culture of life" and the "culture of death."[2] Opposition to embryonic stem cell research and therapy could block the promise of embryonic stem cell science for millions of persons.[3]

In the United States, the debate over ESCs has unfolded more as a conflict over federal funding of research, and less as a direct prohibition on their derivation or use. But funding prohibitions are a powerful brake on the pace of research,

[†] Vinson & Elkins Chair in Law, University of Texas at Austin. The author is grateful for comments on an earlier draft presented at the University of Chicago Legal Forum Symposium and the University of Texas Law School Colloquium.

[1] For an account of those issues, see John A. Robertson, *The (In)Significance of Schiavo*, 35 Stetson L Rev 101, 103-04 (2005).

[2] These terms are shibboleths for positions on such issues of life and death as abortion, contraception, euthanasia, and assisted suicide. Despite the vagueness of the terms, they have figured prominently in the legal, policy, and cultural wars surrounding the ESC debate. Consider George Lakoff, *Moral Politics* 222-44 (Chicago 1996) (discussing liberal and conservative framing of controversial moral issues).

[3] Opponents of ESC research are not against medical research per se, but are against using ESCs to do it. President's Council on Bioethics, *Monitoring Stem Cell Research* 58-60 (2004).

particularly when this brake prevents the National Institutes of Health ("NIH") from playing its traditional role of supporting research that is too far upstream from marketable products to attract private investment.[4] In addition, some states directly prohibit embryo research,[5] and an effort to ban the use of ESC products made through nuclear transfer cloning passed the US House of Representatives by a wide margin.[6]

The focus of the United States debate on federal funding, so different from European and Asian debates over ESC policy, arose from President Bush's 2001 decision to permit ESC research funding only with cell lines then already in existence.[7] Originally touted as making 66 lines available for researchers, in reality only 22 cell lines qualified under the Bush policy.[8] It became rapidly clear that many more lines would be needed to accelerate the science and yield its therapeutic potential. Not only were the original lines contaminated by mouse viruses,[9] but the few genotypes represented could hardly serve as models for the many different diseases that the ESC platform promised to treat. The creation of new ESCs through nuclear transfer to deal with immune system rejection also appeared necessary as research moved into the clinic.

"Culture of life" politics, however, has stymied relaxation of federal funding restrictions. With the Bush administration recalcitrant on more funding, the battle shifted to the halls of Congress. A 50 vote majority of the House in 2005 passed a bill that would lift the administration's time limits on ESC funding, though it left standing the Dickey Amendment ban on

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[4] Uncertainty about the scope of governmental restrictions on future uses also dampens the flow of private funds. See Ronald M. Green and Robert Lanza, *Letter: Bush's Policy Stopped US Gaining Stem Cell Lead*, 438 Nature 401, 422 (2005) (noting that President Bush's restrictive policy on funding stem-cell research created "an extremely hostile funding environment, with no hope of federal support" for private companies engaged in stem-cell research).

[5] See, for example, 720 ILCS 510/6, 510/12-1 (West 2005) (prohibiting research on live embryos); Mich Comp Laws Ann §§ 333.2687-2688 (West 2006) (prohibiting research on live embryos).

[6] HR 1357, 109th Cong, 1st Sess H1690 (2005).

[7] President George W. Bush, *Remarks by the President on Stem Cell Research* (Aug 9, 2001), available at <http://www.whitehouse.gov/news/ releases/2001/08/print/20010809-2.html> (last visited Apr 19, 2006).

[8] National Institutes of Health, *Information on Eligibility Criteria for Federal Funding of Research on Human Embryonic Stem Cells*, available at <http://stemcells.nih.gov/research/registry/ eligibilityCriteria.asp> (last visited Apr 19, 2006).

[9] Emma Young, *Stem Cells Face Xenotransplantation Glitch*, New Scientist (Aug 24, 2001), available at <http://www.newscientist.com/ article/dn1196.html> (last visited Apr 20, 2006).

federal funding of ESC derivation itself.[10] The bill is slated for a vote in 2006 in the Senate. Majority Leader Bill Frist and several centrist Republicans have announced their support.[11] The Senate voted approval on July 17, 2006, but President Bush quickly vetoed the bill and the House of Representatives sustained the veto by 51 votes.[12]

With federal funding blocked by "culture of life" politics, a few states have taken the lead to fill the funding gap, most notably California. Proposition 71, a referendum passed in 2004 at a time of budget deficits, has allocated $3 billion over 10 years to ESC research.[13] Several other states, impelled as much by competition for biotech jobs and research dollars as for the health of their citizens, have also appropriated funds. While every bit of research funding helps, in the long run state efforts are not likely to replace the steam lost by denying NIH a major role in ESC science. In the meantime foreign competitors, most notably the United Kingdom and the Asian tigers—South Korea, Singapore, and China—will move the science along, but not nearly as rapidly as a full United States commitment would.[14]

I. PUBLIC POLICY AND ESC TREATMENTS

With ESC science still undeveloped, the public debate has necessarily focused on research, not treatment, issues. Many scientific issues about ESCs require elucidation, including the factors that keep ESCs in a pluripotent state; the signals that drive them to differentiate; the genes that control the particular lineages that they express; conditions of safe and efficacious use; the viability of nuclear transfer cloning; and many other

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[10] Stem Cell Research Enhancement Act of 2005, HR Rep No 810, 109th Cong, 2d Sess H627 (2005). The text of the Dickey Amendment, named after former Representative Jay Dickey of Arkansas, can be found in each year's Labor/DHSS Appropriations Bill. The original version is in section 128 of the Balanced Budget Downpayment Act, I, Pub L No 104-99, 110 Stat 26 (1996).

[11] *Frist's Support of Stem Cell Research Enhancement Act Increases Chances of Senate Passage; Bush Veto Threat Remains*, Medical News Today (Aug 2, 2005), available at <http://www.medicalnewstoday.com/ medicalnews.php?newsid=28473> (last visited Apr 20, 2005).

[12] Sheryl Gay Stolberg, "First Bush Veto Maintains Limits on Stem Cell Use," New York Times, July 20, 2006 p. A1.

[13] Cal Const Art XXXV § 5.

[14] Clive Cookson, et al, *The Future of Stem Cells*, Scientific Am A20-23 (2005). The scandal surrounding Dr. Hwang Suk Woo's non-existent cloned cell lines may set back the Korean effort, but should not stop the field from going forward. Nicholas Wade and Choe Sang-Hun, *Human Cloning Was All Faked, Korea Reports*, NY Times A1 (Jan 10, 2006) (reporting the revelation that Dr. Hwang Suk Woo's claims were indeed fraudulent). His fraud involved successful performance of a mechanical technique, not a scientific insight on which other research depended.

questions that any clinical science, especially one with the range of the ESC platform, must answer to mature and enter mainstream medical practice.

No schedule exists for when each stage of development will conclude. Phase I clinical trials for ESC treatment of spinal cord injuries appear imminent, but most other touted uses are much farther off. There is no reason why ESCs should provide therapies more quickly than the 15-20 years needed for small molecule drug therapies and the longer time frame needed to bring monoclonal antibodies and gene therapies into the medical marketplace.[15] Even without ESC products as such, ESC science will make important contributions to understanding the pathogenesis of disease and thus aid the development of disease therapy.[16]

At some point, however, the "culture of life" issues animating the ESC research debate will have to be faced in the context of ESC-derived therapies. ESC policy has been a heated issue precisely because the prospect of treating millions of patients has hovered over the warring parties. Because so much of the debate has revolved around research, with claims about what the research might lead to and whether it is necessary, much less attention has been paid to how the "culture of life" debate now centered on embryo research would play out if, in fact, ESCs were shown to have therapeutic benefit. Such effects might be shown in animal studies and then in clinical trials with humans in countries that are more hospitable to ESC research, such as the United Kingdom, Singapore, or South Korea.[17]

At that point, "culture of life" opposition may fade away. Just as there are said to be no atheists in foxholes, there may be few embryo protectionists willing to prevent clinical use of effective treatments. Supporters of the "culture of life" might quickly switch allegiance and recognize, as their opponents have long argued, that a person best respects life by using leftover or

[15] Patricia Robuck and John Wurzelmann, *Understanding the Drug Development Process*, Inflamm Bowel Dis 11 Supp 1:S13-16 (Nov 2005) (citing Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2005 (March, 2005)).

[16] Adult stem cell science, for example, has exploded under the impetus of ESC research. NIH, *Stem Cells and Diseases*, available at <http://stemcells.nih.gov/info/health.asp> (last visited Apr 19 2006) (explaining how adult stem cell research helps understand disease).

[17] Ella De Trizio and Christopher S. Brennan, *The Business of Human Embryonic Stem Cell Research and an International Analysis of Relevant Laws*, 7 J Biolaw & Bus 4, 5-7 (2004).

created embryos to provide treatments that extend life or reduce pain and disability in born persons.

It may, however, be overly sanguine to expect a therapeutic conversion of those who have battled so hard against ESC research. "Culture of life" battalions are too deeply entrenched in their beliefs to switch course once therapeutic benefits are shown, though moderate opponents may shift from erecting legal barriers to other means of marking their opposition. Continuing questions about ESC efficacy, particularly if they or their families will not directly benefit, will also delay a rush to accept ESC therapies. Even if Congress or the states permit treatment with private funds, they might restrict Medicare or Medicaid funding, just as the Hyde Amendment bars federal support of abortions.[18] Having stalwartly opposed ESC research despite its great promise, there is no reason why their position should change once treatments exist.

Opposition to ESC-derived therapies may also vary with the extent of embryo destruction required by the therapies. While more moderate opponents might accept the use of therapies derived from surplus embryos from infertility treatments, they might still try to ban the creation of research embryos or at least the use of federal funding for those purposes.[19] Yet those procedures might be essential to obtain the ESC lines or derivative cells and products that are used in therapy.[20]

In addition to restrictions on public funding of some or all ESC therapies, legislatures might criminalize the creation of embryos needed for effective stem cell therapy, such as the creation of embryos by nuclear transfer to obtain histocompatible ESC progenitor cells. Seven states already have laws that make it a crime to engage in nuclear transfer cloning, whether for research or therapy, and more might join them.[21] The US House

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[18] 42 USC § 1396.

[19] This line is drawn by Senate Majority leader Bill Frist to demarcate his differences with President Bush. See Letter from Jaydee Hanson, Director of Human Genetics Policy, International Center for Technology Assessment (Aug 5, 2005), available at <http://www.icta.org/doc/August%205,%202005%20Update.pdf> (last visited Apr 19 2006) (discussing possible lines to be drawn in the ESC debate).

[20] Other alternatives would include a library of representative ESC types, immunosuppression, or cellular engineering to remove antigens. See Ruth Faden, et al, *Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy*, 33 Hastings Ctr Rep 13, 13-16 (2003).

