FREEDOM, FATE, AND THE FEAR OF FRANKENSTEIN: DUE PROCESS PROTECTION FOR EMBRYONIC STEM CELL RESEARCH

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I. INTRODUCTION

“Further delays in pursuing the clearly viable option of embryonic stem cells will result in an irretrievable loss of time, especially if the new approach fails to prove itself.”¹ This was the appeal of James Thomson shortly after his team of scientists at the University of Wisconsin and another led by Shinya Yamanaka at Kyoto University separately reported in November 2007 that they had reprogrammed adult skin cells to behave like human embryonic stem cells.² What makes this recent discovery so exciting is that it obviates the need to destroy human embryos—a point of heated public controversy³—in the process of deriving pluripotent stem cells: cells that have the ability to develop into any human tissue type and thus possess great potential for

² Gina Kolata, Scientists Bypass Need for Embryo to Get Stem Cells, N.Y. TIMES, Nov. 21, 2007, at 1. For the published report of Dr. Thomson’s team, see Junying Yu et al., Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells, 318 SCIENCE 1917 (2007). For the published report of Dr. Yamanaka’s team, see Kazutoshi Takahashi et al., Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors, 131 CELL 861 (2007).
³ See CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE 195–216 (2005) (describing the controversy between liberals who support embryonic stem cell research for its rich therapeutic potential and conservatives who are morally opposed to the destruction of embryos, despite this potential). Although their claims ultimately proved premature, commentators rushed to declare the embryonic stem cell debate over upon the discovery of how to reprogram adult skin cells. See, e.g., Charles Krauthammer, Stem Cell Vindication, WASH. POST, Nov. 30, 2007, at A23 (giving credit to President Bush’s restrictive federal policy for the discovery of reprogrammed cells); Sheryl Gay Stolberg, Advance on Stem Cells Equalizes Debate, N.Y. TIMES, Nov. 21, 2007, at A23 (explaining that the discovery of reprogrammed cells is likely to transform the debate).
use in regenerative medicine and therapeutic research in general. Yet, despite this breakthrough, leading experts agree that it is imperative for embryonic stem cell research to continue as major research centers have pledged.

Indeed, it is much too early to tell whether reprogrammed cells promise the same therapeutic benefits that scientists believe natural embryonic stem cells do. Interest in embryonic stem cell research

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4 See Junying Yu & James A. Thomson, Embryonic Stem Cells, in NAT’L INSTS. OF HEALTH, REGENERATIVE MEDICINE 2006, at 1–8 (2006) [hereinafter REGENERATIVE MEDICINE 2006]. Stem cells are classified as either embryonic or adult stem cells, depending on the type of tissue from which they are derived. Thomas P. Zwaka, Use of Genetically Modified Stems Cells in Experimental Gene Therapies, in REGENERATIVE MEDICINE 2006, supra, at 46. Embryonic stem cells may be derived from human embryos produced by in vitro fertilization, a process in which oocytes are artificially fertilized with sperm in a culture dish, or by somatic cell nuclear transfer, a technique that involves the cloning of a human embryo. Yu & Thomson, supra, at 3. Their therapeutic potential is far superior to that of adult stem cells because they are undifferentiated and pluripotent, meaning that they have not yet developed into the specialized cells found in an adult human. Id. at 1–3, 6. If cultured and maintained under appropriate conditions, embryonic stem cells can replicate themselves indefinitely while still possessing the capacity to develop into any cell type in the adult human body. Id. at 3. Adult stem cells, on the other hand, are differentiated and multipotent, meaning that they are specialized and can only develop into a select number of cell types. Zwaka, supra, at 46. Therefore, when transplanted to an adult human, adult stem cells only sustain the cell types already present in steady-state numbers over the course of the individual’s lifetime because they rarely divide, rather than regenerating new cells at the rate embryonic stem cells do. See id. However, therapies derived from adult hematopoietic stem cells, which themselves are derived from bone marrow, have been thoroughly studied and are widely used, particularly to treat forms of bone marrow cancer such as leukemia. Jos Domen et al., Bone Marrow (Hematopoietic) Stem Cells, in REGENERATIVE MEDICINE 2006, supra, at 24, 28.

5 See Alice Park et al., The Year in Medicine from A to Z, TIME, Dec. 3, 2007, at 65 (reporting Dr. Yamanaka’s statement: “My hope is to avoid using human embryonic stem cells . . . [b]ut at this point, I am not 100% sure that is possible yet”); Peter N. Spotts, Stem-Cell Advance Opens Up the Field, CHRISTIAN SCI. MONITOR, Nov. 23, 2007, at 1 (reporting Dr. Thomson’s belief that “embryonic stem-cell research is still vital”); Interview by Natasha Pinol, Commc’ns Officer for Science, with Dr. James Thomson & Dr. Junying Yu, in Am. Ass’n for the Advancement of Sci., at 21:29–21:53 (Nov. 20, 2007), available at www.aaas.org/news/releases/2007/media/200711transcript_yu_thomson.pdf [hereinafter Thomson & Yu Interview] (reporting Dr. Yu’s statement: "Personally I don’t think it is a good idea to abandon research on the human embryonic stem cells. This new research is just the beginning. We had to understand how these cells work and how similar these cells are to embryonic stem cells. So I would think most of the people still want to do research on the human embryonic stem cells"); see also ABP, Stem Cell Advance May Not End Debate, CHRISTIAN CENTURY, Dec. 25, 2007, at 14 (discussing the lack of certainty as to the promise of reprogrammed cells).

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The research into embryonic stem cells derives from the belief that it will lead to the development of transplantation therapies to treat individuals with degenerative conditions, such as Parkinson’s disease, leukemia, diabetes, heart disease, and spinal cord injury, caused by the destruction or dysfunction of particular cell types. Short of transplantation therapies, embryonic stem cells may support basic medical research by allowing scientists to study biological developmental processes, especially in early development, and to better understand certain diseases, conditions, and birth defects. Due to the unlimited supply of human tissue that embryonic stem cells could provide, scientists could perform tests on certain organs, such as human hearts, which are currently unavailable for testing, and develop new and more effective drugs. Although embryonic stem cells and reprogrammed cells appear identical under the microscope, the latter are artificial and could very well turn out not to possess the same characteristics as embryonic stem cells. Even to understand reprogrammed cells more fully, scientists will have to continue studying embryonic stem cells. To be sure, the study of embryonic stem cells was essential to the discovery of how to reprogram adult cells in the first place.

Government policy on embryonic stem cell research has already set this young and promising field back approximately five years. While various States and private institutions independently began funding embryonic stem cell research as a result of federal funding restrictions that President Obama only recently lifted on March 9, 2009, other States have taken a more hostile approach, adopting statutes that prohibit or otherwise incidentally burden the performance of this research within state lines. The most restrictive of these statutes specifically ban in vitro fertilization or somatic cell nuclear trans-

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7 See Yu & Thomson, supra note 4, at 1–8.
8 Id. at 4, 7.
9 Since no human heart cell lines exist, scientists typically perform tests on animal models. Id. at 4.
10 See id.
11 See Leshner & Thomson, supra note 1, at A17; Nickerson, supra note 6, at 1A.
12 See Thomson & Yu Interview, supra note 5, at 21:54–22:11, 27:34–28:10 (reporting Dr. Thomson’s suggestion that scientists will not abandon embryonic stem cell research because they “need a gold standard” with which to compare reprogrammed cells).
13 See id. at 21:29–21:53.
14 See Thomson & Yu Interview, supra note 5, at 34:01–34:49.
16 Sheryl Gay Stolberg, Obama Lifts Bush’s Strict Limits on Stem Cell Research, N.Y. TIMES, Mar. 9, 2009.
fer for research purposes—the two techniques used by scientists to create natural human embryos.  

It goes without saying that time is precious in this matter. The slower the pace of research, the longer it will take to develop safe and effective therapies derived from embryonic stem cells to treat the sick and prevent unnecessary suffering and death. Repealing legislative restrictions on embryonic stem cell research is one possible means of aiding its stilted progress, but litigation may be a faster, more effective avenue than the political process. The only way to remove the matter completely from the political process is to challenge these laws on constitutional grounds.

Successful constitutional challenges to laws restricting embryonic stem cell research would likely provide benefits that increased funding alone could not deliver. Indeed, some of the States with restrictive laws on their books have important scientific research centers that could develop flourishing programs in embryonic stem cell research if freed from governmental interference. Additionally, funding of research in any State has its limits, and it is possible that more facilities distributed throughout the country could reap greater cumulative funding than could fewer facilities in only a handful of States. Local donors, for instance, may be inclined to donate to a local program rather than to a program in a State far away. Furthermore, scientists who wish to engage in embryonic stem cell research will have less incentive to emigrate from a State if they can practice their profession close to home, which could promote interest in the field amongst individuals with no previous access. All this could lead to an overall increase of activity in embryonic stem cell research throughout the country.

There has not yet been, as of the writing of this Comment, a constitutional challenge to a law restricting embryonic stem cell research. However, the recent “flurry and scope of legal activity amassing

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17 See STEM CELL RESEARCH, supra note 15.
18 See Leshner & Thomson, supra note 1, at A17.
21 See id.
22 Leshner & Thomson, supra note 1, at A17.
23 See Robertson, supra note 19, at 3 (noting that “[w]hile 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”).
around stem cell research . . . . warns that law is fast becoming the next battleground” in the debate.24

This Comment argues that current substantive due process doctrine provides substantial support for the proposition that laws restricting embryonic stem cell research violate an individual’s right to therapeutic medical treatment, which protects against state interference with the development of prospective therapies derived from embryonic stem cells.25 Part II.A demonstrates that, as a matter of legal tradition, the law has historically protected an individual’s right to therapeutic medical treatment and accommodated the performance of therapeutic research with little, if any, restriction until well into the latter half of the twentieth century. Therefore, history and tradition, at a minimum, should not foreclose the prospect of substantive due process protection for embryonic stem cell research. Part II.B demonstrates that courts have provided substantive due process protec-

24 Judith F. Daar, Decoding the Stem Cell Debate: A Primer Par Excellence, 36 J.L. MED. & ETHICS 184, 188 (2008) (reviewing Russell Korobkin & Stephen R. Munzer, Stem Cell Century: Law and Policy for a Breakthrough Technology (2007)) (citing Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 703 (2007), cert. denied, 128 S. Ct. 1069 (2008), which held that terminally ill patients do not have a substantive due process right to access investigational drugs); see also Doe v. Klein, 254 F. App’x 626, 629 (9th Cir. 2007) (dismissing for lack of venue an action to enjoin California officials administering the State’s embryonic stem cell research institute from engaging in such research on the ground that it deprives embryos of a right to life without due process); Doe v. Shalala, 862 F. Supp. 1421, 1428–29 (D. Md. 1994) (dismissing for lack of standing an action to enjoin an advisory panel from submitting a report supporting fetal tissue research to the Department of Health and Human Services on the ground that such research deprives embryos of a right to life without due process).

25 Alternative substantive due process theories for challenging laws restricting patients’ access to medical treatment and therapeutic research have been made in the past. See Russell Korobkin & Stephen R. Munzer, Stem Cell Century: Law and Policy for a Breakthrough Technology 79–85 (2007) (suggesting that restrictions on embryonic stem cell research should be subject to strict scrutiny); Steven Goldberg, Cloning Matters: How Lawrence v. Texas Protects Therapeutic Research, 4 YALE J. HEALTH POL’Y L. & ETHICS 305, 316–17 (2004) (arguing that restrictions on therapeutic cloning are based on repugnance alone and thus fail rational basis review); B. Jessie Hill, The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines, 86 TEX. L. REV. 277, 341–42 (2008) (arguing that the Supreme Court’s jurisprudence supports a right to make medical treatment choices, which could provide a possible basis for analyzing hypothetical laws restricting therapies derived from embryonic stem cell research); Robertson, supra note 19, at 7–16 (arguing that patients have a negative right to safe and effective therapies derived from embryonic-stem-cell-derived therapies); see also Kristin M. Hicks, Note, Embryonic Stem Cell Research and the Theory of Medical Self-Defense, 21 HARV. J.L. & TECH. 547, 566 (2008) (arguing that the medical self-defense principle, articulated in Eugene Volokh, Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs, 120 HARV. L. REV. 1813 (2007), does not justify constitutional protection for embryonic stem cell research).
tion against state interference with research related to the development of prospective therapeutic medical treatments necessary to preserve individuals’ life or health, and that such protection should logically extend to embryonic stem cell research. Part III evaluates the constitutionality of laws restricting embryonic stem cell research within two frameworks—the undue burden standard and exacting scrutiny—either of which may legitimately apply under current doctrine. Part IV concludes by suggesting that despite a substantial basis for challenging laws restricting embryonic stem cell research on substantive due process grounds, certain doctrinal and ideological limitations should be seriously considered before bringing such an action.

II. THE PROSPECT OF SUBSTANTIVE DUE PROCESS PROTECTION AGAINST STATE INTERFERENCE WITH EMBRYONIC STEM CELL RESEARCH

The threshold doctrinal question in a substantive due process challenge to laws restricting embryonic stem cell research is whether an individual’s right to therapeutic medical treatment, which prohibits state interference with the development of prospective therapies derived from such research, is a “fundamental liberty” protected by

26 Washington v. Glucksberg, 521 U.S. 702, 721 (1997). The Supreme Court has established that the “controlling word” in the Due Process Clause, at least with respect to its substantive component, is “liberty,” not “life.” Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 846 (1992); see also ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES § 7.3.4, at 579 (3d ed. 2006) (explaining that “claims concerning state deprivations of life are litigated under constitutional provisions other than due process,” particularly the Eighth Amendment, “and if they do involve due process, they concern the requirements of due process in capital cases rather than the definition of life”). However, it is arguable that the word “life” also has a substantive component. See Roe v. Wade, 410 U.S. 113, 156–57 (1973) (“If [a fetus is a ‘person’ within the meaning of the Fourteenth Amendment] . . . the appellant’s case, of course, collapses, for the fetus’s right to life would then be guaranteed specifically by the Amendment.”); James Bopp, Jr. & Daniel Avila, The Due Process “Right to Life” in Cruzan and Its Impact on “Right-to-Die” Law, 53 U. PITT. L. REV. 193, 193–94 (1992) (characterizing the right at stake in Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990), as one of “life” rather than “liberty”); Sheldon Gelman, “Life” and “Liberty”: Their Original Meaning, Historical Antecedents, and Current Significance in the Debate Over Abortion Rights, 78 MINN. L. REV. 585, 690 (1994) (arguing that, as originally understood, “life” provides the textual basis for abortion rights in the Constitution’); Douglas O. Linder, The Other Right-to-Life Debate: When Does Fourteenth Amendment “Life” End?, 37 ARIZ. L. REV. 1183, 1296–97 (1995) (arguing that “the plain meaning” of the Due Process Clause protects against state interference with the provision of medical care because it “prohibits states from depriving ‘persons’ of their ‘lives’”). To be sure, according to John Robertson, “a right to medical treatment is anchored by text because the Due Process Clause ‘explicitly protects ‘life’ and ‘liberty.’” Robertson, supra note 19, at 9. Nevertheless, this Comment relies on the Supreme Court’s pronounce-
the Due Process Clause. Indeed, only if this right is deemed fundamental can there be an argument that laws restricting embryonic stem cell research are subject to heightened scrutiny.