[21] Ark Code Ann §§ 20-17-802, 20-16-1001 to 1004; Ind Code § 35-46-5-1 (2005); Iowa Code §§ 707B.1-4; Mich Comp Laws §§ 333.16274-16275, 333.20197, 333.26401-26403, 750.430a (2006); ND Cent Code § 14-02.2-02 (2006); SD Code Laws §§ 34-14-16, 17, 20, 34-23A-17 (2006); Va Code Ann § 32.1-162.22 (2006). These include states with important biotech medical centers and infrastructure, such as Michigan, Indiana, and Iowa. See National Conference of State Legislatures, *State Embryonic and Fetal Research Laws*,

of Representatives in 2005 passed by a large margin a bill that would make it a crime not only to engage in nuclear transfer cloning for research or therapy, but also to ship, transport, or receive any products derived from cloning.[22] This ban would extend to ESCs themselves, as well as the cellular and other products derived from them, including downstream progenitor cells and replacement tissue, and possibly even drugs directly developed from ESC research.[23]

Even if the hard-core "culture of life" base does not succeed in banning nuclear transfer or embryo creation as such, opponents might wield enough political clout to ban the payments to the oocyte donors that are likely to be needed to obtain immunocompetent ESCs. Two states already make paying egg donors a crime,[24] and few countries in the world outside of the United States permit it.[25] If patients or researchers are forced to rely on unpaid volunteers, they will live at the mercy of altruistic strangers or the fortuity of having female family members of reproductive age who are willing to donate.

In this Article, I put aside further discussion of federal funding policy for ESC research and therapy. These are quintessentially policy questions to be decided by the political process. As the abortion funding cases made clear, in positive law there is no constitutional right to have either basic needs or the exercise of constitutional rights funded.[26] Moral objections might then block Congress from providing Medicare and Medicaid coverage of ESC therapies as well. Legislatures and administrative agencies will make these decisions by the prevailing political lights with little judicial oversight. However,

available at <http://www.ncsl.org/programs/health/genetics/embfet.htm> (last visited Feb 14, 2006) (listing the states that have made it a crime to engage in nuclear transfer cloning).

[22] HR 1357, 109th Cong, 1st Sess H1690 (2005).

[23] See generally, Adrienne N. Cash, *Attack of the Clones: Legislative Approaches to Human Cloning in the United States*, 26 Duke L & Tech J 1 (2005).

[24] Cal Health & Safety §§ 125290.35 ("prohibiting compensation to research donors or participants, while permitting reimbursement of expenses"); Mass Gen Laws Ann 111L § 8 (2005) (no "valuable consideration purchase, sell, transfer or otherwise obtain human embryos, gametes, or cadaveric tissue for research purposes").

[25] See Nigel M de S Cameron, *Light From the North: Canada Comprehensively Ban Human Cloning*, Ethics & Medicine (Summer 2004) (discussing a Canandian law to proscribe the selling of embryos and other human tissue along the same lines as resolutions passed by the United Nations).

[26] *Rust v Sullivan*, 500 US 173 (1991); *McCrae v Harris*, 448 US 297 (1980); *Maher v Roe*, 432 US 464 (1977). For a general discussion of the constitutional status of basic needs, see William Forbath, *Constitutional Welfare Rights: A History, Critique and Reconstruction*, 69 Fordham L Rev 1821 (2001) (defining basic needs and describing a variety of descriptive and normative views on constitutional protection of basic needs).

a greater role for the judiciary could arise from direct bans on privately funded ESC therapies or on the research necessary to produce them.

II. IS THERE A RIGHT TO MEDICAL TREATMENT?

Conflicts over a "culture of life" will continue to arise from scientific and clinical uses of the earliest stages of human life. While many of these conflicts will, like funding decisions, be institutionally allocated to legislatures, others will touch more closely the rights-claims traditionally entertained by courts. It is instructive to view how constitutional discourse would frame these issues, both to sharpen our view of the moral conflicts at stake and to identify the institutional arrangements likely to constrain or to facilitate scientific innovation.

In the debate over use of ESC therapies, ESC supporters might plausibly argue that a ban on the use of ESC therapies that will save lives or ameliorate pain and disability would violate a person's Fifth and Fourteenth Amendment rights to life and liberty.[27] A negative right against governmental interference with therapy is claimed, not a positive right to state resources. In essence the claim is that the right against deprivation of "life [and] liberty . . . without due process of law" is most coherently construed as including a person's right to have safe and effective medical treatments paid for with her own funds.[28] Although the Court has never explicitly recognized such a right, some form of it should follow from text, precedent, and other standard moves in constitutional interpretation.[29]

Making such a move, of course, does force yet another confrontation over whether judges are "making" or "interpreting" law in substantive due process adjudication, thus tripping another iteration of the contemporary debate over judicial activism and deference to legislatures. As a result, courts may be

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[27] A similar argument could be made in opposition to bans on the use of fetal tissue or organs for therapy, such as the federal law that now prohibits any use of fetal tissue or organs donated to family members. See John A. Robertson, *Abortion to Obtain Fetal Tissue for Transplant*, 27 Suffolk U L Rev 1359, 1368-69 (1993) (discussing constitutional status of statutory restrictions).

[28] US Const Amend V, cl 3; US Const Amend XIV, § 1.

[29] Justice Souter, for example, calls this right the "traditional right to medical care and counsel." *Washington v Glucksberg*, 521 US 702, 781 (1997). Justice Breyer, on the other hand, talks about the "personal control over the manner of death, professional medical assistance, and the avoidance of unnecessary and severe medical pain and suffering." Id at 790. Both views agree with Chief Justice Rehnquist that "It cannot be disputed that the due process clause protects an interest in life . . . ." *Cruzan v Director, Missouri Department of Health*, 497 US 261, 281 (1990).

hesitant to overrule the will of legislatures strongly committed to "culture of life" policies.

Yet the Supreme Court has long found unenumerated rights to be part of substantive due process, disagreeing only over how broad or specific those derived rights are and to what extent they depend on precisely specified traditions of recognized rights or can be derived from more general conceptions of liberty. The more conservative view holds that substantive due process rights must be "deeply rooted in this Nation's history and tradition" and "implicit in the concept of ordered liberty" such that "neither liberty nor justice would exist if they were sacrificed."[30] In addition, "a careful description of the asserted fundamental liberty interest" is required, using "our nation's history, legal traditions, and practices . . . as guideposts for responsible decisionmaking" in order to rein in "the subjective elements that are necessarily present in due-process review."[31] Less demanding versions of substantive due process identification of fundamental rights would derive the right to medical treatment directly from the autonomy of individuals.[32]

A. Life and the Logic of Rights

The argument for a right to medical treatment is anchored by text, logic, tradition, and precedent. The Constitution explicitly protects "life" and "liberty," [33] which the Court has construed to mean protection against state deprivation without at least a rational or even compelling justification. As Chief Justice Rehnquist noted in *Cruzan*, "It cannot be disputed that the due process clause protects an interest in life . . . ."[34]

Logic strongly supports finding a right to medical treatments that save or extend life, since being alive is a

[30] *Glucksberg*, 521 US at 721 (Rehnquist), citing *Palko v Connecticut*, 302 US 319, 325-36 (1937) and *Moore v City of East Cleveland*, 431 US 494, 503 (1977).

[31] *Glucksberg*, 521 US at 721-22 (Rehnquist), citing *Reno v Flores*, 507 US 292, 302 (1993) and *Collins v Harker Heights*, 503 US 115, 125 (1992).

[32] Such a view is well represented by the plurality opinion in *Casey v Planned Parenthood*, 505 US 833 (1992): "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State." Id at 851. See also *Lawrence v Texas*, 539 US 558, 574 (2003); Steven Goldberg, *Cloning Matters: How* Lawrence v. Texas *Protects Therapeutic Research*, 4 Yale J Health Pol L & Ethics 305, 314-15 (2004) (arguing *Lawrence*'s ban on moral repugnance as a rational ground for proscribing same-sex sodomy also invalidates it as a valid ground for restricting other protected liberties).

[33] US Const Amend XIV, § 1.

[34] See note 29. The quote continues: "as well as an interest in refusing life-sustaining treatment." *Cruzan*, 497 US at 281.

necessary precondition to the exercise of other rights. A right to sexual or reproductive autonomy, to raise children, to practice a religion, to participate in politics, or to pursue any right or interest depends on possessing life itself. It would be surprising if state action that diminished the ability to stay alive did not receive the same scrutiny as infringement of the more particular rights which being alive makes possible. Because life is a primary good on which realizing all other goods depends, it should have at least the same protection as is given to those secondary goods.[35] State deprivation of life, therefore, should require at least as strong a justification as is needed for depriving a person of other fundamental liberties.[36]

While life is a necessary condition for the exercise of rights, it may not be sufficient. One cannot pursue other liberty interests if one is unable to participate in ordinary life activities due to severe disability or pain. Thus the right to use safe and effective medical treatments could also be grounded in liberty rights to be free of pain or disability.[37] As at least five justices voting in *Washington v Glucksberg*[38] to uphold a state ban on physician-assisted suicide noted, their support assumed that terminal sedation and analgesics that might themselves hasten death were available to control the pain of dying patients.[39] If not, a person's liberty right to be free of pain would dwarf the more general concerns about the vulnerability of the poor and incompetent, slippery slopes, and medical ethics that provided

[35] John Rawls' term "natural primary good" would include life and health because they are necessary preconditions to realizing all other goods. John Rawls, *A Theory of Justice* 62 (Harvard 1971) ("Other primary goods, such as health and vigor, intelligence and imagination, are natural goods; although their possession is influenced by the basic structure, they are not so directly under its control."). One might think of free speech rights as a constitutional "primary good," since freedom of thought and speech has been described as "the matrix, the indispensable condition, of nearly every other form of [freedom]." *Palko*, 302 US at 326-27. Yet it too cannot exist unless a person is alive and in sufficient health to exercise that freedom.

[36] The discussion is about the right to life of born persons, not whether unborn persons have a right to be born. Indeed, a higher level of procedural correctness is required in capital punishments cases precisely because life is at stake. Although these issues are usually framed in Eighth Amendment "cruel and unusual punishment" terms, they share a normative bed with the "right to life" component of the Fourteenth Amendment. Similar results could have been articulated under that clause.

[37] A right to bodily integrity may also be involved, most noticeably in cases testing the legality of seizures of the body under the Fourth Amendment. See, for example, *Schmerber v California*, 384 US 757, 771-72 (1966) (compulsory blood test); *Winston v Lee*, 470 US 753, 761 (1985) (surgical removal of bullet); *Tennessee v Garner*, 471 US 1, 3 (1985) (escaping burglar shot dead); *Washington v Harper*, 494 US 210, 238 (1990) (non-consensual administration of psychotropic medication).

[38] 521 US 702 (1997).

[39] Id at 737-38, 748-49.

facial support for the state's ban on assisted suicide. If so, access to safe and effective ESC-derived therapies should be presumptively protected regardless of whether they saved life or only lessened pain and suffering, as many of them are likely to do.

B. History and Tradition

Unless explicit specificity is required, a right to use safe and effective medical treatments to extend life or reduce pain and disability could also cogently be said to be "deeply rooted in this Nation's history and tradition."[40] The right of doctors to use their clinical judgment in treating the ills of patients has long been recognized as part of this professional domain.[41] Unlike claims of rights to abortion and assisted suicide, which had to confront extensive state restriction of those practices at the time of the enactment of the Fourteenth Amendment,[42] there is no comparable tradition of legislative restriction on medical practice until well into the twentieth century.