To be clear, the asserted right under consideration here is a negative right, in the sense that it does not mandate the affirmative provision of medical treatment by the government, but rather “affords protection against unwarranted government interference” with an individual’s access to therapeutic medical treatments derived from embryonic stem cell research. This right belongs to individuals seeking therapeutic medical treatment, and is distinct from a scientist’s right to engage in therapeutic research.

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27 U.S. CONST. amend. XIV, § 1; U.S. CONST. amend. V.
28 See CHEMERINSKY, supra note 26, § 10.1.1, at 792.
29 Harris v. McRae, 448 U.S. 297, 317 (1980) (upholding the Hyde Amendment, which restricted federal funding for medically necessary abortions, on the ground that it did not implicate the right to abortion); accord Maher v. Roe, 432 U.S. 464 (1977) (upholding a state welfare regulation, which restricted funding for nontherapeutic abortions, on the ground that it did not implicate the right to abortion).
30 The Supreme Court, however, has recognized an affirmative substantive due process right to medical treatment for prisoners, but only because they are “wholly dependent on the State.” Youngberg v. Romeo, 457 U.S. 307, 317 (1982). While the affirmative right expressed in Youngberg might seem relevant to the analysis here, “[u]nder current law, it is very unlikely that the Court will find that the government has a duty to provide medical care except when people are incarcerated or institutionalized by the government.” CHEMERINSKY, supra note 26, § 10.5, at 848. For cases suggesting that a “shocks the conscience” standard applies to substantive due process challenges to affirmative government policies that put the life or health of a person with a special relationship to the government in danger, see Collins v. City of Harker Heights, 503 U.S. 115, 126 (1992), Benzman v. Whitman, 523 F.3d 119, 128 (2d Cir. 2008), and Lombards v. Whitman, 485 F.3d 73, 81 (2d Cir. 2007).
As a matter of doctrine, the Supreme Court generally has applied a narrow and a broad conceptual approach in determining whether an asserted right is a fundamental liberty within the meaning of the Due Process Clause. Laurence Tribe has described the narrow approach as a “largely mechanical exercise of isolating ‘fundamental rights’ as though they were a historically given set of data points on a two-dimensional grid, with one dimension representing time and the other representing a carefully defined and circumscribed sequence of protected primary activities,” and the broad theory as “akin to deriving a regression line from a scatter diagram.”

Although the Court has applied these approaches in different thematic contexts, it has consistently evaluated certain factors in deciding whether to recognize rights under both approaches, most important of which are the history and tradition of the law’s treatment of the subject of regulation and the nature of the asserted right at stake. However, the weight the Court has accorded these factors has

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32 See Robertson, supra note 19, at 8; Deana Pollard Sacks, Elements of Liberty, 61 SMU L. REV. 1557, 1574-75 (2008). Several theories of substantive due process have been proposed but never fully adopted by a majority of the Supreme Court. See, e.g., JOHN HART ELY, DEMOCRACY AND DISTRUST: A THEORY OF JUDICIAL REVIEW 73-179 (1980) (arguing that courts should only recognize substantive due process rights that facilitate the representation of minorities and the effective operation of the political processes); HARRY V. JAFFA, ORIGINAL INTENT AND THE FRAMERS OF THE CONSTITUTION: A DISPUTED QUESTION (1993) (arguing that natural law should serve as the basis for determining what rights should be protected under substantive due process); Harry H. Wellington, Common Law Rules and Constitutional Double Standards: Some Notes on Adjudication, 83 YALE L.J. 221, 284 (1973) (arguing that substantive due process requires an inquiry into “the weight of the principle in conventional morality” to determine if an asserted right is to be deemed fundamental).

33 Laurence H. Tribe, Lawrence v. Texas: The “Fundamental Right” that Dare Not Speak Its Name, 117 HARV. L. REV. 1893, 1898-99 (2004); cf. Poe v. Ullman, 367 U.S. 497, 543 (1961) (Harlan, J., dissenting) (“This ‘liberty’ is not a series of isolated points . . . . It is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints . . . .”).

34 For example, the Supreme Court has applied the narrow approach in the right to die cases, including Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990) (finding a right to refuse life-sustaining treatment), Washington v. Glucksberg, 521 U.S. 702 (1997) (finding no right to assisted suicide), and Vacco v. Quill, 521 U.S. 793 (1997) (holding the same under equal protection), but has applied the broad approach in the contraception cases, including Griswold v. Connecticut, 381 U.S. 479 (1965) (finding a right to contraception), Eisenstadt v. Baird, 405 U.S. 438 (1972) (finding the same under equal protection), and Carey v. Population Services International, 431 U.S. 678 (1977) (reaffirming the existence of a right to contraception), and in the abortion cases, including Roe v. Wade, 410 U.S. 113 (1973) (finding a right to abortion) and Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992) (reaffirming the right to abortion).

35 See Sacks, supra note 32, at 1562.
varied depending on the context and the approach adopted. Given the “chaotic” quality of substantive due process jurisprudence, it is necessary to evaluate how both bear on the question of whether a right exists because courts may differ in their approaches to analyzing the issue. Proper consideration of these factors justifies recognition of a fundamental right to therapeutic medical treatment, which embraces protection against state interference with embryonic stem cell research.

A. A Legal Tradition of Accommodation for Therapeutic Research

The Supreme Court has said that an asserted right may be deemed fundamental under the Due Process Clause if it is “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.” While the purpose of an analysis of history and tradition is to “rein in the subjective elements that are necessarily present in due-process judicial review,” an “attempt to reach a definitive historical judgment” is unnecessary. To be sure, the Court has made clear that “[h]istory and tradition are the starting point but not in all cases the ending point of the substantive due process inquiry.” Therefore, history and tradition can be understood as constraints on whether an asserted right may legitimately be recognized, but failure

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36 Id. at 1561 (“The Court’s liberty decisions over the past century reveal that the Court has in fact reviewed certain objective elements repeatedly in analyzing liberty, despite never imposing a duty on itself to consider these elements in every case or identifying them together in any articulated, unified interpretive method.”).
37 Id. at 1558.
38 Glucksberg, 521 U.S. at 720–21 (internal quotation marks omitted) (quoting Moore v. City of E. Cleveland, 431 U.S. 494, 503 (1977)).
40 Glucksberg, 521 U.S. at 722.
42 Id. at 572 (internal quotation marks omitted) (quoting County of Sacramento v. Lewis, 523 U.S. 833, 857 (1998)).
to conclude that the right is deeply rooted does not necessarily fore-
close the prospect of constitutional protection.43

In undertaking an analysis of history and tradition, the Court has
required that an asserted right be “careful[ly] descri[bed]”44 at an
appropriate level of abstraction.45 At a rather general level of abstrac-
tion, the asserted right implicated by restrictions on embryonic stem
cell research may be described as a right to therapeutic medical
treatment. At a more specific level of abstraction, the asserted right
may be described as a right to prospective therapeutic medical treat-
ment derived from embryonic stem cell research. However, given
that embryonic stem cell research is a rather recent phenomenon,
with its earliest breakthroughs only dating back about a decade, it is
obvious that there is no tradition cutting one way or another at such a
precise level of abstraction.46 Therefore, “we are left with the prob-
lem of specifying the next most specific tradition.”47 Given the impos-
sibility of ascertaining a level of abstraction that is exactly on point for
the purposes of this analysis, 48 it is more productive to examine the
asserted right at varying levels of abstraction to understand the poten-
tial bounds imposed by history and tradition.

To this end, the following analysis considers American legal tradi-
tion with respect to therapeutic medical treatment and research to
demonstrate that the law has not only historically protected an indi-
vidual’s right to therapeutic treatment, but also, and perhaps more
importantly, accommodated therapeutic research by remaining free
of serious legal restrictions until well into the latter half of the twenti-
eth century. Therefore, as doctrinal constraints, history and tradi-
tion, at a minimum fail to foreclose the possibility of substantive due
process protection for the asserted right presently at stake, and may
even provide a sufficient basis to conclude that it is deeply rooted.

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43 See id. at 568. Professor Friedman and Mr. Smith have suggested that “[i]t is difficult to
say that proper historical consideration[s] would . . . chang[e] the result” in certain cases.
Friedman & Smith, supra note 39, at 71 (discussing the Court’s treatment of history in Roe
v. Wade, 410 U.S. 113 (1973), and Bowers v. Hardwick, 478 U.S. 186 (1986)).
44 Glucksberg, 521 U.S. at 720–21 (citations and internal quotation marks omitted).
45 See CHEMERINSKY, supra note 26, § 10.1, at 795 (explaining that in determining whether a
fundamental right exists under substantive due process, “there . . . is the question of ab-
straction at which the right is stated”).
46 See TRIBE & DORF, supra note 39, at 103 (“Of course we do not expect to find such ridicu-
los traditions because a basic principle of our legal system is that such a rule of law
would be too specific, and therefore arbitrary.”).
47 Id.
48 See id. at 101–04.
1. The Historical Basis for an Individual’s Right to Therapeutic Medical Treatment

Scholars have suggested that an inquiry into American history and tradition supports recognition of a fundamental right to therapeutic medical treatment. John Robertson has argued that “a right to use safe and effective medical treatments . . . could . . . cogently be said to be ‘deeply rooted in this Nation’s history and tradition’” because:

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. 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, there is no comparable tradition of legislative restriction on medical practice until well into the twentieth century.49

In support of this argument, Professor Robertson cites the lack of restrictions on the clinical judgment of licensed physicians or on the therapies they could administer until the first federal drug law was passed in 1914.50 Even so, not until 1962 did the U.S. Food and Drug Administration (“FDA”) establish an approval process in which it would ensure the safety and effectiveness of therapies before releasing them to market.51

Eugene Volokh has provided an alternative historical argument that well-established statutory and common law principles of self-defense justify broad constitutional protection for what he calls “the right to medical self-defense,” which incorporates the right of individuals to use therapeutic medical treatments to defend against threats to their life or health.52 According to Professor Volokh:

[T]he right to medical self-defense is supported by the long-recognized right to lethal self-defense: the right to protect your life against attack even if it means killing the attacker. The lethal self-defense right has constitutional foundations in substantive due process, in state constitutional rights to defend life and to bear arms, and perhaps in the Second Amendment. But even setting aside those constitutional roots, the right has long been recognized by statute and common law.53

Professor Volokh supports this argument by citing William Blackstone and other early common law commentators for the proposition that defending life was considered a natural right at the time of the

49 Robertson, supra note 19, at 10–11 (citations omitted).
50 Id. at 11.
51 Id.
52 Volokh, supra note 25, at 1815–17.
53 Id. at 1815.
Moreover, Professor Volokh states that forty-four state constitutions currently recognize a right to lethal self-defense, while twenty-one, the first of which dates back to 1776, "expressly secure the right to ‘defend[] life,’” and forty, dating from 1776 to 1998, "secure a right to keep and bear arms in defense of self, which presupposes at least the traditional core of lethal self-defense.” As to the constitutional dimension of this right, Professor Volokh suggests, “[e]ven if due process or the Ninth Amendment is interpreted as protecting only those rights recognized as important common law rights in 1791 or 1868, self-defense qualifies." In his view, the Supreme Court has extended the concept of self-defense to the medical context in its abortion jurisprudence by protecting the right of a woman to receive an abortion to “defend” herself against a threat to her life or health, and this right cannot be logically limited to the abortion context.

While both Professor Robertson and Professor Volokh acknowledge that their theories do not support an absolute right to therapeutic medical treatment, they nevertheless argue in favor of a rather broad conception of this right, which in turn should incorporate embryonic-stem-cell-derived therapies. However, neither theory necessarily justifies extending the scope of the right to therapeutic medical treatment to protect against state interference with embryonic stem cell research. As such, a more in-depth inquiry into the law’s historical treatment of therapeutic research, involving human tissue, fetal tissue, and embryos, is necessary to gain a fuller understanding of the implications of history and tradition on the propriety of making such a move.

2. Failed Legislative Initiatives Prior to World War II and the Decline of the Antivivisectionist Movement

Prior to World War II, virtually every federal and state legislative initiative to restrain human experimentation failed as a result of public support for therapeutic research and the decline in influence of the antivivisectionist movement. Although the antivivisectionist
movement traces its roots back to the mid-nineteenth century, it was not until the turn of twentieth century that antivivisectionists undertook efforts to restrain human experimentation, rather than just animal experimentation.\(^\text{59}\) In 1900, Jacob H. Gallinger, senior Republican senator from New Hampshire, introduced Senate Bill 3424, the first federal legislative proposal for regulating human experimentation, which sought to impose disclosure, consent, and licensing requirements, and to prohibit experimentation on pregnant women, the elderly, the mentally ill, and other incompetents in the District of Columbia.\(^\text{60}\) However, the proposed regulations did not apply to experiments that physicians, scientists, or students performed on one another, nor did it apply to experimentation therapeutic to the subject.\(^\text{61}\) The bill met harsh criticism and was defeated, as was a new version of it in 1902.\(^\text{62}\) Over the next few years, antivivisectionists sponsored similar legislative initiatives in a number of States, including Maryland, Illinois, and Pennsylvania, but all of them were rejected.\(^\text{63}\) Due to a growing number of reported incidents of experimentation on children, Senator Gallinger introduced a bill into the Senate in 1914 which called for a formal commission to investigate charges of human experimentation in public hospitals, and similar proposals were introduced in the New Jersey and New York state legislatures.\(^\text{64}\) However, none materialized because the charges against the hospitals were ultimately dropped.\(^\text{65}\)

As a result of advances in therapeutic medicine on account of animal and human experimentation, the antivivisectionist movement experienced a serious decline in support and influence in the years

\(^{59}\) Id. at 27–29. Although around this time, antivivisectionist groups largely concentrated their efforts on preventing experimentation on animals, they were concerned that animal vivisection would inevitably lead to experimentation on human beings. Id. at 28. By 1909, the American Humane Association, which was founded as a national organization in 1874 to coordinate the activities of local humane societies, was reporting that of the 334 societies in the United States, 104 were devoting their efforts solely to animals, 45 to children, and 185 to both animal and child protection. Id. at 29. Although prominent groups sought the complete eradication of vivisection, others took a more moderate approach, favoring reform, regulation, and exceptions for experimentation therapeutic to the subject instead. Id. at 34.


\(^{61}\) Lederer, supra note 58, at 71–72.

\(^{62}\) Weyers, supra note 60, at 202.

\(^{63}\) Lederer, supra note 58, at 74–75.

\(^{64}\) Id. at 89.

\(^{65}\) Id.
leading up to the time the United States entered World War I. In particular, major setbacks resulted from the movement’s opposition to experimentation generally supported by the public, such as the vaccination of soldiers for typhoid, the military’s use of animals in medical experiments before World War I, and the funding of the Red Cross’s investigation into the nature and prevention of disease affecting soldiers during the war. While the movement had a resurgence in the 1930s due to concern about reports of experimentation on prisoners, soldiers, volunteer subjects, and children, its influence was mitigated not only by medical successes, such as the discovery of insulin through experiments on dogs, but also an increasing confidence in the medical profession and a reduction in public suspicion of dubious research. It was not until the Nuremberg Doctor’s Trial after World War II, which revealed a pervasive practice of human experimentation by the Nazis, that the public and medical community thought some type of regulatory framework for experimentation was necessary.

3. The Nuremberg Code as a Regulatory False Start

The Nuremberg Code represented the first “legalistic” guidelines worldwide with respect to medical research. The Code sets forth ten principles to govern the practice of human experimentation, including informed and voluntary consent requirements, a provision requiring the purpose of an experiment to be for the benefit of society, safeguards against injury or death to the subject, and provisions allowing for the prompt termination of the experiment by the scientist or the subject. In 1953, the National Institutes of Health, an agency currently of the U.S. Department of Health and Human Services charged with conducting and supporting medical research, adopted research guidelines based on the Code. While American courts could use the Code as a basis for imposing criminal or civil li-

66 Weyers, supra note 60, at 213.
67 Lederer, supra note 58, at 102.
68 Id. at 103.
69 Weyers, supra note 60, at 213–14; Lederer, supra note 58, at 125.
70 Weyers, supra note 60, at 351.
71 Id. at 351, 383–84.
73 See Weyers, supra note 60, at 381.
ability, no court to date has imposed either on account of a violation of the Code. Immediately after the Code’s adoption, the propriety of applying it in the United States was questioned because it excessively constrained medical research, given that it was tailored to the deliberately cruel experimentation practiced by the Nazis, in which death was viewed as an acceptable outcome of study and ethnic and political groups were specifically targeted as subjects. Therefore, since the Code did not reflect the realities of the practice in the United States, it eventually “lost its binding character and came to be viewed as an informal set of recommendations.”

In response to the Nuremberg Code’s deficiencies, the World Medical Association adopted the Declaration of Helsinki in 1964. Although the Declaration was based on many of the same principles as the Code, it did not address consent of subjects and was overall far more “permissive” than the Code. More importantly, however, the Declaration only provided non-binding “recommendations as a guide to each doctor in clinical research,” and therefore did not carry with it the force of law. Nevertheless, the Declaration represented an attempt to develop universal standards of medical ethics that would better suit the practice of human experimentation than the Nuremberg Code.

4. Informed Consent’s Departure from Legal Tradition

Despite the Nuremberg Code’s inability to provide an appropriate regulatory framework for medical research in the United States, the common law doctrine of informed consent became “a cardinal principle for judging the propriety of research with human beings” in the aftermath of World War II. However, informed consent was distinctly different from the traditional doctrine of consent that previously governed the physician-patient relationship. The modern doctrine of informed consent, as we know it today—in which a physician

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74 Id. at 361.
75 See id. at 358 (emphasizing the “woeful lack of respect given to an individual test subject by the Germans”).
76 Id. at 384.
77 Id. at 382.
78 Id. at 382–84.
79 Id. at 384.
80 See id. at 382.
82 See WYERS, supra note 60, at 178; KATZ, supra note 81, at 525–29.
may be liable for negligence in a malpractice suit if she breaches her
duty to inform a patient with adequate information of the attendant
risks of a procedure, or for battery if the physician’s failure to inform
is found to have invalidated the patient’s voluntary consent to the
procedure—derives from two state court decisions, Salgo v. Leland
Stanford Jr. University Board of Trustees and Natanson v. Kline, handed
down in 1957 and 1960, respectively. The idea espoused by these
cases, that consent must not only be voluntary but also adequately in-
formed, was a novel innovation to the simpler traditional doctrine of
consent: that the performance by a physician of a medical procedure
without a patient’s written consent results in an assault and battery
for which the physician is liable. Although American courts began
applying the traditional doctrine of consent in the late nineteenth
century, the modern doctrine of informed consent “constituted a
radical break with the silence that had been the hallmark of physi-
cian-patient interactions throughout the ages.”

5. The Rise of Modern Legislative Restrictions on Therapeutic Research

It was not until the 1970s that any significant federal or state legis-
lation restraining human experimentation existed. In 1974, Congress enacted the National Research Act in response to public outcry
over several widely publicized cases of experimentation, including the
revelation of experiments involving the infection of mentally chal-
lenged children with hepatitis at the Willowbrook School, the injec-
tion of live cancer cells into elderly patients at the Jewish Chronic
Disease Hospital, and the infection of hundreds of African American
men with syphilis by the U.S. Public Health Service in the infamous
Tuskegee Experiment. The Act mandated formal protections

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86 See Katz, supra note 81, at 525–29; Weyers, supra note 60, at 178.
87 See Katz, supra note 81, at 525–29; Weyers, supra note 60, at 178.
88 Katz, supra note 85, at 72.
89 See id.; M.H. PAPPWORTH, HUMAN GUINEA PIGS: EXPERIMENTATION ON MAN 201 (1968)
(“[A]lthough it is technically inaccurate to state that ‘there is no law’ on the subject of
human experimentation, it is true that there are no statutes and no reported cases deal-
ing directly with clinical investigation as such. However, medical research activity, like all
activities in our society, is subject to common-law principles of general applicability.”).
90 Lederer, supra note 58, at 140; see also JAMES H. JONES, BAD BLOOD: THE TUSKEGEE
SYPHILIS EXPERIMENT 1 (2d ed. 1993).
against human experimentation, including written consent requirements and institutional review boards responsible for evaluating proposals to experiment on human subjects, and with some modification has remained intact since.91

The National Research Act also established the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, which subsequently issued two relevant reports in the late 1970s: the Belmont Report92 and Research on the Fetus Report.93 The Belmont Report articulated three basic principles intended to guide investigators in the course of their research in general: respect for persons, beneficence, and justice.94 The Research on the Fetus Report made several recommendations with respect to the performance of fetal experimentation.95 Notably, the report concluded that “[t]herapeutic research directed toward the pregnant woman may be conducted or supported, and should be encouraged,” provided the woman gives her informed consent and the research places the fetus at as little risk as possible without affecting the health needs of the woman.96 While the report also concluded that research not therapeutic to the fetus could be conducted, it recommended that such research be more limited.97

In response to the Research on the Fetus Report, the Health Department promulgated regulations that provided federal funding for fetal experimentation, subject to various limitations.98 The regulations conditioned research on the fetus ex utero on parental consent and required that such research be therapeutic to the fetus or that the risk to the fetus be minimal.99 Moreover, the regulations left the

91 Lederer, supra note 58, at 141–42.
94 See Belmont Report, supra note 92.
95 Research on the Fetus, supra note 93, at 73–76.
96 Id. at 73 (emphasis added).
97 See id. at 73–76.
99 Id.
job of regulating research on a dead fetus or fetal material to the States.\textsuperscript{100} Although all fifty States plus the District of Columbia adopted the Uniform Anatomical Gift Act—which permitted research on a dead fetus and fetal material, provided that one parent gave consent and the other did not object\textsuperscript{101}—several States, in the wake of \textit{Roe v. Wade},\textsuperscript{102} passed legislation imposing restrictions on fetal experimentation.\textsuperscript{103} In 1975, five States had laws on their books prohibiting research on the dead fetus but only if it was the product of induced abortions.\textsuperscript{104} Criminal and civil laws in various States had already safeguarded the fetus in utero from life-threatening intentional injury, and if born alive from death or impairment,\textsuperscript{105} but the common law permitted research therapeutic to the viable fetus.\textsuperscript{106} Furthermore, twenty-one States recognized causes of action for injuries to the viable fetus that led to its stillbirth.\textsuperscript{107} Nevertheless, courts invalidated a number of these fetal experimentation laws on the grounds that they were unconstitutionally vague or infringed on a woman’s right to abortion.\textsuperscript{108}


Current state laws restricting embryonic stem cell research derive from older laws originally enacted to address fetal experimentation, abortion, and in vitro fertilization.\textsuperscript{109} While the current restrictions do not all directly prohibit embryonic stem cell research, they nevertheless limit scientists’ ability to engage in it. A number of States still restrict research on aborted fetuses or embryos, although some allow it if consent is given by the patient.\textsuperscript{110} Approximately half the States restrict the sale of fetuses or embryos.\textsuperscript{111} South Dakota prohibits research on all embryos, even those created outside a woman’s body, and on cells or tissues derived from embryos created outside a wom-

\begin{footnotesize}
\begin{enumerate}
\item Id.
\item \textit{See Research on the Fetus}, \textit{supra} note 93, at 25.
\item 410 U.S. 113 (1972).
\item \textit{See generally Terry}, \textit{supra} note 98, at 446–49 (providing a synopsis of these statutes).
\item \textit{See Research on the Fetus}, \textit{supra} note 93, at 25.
\item Id. at 27.
\item Id. at 26.
\item Id. at 27.
\item \textit{See discussion supra} Part II.B.2.
\item \textit{STEM CELL RESEARCH}, \textit{supra} note 15.
\item Id.
\item Id.
\end{enumerate}
\end{footnotesize}
an’s body.¹¹² Louisiana expressly prohibits research on in vitro fertilized embryos.¹¹³ Arkansas, Indiana, Michigan, North Dakota, and South Dakota prohibit nuclear transfer cloning, even for therapeutic research.¹¹⁴ It is uncertain if Virginia also bans research on cloned embryos because the State’s law on the subject is open to textual interpretation.¹¹⁵

In recent years, there has been a tendency to relax previously existing restrictions in order to promote certain forms of embryonic stem cell research. In 2007, Iowa repealed its ban on nuclear transfer cloning.¹¹⁶ Additionally, in 2008, even though the State’s ban on nuclear transfer cloning remains in place, Michigan voters passed a constitutional amendment permitting research on excess embryos from fertility clinics.¹¹⁷ Previously, Michigan prohibited research on live embryos altogether.¹¹⁸

Despite the restrictive approaches of some States, others have taken the opposite path and allocated significant funding to embryonic stem cell research programs as a testament to the confidence in their therapeutic potential. Most impressively in 2004, California voters passed Proposition 71, which allocated $3 billion to embryonic and other types of stem cell research initiatives in the State.¹¹⁹ In addition, Connecticut, Illinois, Maryland, Massachusetts, New Jersey, New York, and Wisconsin authorized state funding for such ends, either by virtue of legislation or executive order.¹²⁰

At the federal level, President Obama issued an executive order on March 9, 2009, lifting a ban on federal funding for embryonic stem cell research imposed by President Bush in 2001, even though the Dickey-Wicker amendment—legislation that prohibits federal funding for the creation or destruction of a human embryo for research purposes—remains in place.¹²¹ Before imposing the federal funding ban on all future stem cell lines, President Bush made ap-

¹¹⁵ VA. CODE ANN. § 32.1-162.22 (2004); see also STEM CELL RESEARCH, supra note 15.
¹¹⁷ MICH. CONST. art. 1, § 27.
¹¹⁹ See STEM CELL RESEARCH, supra note 15.
¹²⁰ See id.
¹²¹ Stolberg, supra note 16; see also MOONEY, supra note 3, at 195–96.
proximately twenty-two existing stem cell lines eligible for federal funding. In justifying his decision to lift the federal funding ban, President Obama explained that a majority of Americans “have come to a consensus that we should pursue this research; that the potential it offers is great, and with proper guidelines and strict oversight the perils can be avoided.”

7. A Look Back at History

Despite greater regulation of therapeutic treatment and research in the late-twentieth century, it cannot be said that there exists a legal tradition of restraint. To the contrary, given the generally persistent rejection of serious constraints on therapeutic research as a result of public support for its rich therapeutic benefits, it would be more accurate to characterize this nation’s legal tradition with respect to subject at hand as one of accommodation. Whether this demonstrates that an individual’s right to therapeutic medical treatment, which protects against state interference with embryonic stem cell research, is deeply rooted is not entirely clear. But it is enough to say that the historical record, at a minimum, should not foreclose the possibility of extending substantive due process protection to embryonic stem cell research.

B. Constitutional Protection Against State Interference with Therapeutic Research

Since history and tradition do not preclude recognizing a fundamental right to therapeutic medical treatment that embraces protection against state interference with embryonic stem cell research, as demonstrated in Part II.A, it is necessary to evaluate whether constitutional precedent justifies such recognition. Indeed, “the elaboration of constitutional values proceeds mostly from prior decisions.”

MOONEY, supra note 3, at 198–201. President Bush subsequently vetoed two bills that would have lifted the ban, and in 2007 issued an executive order intended to encourage scientists to pursue alternative research methods that would not destroy human embryos. Sheryl Gay Stolberg, Bush Vetoes Bill Removing Stem Cell Limits, Saying ‘All Human Life Is Sacred,’ N.Y. TIMES, June 21, 2007, at A21.

Stolberg, supra note 16.


Typically, “[t]he starting point of the analysis [is] Supreme Court cases” and “new issue[s] will presumptively be decided according to the logic that those cases expressed.”