Medical practice was not regulated by the states in 1789 and not much more so in 1868.[43] Medical licensure began in the 1830s, spurred by the drive to oust itinerant and irregular healers. But persons licensed to practice medicine had no restrictions placed on clinical judgment or on the products that they could use. The first federal drug law passed in 1914 to control non-medical drug abuse left physicians free to prescribe cocaine and opiates for legitimate medical purposes.[44] The Food and Drug Administration, founded in 1906, did not begin to exercise pre-market approval of the safety and efficacy of drugs and biologics until the thalidomide scandal in 1962.[45]

With a tradition of little or no regulation until well into the twentieth century, one cannot point to a deeply rooted regulatory tradition restraining medical practice as existed with abortion and assisted suicide. This no doubt was due to the relatively

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[40] *Moore v City of East Cleveland*, 431 US 494, 503 (1977).

[41] *Roe v Wade*, 420 US 113, 153 (1973).

[42] *Cruzan v Director, Missouri Department of Health*, 497 US 261, 294-95 (1990) (Scalia concurring).

[43] See generally, Paul Starr, *The Social Transformation of American Medicine* 3-60 (Basic 1982).

[44] Harrison Narcotics Act of 1914, Pub L No 63-223, 38 Stat 785; William Butler Eldridge, *Narcotics and the Law; A Critique of the American Experiment in Narcotic Drug Control* 9 (Chicago 1967); Alfred R. Lindesmith, *The Addict and the Law* 5 (Indiana 1965).

[45] Philip Hilts, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation* 158-65 (Knopf 2002).

unscientific basis of most medicine and the great deference given to professional self-regulation. Medicine, which relied heavily on empirics, was in 1868 still ignorant of Koch's germ-theory, and had minimally effective anesthesia and antisepsis for surgery. Indeed, doctors relied on leeches, blistering, and bleeding well into the late 1800s.[46] Until the development of sulfa drugs and antibiotics in the 1930s, the chance that going to a doctor would help a patient was small. There were no ethical issues or legal restrictions on research with human subjects until the development of the Nuremburg Code for human experimentation in the 1940s.[47]

C. The Reverse of a Right to Die

The claim of a right to medical treatment to save life and reduce suffering might also be usefully understood as the reverse of a right to end life by termination of treatment or assisted suicide. The main argument against a right to die has been protection of human life. Given the importance of the state's interest in protecting life, it would be odd if the state were free to adopt policies that threatened life or caused a person's death.

The claim of a right to control the timing of one's death has been a centerpiece of substantive due process struggles beyond issues of reproduction and sexuality. The Supreme Court first grappled with this issue in *Cruzan v Missouri Dept of Health*,[48] in the context of withdrawal of life-support from a person in a persistent vegetative state. That case engaged questions of whether an incompetent person had a right to have medical treatment ended, and if so, whether that right extended to advance directives to that end.[49] More recently, in *Washington v Glucksberg*[50] and *Vacco v Quill*,[51] the Court confronted the question of whether a competent, terminally-ill person had a right to physician assistance in obtaining the drugs the patient needed to end his own life. *Gonzales v Oregon*,[52] which found that the Attorney General lacked authority to determine

[46] Michael Bliss, *Harvey Cushing: A Life in Surgery* 17-18 (Oxford 2005).

[47] *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Vol 2, 181-82 (GPO 1949), available at <http://ohsr.od.nih.gov/guidelines/nuremberg.html> (last visited Apr 19, 2006).

[48] 497 US 261 (1990).

[49] John A. Robertson, *Cruzan and the Constitutional Status of Nontreatment Decisions for Incompetent Patients*, 25 Ga L Rev 1139, 1144-45 (1991).

[50] 521 US 702 (1997).

[51] 521 US 793 (1997).

[52] 126 S Ct 904 (2006).

whether prescription of Schedule II drugs for assisted suicide was a legitimate medical practice, shows another limitation on governmental interference in end of life decisionmaking.[53]

Arrayed against autonomy claims to end one's life are "culture of life" claims that such a right will undermine the sanctity of life, violate the ethics of the medical profession, and impair the welfare of incompetent and vulnerable patients. While the Court has not accepted all claims, it has gone a long way in honoring a large measure of individual and physician discretion in these matters. Enticing dicta even suggest that there is a right to have advance directives to terminate treatment honored and/or to have physician assistance in ending life if effective pain control alternatives are not available.[54]

The use of safe and effective ESC-derived therapies provides a unique twist on the theme of patient autonomy. While end-of-life cases involve rights to bring death about, ESC treatment involve efforts to avoid death and reduce suffering. In the former case, opponents argue on the side of life to prevent its cessation by individual choice or the actions of others. In the latter, they appeal to respect for the life of embryos, while ignoring the lives of the born persons who would benefit from such treatments.[55]

Although proponents of ESC treatment seek to extend life, "culture of life" enthusiasts frame the issue as participating in a "culture of death." They assert deontic, consequentialist, and symbolic claims akin to those used to oppose reproductive and sexual liberty. But life itself and freedom from severe pain and or disability is central to all lives. The case for a negative right to medical treatments should therefore be as strong, if not stronger, than the case for other rights. Since the main argument against robust autonomy at the end of life has been the need to protect that life, it would indeed be anomalous if the state could adopt policies that directly interfered with life and health without a compelling justification.[56]

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[53] Id at 925.

[54] Only Justice O'Connor has spoken directly to this issue, but it would not be surprising if other justices also found that the right to refuse medical care encompassed some advance control over such a decision. *Cruzan*, 497 US at 292; *Glucksberg*, 521 US at 737-38. But see Robertson, 25 Ga L Rev at 1179 (cited in note 49).

[55] For an analysis of whether the state may elevate the interests of non-constitutional persons over those of persons clearly protected by the 5th and 14th Amendments, see Ronald Dworkin, *Unenumerated Rights: Whether and How* Roe *Should be Overruled*, 59 U Chi L Rev 381, 398-402 (1992).

[56] Whether "culture of life" concerns with protecting all stages of human development after fertilization constitute a compelling justification is discussed below. See also, *Abigail Alliance for Better Access to Developmental Drugs and Washington Legal Foundation v Eschenbach*, 445 F3d 470 (DC Cir 2006) (noting that the right to treatment

D. Limits and Scope of the Right

A negative due process right to use safe and effective medical treatments to save life or reduce pain and suffering plausibly follows from text, history, logic, and precedents. If due process protects a person's life and liberty, then laws that prohibit the prescription, application, or use of a drug, a biologic, or a medical procedure needed to save life or reduce suffering would infringe that right. The state would then have the burden of showing sufficiently strong grounds to justify the infringement. One may disagree over the correct label for the claimed right—whether it is a fundamental right or merely a "protected liberty interest."[57] One may also disagree about whether the state must satisfy strict or intermediate scrutiny or the more rigorous rationality assessment applied in *Lawrence v Texas*.[58] But whatever the precise term used, scrutiny beyond the minimal rationality review used for economic and social legislation should be applied to governmental interests said to justify infringement of the claimed right to medical treatment. As argued in the next section, none of the interests asserted in support of such a ban justify denying a person the right to use ESC-derived therapies to save life or to reduce pain and disability.

Persons inclined to a large measure of deference to legislatures will be hesitant to accept judicial articulation of a new "right to receive medical care" because of its potentially broad reach. It could call into question many aspects of federal or state regulation of drugs, medical and surgical procedures, organ transplantation, and medical licensure. A Supreme Court leery of substantive due process lawmaking might also be reluctant to interfere in legislative judgments about tradeoffs between health, safety, protection of unborn human life, and patient needs for therapy.

But several factors should modulate that fear. First, it would not be the first time that the Court has struck down legislation because it interfered with the life or health of a patient. The Court's abortion jurisprudence has long refused to compromise

to extend life is implied by the right to end life by refusing treatment).

[57] See *Cruzan*, 497 US at 278 ("[A] competent person has a constitutionally protected liberty interest . . . .")

[58] 539 US 558, 577-78 (2003) (concluding that a majority's judgment that a liberty granted by substantive due process is immoral is not sufficient in itself to proscribe that activity).

the woman's life or health for the sake of the fetus.[59] Indeed, even when the state may ban abortion to protect fetal interests, it may not do so at the expense of the woman's life or health.[60] Nor may it ban certain abortion techniques on grounds of repugnancy, such as partial-birth abortion, when those techniques are necessary to protect the life or health of the woman.[61]

Second, nothing in a right to medical care prevents the state from enacting regulations that are reasonably related to protecting the health and safety of patients. The state will not lose the power to guard patient health and safety through drug approval, medical licensure, and other regulatory efforts. It will simply have to present a stronger justification to do so.

Third, recognition of such a right would not itself empower health care professionals to claim greater rights than they previously had. Justice Blackmun's broad language of doctor and patient rights opened the door to such claims in the late 1970s.[62] It soon became clear, however, that doctors' rights derived from the patient's right to choose treatment. Similarly, a right to receive medical treatment might lead to doctors' claiming rights in the name of patients, but it would not in itself clothe doctors with an independent right to be free of state regulation.

Finally, recognition of such a right will invalidate legislation only if a law that infringes a patient's right to treatment lacks substantial justification. In some cases, alternatives will exist; in others, the health and safety justification will be easily established. The existence of adequate alternatives, for example, could dispose of claims that the federal Controlled Substances Act,[63] which lists both heroin and marijuana as drugs with no

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[59] *Roe*, 410 US at 152-53.

[60] Id.

[61] *Stenberg v Carhart*, 530 US 914, 929-30 (2000). The Supreme Court will revisit the issue in *Gonzales v Planned Parenthood*, 546 US ___ (2006) (does Congress have the power to make medical findings that partial birth abortion is never needed to protect a woman's health). The case will also give Chief Justice Roberts and Justice Alito the opportunity to tip their hand on abortion issues. Culture of life enthusiasts refuse to swallow the health exception pill because they fear that it will open the door to "abortion on demand" because abortion is generally safer than childbirth. If the Court continues to adhere to the need for a health exception, see, for example, *Ayotte v Planned Parenthood of North New England*, 546 US ___ (2006), laws that restrict the use of safe and effective ESC therapies may also be in doubt. See also *Planned Parenthood Cincinnati Region v Taft*, 439 F3d 304 (6th Cir 2006) (state law restricting RU-486 abortion pill invalid because would impose significant risk on woman's health in off-label use situations).

[62] *Roe*, 410 US at 152-53.

[63] 21 USC § 812.

accepted medical uses, is an unconstitutional interference with the right to pain relief.[64]

Still, recognition of a right to medical treatment could call into question regulatory policies in areas as diverse as organ transplantation, control of chronic pain, cancer therapy, and the use of fetal tissue.[65] As a general proposition, courts should defer to legislative oversight, but judicial deference need not mean judicial withdrawal from the field. Courts do have a role in policing the boundary between an individual's life or liberty and legislative authority.[66] Although legislatures are competent to resolve many issues of medical and health care policy, their authority should be limited when they have only minimally rational grounds for preventing patients from obtaining safe and effective medical treatments.[67]

III. STATE INTERESTS IN BANNING ESC-DERIVED THERAPIES

Having established the case for a presumptive negative right to medical treatment, I turn to the sufficiency of governmental interests relied on to limit ESC treatments. Three sets of interests have dominated the debate. First, there is a regulatory interest in the safety and efficacy of ESC treatments. Second, and by far the most important, there is the embryo status issue—the belief that a protected human individual exists from the time of fertilization and should be protected. The third is a set of concerns or fears that ESC will produce a slide down a slippery slope toward more abusive or repugnant practices, such as reproductive cloning and genetic engineering of offspring.