An analysis of case law demonstrates not only that the Supreme Court has recognized a fundamental right to therapeutic medical treatment in the abortion context, but also that lower courts have extended this right to encompass protection against state interference with research related to the development of abortion techniques necessary to preserve a mother’s life or health. Moreover, the Supreme Court has intimated a willingness to expand the scope of this right to other therapeutic treatment contexts. The logic of these cases should justify due process protection against state interference with embryonic stem cell research as well.

1. The Right to Therapeutic Abortion

The Supreme Court has consistently recognized a fundamental right to therapeutic medical treatment in its abortion jurisprudence. Roe v. Wade\(^\text{127}\) and Planned Parenthood of Southeastern Pennsylvania v. Casey\(^\text{128}\) can be understood as holding that the Due Process Clause protects two different kinds of abortion rights.\(^\text{129}\) The first right is to non-therapeutic abortion where a woman has the right “to choose to have an abortion before viability and to obtain it without undue interference from the State.”\(^\text{130}\) The second right is to therapeutic abortion, which “forbids a State to interfere with a woman’s choice to undergo an abortion procedure [even after viability] if continuing her pregnancy would constitute a threat to her health.”\(^\text{131}\) In order to protect

\(^{126}\) Antonin Scalia, A Matter of Interpretation: Federal Courts and the Law 39 (1997) (criticizing this approach because it tends to “dissoc[ate] us from the original text and understanding”).

\(^{127}\) 410 U.S. 113 (1973).


\(^{129}\) Volokh, supra note 25, at 1824.

\(^{130}\) Casey, 505 U.S. at 846.

\(^{131}\) Id. at 880; accord Stenberg v. Carhart (Carhart I), 530 U.S. 914, 930 (2000) (“Since the law requires a health exception in order to validate even a postviability abortion regulation, it at a minimum requires the same in respect to previability regulation.”); id. at 948 (O’Connor, J., concurring) (“Because even a postviability proscription of abortion would be invalid absent a health exception, Nebraska’s ban on previability partial birth abortions, under the circumstances presented here, must include a health exception as well, since the State’s interest in regulating abortions before viability is ‘considerably weaker’ than after viability.”).
the right to therapeutic abortion, the Court has required two exceptions in any law regulating or proscribing abortion "where it is necessary, in appropriate medical judgment for the preservation of the life or health of the mother."$^{132}$ In other words, even in an otherwise valid abortion law, one exception is required to ensure a woman’s access to an abortion in order to combat life-threatening risks, and another is required to ensure her access to an abortion in order to combat other "significant health risks . . . with substantial and irreversible consequences."$^{133}$—whether they be physical, psychological, or emotional.$^{134}$ These exceptions are required not only in "situations where the pregnancy itself creates a threat," but also "where state regulations force women to use riskier methods of abortion."$^{135}$ This means that the absence of a safer alternative procedure entitles a woman to the regulated procedure should her life or health so demand.$^{136}$ According to the Court, these principles derive from the long-standing view that “a State may promote but not endanger a woman’s health when it regulates the methods of abortion.”$^{137}$ As such, when evaluating laws implicating the right to therapeutic abortion, the Court has always applied heightened scrutiny.$^{138}$ This treatment is testament to the Court’s implicit value judgment that indi-

Eugene Volokh describes the rights to nontherapeutic and therapeutic abortion as the “abortion-as-choice” right and the “abortion-as-self-defense” right, respectively. Volokh, supra note 25, at 1824–25. According to Professor Volokh:

[The rights recognized in] Roe and Casey . . . are different in scope, justification, and popular support. The first is the highly controversial right to abortion as reproductive choice, which generally allows previability abortions for all women who choose them. The second is the right to abortion even after viability but only when necessary “to preserve the life or health of the mother”—a right to defend oneself using medical care, even when this requires destroying the source of the threat.

Id. at 1824 (citations omitted) (quoting Casey, 505 U.S. at 846; Roe, 410 U.S. at 163–64). Professor Volokh argues that the latter right is primarily supported by the traditional common law and statutory tort principle of lethal self-defense, which should protect access to other medical treatments in addition to the abortion procedure. See Volokh, supra note 25, at 1824–28.

$^{132}$ Carhart I, 530 U.S. at 931 (quoting Casey, 505 U.S. at 879).

$^{133}$ Casey, 505 U.S. at 880.


$^{135}$ Carhart I, 530 U.S. at 931.

$^{136}$ See Gonzales v. Carhart (Carhart II), 127 S. Ct. 1610 (2007) (holding that the existence of a safer alternative procedure obviated the need for a health exception in a law proscribing another procedure).


$^{138}$ See discussion infra Part III.
vidual interests in life and health deserve substantial constitutional protection.

Indeed, concern for women’s interests in life and health has always been an “important theme” in justifying protection for the abortion right. While all of the opinions in Roe touched on this concern, Justice Douglas went so far in his concurrence as to frame the right at issue as coming under the rubric of “the freedom to care for one’s health and person,” given that “[t]he vicissitudes of life produce pregnancies . . . which may impair ‘health’ . . . [or] imperil the life of the mother, or which in the full setting of the case may create such suffering, dislocations, misery, or tragedy as to make an early abortion the only civilized step to take.” When the Court reaffirmed Roe’s essential holdings in Casey almost two decades later, the plurality rested its decision in part on the health implications of requiring a woman to carry a pregnancy to term. According to the plurality:

Though abortion is conduct, it does not follow that the State is entitled to proscribe it in all instances. That is because the liberty of the woman is at stake in a sense unique to the human condition and so unique to the law. The mother who carries a child to full term is subject to anxieties, to physical constraints, to pain that only she must bear. That these sacrifices have from the beginning of the human race been endured by woman with a pride that ennobles her in the eyes of others and gives to the infant a bond of love cannot alone be grounds for the State to insist she make the sacrifice. Her suffering is too intimate and personal for the State to insist, without more, upon its own vision of the woman’s role,

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139 Harris v. McRae, 448 U.S. 297, 316 (1980).
140 See Roe v. Wade, 410 U.S. 113, 153 (1973) (explaining that should the State deny pregnant women the abortion choice, “[s]pecific and direct harm medically diagnosable even in early pregnancy may be involved”); id. at 170 (Stewart, J., concurring) (noting that “the interests of a woman in giving of her physical and emotional self during pregnancy . . . are of a far greater degree of significance and personal intimacy” than other substantive due process rights previously recognized by the Court (quoting Abele v. Markle, 351 F. Supp. 224, 227 (D. Conn. 1972))); id. at 207 (Burger, J., concurring) (emphasizing that the statutes before the Court “impermissibly limit the performance of abortions necessary to protect the health of pregnant women, using the term health in its broadest medical context”); see also infra notes 149–50 and accompanying text (discussing the dissenting opinions of then-Justice Rehnquist and Justice White with respect to their take on the Constitution’s protection for women’s health interests). But see McRae, 448 U.S. at 316 (questioning ‘whether the freedom of a woman to choose to terminate her pregnancy for health reasons lies at the core or the periphery of the due process liberty recognized in [Roe]’); Hill, supra note 25, at 310 (noting that the majority opinion in Roe “did not explain [its] holding [regarding the right to therapeutic abortion] beyond saying that the state’s interest in the fetus becomes compelling at the point of viability”).
however dominant that vision has been in the course of our history and our culture.

This interpretation followed a line of reasoning expressed in earlier cases that because a pregnancy is by nature dangerous and thus ipso facto increases the risk to a woman’s health and potentially her life, the decision to terminate it commands special protection.

In contrast to the widespread disagreement over the degree of constitutional protection for the nontherapeutic abortion right or even the propriety of protecting it at all, there is general acceptance that the therapeutic abortion right should be protected to a greater extent. To be sure, even when the Casey plurality dispensed with Roe’s trimester framework and substituted the less demanding undue burden standard for the standard of strict scrutiny that previously governed the nontherapeutic abortion right, the plurality left Roe’s requirements with respect to the life and health exceptions completely

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143 Id.

144 See Colautti v. Franklin, 439 U.S. 379, 400 (1979) (invalidating on vagueness grounds a law requiring physicians, when performing abortions, to use the procedure with the best chance of preserving the life of the fetus, given that the law “d[id] not clearly spec- ify . . . that the woman’s life and health must always prevail over the fetus’s life and health when they conflict” because the government may not “requir[e] a physician to make a ‘trade-off’ between the woman’s health and additional percentage points of fetal sur- vival”); Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 78–79 (1976) (invali- dating a law prohibiting amniocentesis, one of the most common abortion procedures nationwide, in part because it was “safer, with respect to maternal mortality, than even continuation of the pregnancy until normal childbirth”).


146 See Volokh, supra note 25, at 1825.
intact.\textsuperscript{147} Perhaps even more indicative of the therapeutic abortion right’s durable place in substantive due process jurisprudence is its embrace, however moderate, by some of the most ardent opponents of the nontherapeutic right who have served on the Court.\textsuperscript{148} For example, in his dissent in \textit{Roe}, then-Justice Rehnquist, without recognizing abortion as a fundamental right, explained that if a statute “were to prohibit an abortion even where the mother’s life is in jeopardy, [there would be] little doubt that such a statute would lack a rational relation to a valid state objective”\textsuperscript{149}—or in other words, it would be unconstitutional under rational basis review. Additionally, Justice White’s dissent in \textit{Roe} implied that if the plaintiff had alleged that her life or health was threatened, the case would present an entirely different constitutional question.\textsuperscript{150} Most notably, however, the full Court recently agreed, in the only unanimous abortion decision to date, \textit{Ayotte v. Planned Parenthood of Northern New England},\textsuperscript{151} that a state statute requiring minors to obtain parental notice to receive an abortion was unconstitutional on the ground that it lacked a health exception.\textsuperscript{152} According to the Court, “a State may not restrict access to abortions that are necessary, in appropriate medical judgment, for the preservation of the life or health of the mother” and that “it would be unconstitutional to apply the Act in a manner that subjects minors to significant health risks.”\textsuperscript{153} Though unremarkable in its restatement of the law, the decision even gained the support of Justices Scalia and Thomas, who both had dissented in every Supreme Court decision invalidating abortion laws during their tenures on the bench.\textsuperscript{154} Michael Dorf suggests that the best explanation for this outcome is that since the case involved a highly restrictive law, Justices Scalia and Thomas did not necessarily consider it to be an abortion case, but rather a case about health more broadly.\textsuperscript{155}

That said, the therapeutic abortion right is not without limitation. In the Court’s most recent abortion case, \textit{Gonzales v. Carhart} (\textit{Carhart

\textsuperscript{147} See \textit{Casey}, 505 U.S. at 878–79.

\textsuperscript{148} See Volokh, supra note 25, at 1825 (citing then-Justice Rehnquist as an example).


\textsuperscript{150} \textit{Roe}, 410 U.S. at 222–23 (White, J., dissenting).

\textsuperscript{151} 546 U.S. 320 (2006).

\textsuperscript{152} Id. at 323–24.

\textsuperscript{153} Id. at 327–28 (internal quotation marks omitted).

\textsuperscript{154} These cases include \textit{Planned Parenthood of Southeastern Pennsylvania v. Casey}, 505 U.S. 833 (1992), and \textit{Carhart I}, 530 U.S. 914 (2000).

it upheld the Partial Birth Abortion Ban Act of 2003, which prohibited the dilation and extraction (“D&X”) abortion procedure, even though the Act did not include a health exception. According to the Court, the test to determine whether the Act required a health exception was whether the prohibited procedure was ever necessary, in professional medical judgment, to protect a woman’s health. Since the Court found that there was uncertainty in the medical community on this point and that adequate alternative procedures were available to protect women’s health, it believed legislative deference was warranted. In so holding, the Court said:

The Act is not invalid on its face where there is uncertainty over whether the barred procedure is ever necessary to preserve a woman’s health, given the availability of other abortion procedures that are considered to be safe alternatives.

However, the Court made clear that its holding did not detract from the value of the liberty interests at stake. Rather, the Court disagreed with the manner in which the case was brought—as a facial challenge instead of an as-applied challenge. In the Court’s view:

This is the proper manner to protect the health of the woman if it can be shown that in discrete and well-defined instances a particular condition has or is likely to occur in which the procedure prohibited by the Act must be used. In an as-applied challenge the nature of the medical risk can be better quantified and balanced than in a facial attack.

Therefore, had circumstances shown that the Act indeed threatened a woman’s health by virtue of its prohibition of the D&X procedure, the outcome likely would have been different.

2. Constitutional Protection for Fetal Experimentation as a Necessary Precursor Activity to the Exercise of the Right to Therapeutic Abortion

The Supreme Court has intimated that the right to therapeutic abortion encompasses protection against state interference with the development of prospective safe and effective abortion procedures. In <i>Planned Parenthood of Missouri v. Danforth</i>, the Court struck down

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157 <i>Id.</i> at 1639.
158 <i>Id.</i>
159 <i>Id.</i> at 1631–37.
160 <i>Id.</i> at 1638.
161 <i>Id.</i> at 1638–39.
162 The standard of review the Supreme Court adopted in <i>Carhart II</i> and its implications for laws restricting embryonic stem cell research are discussed infra Part III.
a state statute that prohibited saline amniocentesis—one of the most common abortion procedures after the first trimester nationwide—because, “as a practical matter, it forces a woman and her physician to terminate her pregnancy by methods more dangerous to her health than the method outlawed.” According to the Court, one of “several significant facts” that formed the basis for this conclusion was that the language of the statute not only included within its proscription saline amniocentesis but also “other methods that may be developed in the future and that may prove highly effective and completely safe.” Therefore, by invalidating the statute, the Court was removing what it viewed as an unconstitutional burden to future access to “other methods” of abortion that did not yet exist. And despite the fact that their development was speculative, the Court still believed that burdening such access implicated women’s constitutionally protected interest in health. Based on the Court’s analysis in Danforth, it is no great leap to suggest that the Court would be equally willing to protect the process of development of prospective abortion procedures if it was so inclined to protect the procedures themselves.

Indeed, lower courts have relied on this notion of constitutional protection for potentially safe and effective abortion procedures in invalidating laws proscribing fetal experimentation by physicians and scientists. These cases can be framed as protecting against state interference with the practice of fetal experimentation because it is a necessary precursor activity to the exercise of a constitutional right, namely a woman’s right to therapeutic abortion. In Forbes v. Napoli-tano, the Ninth Circuit struck down an Arizona statute prohibiting experimentation on fetal tissue obtained from induced abortions, except for the therapeutic benefit of the fetus or the mother. However, the plaintiffs—patients suffering from Parkinson’s disease and

164 Id. at 79.
165 Id. at 77–78 (emphasis added).
166 See Robertson, supra note 19, at 34 (explaining that it would be “paradoxical to find that the state could not prohibit the use of safe and effective ESC medical treatments but could prohibit the scientific and clinical research necessary to determine whether they were safe and effective”). The Supreme Court has traditionally relied on the necessary precursor rationale in its First Amendment jurisprudence to protect a number of activities without which the exercise of the right to free speech would not be possible. See Ex parte Jackson, 96 U.S. 727, 733 (1877) (“Liberty of circulating is as essential to that freedom as liberty of publishing; indeed, without the circulation, the publication would be of little value.”); Robertson, Scientist’s Right, supra note 31, at 1215–18 (analogizing research to protected newsgathering and reporting).
167 236 F.3d 1009 (9th Cir. 2000).
168 Id. at 1012–13.
physicians who believed fetal research held out considerable promise for developing various therapeutic and fertility treatments—argued, inter alia, that despite the health exception the statute “prevent[ed] patients from receiving critical medical care without compelling or even rational justification, thus violating [their] rights to privacy and liberty guaranteed under the Fourteenth Amendment.” While the court did not reach this issue and instead decided the case on vague-ness grounds, Judge Sneed, in a concurring opinion, agreed with the plaintiffs’ substantive due process theory on the basis that the statute contravened the teachings of the Supreme Court’s abortion jurisprudence. According to Judge Sneed, not only would the prohibition of fetal experimentation prevent the development of therapeutic medical treatments and diagnostic techniques, but it would also prevent the development of a variety of technologies that bear on the choice to have an abortion:

*Roe* and its progeny established that the pregnant woman has a right to be free from state interference with her choice to have an abortion.

A prohibition on aborted fetal tissue research could burden the rights of women and couples to make both present and future reproductive choices. Fetal tissue experimentation may aid in the development and continued improvement of techniques and procedures necessary to make such choices. Prohibiting research on aborted fetal tissue could prevent the advancement of important diagnostic techniques, the creation of safer abortion techniques, and the discovery of medical defects that would influence a woman’s decision regarding future pregnancies.

To Judge Sneed, of the three asserted state interests in support of the statute—promoting the health of the mother, protecting potential fetal life, and regulating the medical profession—none justified the prohibition of fetal experimentation because such conduct was effectively a necessary precursor activity to the exercise of the right to abortion, therapeutic or otherwise.

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170 *Napolitano*, 236 F.3d at 1010–13. See generally *Woods*, 71 F. Supp. 2d at 1021 (noting that “[t]here is a longstanding precedent that courts should decide constitutional issues on the narrowest grounds possible” (citing Brockett v. Spokane Arcades, 472 U.S. 491, 501 (1985)).

171 *Napolitano*, 236 F.3d at 1013–14 (Sneed, J., concurring).

172 *Id.* at 1014.

173 *Id.*
In a similar vein, a Louisiana district court, in Margaret S. v. Treen,\(^{174}\) relied on the necessary-precursor-activity rationale to invalidate a state law that prohibited experimentation on an aborted fetus, whether aborted alive or dead, except for the therapeutic benefit of the fetus.\(^{175}\) The plaintiffs—two pregnant women and three physicians—alleged, inter alia, that the statute prohibited procedures “necessary to preserve the life or health of the mother” and would have “the disastrous effect of preventing scientific research.”\(^{176}\) In the court’s words:

[T]his statute unduly limits the medical information obtainable through experimentation . . . . which might be therapeutic to the woman . . . . [E]nforcement of [the statute] would substantially burden the right of women in Louisiana to choose specifically to terminate their pregnancies. The prohibition on experimentation involving aborted fetal tissue is likely to impede the thorough, complete pathological examination of such tissue, thereby potentially endangering the health of women who choose abortion. The Court finds that this statute, which carries substantial criminal penalties, would cause pathologists to refrain from using experimental procedures to diagnose possible infections or illnesses in women who have undergone abortions. The denial of such health care for women having abortions is a significant burden on their right to chose [sic] to terminate their pregnancies.

Since the statute did not further the asserted state interest in “protecting the pregnant woman’s health” and the evidence established that there was “no threat to the public health from the use of aborted tissue in experimentation,” the district court held the statute unconstitutional.\(^{178}\)

\(^{174}\) 597 F. Supp. 636 (E.D. La. 1984), aff’d on other grounds sub nom. Margaret S. v. Edwards, 794 F.2d 994 (5th Cir. 1986). Prior to the filing of the lawsuit in Margaret S. v. Treen, the same plaintiffs filed a similar lawsuit in which a district court upheld the previous iteration of the fetal-experimentation statute because it only purported to regulate experimentation of in-utero fetuses. See Margaret S. v. Edwards, 488 F. Supp. 181 (E.D. La. 1980). In response to the judgment, the Louisiana legislature amended the statute to impose tighter restrictions on fetal experimentation. See Treen, 597 F. Supp. at 672–73. Notably, the court in Margaret S. v. Treen distinguished the prior case on the basis that the statute “has since been amended to include a fetus ‘whether alive or dead’ . . . . [and] the plaintiffs in [Margaret S. v. Edwards] presented no evidence that the prior version of [the statute] imposed a significant burden on any fundamental right.” Id. at 672–73 (citations omitted).

\(^{175}\) Id. at 671 n.29.

\(^{176}\) Id. at 672.

\(^{177}\) Id. at 673 (citations omitted).

\(^{178}\) Id. at 674–75.
Although the Fifth Circuit, in *Margaret S. v. Edwards*, affirmed this judgment on vagueness grounds, Judge Williams wrote a separate concurring opinion agreeing with the rationale of the district court. In a rather sharp critique of the majority’s failure to consider the substantive due process issue and its “completely one-sided emphasis” on the extant opposition to the Supreme Court’s abortion jurisprudence, Judge Williams went out of his way to say that “[t]he majority’s analysis strains unnecessarily to restrict the scope of this case, resulting in unrealistic and unconvincing justifications for the decision.”

Refusing to frame the claim at issue as one sounding in vagueness, he stated: “It is a claim that a ban on experimentation will inevitably preclude the development of tests that may prove beneficial in future medical and surgical treatment[,] . . . which] is in actuality a claim on the merits.” After explaining that the statute did not have any reasonable relationship to an important state interest, despite the State’s “admittedly broad” regulatory authority in the context of medical experimentation, Judge Williams concluded that “under the guise of police regulation the State has actually undertaken to discourage constitutionally privileged induced abortions.” As such, Judge Williams for all intents and purposes adopted the district court’s analysis treating fetal experimentation as a necessary precursor activity to the exercise of a constitutional right.

The adoption of the necessary-precursor-activity rationale demonstrates that courts do not necessarily see a causation problem in protecting research under the rubric of the right to therapeutic abortion. In theory, there is inherent uncertainty in the prospect of developing therapeutic treatments from research because the research might not ultimately deliver the benefits that scientists hope. As a result, the connection between research and therapeutic treatment might be perceived as too attenuated, which could create issues of standing or causation on the merits when balancing the compet-

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179 794 F.2d 994.
180 *Id.* at 999 (Williams, J., concurring).
181 *Id.*
182 *Id.* at 1001.
183 *Id.* at 1002.
184 See *Allen v. Wright*, 468 U.S. 737, 751 (1984) (requiring a plaintiff to prove that an alleged injury is “fairly traceable to the defendant’s allegedly unlawful conduct” in order to have standing). However, in *Danforth*, the Supreme Court found no issue with allowing physicians and family planning organizations to assert the rights of women seeking access to future, yet undeveloped, abortion procedures. See *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 77–79 (1976). This suggests that a physician or other third party could assert the rights of ill individuals to challenge laws restricting embryonic stem cell
ing individual and state interests at stake to determine whether to protect particular types of research. However, courts seem to have resolved these issues in favor of the individual by acknowledging that “scientific research is an essential stage in producing . . . medical treatments” and thus equally deserving of constitutional protection as a necessary precursor activity to the exercise of the therapeutic abortion right.

3. The Case for Expanding the Scope of the Right to Therapeutic Medical Treatment

While the Supreme Court has only formally recognized a right to therapeutic medical treatment in the abortion context, it is difficult to argue that the scope of the right should be so limited. Indeed, if other therapeutic treatments are excluded from protection under the right to therapeutic medical treatment, then becoming pregnant is a prerequisite to the exercise of the right, implying that a pregnant woman’s interests in life and health are of greater value than those of other individuals, including the disabled and the terminally ill. Although it is arguable that women deserve special constitutional protection to the exclusion of others by virtue of being a subset of the general population susceptible to the risks of pregnancy, this line of research because such research may lead to the development of safe and effective therapies.

185 Carhart II’s preference for as-applied challenges can be read as imposing a causation requirement. See Carhart II, 127 S. Ct. 1610, 1638 (2007) (suggesting that an as-applied challenge would be “the proper manner to protect the health of the woman if it c[ould] be shown that in discrete and well-defined instances a particular condition has or is likely to occur in which the procedure prohibited by the Act must be used,” given that allegations of speculative harm are disfavored).

186 See Robertson, supra note 19, at 33–34.

187 While Danforth and the Margaret S. cases date from the pre-Casey era in abortion jurisprudence, they are nevertheless still good law. See Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 881–84 (1992) (limiting Danforth with respect to its holding concerning the nontherapeutic right to abortion, not the therapeutic right to abortion). Nevertheless, it is arguable that these cases are primarily focused on the health of the woman undergoing a present abortion, rather than the development of techniques for future abortions.

reasoning proves too much because the same can be said with respect to cancer patients or other individuals subject to peculiar conditions that threaten their lives or their health.\textsuperscript{189} Regardless, the Court has expressed concern for individual interests in the preservation of life and health in several other medical care contexts, which could suggest a willingness to expand the scope of the right to therapeutic medical treatment beyond abortion.

The Court’s jurisprudence concerning end-of-life decisions is most instructive in this regard. For starters, although \textit{Cruzan v. Director, Missouri Department of Health}\textsuperscript{190} is generally known for suggesting that “competent” individuals have a constitutionally protected liberty interest in refusing unwanted medical treatment,” including “lifesaving hydration and nutrition,”\textsuperscript{191} it can be understood as implying that a constitutional right to receive such treatment might exist as well. In justifying protection for the presumptive right to refuse medical treatment, the Court emphasized “[t]he choice between life and death [a]s a deeply personal decision of obvious and overwhelming finality.”\textsuperscript{192} Yet, the Court ultimately held that the State of Missouri could constitutionally require a showing by clear and convincing evidence that an individual in a persistent vegetative condition would not have wanted life-saving medical treatment before allowing her guardian to discontinue it, and that the substituted judgment of family members will not suffice for withdrawal of treatment.\textsuperscript{193} This holding rested on the Court’s view that such procedural requirements “sa-

\[\text{\textsuperscript{189} Cf. Volokh, supra note 25, at 1826 (“Nothing about therapeutic postviability abortion makes it deserve protection more than any other medical self-defense procedure. . . . Postviability abortions cannot be distinguished on the ground that they involve the woman’s reproductive choice. After viability, the time for that choice has passed, and the right to get a therapeutic abortion is a consequence of the woman’s medical self-defense right, not her abortion-as-choice right.”). For a discussion of how “[i]logic strongly supports finding a right to medical treatments that save or extend life, since being alive is a necessary precondition to the exercise of other rights,” see Robertson, supra note 19, at 9–10.}\

\[\text{\textsuperscript{190} 497 U.S. 261 (1990).}\

\[\text{\textsuperscript{191} Id. at 278–79. Although Chief Justice Rehnquist, writing for the majority, did not explicitly say but rather “assumed” that such a right incorporates “the right to refuse lifesaving hydration and nutrition,” id. at 279, five Justices explicitly did say so in separate opinions. See id. at 287 (O’Connor, J., concurring); id. at 302 (Brennan, J., dissenting) (writing on behalf of Justices Marshall, Blackmun, and Stevens).}\

\[\text{\textsuperscript{192} Id. at 281 (majority opinion).}\

\[\text{\textsuperscript{193} Id. at 284, 286–87.}\

feguard the personal element” in an end-of-life decision and that failing to impose them could even offend due process, given that the interests of a surrogate decisionmaker will not always coincide with those of the individual whose life is at stake. In the Court’s words: “It cannot be disputed that the Due Process Clause protects an interest in life as well as an interest in refusing life-sustaining medical treatment.” Thus, the implication is that permitting a State to impose a mechanism that does not sufficiently protect an individual’s ability to receive life-saving medical treatment, if she so intends, would implicate her constitutionally protected liberty interest in life.