Legislatures are ordinarily best situated to assess those interests; there are good institutional reasons to be wary of

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[64] Advocates of medical marijuana argue that the federal ban is unconstitutional because alternative treatments are not adequate, such as the case of Angel Raich, who asserts that only cannabis can relieve her excruciating pain and counter her life-threatening wasting disorder. Appellants' Opening Brief, pp 6-7. *Raich v Gonzalez*, 545 US 1 (2005).

[65] An aggressive federal enforcement policy, for example, deters some doctors from prescribing the most effective means of pain relief. Timothy E. Quill and Diane E. Meier, *The Big-Chill-Inserting the DEA into End-of-Life Care*, 354 N Eng J Med 1, 1-3 (2006); Beth Weinman, *Freedom from Pain*, 24 J Leg Med 495, 508-11 (2003); Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J Law, Med & Ethics 55-74 (2003).

[66] See Laurence C. Tribe, *Foreword: Toward a Model of Rules in the Due Process of Life and Law*, 87 Harv L Rev 1, 10-11 (1973) (arguing that the Court, in *Roe*, was not just balancing abortion versus continued pregnancy, but also balancing "alternative allocations of decisionmaking authority").

[67] Some cases may not be easily resolved, as in the dog torture hypothetical discussed below at notes 100-102 and accompanying text.

strenuous judicial oversight. As noted, however, courts should not refuse their constitutional duty to review the allocation of authority between government and individuals on basic questions of life and health.[68] When measured against the traditional compelling interest standard or a post-*Lawrence* invigorated rational basis test, none of the asserted state interests is sufficiently robust to justify the health loss to individuals denied safe and effective ESC therapies.

A. Health and Safety: The Role of the FDA

A finding that the life and liberty clauses of the Fifth and Fourteenth Amendments protect a right to receive medical treatment does not mean that the FDA or other agencies cannot regulate such a right in the interest of the health and safety of patients and the community. No claimant of the right to use ESC-derived treatments argues otherwise.[69]

They would be on very weak ground if they did. In 1979, the Supreme Court put to rest the idea that a right to medical treatment or pain relief exempts regulatory review in a case brought by proponents of laetrile for terminally ill cancer patients.[70] The government took the position that laetrile was a "drug" subject to the federal labeling and approval requirements administered by the FDA. With the threat of federal enforcement looming, several states authorized the use of laetrile within their own borders.[71]

In *United States v Rutherford*,[72] the Supreme Court upheld the requirement of FDA approval of drugs for terminally ill cancer patients who had no other options. It found that laetrile, a derivative of apricot pits and almonds, was subject to FDA approval for health and safety just as other drugs and biologics were.[73] Terminal illness did not lessen a person's interest in

[68] See Tribe, 87 Harv L Rev at 10 (cited in note 66).

[69] Similarly, proponents of a right to physician-assisted suicide concede that the state might legitimately limit its exercise to situations of terminal illness, medical confirmation of the prognosis, waiting periods, and other regulations to ensure that only competent persons have freely chosen assisted suicide. The Oregon Death With Dignity Act, Or Rev Stat § 127.800 et seq (2003), at issue in *Gonzales v Oregon*, 126 S Ct 904 (2006), is typical of a proceduralist approach to assisted suicide.

[70] *United States v Rutherford*, 442 US 544, 550-51 (1979).

[71] In the laetrile controversy, the FDA ceded control of intrastate use to the states. See generally, Note, *Laetrile: Statutory and Constitutional Limitations on the Regulation of Ineffective Drugs*, 127 U Pa L Rev 233 (1978-79). Under *Gonzales v Raich*, 125 S Ct 2195, 2209 (2005), Congress could assign control of intrastate use to the FDA, if it has not already done so.

[72] 442 US 544 (1979).

[73] Id at 551.

avoiding toxic treatments nor in being sold "remedies" that had no efficacy.[74] Just as terminally ill persons were later found in *Glucksberg* to have no right to physician-assisted suicide,[75] so *Rutherford* implicitly found that they did not have the right to ineffective and untested therapies.[76] Left untouched in that case, however, was a rights claim to use medical treatments *that are safe and effective* under standard FDA criteria.[77]

Few ESC proponents question the necessity of FDA involvement in regulating ESC use, paternalistic though it may be.[78] Indeed, they desire it so that ESC therapies are not used prematurely or without proven benefit to patients. Snake-oil salesmen exist with every new technology.[79] The need for public review is as great now as it has ever been. Thus ESC-derived therapies will have to meet the same demands of safety and efficacy that any drug or biologic maker must meet—including a license to conduct clinical research and proof of a favorable ratio of patient benefits to toxicity.[80]

It may be naïve, however, to expect that FDA review of the safety and efficacy of ESC products will be untainted by "culture of life" influence. The FDA has traditionally relied on scientific and clinical data, not politics, in making its judgments. As the "culture of life" has gained political ascendancy in Washington, however, the FDA's record of independence has been tarnished. The most glaring case has been the agency's refusal to approve

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[74] Id at 557-58.

[75] *Glucksberg*, 521 US at 745.

[76] See *Rutherford*, 442 US at 551 (grounding the holding on FDA authority).

[77] Although the district court in *Rutherford* also found that the law infringed a patient's right to treatment, both the Court of Appeals and Supreme Court addressed only the question of FDA authority. *Rutherford*, 442 US at 551. But see *Andrews v Ballard*, 498 F Supp 1038, 1039 (S D Tex 1980) (finding that refusal to license acupuncturists violates a patient's right to medical treatment); *Abigail Alliance v Eschenbach*, 445 F3d 470 (DC Cir 2006) (noting that the right to life may include right of terminally ill patients to use post-Phase I investigational drugs).

[78] Market libertarians such as Milton Friedman have argued that food and drug safety agencies such as the FDA should be abolished. Milton Freedman, *Capitalism and Freedom* 35 (Chicago 1962).

[79] Doctors and clinics in India, China, and Portugal have claimed a high success rate with adult stem cells, despite any good evidence that injecting adult or hematopoietic stem cells for spinal cord injuries, Parkinson's disease, or other ailments works. See Joyce Howard Price, *Stem-cell Ambivalence*, The Washington Times (Jan 9, 2005), available at <http://washingtontimes.com/specialreport/20050109-120809-5421r.htm> (last visited Apr 20, 2006) (discussing desperate patient's turn to Portugal and China for expensive treatments based on advances in stem cell research); Randeep Ramesh, *Row Over Doctors' 'Miracle' Cures: West Urges Curb on Indian Clinic's Untested Treatment*, The Guardian 17 (November 18, 2005).

[80] ESC treatments could take the form of progenitor cells that are introduced into the body or small molecules that block pathogenic pathways.

non-prescription sales of Plan B, an emergency contraceptive, because of the possibility that the product might prevent implantation of fertilized eggs or encourage promiscuity.[81] Despite near unanimous advisory committee approval of the benefits from over-the-counter sales of Plan B, the Commissioner of the FDA refused to approve it, disingenuously issuing a notice for further comment and rulemaking instead.[82]

Continued "culture of life" dominance of the FDA does not bode well for ESC-derived therapies. A "culture of life" movement that has final say over whether ESC products are safe and effective enough to be used in practice will be sorely tempted to obstruct their use. The power of ESC therapy should eventually win out, but it will take longer and require more political capital than FDA decisions usually do.

B. Embryo Status Issues

The key to the ESC debate, of course, is the profound disagreement that surrounds the moral status of the embryo. The issue concerns when duties to new human entities attach—when an individual becomes, or the state might legitimately regard it as, a rights-bearing entity. Persons firmly within the "culture of life" camp, who believe that fertilized eggs and blastocysts are new persons or human lives from fertilization, will not accept destroying embryos to obtain ESCs to save born lives, even if the embryos to be used will never be placed in a uterus.[83] In addition, persons who view the embryo as too rudimentary in development to have rights or interests have no rights-based objection, but they might choose to protect embryos

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[81] See GAO, *Food and Drug Administration: Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B was Unusual* (Nov 2005), available at <http://www.gao.gov/new.items/d06109.pdf> (last visited Mar 15, 2006) (detailing the FDA's denial of over-the-counter access to plan B); Meredith Waldman, *US Watchdog Finds Bias Against Morning-After Pill*, 438 Nature 401 (2005) (describing the FDA's response to the GAO report). Note also the case of Norplant, the implantable contraceptive, and RU-486 (mifipristone) used to produce non-surgical abortions. Consider Karen F. Richards, *Case Note, RU 486: A Promising Birth Control Device Entangled in the Abortion Debate*, 6 J Pharmacy & Law 117 (1996) (discussing how the political opposition to RU 486 influenced the FDA's hesitation to approve the drug for use as a contraceptive, despite the drug's promise).

[82] The Director of the FDA's Division of Women's Health, Dr. Susan Woods, resigned in protest of the politicization of the decision. Marc Kaufman, *FDA Official Quits Over Delay on Plan B*, Wash Post A08 (Sept 1, 2005).

[83] As President Bush put it, "I do not believe in the destruction of life in order to save life." Remarks by President George W. Bush on Stem Cell Research (Aug 9, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/20010811-1.html> (last visited Apr 19, 2006).

as a symbolic expression of "special respect" for human life generally.[84]

One's position on the moral status of the embryo determines where one stands in the "culture of life" versus "culture of death" debate. The arguments on either side are so well-known that there is little need to rehash them here. Yet the resistance of the issue to rational solution justifies some mention of recent themes in the discussion. Most notable here has been the Leon Kass-led President's Council on Bioethics' engagement with the issue in its reports on human cloning and ESCs.[85] It is worth looking at their account to refresh our recollection about the structure of the argument and key points of difference.

1. Membership in the human community.

Most striking in the Council's reports is its rhetorical shift from "potentiality" to "continuity" and "membership in the human community." Past pro-life argumentation had emphasized potentiality. The Council focused instead on the continuity of individual members of the human community from their first embryonic stages through implantation, gestation, birth, youth, maturity, and senescence. Although no substance is added by this word shift, appeal to fertilization as a stage that we all experienced/underwent in our life histories carries a powerful rhetorical charge. It also is blatantly essentialist. Simply because a collection of living cells has human DNA it is to be accorded all the rights and moral and legal status accorded to born individuals.[86]

The Council's reports, however, do not provide any argument for why the characteristic of human DNA per se confers rights and imposes duties. It is not obvious why a multi-celled entity with particular DNA has rights which other mammals, including primates that share 98.5% of human genes and sentience, do not.

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[84] For the original use of "special respect" see American Fertility Society, *Ethical Considerations of Assisted Reproductive Technologies*, 62 Fertility and Sterility 33S (1994) (Supplement 1).

[85] President's Council on Bioethics, *Human Cloning and Human Dignity* (2002); President's Council on Bioethics, *Monitoring Stem Cell Research* at 58-60 (cited in note 3).