In addition, a right to palliative care that reduces extreme suffering, which the Court has intimated exists, would presumably incorporate a right to certain therapeutic treatments that serve the same purpose. Even though the Court refused to recognize a right to physician-assisted suicide in Washington v. Glucksberg and its companion case Vacco v. Quill, scholars have argued that a majority of the Justices in Glucksberg nevertheless effectively recognized the existence of a right to palliative care, even when it hastens death, or at the least expressed a willingness to approve of such measures in appropriate circumstances. Typically, physicians administer palliative care to

194 Id. at 281.
195 Id. (emphasis added).
196 Cf. Robertson, supra note 19, at 9–10, 12–13 (arguing that Cruzan supports recognition of a “negative due process right” to life, which can otherwise be understood as the “reverse of a right to end life”).
199 See CHEMERINSKY, supra note 26, § 10.5, at 854; Robert A. Burt, The Supreme Court Speaks: Not Assisted Suicide but a Constitutional Right to Palliative Care, 337 New Eng. J. Med. 1234 (1997); Yale Kamisar, Can Glucksberg Survive Lawrence?: Another Look at the End of Life and Personal Autonomy, 24 Issues L. & Med. 95, 101–08 (2008); Yale Kamisar, On the Meaning and Impact of the Physician-Assisted Suicide Cases, 82 Minn. L. Rev. 895, 908–09 (1998). Indeed, the majority in Glucksberg left open the question of whether the Constitution protects a physician’s assistance in aiding death in all circumstances, and its holding does not “foreclose the possibility that an individual plaintiff seeking to hasten her death, or a doctor whose assistance was sought, could prevail in a more particularized challenge.” Glucksberg, 521 U.S. at 735 n.24. Justice O’Connor, writing on behalf of herself and Justice Ginsburg, emphasized that if “a patient who is suffering from a terminal illness and who is experiencing great pain has . . . legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness and hastening death,” the constitutional question would be different. Id. at 736–38 (O’Connor, J., concurring); id. at 789 (Ginsburg, J., concurring). According to Justice Breyer:

[T]he avoidance of severe physical pain (connected with death) would have to constitute an essential part of any successful claim . . . . Were the legal circum-
their patients in order to relieve them of pain arising from threats to their health, even though it may cause their health to deteriorate.\textsuperscript{200} Alternatively, physicians administer therapeutic care as a curative measure to restore their patients' health.\textsuperscript{201} But by restoring health, therapeutic care can and often does reduce pain, albeit indirectly, by striking at the source of the pain—the health threat—rather than the pain itself, as palliative care does.\textsuperscript{202} Therefore, it would be anomalous for the Court to conclude that patients have a right to medical treatment that reduces suffering and hastens death, but do not have a right to medical treatment that reduces suffering and prolongs life, especially in light of the Court's recognition of constitutional protection for health and life interests in other therapeutic treatment con-

\begin{itemize}
\item \textsuperscript{200} The main objective of palliative care, however, is not to cure or decrease an actual health threat, but rather to manage and decrease the pain arising from the threat. See World Health Organization, WHO Definition of Palliative Care, http://www.who.int/cancer/palliative/definition/en/ (last visited Mar. 26, 2009). In fact, the nature and strength of many types of palliative care treatments, like analgesics such as morphine, may cause the health of patients to deteriorate and even hasten their death. See Robertson, \textit{supra} note 19, at 10.
\item \textsuperscript{201} Sometimes, however, the administration of therapeutic treatment for the purpose of restoring a patient's health may actually cause the patient to endure a temporarily increased level of pain, as is the case in chemotherapy for the treatment of cancer. See National Cancer Institute, Understanding Chemotherapy, http://www.cancer.gov/cancer-topics/chemo-side-effects/understandingchemo (last visited Mar. 26, 2009). Therefore, physicians often administer both palliative care and therapeutic care in conjunction with one another to reap the gains of both while offsetting their downsides. See World Health Organization, WHO's Pain Ladder, http://www.who.int/cancer/palliative/painladder/en/index.html (last visited Mar. 26, 2009). Certain treatments, such as marijuana, also serve both therapeutic and pain-reducing purposes. See Gonzales v. Raich, 545 U.S. 1, 9 (2005).
\item \textsuperscript{202} See \textit{supra} notes 200–01.
\item \textsuperscript{203} See Robertson, \textit{supra} note 19, at 10 (arguing that "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").
\end{itemize}
texts. For this reason, the Court might even be more willing to protect access to therapeutic treatments that reduce pain than to protect access to palliative care treatments.

Indeed, in justifying both protection for access to palliative care and non-recognition of a right to physician-assisted suicide, Justice Stevens, in his concurrence in Glucksberg, echoed the very principle at play in Cruzan—that inadequate protection by the State of an individual’s ability to choose to live might offend due process. Emphasizing the State’s “unqualified interest in the preservation of human life,” Justice Stevens explained:

That interest not only justifies—it commands—maximum protection of every individual’s interest in remaining alive, which in turn commands the same protection for decisions about whether to commence or to terminate life-support systems or to administer pain medication that may hasten death. Properly viewed, however, this interest is not a collective interest that should always outweigh the interests of a person who because of pain, incapacity, or sedation finds her life intolerable, but rather, an aspect of individual freedom. This rationale implies that the value of a terminally ill patient’s interest in the preservation of life not only coincides with the State’s interest to the same end, but independently supports the imposition of a mechanism by the State—in this case, a law prohibiting physician-assisted suicide—to ensure that the patient has full opportunity, free from interference such as “coercion or abuse” by others, to determine her own “quality of life” as it nears the end, whether that means remaining alive in pain or choosing to reduce it with medication.

In all of the contexts discussed above—therapeutic abortion, life-sustaining treatment, and palliative care—the Court in part relied on a common rationale related to individual life and health interests to justify protecting access to the given treatment at issue: that state action implicated individual “bodily integrity.” Seth Kreimer has described the concept of bodily integrity as “an extratextual constitu-

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205 Id. (emphases added). The individual’s “interest in remaining alive” can thus be construed either as a constitutional liberty interest or as a non-constitutional interest. However, the former construction is more plausible, considering a State would presumably have no obligation to ensure that individuals are able to exercise the interest unless the Constitution mandated as much.

206 See id. at 746–47 (noting that “[m]any terminally ill people find their lives meaningful even if filled with pain . . . . [or] find value in living through suffering”).

tional doctrine of moral minimalism that denies the State—even in pursuit of legitimate public ends—‘uncontrolled authority over the bodies’ of those who are subject to its power.”

According to Professor Kreimer:

When the Supreme Court revisited Roe v. Wade in Planned Parenthood of Southeastern Pennsylvania v. Casey, the plurality opinion of Justices O’Connor, Souter and Kennedy and the separate opinions of Justices Blackmun and Stevens invoked a right to “bodily integrity” enumerated in no clause of the Constitution. That right had not underpinned prior reasoning in abortion cases, but as the prevailing Justices pointed out, it had blossomed elsewhere in the years between Roe and Casey.

However, adoption of this rationale was not limited to Justices who typically favored broader conceptions of “liberty.”

Every member of the Rehnquist Court, indeed, recognized extratextual protections against physical violation by the state.... [and t]he first intimations of this détente came in Washington v. Glucksberg. In addressing the claims for a right to assisted suicide, Justices Souter and Stevens reiterated their position that the Constitution provides protections for bodily integrity and the right to refuse unwanted medical treatment. Justices O’Connor, Breyer, and Ginsburg suggested as well the possibility that “suffering patients have a constitutionally cognizable interest in obtaining relief from the suffering that they may experience in the last days of their lives,” though as interpreted the challenged statutes did not raise the issue. More surprising, Chief Justice Rehnquist, writing for himself, Justices O’Connor, Kennedy, Scalia and Thomas, acknowledged that:

[t]he Due Process Clause guarantees more than fair process, and the ‘liberty’ it protects includes more than the absence of physical restraint. The Clause also provides heightened protection against government interference with certain fundamental rights and liberty interests. In a long line of cases, we have held that, in addition to the specific freedoms protected by the Bill of Rights, the ‘liberty’ specially protected by the Due Process Clause includes the rights... to bodily integrity and to abortion. We have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment.

What is at work here is the notion that a State is limited in what it can do with respect to individuals’ physical bodies, whether that means its constrained ability to force a woman to carry a pregnancy to term, to deny a vegetative individual life-saving treatment, or to force a patient to endure extreme pain without palliative care that is readily available. Therefore, in light of the Court’s willingness to protect bodily

208 Id. at 423.
209 Id. at 423, 438–39 (citations omitted).
210 Id. at 440–41 (citations omitted) (emphasis added).
integrity “under several doctrinal rubrics,”\textsuperscript{211} forcing individuals to suffer from threats to their life or health by restricting their access to other therapeutic treatments should, as a matter of doctrine, be no exception.\textsuperscript{212}

4. Limitations Imposed by the State’s Power to Promote Public Health and Safety

Despite doctrinal support for the argument that courts would be willing to expand the scope of constitutional protection for the right to therapeutic medical treatment beyond the abortion context, case law reveals that such expansion is not unlimited. To be sure, beginning with two Prohibition era cases decided by the Supreme Court which predate modern substantive due process jurisprudence, courts have relied on the power of the government to promote the public health and safety to refuse protection against state interference with access to unsafe or ineffective therapeutic treatments. In \textit{James Everard’s Breweries v. Day},\textsuperscript{213} the Court unanimously rejected the argument that a federal law prohibiting the manufacture and sale of malt liquors for medicinal purposes infringed on “the constitutional right of the patient to receive from the physician the prescription of malt liquors [when] the physician deems it best for the health of his patient.”\textsuperscript{214} The Court upheld the law on the grounds that it was not “an arbitrary and unreasonable prohibition on the use of valuable medicinal agents” and that it was within the judgment of Congress “as a matter affecting the public health” to prohibit the medicinal use of intoxicating malt liquors while allowing the medicinal use of other liquors.\textsuperscript{215} Similarly, in \textit{Lambert v. Yellowley},\textsuperscript{216} the Court rejected the argument that the same federal law’s limitation on the quantity of alcohol that physicians could prescribe infringed on “the right of the

\textsuperscript{211} Id. at 423.
\textsuperscript{212} Cf. Volokh, supra note 25, at 1826 (“Nor can one distinguish therapeutic abortions on the grounds that they involve control over the woman’s own body . . . . [because a] patient’s adding substances (such as medications or an organ) to her body, as well as her removing substances from her body (say, through medications that kill cancer cells), involves her control over her body as much as does a doctor’s inserting a surgical instrument to remove a fetus.”).
\textsuperscript{213} 265 U.S. 545 (1924).
\textsuperscript{214} Id. at 553.
\textsuperscript{215} Id. at 561–62 (deferring to Congress’s findings “that intoxicating malt liquors possessed no substantial and essential medicinal properties which made it necessary that their use for medicinal purposes should be permitted”).
\textsuperscript{216} 272 U.S. 581 (1926).
patient to receive the benefit of the judgment of the physician of his choice.

Even though the plaintiff-physician testified that in his judgment the use of alcohol in quantities higher than permitted were “necessary for the proper treatment of patients in order to afford relief from human ailments,” the Court, relying on *James Everard’s Breweries*, upheld the law as within Congress’s power to promote the public health.

Although the abortion cases are the only instances in which the Court has decided challenges to laws restricting access to therapeutic treatment on substantive due process grounds since *James Everard’s Breweries* and *Lambert*, the Court has employed the public-health rationale to deny terminally ill patients access to therapeutic medical treatments in two relevant cases decided on statutory grounds. In *United States v. Rutherford*, the Supreme Court refused to read a medical necessity exception for terminally ill patients to access the unapproved cancer drug Laetrile into the Federal Food, Drug, and Cosmetic Act, which prohibited the marketing of drugs not recognized as “safe” and “effective.” In justifying this conclusion, the Court emphasized the risks of reading an exception into the statute, including the drug’s potential for harm with no therapeutic benefit, especially among terminally ill patients who are most susceptible to negative effects from unapproved therapies; the possibility that the drug would be even more dangerous because forms of cancer react differently to certain therapies; the possibility of undermining the FDA’s authority for determining the safety and effectiveness of all drugs; and the potential exploitation of terminally ill individuals by

217 Id. at 586.

218 Id. at 588. While Congress did not make any specific findings as to the medicinal value of particular quantities of alcohol, the Court nevertheless deferred to what it believed to be the congressional intent behind the law:

[T]he limitation as to quantity must be taken as embodying an implicit congressional finding that such liquors have no such medicinal value as gives rise to a need for larger or more frequent prescriptions. Such a finding, in the presence of the well-known diverging opinions of physicians, cannot be regarded as arbitrary or without a reasonable basis.

Id. at 595.

219 However, it should be noted that the Court has declined to address substantive due process challenges to laws restricting access to therapeutic treatments in recent years. See *Hill*, supra note 25, at 287–88 (noting that the plaintiffs in *United States v. Oakland Cannabis Buyers’ Cooperative*, 532 U.S. 483 (2001), and *Gonzales v. Raich*, 545 U.S. 1 (2005), raised the claim that they had a substantive due process right to use marijuana for therapeutic purposes, but that the Court did not address it in either case).

220 *Hill*, supra note 25, at 302 (suggesting that these cases “fit the public-health model”).


222 Id. at 551.
entrepreneurs marketing ineffective therapies. In the end, the Court made clear that whether “an exemption should be created is a question for legislative judgment, not judicial inference.”

Similarly, in United States v. Oakland Cannabis Buyers’ Cooperative, the Court refused to read a medical necessity defense for terminally ill cancer patients into the federal Controlled Substances Act’s criminal prohibitions on the manufacturing and distribution of marijuana. Although there was evidence before the Court that marijuana could alleviate severe pain and wasting, and the district court found that “human suffering” could result from restricted access to the drug, the Court, relying in part on Rutherford, deferred to Congress’s judgment that marijuana was not an effective medicinal agent acceptable for public use:

Under any conception of legal necessity, one principle is clear: The defense cannot succeed when the legislature itself has made a “determination of values.” In the case of the Controlled Substances Act, the statute reflects a determination that marijuana has no medical benefits worthy of an exception (outside the confines of a Government-approved research project). Whereas some other drugs can be dispensed and prescribed for medical use, the same is not true for marijuana. Indeed, for purposes of the Controlled Substances Act, marijuana has “no currently accepted medical use” at all.

However, Justice Stevens, in a concurrence, limited the holding by suggesting that “the defense might be available to a seriously ill patient for whom there is no alternative means of avoiding starvation or extraordinary suffering,” rather than to distributors of marijuana, as was the case here.