[86] Professor Robert George has been an active proponent of this variant on the potentiality argument. As he puts it, "the embryo is a whole living member of the species homo sapiens at the earliest stage of his or her natural development" and that the hydatiform mole or teratoma (collection of cells) is not a whole living member of the species at any developmental stage because "[s]uch entities lack the internal resources to actively develop themselves to the next more mature stage of the life of a human being." President's Council on Bioethics, *Human Cloning and Human Dignity* at 258-59 (cited in note 85).

It appears then that the Council, like other holders of a strict pro-life position, still relies on some version of a potentiality argument, though they do not address it as such.

The potentiality argument, however, overlooks the fact that rights and interests are ordinarily assigned on the basis of actual characteristics, not potential alone.[87] There is strong debate about what those characteristics are, with birth, consciousness, sentience, sense of identity, rationality, or some other characteristics put forth as candidates.[88] Animal rights advocates, by contrast, in arguing against specism, rely almost exclusively on sentience as the key characteristic.[89] Whatever the characteristic chosen, all of them depend on some degree of development beyond undifferentiated cells that lack organs, a body, or a functioning neurological system. Moreover, the embryos used as a source for ESCs will otherwise be discarded, thus having a vanishingly small chance of ever producing those other characteristics.[90]

When pushed further, the Council's position, like many potentiality arguments, backs on to a consequentialist appeal to the bad consequences for born humans if all post-fertilization stages of human life are not treated equally. The continuity/human community argument in *Monitoring Stem Cell Research* clearly shows this reliance on consequentialism.[91] As

[87] Dan Brock, *Is a Consensus Possible on Stem Cell Research? Moral and Political Obstacles*, 32 J Med Ethics 36, 38 (2006); Michael J. Sandel, *Embryo Ethics—The Moral Logic of Stem-Cell Research*, 351 N Eng J Med 207 (2004); Louis Guenin, *Morals and Primordials*, 292 Science 1659, 1659-60 (2001) (considering the principled basis of the position that killing an embryo is always wrong).

[88] The Supreme Court in *Roe* and *Casey* drew the line at viability—the ability to survive outside of the womb—but never gave more than the definition of viability for its position. If it had, it might have argued that viability is a rough marker for when substantial neurological development, possibly even sentience, has occurred, thus providing a less subjective, moral-religious reason for state protection.

[89] Their recognition of sentience as the ground for having interests and rights then leads them to argue that any living organism that is sentient, as other mammals appear to be, also has interests that should be respected. Peter Singer, *Animal Liberation*, 1-25 (Random House 1975); Thomas Regan, *The Case For Animal Rights* (University of California Press 2004). But see Taimie L. Bryant, *Animals Unimodified: Defining Animals/Defining Human Obligations to Animals*, 2006 U Chi Legal F 133, 161 (arguing that animal rights' activists who premise their arguments on sentience draw an arbitrary line, thereby excluding from protection "a vast number of beings whose existence is completely intertwined with those on the other side of the line").

[90] The Council's counterargument is that the decision to discard or not place in a uterus is an act of human will, which could be made differently. President's Council on Bioethics, *Monitoring Stem Cell Research* at 84-90 (cited in note 3). This response begs the question of whether those embryos would have been created if all had to be transferred to a uterus.

[91] Id at 76-77. The report notes: "Nonetheless, advocates of the argument from continuity suggest that it is dangerous to begin to assign moral worth on the basis of the

Leon Kass puts it elsewhere, "no decent society can afford to treat human life, at whatever stage of development, as a mere natural resource to be mined for the benefit of others," presumably because of the effects which it will have on that society.[92]

Viewed in consequentialist terms, however, the pro-lifers again have not made a case that such dire consequences will ensue. It is the barest of slippery slope arguments, wanting flesh to be taken seriously. Its proponents assert possible dire consequences but provide no account, much less evidence for, the sequence of how such a result will come about. Nor do they show why the mere risk of such consequences outweighs the loss to patients denied ESC treatments.

In a different context, greater patient and family control over termination of treatment has apparently led to little abuse or neglect. Courts, for example, have upheld the right of parents to insist on futile treatment for anencephalic infants, and standard proposals for physician-assisted suicide include protections against discrimination and involuntary choice.[93] Because ESC therapies are sought to extend life, it is difficult to see how using undifferentiated ESCs that never will implant in a uterus will harm post-birth human life, much less to the degree necessary to justify depriving born persons of the benefits those treatments might provide.

2. Institutional competence in determining the value of prenatal life.

It is a truism of constitutional law that legislatures are better situated than courts to make judgments about the acceptability of policy tradeoffs. Despite a presumption of deference to legislatures, a residual role for the courts remains based on their competency in principled reasoning about basic rights from text, history, and precedent about the meaning of open-ended textual clauses. In the throes of politics, legislatures may overlook more basic values and disregard minority interests. Asking legislatures to meet a more robust standard of justification than mere rationality is proper when public policies infringe protected individual interests in life and liberty.

presence or absence of particular capacities and features, and that instead we must recognize each member of our species from his or her earliest days as a human being deserving of dignified treatment." Id at 78.

[92] Leon Kass, *A Way Forward on Stem Cells*, Wash Post A21 (July 12, 2005).

[93] *In re Baby K*, 832 F Supp 1022 (4th Cir 1993); Or Rev Stat § 127.800 et seq (2003); Americans with Disabilities Act 42 USC §12182 (2002).

Something more than consequentialist speculation or essentialist moral beliefs about embryos should be shown to justify barring patient access to safe and effective ESC treatments.

Variations on this point have long animated the abortion debate. But there the question has focused on the moral status of implanted embryos and fetuses. Whatever the strength of arguments to limit abortion of implanted fetuses, the preimplantation embryo has no nervous system, no organs, and no differentiated cells beyond a trophoblastic layer forming the placenta, much less sentience or consciousness. Even if transferred to the uterus, few embryos will implant. Nor is there a uterus available to accept every embryo. Assignment of legal rights to such undeveloped entities on the basis of human DNA and developmental potential alone is not a justifiable ground for denying born persons safe and effective medical treatments.[94]

In fact all justices in *Roe v Wade*[95] and *Casey v Planned Parenthood*[96] agreed that fetuses are not "persons" within the meaning of the Fourteenth Amendment.[97] Those who question the legitimacy of *Roe* seek to empower government to impose greater regulation on abortion, not to have fetuses treated in all regards as persons protected by the Fifth or Fourteenth Amendments. As a result, there is no constitutional duty to treat pre-natal life equally with post-natal life.

The constitutional question in *Roe*, however, is not whether the state *must protect* pre-natal life, but whether it *may choose* to do so if it wishes. If born persons but not fetuses and embryos have Fourteenth Amendment rights, then the state should not be free to protect the latter at the expense of the life or health of born persons.[98] Government might convey its views of the

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[94] *Roe v Wade*, 410 US 113 (1973).

[95] Id.

[96] 505 US 833 (1992).

[97] By contrast, the German Constitutional Court has held that fetuses are protected by Article I of the Basic Law which protects "the right to life of all persons." However, it has also found that a person's "right of free development of personality" gives them a right to pre-viability abortions in circumstances remarkably similar to those recognized in *Casey*. John A. Robertson, *Reproductive Technologies in Germany and the United States: An Essay in Comparative Law and Bioethics*, 43 Colum J Transnatl L, 191, 196-202 (2004). The German Court has not yet held that that protection also extends to fertilized eggs and pre-implantation embryos, though embryos are protected by legislation. Id at 195, 205. This protection bars the destruction of embryos to obtain ESCs. However, ESCs derived legally outside of Germany before January 1, 2002 may be imported for research. Id at 212-21.

[98] Dworkin, 59 U Chi L Rev at 400-01 (cited in note 55). Justice Samuel Alito has objected to the term constitutional person to distinguish born persons who are protected from unborn humans which are not as "fortunate." *Alexander v Whitman*, 114 F3d 1392, 1409 (3d Cir 1997) (Alito concurring) (finding that state exclusion of stillborn fetuses from

importance of all stages of human life by funding decisions and regulation, but it cannot do so by denying safe and effective medical treatment without a stronger justification than an essentialist *ipse dixit* about the inherent rights of embryos.[99] If moral repugnance is not an acceptable basis for denying a person sexual intimacy or reproductive freedom, it should not justify denying the right to life and health on which sexual freedom and the exercise of other liberties depend.[100]

If this is true, then the state might also be limited in the steps it might take to protect the welfare of non-human animals. Consider a law that banned animal use practices that substantially interfered with the ability to discover or produce drugs or therapies essential to life or health.[101] Such a law could be found to infringe a person's right to life and health because it bans a needed precursor activity to providing safe and effective medical care.[102] If so, the state's justification for such a ban should be strictly scrutinized. Whether the interest in preventing suffering in sentient, non-human animals was compelling enough to justify a particular law's burden on patients would require a close analysis of the competing human and animal interests at stake, alternative ways of protecting those interests, consistency with other practices regarding animals, and other factors. While overbroad bans might be found unconstitutional, the state may be free to use more narrowly tailored means to restrict certain uses of sentient animals in medical research or treatment despite a reduced availability of therapy. Depending on the facts of the situation, a ban on use of animals in research might be valid while a ban on use of embryos would not be.[103]

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wrongful death and survival statutes does not violate constitutional rights of fetuses or parents).

[99] The essentialist nature of the embryo protectionist position may also distinguish the interest in preventing suffering to sentient non-human animals.

[100] The right claimed is thus independent of the right to terminate pregnancy. While reversal of *Roe v Wade* would allow states to prefer fetal interests over a woman's choice, it would not necessarily extend to early embryos that have not yet implanted in the uterus.

[101] I am indebted to Jordan Steiker for this hypothetical. See generally Martha Nussbaum, *The Frontiers of Justice: Nationality, Disability, Species* (Harvard 2006) (showing that the social contract tradition, despite its great insights, cannot handle the moral boundary between humans and animals).

[102] There are important parallels here to the precursor basis for a first amendment right to research that is discussed in Part IV.

[103] Unlike sentient animals, embryos are not yet differentiated into organs or a nervous system, and thus cannot suffer. National Institutes of Health, *Report of the Human Embryo Research Panel*, Bethesda, MD:NIH (1994).

3. An Equal Protection approach.

Those persons uncomfortable with the Court's normativizing in substantive due process cases may prefer that they make such moves in the plain(er) clothes of the Equal Protection Clause.[104] Equal protection analysis, however, is never free of the normative choices that underlay a due process approach.[105] Because those choices are not as immediately center-stage, however, some persons find an equal protection approach more neutral.[106]

Equal protection, if only fitfully, draws on notions of moral consistency. "Culture of life" enthusiasts, however, are not consistent in their protection of embryos and born life. They argue that fertilized eggs and embryos deserve all the rights of other human beings, but then do not mourn the loss of embryos and fetuses in the same way or impose the same degree of liability for their destruction.[107] Nor do they campaign actively for restrictions on the large number of embryos routinely created and discarded in assisted reproduction. People undergoing infertility treatment typically fertilize all healthy eggs even if only one or two will be transferred or fewer still will implant, with the rest frozen before eventual discard. Efforts to limit this practice would most certainly run afoul of rights of procreative liberty.[108] If there is a right to create and discard embryos to

[104] Some readers may catch the allusion to my colleague Larry Sager's investigation of the partnership and agency aspects of our constitutional practice in his elegant work, Lawrence G. Sager, *Justice in Plainclothes: A Theory of American Constitutional Practice* (Yale 2004). See also Justice O'Connor's concurrence in *Lawrence*, 539 US at 579 (arguing for the result on equal protection grounds because of the state's failure to ban heterosexual sodomy while banning it by gays).

[105] *Bolling v Sharp*, 347 US 497 (1954) is the locus classicus, finding an equal protection component in the Fifth Amendment's due process clause. See id (school segregation in the District of Columbia violates due process). See also Peter Westen, *The Empty Idea of Equality*, 95 Harv L Rev 537 (1982).

[106] Thus Justice Scalia, after decrying the lack of expertise in judges to determine values at the end of life, proclaimed that "our salvation against arbitrary government action" lay in the equal protection clause. *Cruzan v Director, Department of Health*, 497 US 261, 300-301 (1990) (Concurring opinion).

[107] Brock, 32 J Med Ethics at 37-38 (cited in note 87). The homicide liability for culpable destruction of fetuses that now exists in 30 or more states in most cases does not extend to previable fetuses, much less to preimplantation embryos. Nor are embryo protectionists likely in a pinch to save 100 embryos rather than one child, for example, if a lab fire presented that dilemma. Id at 38 (citing Michael Sandel).

[108] The tradeoff is the added intrusion and cost to the woman versus avoiding the destruction of embryos by limiting the number that are created or discarded. See John A. Robertson, *Children of Choice: Freedom and the New Reproductive Technologies* 107-09 (Princeton 1994) (exploring constitutional issues surrounding the decision to discard embryos); John A. Robertson, *Protecting Embryos and Burdening Women: Assisted Reproduction in Italy*, 19 Human Reproduction 1693-96 (2004) (exploring the tradeoff

achieve pregnancy, then *a fortiori* the right to create and destroy embryos to stay alive and reduce pain and disability should also be recognized.

4. Non-embryonic alternatives.

Proposals to find non-embryonic sources of pluripotent stem cells do not escape the constitutional problems identified here. Some embryo protectionists suggest that viable ESCs could be derived from eight-celled blastomeres, from dead mosaic embryos, from turning off implantation genes in putative embryos, and other sources that do not require destruction of embryos.[109] If they can convince fellow protectionists that the biologic entities in question lack the developmental potential that warrants respect for the lives of embryos, they must then show that equally good ESCs can be obtained from these non-embryonic sources. Since no studies have indicated that this is possible, much research lies ahead to establish the viability of non-embryonic alternatives. Unless the cost and functional equivalency of non-embryonic sources of ESCs can be shown, this attempt to finesse the issue will not succeed.

Funding some research toward non-embryonic sources of ESCs may be justified, but refusing to fund or banning ESC therapy pending the outcome of those investigations betrays the delaying strategy intended by backers of such alternatives. The pursuit of embryo alternatives drains researcher attention and effort from the harder questions of ESC science that must be answered to obtain safe and effective therapies.[110] Without proof of equal efficacy the theoretical prospect of non-embryonic alternatives does not justify a bar on ESC treatments sourced from true embryos.

C. Slippery Slope Consequentialism

I have already referred to the consequentialist basis of the continuity-of-life position in the embryo status debate. Opponents of ESC research and therapy are sometimes more specific. They assert that the creation and destruction of ESCs, particularly through nuclear transfer cloning to obtain ESCs compatible for therapy, will necessarily pitch us on to a slippery

calculus).

[109] President's Council on Bioethics, *White Paper: Alternative Sources of Human Pluripotent Stem Cells* (2005).

[110] Douglas A. Melton, George Q. Daley, and Charles G. Jennings, *Altered Nuclear Transfer in Stem Cell Research—A Flawed Proposal*, 351 New Eng J Med 27-28 (2004).

slope toward reproductive cloning and other genetic horribles. Avoidance of that possibility, they argue, justifies prohibition of ESC treatments for those who could presently benefit from them.[111]

Some slippery slope opponents of ESC therapy focus on treatments that involve nuclear transfer cloning. They argue that once the technical skills to transfer nuclei from somatic to germ cells are developed, it will be relatively simple to transfer cloned embryos to the uterus for reproductive cloning.[112] They foresee a resulting unstoppable demand for cloned children.

The common-sense response to that fear, as with any slippery slope argument, is to deny that there is a slope at all, much less that it is so slippery that no stopping point exists short of a slide down the reproductive mountain to cloned children. This response denies both that doing X in the present will inexorably lead to doing Y in the future and that a future Y is so unpalatable that preventing its feared occurrence justifies the loss of present benefits from X.

If reproductive cloning is perceived as so horrible, there is no reason why a criminal ban on transfer of cloned embryos to a uterus would be any less likely to discourage its use than the line-drawing that occurs in myriad areas of law and policy.[113] Indeed, realistic scenarios of great demand for reproductive cloning are very hard to conjure. No primate has yet been cloned, mammalian success rates are low, and there is a high incidence of defects and anomalies due to the epigenetic flaws that reprogramming differentiated cells engender.[114] An otherwise fertile person will seldom have a rational interest in cloning

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[111] Consider Leon R. Kass and Daniel Callahan, *Cloning's Big Test: Ban Stand*, New Republic 10 (Aug 6, 2001); President's Council on Bioethics, *Human Cloning and Human Dignity* (2002) (cited in note 85).

[112] Dr. Hwang Suk Woo and his Korean team were thought to have shown that it is simply a matter of acquiring the manual dexterity needed for transplanting cellular nuclei and cytoplasm requires. Reared in the use of steel chopsticks, Hwang's team appeared to have become more quickly adept in immunosurgery and the micromanipulation of nuclei and cytoplasm than westerners. Exposure of Dr. Hwang's false claims of cloning 10 lines of ESCs shows that US researchers may not be as far behind as thought. See Wade and Sang-Hun, *Human Cloning Was All Faked*, NY Times at A1 (cited in note 14) (reporting the revelation that Dr. Hwang Suk Woo's claims were indeed fraudulent).

[113] One is reminded of Justice White's observation in *Griswold v Connecticut* that it is irrational for the state to expect a person to comply with a ban on contraception in marital relations but not in adulterous ones. *Griswold*, 381 US 479, 505 (1965) (White concurring).

[114] *Failures In Primate Cloning May Signal Impossibility Of Human Reproductive Cloning*, available at <http://www.sciencedaily.com/ releases/2003/04/030411070915.htm> (last visited Feb 16, 2006) (describing the problems experienced in attempted primate cloning).

herself rather than in reproducing sexually. Nor would such a desire have a strong claim to protection as an aspect of procreative freedom.[115] Even most gametically infertile persons are unlikely to have the desire or be willing to spend the money to clone themselves. The speculative fear that some unknown amount of reproductive cloning might occur if we allow ESC cloning for research or therapy is hardly a sufficient basis for denying persons the present ability to use safe and effective ESC treatments.

Yet Leon Kass and Daniel Callahan persist in spinning a web of cloning skullduggery.[116] They assert that a criminal ban could not be effectively enforced because monitoring of laboratories is not practicable, and inspection alone could not tell whether any person was in fact a clone. They also argue that once research embryos exist, someone will be tempted to have them implanted, thus producing a cloned child.[117] Also, persons who believe that it is morally wrong to destroy embryos created by fertilization or nuclear transfer might not comply with a law that orders destruction of a cloned human embryo.[118] For them, the risk of the existence of even one cloned person is a sufficient evil to stop all research on cloning.[119]

As Fred Schauer has argued, appeals to slippery slopes as a basis for policy operate as a kind of pre-commitment device to guard against future deciders assessing the merits of a situation differently than present deciders do.[120] Although future decisionmakers may be acting rationally once that future occurs, a Time 1 policy based on slippery slope fears prevents such a choice from being made at Time 2. Like other preemptive pre-commitments, avoidance of a slippery slope forecloses the need to

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[115] John A. Robertson, *Two Models of Human Cloning*, 27 Hofstra L Rev 609, 618-24 (1999); John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 Am J L & Med 7, 39-40 (2004).

[116] Kass and Callahan, *Cloning's Big Test*, New Republic at 10 (cited in note 111). See also Alexander Morgan Capron, *Placing a Cloning Moratorium on Research Cloning to Ensure Effective Control Over Reproductive Cloning*, 53 Hastings L J 1057 (2001-02) (proposing an international moratorium on human cloning).

[117] Kass and Callahan, *Cloning's Big Test*, New Republic at 10 (cited in note 111).

[118] But this assumes that all embryos have a right to be implanted in a woman, even if there is no willing recipient to receive them. Guenin, 292 Science at 1659-60 (cited in note 87).

[119] Kass and Callahan, *Cloning's Big Test*, New Republic at 10 (cited in note 111).

[120] Frederick Schauer, *Slippery Slopes*, 99 Harv L Rev 361, 362-64 (1985). See also Eugene Volokh, *The Mechanisms of the Slippery Slope*, 116 Harv L Rev 1026, 1102-03 (2003) (discussing the persistence of the is-ought fallacy despite its illogical quality).

make a future decision on an issue by removing the chance that a need for that decision will ever arise.[121]

Slippery slope appeals may rationally serve present values but they do so at a cost in both present and future interests that is all too rarely factored into the decisional calculus. The appeal of present assessment over a future reevaluation of the question will depend on the situation or context at issue and the costs of foregoing the challenged procedures.[122] Chief Justice Rehnquist in *Glucksberg* quite rationally cited "the fear that permitting assisted suicide will start down the path to voluntary and perhaps even involuntary euthanasia" thus constituting "a much broader license, which could prove extremely difficult to police and contain," as one of several acceptable bases for Washington's prohibition on physician-assisted suicide.[123] He concluded that, "Washington, like most other States, reasonably ensures against this risk by banning, rather than regulating, assisted suicide."[124]

Rational slippery slope concerns also figured in Justice Souter's concurrence in the judgment in *Glucksberg*.[125] He too cited a fear of progression from assisting the suicide of competent dying persons to those who are poor, vulnerable, and less able to exercise free choice. He feared that doctors "would abuse a limited freedom to aid suicides by yielding to the impulse to end another's suffering under conditions going beyond the narrow limits" proposed in the case.[126] While recognizing the contested nature of the evidence concerning the Dutch regulatory system for active euthanasia, the mere fact that some persons thought that the Dutch restrictions had been violated with impunity sufficed to sustain the rationality of the Washington ban.

Both Justice Rehnquist and Justice Souter, however, were addressing the rationality of a slippery slope claim in circumstances where alternative ways to control severe pain existed. Justice Souter, and possibly even Justice Rehnquist, would have been much more skeptical of a slippery slope justification if stronger scrutiny were required. Just as those

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[121] John A. Robertson, *Precommitments in Bioethics*, 81 Tex L Rev 1849-76 (2003) (distinguishing precommitments that remove the possibility of a different choice at Time 2).

[122] Schauer recognizes the context-laden nature of evaluation of slippery slope arguments. Schauer, 99 Harv L Rev at 381-83 (cited in note 120).

[123] 521 US at 732-33.

[124] Id at 734-35.

[125] Id at 785-86 (Souter concurring).