Two recent circuit court cases followed the public-health rationale to refuse recognition of substantive due process rights to modern therapeutic treatments. In Raich v. Gonzales, on remand after the Supreme Court rejected a Commerce Clause challenge to the Controlled Substances Act, the Ninth Circuit denied an as-applied challenge to the Act alleging that a cancer patient suffering from wasting

223 Id. at 555–58.
224 Id. at 559.
226 Id. at 494.
227 See id. at 487–88.
228 See id. at 490.
229 Id. at 491.
230 Id. at 501 (Stevens, J., concurring).
231 500 F.3d 850 (9th Cir. 2007).
232 Gonzales v. Raich, 545 U.S. 1 (2005).
disorder and severe pain had a fundamental right to marijuana for therapeutic use.\textsuperscript{235} Despite acknowledging the “medical and conventional wisdom that recognizes the use of marijuana for medical purposes is gaining traction in the law,” the court found “that legal recognition has not yet reached the point where a conclusion can be drawn that the right to use medical marijuana is ‘fundamental’ and ‘implicit in the concept of ordered liberty.’”\textsuperscript{234} In reaching this conclusion, the court pointed to the existence of expansive prohibition of marijuana, even for therapeutic use, among the States and emphasized the traditional legislative power to combat perceived threats to the public health.\textsuperscript{235} However, in the end, the court made clear that recognition of the asserted right was not permanently foreclosed:

For now, federal law is blind to the wisdom of a future day when the right to use medical marijuana to alleviate excruciating pain may be deemed fundamental. Although that day has not yet dawned, considering that during the last ten years eleven states have legalized the use of medical marijuana, that day may be upon us sooner than expected.\textsuperscript{236}

Next, in \textit{Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach},\textsuperscript{237} the D.C. Circuit sitting \textit{en banc} reversed a previous panel decision, which held unconstitutional the Food, Drug, and Cosmetic Act’s grant of sole authority to the FDA to approve drugs for public use, on the ground that it violated the right of terminally ill cancer patients to access investigational drugs that had qualified for human testing.\textsuperscript{238} The Alliance—a non-profit organization advocating greater access to experimental drug therapies on behalf of the terminally ill—argued, inter alia, that constitutional protection for therapeutic treatment in the abortion context extended to investigational drugs,\textsuperscript{239} but the court distinguished the therapeutic abortion right from the asserted right at bar:

\begin{quote}
[T]his case is not about . . . access to life-saving medical treatment. This case is about whether there is a constitutional right to assume, in the Alliance’s own words, “enormous risks,” in pursuit of \textit{potentially} life-saving drugs. Unlike the cases in which the doctrine of self-defense might properly be invoked, this case involves risk from drugs with no proven
\end{quote}

\textsuperscript{233} \textit{Raich}, 500 F.3d at 866.
\textsuperscript{234} \textit{Id}.
\textsuperscript{235} \textit{Id.} at 864–66.
\textsuperscript{236} \textit{Id.} at 866.
\textsuperscript{238} 495 F.3d at 701.
\textsuperscript{239} \textit{Id.} at 709.
therapeutic effect, which at a minimum separates this example from the abortion “life of the mother” exception.\textsuperscript{240} In ultimately upholding the Act, the court stressed the “historical tradition of prohibiting the sale of unsafe drugs”\textsuperscript{241} and the legislature’s “well-established power to regulate in response to scientific, mathematical, and medical advances.”\textsuperscript{242} Although the public-health rationale foreclosed recognition of constitutional protection for therapeutic treatment here, the court acknowledged the possibility of protecting therapeutic treatment in other contexts by stating: “We do not address the broader question of whether access to medicine might ever implicate fundamental rights.”\textsuperscript{243}

These cases do not foreclose the possibility of extending the scope of the right to therapeutic medical treatment beyond the abortion context. Rather, they can be understood as suggesting that constitutional protection will not extend to other therapeutic treatments so long as they are unsafe or ineffective because they thus constitute threats to public safety and health. In practice, this means that a particular therapeutic treatment will likely have to be approved by the FDA, the federal regulatory body responsible for approving new medical treatments, before courts will protect individual access to it.

However, it is unclear how the public-health rationale will play out in evaluating laws restricting embryonic stem cell research. Although the district court in Margaret S. v. Treen and Judge Williams’s concurrence in Margaret S. v. Edwards suggested that protecting the public health is not a cognizable state interest in support of fetal experimentation restrictions,\textsuperscript{244} the same cannot necessarily be said about restrictions on embryonic stem cell research because, unlike experimentation on fetal tissue, it may involve somatic cell nuclear transfer (SCNT). SCNT is one of two techniques used to create human embryos for therapeutic research, and there is concern that if left unrestrained scientists may utilize it to engage in more abhorrent practices such as reproductive cloning and genetic engineering. Whether a State’s interest in protecting against such abuses would persuade courts to deny constitutional protection to embryonic stem cell research is too speculative an inquiry to pursue further. However, even if it does not foreclose the possibility of constitutional protection as a

\textsuperscript{240} Id. at 709–10.
\textsuperscript{241} See id. at 703–07.
\textsuperscript{242} Id. at 706.
\textsuperscript{243} Id. at 701.
\textsuperscript{244} See discussion supra Part II.B.2.
general matter, courts still might find that certain restrictions on embryonic stem cell research are sufficiently tailored to further this interest and thus outweigh any burden they impose on the right to therapeutic treatment.

Yet, despite these hypothetical doctrinal constraints, a constitutional attack on laws restricting embryonic stem cell research presents an altogether different challenge than those raised in the public health cases described above. Indeed, a challenge to laws restricting embryonic stem cell research does not seek access to the use of actual therapies, given that none currently exist, but rather protection against state interference with the prior research necessary to develop them. As such, the public health cases may very well be inapplicable in the research context given that access to potentially harmful or ineffective therapies is not even at issue.

III. EVALUATING THE CONSTITUTIONALITY OF LAWS RESTRICTING EMBRYONIC STEM CELL RESEARCH

Assuming that the Due Process Clause protects against state interference with embryonic stem cell research, as argued in Part II, there is then a question of the appropriate standard of review to evaluate the constitutionality of laws restricting this research. To this end, the standards of review the Supreme Court has used to analyze laws implicating the therapeutic abortion right are most instructive. For one, the Court has thus far only recognized a right to therapeutic medical treatment in its abortion jurisprudence. More importantly, however, the abortion cases have provided the Court with numerous opportunities to evaluate the competing individual and state interests at stake in laws restricting access to therapeutic medical treatment and arrive at a standard of review that strikes an appropriate balance between them. Therefore, given the lack of alternatives, it is reasonable to presume that a court would invoke a standard derived from cases involving the therapeutic abortion right if presented with a substantive due process challenge to a law restricting embryonic stem cell research.

Until its most recent abortion decision, Carhart II, the Supreme Court had subjected laws allegedly lacking an adequate health exception to such an exacting scrutiny—under which the government bore the burden of demonstrating that the law in question would never

threaten a woman’s health—that its application was almost always fatal. However, in Carhart II, the Court “analyzed the need for a health exception under the ‘undue burden’ rubric . . . in which the burden is on the challenger to show that the abortion regulation puts a substantial obstacle in the path of women seeking abortions.” Although the undue burden standard is a form of heightened scrutiny, it is a less rigid standard of review that differs in material respects from exacting scrutiny. Yet, Carhart II arguably did not modify the application of the stricter standard of review that the Court has traditionally used in determining the need for a life exception because the Court found it unnecessary to address the issue.

Therefore, following the Court’s abortion jurisprudence for guidance, there are two different standards that might be applicable in

246 See Carhart I, 530 U.S. 914, 938 (2000) (invalidating a law prohibiting a particular partial-birth abortion procedure because the State could not prove that it was never “necessary, in appropriate medical judgment, for the preservation of the life or health of the mother” (quoting Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 879 (1992))); Thornburgh v. Am. Coll. of Obstetricians and Gynecologists, 476 U.S. 747, 770–71 (1986) (invalidating a law requiring the presence of two physicians when performing late-term abortions on potentially viable fetuses because it was not “worded sufficiently to imply an emergency exception . . . [and] contain[ed] no such comforting or helpful language and evince[d] no intent to protect a woman whose life may be at risk”); City of Akron v. Akron Ctr. for Reprod. Health, 462 U.S. 416, 437 (1983) (invalidating a law requiring second trimester abortions to be performed in a hospital in part because there was “impressive evidence that—at least during the weeks of the second trimester—[certain] abortions may be performed as safely in an outpatient clinic as in a full-service hospital”); Colautti v. Franklin, 439 U.S. 379, 400 (1978) (invalidating on vagueness grounds a law requiring physicians, when performing abortions, to use the procedure with the best chance of preserving the life of the fetus, given that the law “d[id] not clearly specify . . . that the woman’s life and health must always prevail over the fetus’s life and health when they conflict” because the government may not “requir[e] the physician to make a ‘trade-off’ between the woman’s health and additional percentage points of fetal survival”); Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 78–79 (1976) (invalidating a law prohibiting amniocentesis, one of the most common abortion procedures nationwide, in part because it was “safer, with respect to maternal mortality, than even continuation of the pregnancy until normal childbirth”); cf. Planned Parenthood Ass’n of Kan. City v. Ashcroft, 462 U.S. 476, 485 n.8 (1982) (employing an avoidance canon to construe a law requiring the presence of two physicians during the performance of abortions subsequent to viability to apply to “emergency situations where, for example, the woman’s health may be endangered by delay”).

247 Hill, supra note 25, at 322.

248 See Brief of Constitutional Law Professors et al., as Amici Curiae Supporting Respondents at 4, Gonzalez v. Carhart, 127 S. Ct. 1610 (2007) (No. 05-380) (“[T]he undue burden test is not a form of intermediate scrutiny. Rather, notwithstanding this Court’s recognition that governments possess powerful, compelling interests in regulating abortion, the undue burden test remains a form of strict scrutiny.”).

249 See Hill, supra note 25, at 322.

250 Carhart II, 127 S. Ct. at 1639.
analyzing the constitutionality of laws restricting embryonic stem cell research: The undue burden standard and a more exacting form of scrutiny. Given that prospective therapies derived from embryonic stem cells are believed to both combat significant risks to individuals’ health and treat life-threatening illnesses, it is uncertain which standard of review might be more appropriate. Although laws restricting embryonic stem cell research would be subject to more searching review under exacting scrutiny, there is a strong indication that they would fail to pass constitutional muster within the undue burden standard as well.

A. The Adoption of the Undue Burden Standard in Assessing the Need for a Health Exception in Laws Implicating the Therapeutic Abortion Right

Stenberg v. Carhart (“Carhart I”), the Supreme Court’s first partial-birth abortion case, epitomized the exacting scrutiny the Court had applied to laws lacking an adequate health exception before Carhart II. In Carhart I, the Court invalidated a Nebraska statute that it interpreted to proscribe the performance of two partial-birth-abortion procedures before viability—the prevalent dilation-and-evacuation procedure (“D&E”) and the controversial dilation-and-extraction procedure (“D&X”)—partly on the ground that the statute did not include an exception for the preservation of the mother’s health. The Court held that such an exception was not required if the State could prove that the prohibited procedure was never “necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.”

The Court held that such an exception was not required if the State could prove that the prohibited procedure was never “necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.” Because the record showed that significant medical authority supports the proposition that in some circumstances, D&X would be the safest procedure,” the State did not meet its burden of proof.

Significantly, the Court in Carhart I did not consider Nebraska’s state interests in support of the statute in its analysis. According to the Court, the State’s interests did not “make any difference to the question at hand, namely, the application of the ‘health’ requirement.” That the Court was willing to strike down the statute for the mere possibility that some women might require the procedure in

251 530 U.S. 914 (2000).
252 Id. at 930.
253 Id. at 938 (quoting Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 879 (1992)).
254 Id. at 932.
255 Id. at 931.
“certain circumstances”\textsuperscript{256} suggests that the Court believed the individual health interests implicated by the statute carried enough weight to entirely subjugate the asserted state interests and make irrelevant the possibility that the health exception would be unnecessary in practice. In light of the Court’s analysis in \textit{Carhart I}, some lower courts and commentators considered the health exception a virtual per se constitutional requirement.\textsuperscript{257}

However, in \textit{Carhart II}, the Court changed course by applying the less demanding undue burden standard rather than the exacting scrutiny it previously applied to uphold the federal Partial-Birth Abortion Ban Act of 2003, which prohibited the D&X procedure, even though it did not include a health exception.\textsuperscript{258} Reiterating the inquiry in \textit{Stenberg}, the Court examined whether the prohibited D&X procedure was ever necessary, in professional medical judgment, to protect a woman’s health.\textsuperscript{259} As in \textit{Carhart I}, the Court found that there was uncertainty in the medical community on this point, based on evidence presented by the parties.\textsuperscript{260} However, unlike the Nebraska legislature in \textit{Carhart I}, Congress had made specific findings that the D&X procedure was never necessary to preserve a woman’s health.\textsuperscript{261} According to the Court, the existence of “medical uncertainty over whether the Act’s prohibition creates significant health risks provide[d] a sufficient basis to conclude . . . that the Act does not impose an undue burden."\textsuperscript{262} Although the Court did not explic-
ity overrule *Carhart I* by deferring to the legislature instead of the plaintiff when confronted with a constitutional question that turned on a legislative fact surrounded by scientific uncertainty, the inescapable implication is that it did.

Additionally, although the existence of scientific uncertainty was a “sufficient basis” for deferring to Congress, the Court in *Carhart II* explained that the availability of safer adequate alternatives to the prohibited procedure also supported its conclusion that a health exception was unnecessary. Since the Act proscribed only D&X, a pregnant woman could still obtain the more common D&E procedure, which was “generally the safest method of abortion during the second trimester,” in the event she should need a therapeutic abortion. That D&E might have carried some risk did not foreclose upholding the Act: “When standard medical options are available, mere convenience does not suffice to displace them; and if some procedures have different risks than others, it does not follow that the State is altogether barred from imposing reasonable regulations.” What the Court meant by “reasonable regulations” is not entirely clear, but the implication is that regulations are reasonable insofar as they permit access to adequately safe alternative treatments to protect the health of the mother; otherwise, the regulations would unduly burden a woman’s right to a therapeutic abortion.

Notably, while the Court in *Carhart II* affirmed that the health exception was a constraint on the government’s ability to regulate abortion, it rejected *Carhart I*’s contention that governmental interests in support of a law prohibiting a particular abortion procedure do not bear on the issue of whether a health exception is required. Indeed, unlike in *Carhart I*, the Court emphasized the State’s interests in “regulating the medical profession in order to promote respect for life” in justifying the prohibition on the D&X procedure. Therefore, the Court’s adoption of the undue burden standard in *Carhart II* can be understood as a reevaluation of the weight it had previously accorded the individual health interests and the state interests at stake in laws implicating the therapeutic abortion right to arrive at a more appropriate balance, where health interests do not necessarily trump state interests.

263 *Id.*
264 *Id.* (quoting *Carhart v. Ashcroft*, 331 F. Supp. 2d 805, 1031 (D. Neb. 2004)).
266 *Id.* at 1633.
It is not entirely clear how, if at all, the undue burden standard the Carhart II Court used to evaluate the necessity of a health exception differs from the undue burden standard the Casey plurality articulated to govern laws burdening the nontherapeutic abortion right. In Casey, the plurality dispensed with Roe’s trimester framework and the use of strict scrutiny in evaluating laws implicating the right to nontherapeutic abortion, and held that the undue burden standard should be applied to such laws instead because “the undue burden standard is the appropriate means of reconciling the State’s interest with the woman’s constitutionally protected liberty.”