[126] Id at 785-87 (Souter concurring), citing evidence that Dutch regulation of active euthanasia had not prevented its extension beyond competent, terminally ill adults to severely disabled neonates and elderly demented persons.

fears would not have justified a ban on physician assisted suicide when no other effective pain relief was available, neither should they provide justification for interfering with a patient's right to medical treatment to save life or reduce suffering.

The case for present action to prevent a slippery slope toward reproductive cloning is weaker than the fear that physician assisted suicide will lead to active euthanasia of incompetent persons. Given the degree of suffering in many medical situations at the end of life, there is a potentially large pool of persons who might seek more active means to end their lives. It is highly fanciful, however, to think that the temptation to engage in reproductive cloning would be as strong, if only because of high cost, low efficacy, and considerable doubts about safety. With context mattering so mightily in assessing slippery slope claims, there is little reason to think that the greater pressure to burst normative lines in terminal illness would also operate with reproductive cloning.

In short, the fear of a slippery slope to reproductive cloning provides neither a compelling nor even a substantial basis for denying people safe and effective ESC treatments. If slippery slope arguments are rational in some circumstances, they need more substance in other situations, such as when they are used to deny safe and effective ESC treatments that save life or reduce suffering. Such fears have even less credence when based on "post-human" fears of genetic engineering and manipulation of the life cycle.[127]

IV. EMBRYO STATUS AND THE RIGHT TO RESEARCH

The discussion thus far has analyzed the constitutional issues that would arise if the state banned the use of safe and effective ESC therapies. ESC science has made great strides since the first culture of human ESCs in 1998, and a few treatments will soon be in clinical trials. But it is still too soon to know what their ultimate contribution to medical science will be.

[127] Francis Fukuyama, Paul Lauritzen, and other anti-technologists who fear a "post-human" future of genetic engineering of offspring and shifts in the trajectory of life and death make such claims. The abstract and general nature of such charges, however, gives them even less credence as a basis for infringing the right to safe and effective medical treatment in the present. For a general discussion see Francis Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (Farrar, Straus and Giroux 2002) (noting the erosion of the foundations of liberal democracy under pressure from new concepts of humans and human rights, ultimately arguing for strong international regulation of human biotechnology); Paul Lauritzen, *Report on the Ethics of Stem Cell Research*, in President's Bioethics Council, *Monitoring Stem Cell Research* at 237, 257-63 (Appendix G) (cited in note 3).

They might, for example, be more important as a means of elucidating disease mechanisms and identifying targets for small molecule drugs than as specific cell replacement therapies.[128] Nor is it clear that the regulatory atmosphere will be negative when safe and effective ESC therapy are at hand. By then, "culture of life" debates might have shifted into other arenas or lost their fire. While I have presented arguments for why the state could not ban safe and effective ESC treatments, the situation is too speculative to pursue further.

A more immediate issue is the constitutional acceptability of bans on the research on which the growth of ESC science depends. Some states have highly restrictive laws regarding embryo research or nuclear transfer cloning.[129] These laws have also been justified on grounds of protecting embryos and preventing a slippery slope to future abuses. The attentive reader will notice that embryo status and slippery slope arguments have no different structure at the research than at the therapy stage.

But whether they have a different constitutional valence when treatment is still hypothetical is another question. In the one case, it is the desire to use safe and effective treatments to extend life or reduce pain and disability. In the other, it is the desire to engage in the scientific and clinical practices that are necessary to ascertain whether ESC therapies work. Although the former cannot occur without the latter, the constitutional status of the latter is much less clear than is the right to treatment sketched above. Only if there is a right to research of near equivalent constitutional status would the same demanding scrutiny apply.

But that question is unresolved and, since the 1980s, largely unexamined.[130] Although a right to research has come up in the

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[128] Jamie Thomson, who first cultured human ESCs at the University of Wisconsin, has consistently made this point. Suzanne Rust and Kathleen Gallagher, *Stem Cell Work Crosses Boundaries: UW Scientists Aim to Make Wisconsin the Epicenter of a Medical Revolution*, Milwaukee Journal A1 (April 22, 2006).

[129] Those bans take the form of criminal penalties for research with embryos or even doing ESC research itself. For a list of states, see National Conference of State Legislatures, *State Embryonic and Fetal Research Laws*, available at <http://www.ncsl.org/programs/health/ genetics/embfet.htm> (last visited Feb 14, 2006).

[130] Historically, there were few restrictions on medical research before body snatching for anatomy studies and the animals' rights-based opposition to anti-vivisectionism arose in the early and mid 19th century. Serious policy attention to research with living human subjects did not occur until after Nuremburg in the 1940s. It took the Tuskegee Syphilis study revelations in the 1960s to spur legislative action. See Jay Katz, *Experimentation with Human Subjects* (Russell Sage Foundation 1972) (detailing the authority of various private and public actors in the human experimentation process). See also Barry P. McDonald, *Government Regulation or Other 'Abridgments' of Scientific Research: The*

cryptography, national security, and now bioterrorism contexts, legitimate health and safety reasons appear to justify those restrictions.[131] Embryo and cloning research, by contrast, are restricted because of disputes over the moral status of embryos, not because of threats to community health or safety. Indeed, current regulatory restrictions remind some ESC scientists of the barriers placed in the path of Galileo, the acceptance of Darwinism in education, and Lysenko's rejection of genetics in the Soviet Union.[132]

Whether the weakness of "culture of life" positions with regard to ESC treatment defeats bans on ESC research will thus depend on whether scientific research has a protected status that would require more than a minimally rational basis for governmental prohibition.[133] If not, a paradox would exist: a patient has a right to use an ESC treatment once developed but no one has a right to do the research necessary to develop it.

The most cogent version of the argument for a right to research relies on the connection between research and protected interests in free speech and medical treatment.[134] Even if bans on research do not warrant the same scrutiny as bans on publication or treatment, they deserve some heightened scrutiny because of the role of research in making free speech and medical treatment possible. Science and medicine cannot advance

Proper Scope of Judicial Review Under the First Amendment, 54 Emory L J 979 (2005) (noting a recent exposition of First Amendment issues in this area).

[131] These justifications are not without dispute. See McDonald, 54 Emory L J at 1031-1048 (cited in note 130).

[132] Irving Weissman, *Stem Cell Research: Paths of Cancer Therapy and Regenerative Medicine*, 294 JAMA 1359, 1365 (2005). Whether ESC research is actually banned or just subject to funding restrictions, many ESC scientists share those concerns. This perception, which might discourage young scientists from entering the field or using ESCs in experiments, call to mind the Supreme Court's view of the importance of academic freedom: "Scholarship cannot flourish in an atmosphere of suspicion and distrust. Teachers and students must always remain free to inquire, to study and to evaluate, to gain new maturity and understanding; otherwise our civilization will stagnate and die." *Sweezy v New Hampshire*, 354 US 234, 250 (1957).

[133] McDonald, 54 Emory L J at 1087-88 (cited in note 130).

[134] First Amendment traditions also gives special protection to values of academic freedom. *Board of Regents of the University of Wisconsin v Southworth*, 529 US 217, 237 (2000); *Keyishian v Board of Regents*, 385 US 589, 503 (1967); *Sweezy*, 354 US at 250. That freedom includes not only the right to select and judge students and faculty, but also the right of faculty to wide freedom in teaching, research, or writing. The research choices and methods of scientific and clinical faculty fall within the broad confines of academic freedom. Consider David M. Rabban, *A Functional Analysis of 'Individual' and 'Institutional' Academic Freedom Under the First Amendment*, 53 L & Contemp Probs 227, 230-31 (1990). Many ESC scientists are university faculty, and many students, post-docs and others are trained by them. The use of human embryos and ESCs is an important area of investigation in developmental biology and clinical medicine, which affects both the content of resulting publications and training of students.

without research. Bans on research could stifle scientific and medical progress as much as bans on publication.

The argument for a constitutional right to research has several strands. It hinges first on finding that publication of scientific speech is as protected as is political or other speech. While that step is now uncontroversial, it would also be necessary to find that research, information gathering, or other activities that make protected publication possible receive protection because of their link with publication itself.[135] Alternatively, one could argue that scientific research is an essential stage in producing the medical treatments protected by the right to medical treatment. Some persons have even argued that research is itself a form of protected speech.[136]

I do not claim that any activity essential to develop medical knowledge or otherwise obtain publishable information is as protected as publication or treatment itself. But much scientific publication and many clinical treatments depend on prior research and experimentation. Indeed, the methodological naturalism that is at the heart of science relies on experimentation and then informing others of those results.[137] It would be strange if the state could not ban scientific publication or communication but could ban the experimentation and research that is a necessary precursor to the protected publication without showing a strong need for the restriction.[138] It would be equally paradoxical to find that the state could not prohibit the use of safe and effective ESC medical treatments but

[135] Just as a ban on the sale of ink or printing presses would interfere with the right of speech and publication, so to could a ban on research interfere with publication or treatment. If the latter stage cannot be banned without more than minimal scrutiny, then the precursor activity needed to make the latter stage should also receive some form of heightened protection, even if there is no certainty that any particular research will lead to publication or medical treatments. Compare *Buckley v Valeo*, 424 US 1 (1976) (holding that the First Amendment protects campaign contributions as precursor to political speech).

[136] Professor Alta Charo has argued that scientific research itself is a form of expression that independently deserves First Amendment protection. United States Senate, Commerce, Science, and Transportation Subcommittee on Science, Technology, and Space, *Hearing on Cloning and Women's Health* (Mar 27, 2003). Holders of this view must still contend with the content-neutral reach of legal bans on embryo or other research. See notes 139-146 and accompanying text.

[137] Methodological naturalism is the search for natural causes to explain natural phenomena. *Kitzmiller v Dover Area School District*, 400 F Supp 2d 707, 735 (M D Pa 2005) (teaching intelligent design theory violates the establishment clause of the First Amendment).

[138] There is an obvious analogy to news-gathering and reporter's privilege that is too complicated to pursue further here. For a start on that analysis, see John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S Cal L Rev 1203, 1215-18 (1978).

could prohibit the scientific and clinical research necessary to determine whether they were safe and effective.[139] In addition, academic freedom, which the First Amendment also protects, also recognizes some right to acquire and develop knowledge.

Rather than lurk further in these doctrinal precincts, I will simply assume that the connection between scientific and clinical research and the production of scientific knowledge and medical treatment endows research, including ESC research, with some level of protected status beyond that of general economic and social liberties. If so, restrictions on ESC research should first be assessed to see if they are viewpoint or content-based, that is, whether they are aimed at preventing the development of publishable knowledge about ESCs because of the knowledge it would develop or the uses to which it could lead.[140] A viewpoint-based restriction on ESC research would have great difficulty overcoming the strict scrutiny applied to content-based restrictions on publication.[141]

In most instances, however, the restriction at issue will be content-neutral, applying to all research or experimentation using those means, such as bans on the use of embryos or animals in scientific or medical research. If so, it deserves assessment under the same standard used by the Supreme Court to assess non-content, non-viewpoint regulation of speech in other areas. Although doctrinal decision rules have not thoroughly crystallized here, in cases such as *Ward v Rock Against Racism*[142] and *Turner Broadcasting, Inc v FCC*,[143] the Supreme Court has applied a more fact-driven analysis than minimal rational basis analysis alone would demand.[144] This

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[139] Acceptable non-content grounds of regulation would include protection of the autonomy and safety of research subjects or the ownership of research materials.

[140] The fear would be that it would lead to creation and destruction of embryos for research or therapy as well as to nuclear transfer cloning and related activities thought to be harmful.

[141] The fear that publication of knowledge will lead to bad uses has never been a sufficient basis for content-based restrictions on speech. See, for example, *United States v Progressive*, 467 F Supp 990, 992-95 (W D Wis 1979) (discussing how prior restraint doctrine applies in the context of disseminating hydrogen bomb blueprints). At the very least the danger posed would have to be imminent and publication viewed as an incitement. *Brandenburg v Ohio*, 395 US 444 (1969).

[142] 491 US 781 (1989).

[143] 512 US 662 (1994).

[144] Under the narrow tailoring requirement applied in *Ward*, an ordinance may not "burden substantially more speech than is necessary to further the government's legitimate interests." 491 US at 799. However, this does not require that the Court adopt the less-restrictive-means approach of strict scrutiny or make it as rigorous as the scrutiny of commercial speech regulation under *Central Hudson Gas v Public Service Commn*, 447 US 557, 572 (1980).

approach allows courts to ask whether the state's content-neutral interests in restricting research justify the burden imposed on scientific speech and medical treatment.[145]

If the intermediate scrutiny applied in non-content based restrictions on speech is applied to scientific and medical research, bans on embryo and ESC research will have difficulty surviving.[146] Society does not act irrationally by seeking to promote a "culture of life" in medical research or by protecting existing persons and research subjects. But it should have more than merely rational justification for policies that directly block research essential to obtain scientific and clinical knowledge that could save life or reduce suffering.

An assessment of state bans on embryo research shows that their justification is particularly weak. Such bans prohibit the derivation of ESC cells from surplus embryos no longer needed to treat infertility. Yet embryo protectionists find derivation or use of ESCs in research morally objectionable because it directly destroys a human life. No matter that the embryo's demise is imminent and that it has not yet developed specialized cells or organs. As the discussion of embryo status has shown, protection of embryos is not a compelling ground for burdening a person's life or health.[147] Nor should it be sufficient to justify placing significant obstacles based on embryo status in the way of developing the knowledge on which future ESC treatments may depend.

Viewing the issue through an equal protection lens leads to the same conclusion. Infertile couples now routinely fertilize all eggs retrieved from hyper-stimulated ovaries, even though not all of those which successfully fertilize will implant in a uterus.[148] There is no movement to ban or limit such actions. Indeed, limits on the number of embryos created or transferred

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[145] See, for example, *City of Erie v Paps AM,* 529 US 277, 332 (2000), and Justice Souter's demand for a more vigorous evidentiary scrutiny than was applied in *Barnes v Glen Theater, Inc*, 501 US 560, 578-79 (1991).

[146] This is true even if they are drafted with enough specificity to avoid the vagueness that has doomed some past bans on embryo research. See *Margaret S v Edwards*, 794 F2d 994, 998-1001 (5th Cir 1986) (considering how vagueness in ban on embryo experimentation violates due process); *Lifchez v Hartigan*, 735 F Supp 1361, 1373 (N D Ill 1990) (asserting that vagueness in differentiating between "tests" and "experiments" renders state ban on embryo research invalid).

[147] See generally Parts II and III.

[148] Robertson, 19 Human Reproduction at 1693-96 (cited in note 108) (exploring the tradeoff calculus faced when deciding to produce excess embryos when preparing for artificial reproduction or run the risk of having to repeat the procedure).

might so trench on the ability to get pregnant that they would very likely infringe reproductive liberty.[149]

If infertile couples are permitted to discard unwanted embryos, no rational purpose is served by disallowing research to occur on them before or during discard. Surely the production of embryos for medical research is as important—or nearly as important—as reproductive freedom. The more rigorous judicial scrutiny of state ends and means applied under *Turner Broadcasting* and *Ward* should invalidate laws against using unwanted embryos for ESC research.

More specific bans on creating embryos for research through laboratory fertilization or by nuclear transfer cloning should also fall.[150] If research on discarded embryos is permitted, there is no strong reason for banning their creation for research in the first place. The embryos in question will have no chance to implant in a uterus and are too rudimentary in form to have rights or interests. Nor is the claim that it is worse to create them for research credible other than as a symbolic practice to mark respect for potential human life.

This analysis would also invalidate laws that ban nuclear transfer cloning for research, as is now the case in seven states and in a bill that passed the House of Representatives in 2005.[151] There are important scientific and medical reasons for nuclear transfer research—for cloning the genomic source of ESCs. A ban on nuclear transfer cloning directly impedes the ability of scientists to investigate important questions about biological development that cannot be addressed without cloning. If embryo status is insufficient to justify a ban on creating embryos for research, it should have even less weight in justifying a ban on creating embryos by nuclear transfer. Indeed, it is questionable whether the products of nuclear transfer are embryos at all, since they have not been created by fertilization and have never produced a pregnancy or live birth.[152]

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[149] For example, a law that prohibited creation of more than three embryos for infertility treatment could be found to violate a person's right to reproduce if it then led to additional cycles of hormonal stimulation and egg retrieval to produce a pregnancy. On the Italian law, see id.

[150] Massachusetts enacted such a law in 2005. Mass Gen Laws Ann 111l, § 8.

[151] HR 1357, 109th Cong, 1st Sess H1690 (2005).

[152] See Rudolf Jaenisch, *The Biology of Nuclear Cloning and the Potential of Embryonic Stem Cells for Transplantation Therapy*, in President's Council on Bioethics, *Monitoring Stem Cell Research* at 385, 387-403 (Appendix N) (cited in note 3) (providing a biological argument for therapeutic cloning). This fact might explain why a pro-life state such as Missouri has refused to ban nuclear transfer cloning, and why Massachusetts bans creation of embryos for research by fertilization but not by nuclear transfer cloning. See note 21 and note 150.

Nor is the risk great that research cloning will start a slippery slope slide to reproductive cloning or the genetic engineering of offspring characteristics that "post-human" jeremiahs fear. Our earlier analysis has shown the weakness of slippery slope approaches to complex problems. Speculative fears, particularly when so many legal stopping points exist, should have no greater weight in justifying bans on nuclear transfer research than they would on other protected activities.

Nothing said so far would prevent the state from adopting reasonable measures to protect the choice of couples in determining whether their gametes and embryos are used in research. Informed consent, remedies for violations, and prior review by IRBS and ESC review committees may legitimately be required for the creation, use, and donation of embryos for research.[153] But these are process and regulatory measures that do not prevent creating embryos or using them in research. I leave questions of banning payments to egg or embryo donors for another time.[154]

V. A NOTE ON FEDERALISM

In recent years, federalism has figured so prominently in constitutional debates that some mention of its implications for regulation of ESC research and therapy is in order. *Gonzales v Raich*[155] has shrunk the limits on federal commerce power imposed by *United States v Lopez*[156] and *United States v Morrison,*[157] making clear that Congress may regulate local activities because of their aggregate effect on interstate commerce.[158] Although states have traditionally regulated medical practice, with the federal government playing a stronger role in science funding and food and drug safety, the methodological naturalism of science and clinical medicine transcends state and even national borders. Unrestricted availability of a treatment locally in one state could undermine federal efforts to regulate it on a national basis.

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[153] National Academy of Sciences, *Guidelines for Human Embryonic Stem Cell Research* (2005).

[154] See Robert Steinbrook, *Egg Donation and Human Embryonic Stem-Cell Research*, 354 N Eng J Med 324, 324-26 (2006) (discussing ESC donation and subsequent research).

[155] 125 S Ct 2195 (2005) (holding that Congress has power under the commerce clause to regulate state authorized intrastate production and use of marijuana for medical reasons).

[156] 514 US 549 (1995).

[157] 529 US 598 (2000).

[158] 125 S Ct at 2205-09.

If that is so, Congress has power under the Commerce Clause to play an active role on either side of the ESC debate as long as it has clearly expressed its intent to do so.[159] A different political alignment in Congress could lead to federal laws protecting the right of all persons to engage in ESC research and receive ESC treatments. By the same token, a Congress driven by "culture of life" loyalties could ban state-permitted embryo research and ESC therapy on Commerce Clause grounds. However, such bans would have to clear the First, Fifth, and Fourteenth Amendment hurdles discussed in this Article. In the end, federalism concerns may be less central to "culture of life" debates than are substantive constitutional rights.

CONCLUSION

The impact of "culture of life" politics on the life sciences is likely to continue for some time, with shifting political winds sculpting new variations in the debate. One should not forget that both sides share many premises. Both believe in the methodological naturalism of science, the need to find better cures, and the legitimacy of some societal oversight of science.[160] Bitter differences, however, exist over the extent to which embryos and fetal tissue may be used as tools in scientific research and medical therapy. This has retarded the pace of ESC science and if maintained in the future could deprive patients of safe and effective medical treatments.

"Culture of life" and science policy debates commonly unfold in legislative and administrative arenas (as well as cable TV and internet blogs) with little role for the judiciary. The prospect of treating people with cells obtained by destroying embryos has now raised the prospect of a potential role for courts in this important area of science policy. Regardless of whether litigation will ever ensue, at the very least, thinking in constitutional terms sharpens understanding of the competing interests and of the institutional forms that regulation of science takes.

Yet no question in constitutional law is more radioactive than overturning "culture of life" legislation on substantive due

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[159] In *Gonzalez v Oregon*, the Court found that Congress had not intended to delegate its authority to regulate medical practice affecting interstate commerce to the Attorney General. 125 S Ct at 2215.

[160] Both market conservatives and liberals share this view. Market conservatives want to develop and sell their products, and liberals want to save lives and relieve suffering. Social conservatives, who see moral threats here, would limit the market. See generally Daniel Callahan, *Conservatives, Liberals, and Medical Progress*, 10 New Atlantis 3 (2005).

process grounds. Still, a fair look at textual, historical, logical, and precedential modes of constitutional argument support a finding that a negative right to privately funded safe and effective medical treatments exists, and that protection of embryos or fears of slippery slopes will not justify infringement of that right. If that is true, then some constitutional protection should also exist for embryo and nuclear transfer cloning research, because of the link between research, scientific knowledge, and treatment.

I cannot predict how the ESC debate will ultimately be resolved, but it will not be the last instance of societal fisticuffs over the regulation of science and medicine.[161] We respect, nay, *we adore*, science and clinical medicine. But we also recognize that scientists do not have total license in how they conduct their business. The ESC debate has been another instance of whether scientists or non-scientists will control the means of clinical treatment and scientific research. That debate will continue until political winds shift or ESC science renders it obsolete.

The role of the courts will continue to be a small one but there are situations in which the judiciary might get more involved. If restrictions on research become intolerable, then lawsuits about rights to research will arise. Or if safe and effective treatments are available but cannot be used, then constitutional rights to treatment will be asserted. Both possibilities raise the question of whether the courts will recognize and protect substantive rights to research and treatment. The length and quality of people's lives may depend on their decisions.

[161] For a comparative view of how different liberal societies mediate these questions see Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (2005). A very different situation exists in the United States with interest groups now allowed to contest the science on which federal health and environmental policy is based. Wendy Wagner, *Perils of Relying on Interested Parties to Evaluate Scientific Quality*, 95 Am J Pub Heath S99 (2005).