According to the plurality, a law constitutes an undue burden to the nontherapeutic abortion right if it “has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion” prior to viability. Acknowledging the government’s “profound interest in potential life,” the plurality held that “throughout pregnancy the State may take measures to ensure that the woman’s choice is informed, and measures designed to advance this interest will not be invalidated as long as their purpose is to persuade the woman to choose childbirth over abortion.”

In applying this formulation to the Pennsylvania statute at issue, the plurality upheld a twenty-four-hour waiting period provision and a reporting-and-recording requirement, but struck down a spousal consent requirement because it was “likely to prevent a significant number of women from obtaining an abortion,” whereas the other provisions were not likely to do any such thing. As such, the plurality “seem[ed] . . . to be saying that an undue burden exists only if there is a showing that the regulation will keep someone from getting an abortion,” which would be consis-

267 505 U.S. at 876–77.
268 Id. at 877.
269 Id. at 878.
270 Id. at 879–901.
271 CHEMERINSKY, supra note 26, § 10.3.3.1, at 830. Following this rationale, the Court in Carhart I invalidated the Nebraska partial-birth-abortion statute, in part, on the ground that it “impose[d] an undue burden on a woman’s ability to choose a D&E abortion, thereby unduly burdening the right to choose abortion itself.” Carhart I, 530 U.S. 914, 930 (2000) (quoting Casey, 505 U.S. at 874). According to the Court, the statute’s reach was what ultimately doomed it under this theory, given that it proscribed D&E—“the most commonly used method for performing previability second trimester abortions”—even though it aimed only to proscribe D&amp;X. Id. at 945. However, in Carhart II, 127 S. Ct. at 1628–31, the Court distinguished Carhart I and upheld a similar proscription in the Federal Partial Birth Abortion Ban Act of 2003 on the ground the statute only prohibited the performance of D&amp;X, and not D&amp;E.
tent with *Carhart II*’s application of the undue burden standard to determine the necessity of a health exception.

However, the *Casey* plurality also suggested that a law’s purpose, and not just its effect, is relevant to determine whether a particular abortion regulation constitutes an undue burden.\(^{272}\) Although neither the plurality in *Casey* nor the Court in *Carhart II* examined the laws *sub judice* for evidence of an improper purpose, it is reasonable to conclude that a law which has the purpose of creating a substantial obstacle to obtaining an abortion, nontherapeutic or therapeutic, would constitute an undue burden and thus be unconstitutional.

### B. The Application of the Undue Burden Standard to Laws Restricting Embryonic Stem Cell Research

The foregoing discussion demonstrates that several factors should be considered when analyzing laws restricting embryonic stem cell research within the undue burden standard. These factors include: whether there is uncertainty as to the need for embryonic stem cell research to combat significant health risks; whether adequate alternative therapies or research that would obviate the need for embryonic stem cell research are available; whether laws restricting embryonic stem cell research have the purpose of placing a substantial obstacle in path of individuals seeking therapeutic medical treatment; and whether balancing the state interests in support of laws restricting embryonic stem cell research outweigh the individual interests in the preservation of life and health at stake.

#### 1. Scientific Uncertainty as to the Therapeutic Need for Embryonic Stem Cell Research

In *Carhart II*, the Court justified upholding the Partial Birth Abortion Ban Act of 2003 on the ground that the existence of uncertainty within the medical community as to whether the D&X procedure constituted an undue burden on the therapeutic abortion right mandated deference to Congressional findings that indicated the procedure was never necessary to protect women’s health. In light of “documented medical disagreement” presented by the parties, the Court explained:

State and federal legislatures [have] wide discretion to pass legislation in areas where there is medical and scientific uncertainty. . . . Medical uncertainty does not foreclose the exercise of legislative power in the abortion context any more than it does in other contexts. The medical uncertainty over whether the Act’s prohibition creates significant health risks provides a sufficient basis to conclude in this facial attack that the Act does not impose an undue burden. Although the Court went on to explain that “[t]he conclusion that the Act does not impose an undue burden is supported by other considerations,” the Court’s plain language makes clear that the existence of uncertainty alone was “sufficient” to uphold the Act within the undue burden standard.

While Carhart II’s application of this so-called “traditional rule” suggests that the existence of uncertainty as to the therapeutic benefits of therapies derived from embryonic stem cell research would command upholding laws restricting this research, it is unclear how to determine whether such uncertainty actually exists. Given that no effective therapies have been derived from embryonic stem cell research as of yet, there is inherent uncertainty as to whether prospective treatments will someday prove therapeutic. However, the scientific community is in substantial agreement that embryonic stem cells are necessary for the development of effective therapies for a variety of currently incurable conditions. Therefore, the ultimate effect of the “traditional rule” on laws restricting embryonic stem cell research depends on how a court should choose to determine whether uncertainty within the meaning of the rule exists. If the inherently uncertain nature of embryonic stem cell research is the appropriate determinant, then the rule would mandate upholding a law restricting this research. On the other hand, if the medical consensus as to the need for prospective treatments derived from embryonic stem cell research is the appropriate determinant, then the rule probably would not mandate legislative deference.

Despite this dichotomy, there are several strong arguments that the latter is the appropriate determinant, and that the mere existence of inherent uncertainty in embryonic stem cell research should not automatically warrant upholding laws restricting it. For one, the Court in Carhart II specifically addressed a conflict of medical opinion

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273 Carhart II, 127 S. Ct. at 1636–37 (emphasis added).
274 Id. at 1637.
275 Id. at 1618.
276 See MOONEY, supra note 3, at 195–216 (rejecting claims by minority of scientists that embryonic stem cell research is unnecessary in this regard).
over the therapeutic necessity of the D&X procedure, not the inherent uncertainty of ever knowing that the procedure would be necessary to preserve women’s health. To be sure, it is impossible to know if any therapeutic treatment, whether it currently exists or is in development, will be safe and effective in combating health risks in certain circumstances in the future. Therefore, given that there is some degree of inherent uncertainty always present in therapeutic medical science, a rule that turns on the existence of inherent uncertainty would be meaningless because it would always mandate legislative deference. Furthermore, it is arguable that the rule mandating legislative deference in the face of medical uncertainty does not apply where the legislative body responsible for enacting the law at issue is “an entirely separate sovereign,” namely a state legislature as in Carhart I, opposed to Congress as in Carhart II. Accordingly, federal courts hearing challenges to laws restricting embryonic stem cell research, all of which are state laws, would not have to apply the traditional rule simply because they were enacted by state legislatures, opposed to Congress. Last, the application of the traditional rule in Carhart II and not in Carhart I can be justified on the bases that Congress made specific findings as to the therapeutic necessity of the D&X procedure, whereas the Nebraska legislature did not. As such, absent findings by the state legislatures responsible for enacting restrictions on embryonic stem cell research that this research would not lead to the development of therapeutic treatments, the traditional rule should not foreclose the possibility that laws restricting embryonic stem cell research constitute an undue burden to the right to therapeutic medical treatment.

2. The Availability of Adequate Alternatives to Embryonic Stem Cell Research and Prospective Treatments Derived Therefrom

In Carhart II, the Court said that the availability of the D&E procedure, an adequately safe and effective alternative to the D&X procedure, supported its conclusion that the Partial Birth Abortion Ban Act of 2003 constituted an undue burden to the therapeutic abortion

277 See Northland Family Planning Clinic, Inc. v. Cox, 487 F.3d 325, 340 (6th Cir. 2007) (“[T]he factual findings that cast doubt on the safety implications of D&X . . . were made by the legislative body of an entirely separate sovereign, suggesting the possibility that they could be of diminished relevance here.” (emphasis added)).

278 See Carhart II, 127 S. Ct. at 1634.
right for lack of a health exception. The Court based its determination that the D&E procedure was an adequately safe and effective alternative on the grounds that it carried “extremely low rates of medical complications,” was “generally the safest method of abortion during the second trimester,” and could be performed under the Act if “truly necessary” to preserve women’s health.

According to this logic, the availability of adequate alternative forms of therapeutic experimentation to embryonic stem cell research or the existence of adequately safe and effective therapeutic treatments for conditions that prospective therapies derived from embryonic stem cells could potentially treat weigh against invaliding laws restricting embryonic stem cell research. However, scientists believe that embryonic stem cell research will lead to the development of various therapies to treat degenerative conditions, such as Parkinson’s Disease, leukemia, diabetes, heart disease, and spinal cord injury, for which there are no superior treatments—certainly none that could ultimately provide cures for these conditions—currently in existence. Moreover, although some in the medical community believe that alternative therapeutic research methods that do not involve the destruction of embryos could provide treatments on par with those that embryonic stem cell research is believed to deliver, there is overwhelming medical authority to the contrary. That said, it is difficult to argue that existing alternatives to embryonic stem cell research and prospective therapies derived therefrom are adequate substitutes to protect the health interests of individuals suffering from degenerative conditions. Indeed, this position has been “resoundingly rejected by researchers actually working

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279 Id. at 1637.
280 Id. (quoting Carhart v. Ashcroft, 331 F. Supp. 2d 805, 1031 (2004)).
281 It may not even be necessary to consider this factor in an analysis of laws restricting embryonic stem cell research, given that Carhart II may only apply to laws prohibiting certain abortion procedures, and not every type abortion regulation. See Planned Parenthood of Idaho, Inc. v. Wasden, 376 F.3d 908 (9th Cir. 2004), cert. denied, 544 U.S. 948 (2005) (invalidating parental consent statute for lack of an adequate health exception); Planned Parenthood of the Rocky Mountains Servs. Corp. v. Owens, 287 F.3d 910 (10th Cir. 2002) (invalidating parental notification and waiting period requirements for lack of health exceptions); cf. Planned Parenthood of Cincinnati Region v. Taft, 444 F.3d 502 (6th Cir. 2006) (en banc) (requiring health exception in state law prohibiting off-label use of abortion-inducing drug RU-486). If this is the case, then Carhart II should not apply to restrictions on research, even though it may apply to prohibitions on treatments derived from embryonic stem cell research.
282 See Yu & Thomson, supra note 4, at 1–8.
283 See Mooney, supra note 3, at 195–216. Reprogramming has yet to become an adequate alternative substitute for embryonic stem cell research. See discussion supra Part I.
in the field.\textsuperscript{284} Therefore, consideration of this matter weighs in favor of finding that laws restricting embryonic stem cell research constitute undue burdens to the right to therapeutic medical treatment.

3. The Purpose of Creating a Substantial Obstacle to Individuals’ Access to Therapeutic Medical Treatment

\textit{Casey} suggests that if a law “has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion,” it constitutes an undue burden.\textsuperscript{285} Accordingly, if a law restricting embryonic stem cell research has the purpose of placing a substantial obstacle in the path of individuals seeking therapeutic medical treatment, it should similarly constitute an undue burden.

While laws restricting embryonic stem cell research unquestionably have the purpose of preventing the development of therapies derived from the destruction of human embryos, it would probably be unreasonable to conclude that they intend to deprive individuals of therapeutic treatment in general. Indeed, supporters of these laws typically claim that embryonic stem cell research is unnecessary to develop therapies to treat individuals with degenerative conditions; they just disagree with proponents of embryonic stem cell research about the means of attaining this objective. Considering in the abortion context a law that “has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it,”\textsuperscript{286} even though “[e]very law adopted to limit abortion is for the purpose of discouraging abortions and encouraging childbirth,”\textsuperscript{287} it is unlikely that a law restricting embryonic stem cell research would constitute an undue burden on account of an unconstitutional purpose.

4. Balancing Competing State and Individual Interests at Stake in Laws Restricting Embryonic Stem Cell Research

A distinction of the undue burden standard is that it necessarily entails the balancing of competing state and individual interests at stake. The Court has specified several cognizable state interests in support of abortion regulations: protecting fetal life and respect for

\textsuperscript{284} \textit{Id.} at 196.
\textsuperscript{287} CHEMERINSKY, supra note 26, § 10.3.3.1, at 830.
it, promoting the integrity and ethics of the medical profession, and promoting women’s health.\textsuperscript{288} Indeed, in applying the undue burden standard in \textit{Carhart II}, the Court emphasized these latter two interests in upholding the Partial Birth Abortion Ban Act of 2003 without a health exception. According to the Court:

There can be no doubt the government has an interest in protecting the integrity and ethics of the medical profession. Under our precedents it is clear the State has a significant role to play in regulating the medical profession . . . .

. . . The government may use its voice and its regulatory authority to show its profound respect for the life within the woman. . . . [T]hat the State, from the inception of the pregnancy, maintains its own regulatory interest in protecting the life of the fetus that may become a child, cannot be set at naught by interpreting \textit{Casey’s} requirement of a health exception so it becomes tantamount to allowing a doctor to choose the abortion method he or she might prefer. Where it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn.\textsuperscript{289}

Considering the outcome of a balancing test turns on the specific facts and laws involved in a given case, there is ultimately no telling if courts would find that the state interests in support of laws restricting embryonic stem cell research trump the individual interests in the preservation of life and health at stake, as in \textit{Carhart II}.

However, there is good reason to believe that the outcome of a balancing test would favor the individual interests in the preservation of life and health. While the state interests in support of laws restricting embryonic stem cell research include some of those interests in support of abortion regulations—promoting the ethics and integrity in the medical profession and respect for human life\textsuperscript{290}—it is arguable that the result of a challenge to a law restricting embryonic stem cell research should be the same as that reached in \textit{Carhart II}. But this overlooks the fact that the State’s interest in promoting respect for human life is much weaker in the research context than in the abortion context. For one, “[w]ith therapeutic cloning, there is no intention of bringing the embryo to term[,] . . . [given that its] stem cells are removed for research, with the hope that this research will contribute to progress in the development of treatments for individu-

\textsuperscript{289} \textit{Carhart II}, 127 S. Ct. at 1633.
\textsuperscript{290} See \textit{Robertson}, supra note 19, at 16 (describing state interests in support of regulations on hypothetical therapies derived from embryonic stem cells).
Furthermore, the fact that the disposal of spare embryos occurs in a variety of widely accepted fertilization practices, even in States that restrict embryonic stem cell research, cuts against the argument that embryos should be accorded the same respect as a potentially viable fetus. Therefore, the scale should tip in favor of protecting embryonic stem cell research.

Yet, there is another state interest unique to restrictions on embryonic stem cell research that might influence the balancing test: preventing “a slide down a slippery slope toward more abusive or repugnant practices, such as reproductive cloning and genetic engineering of offspring.” Although “[t]he speculative fear that some unknown amount of reproductive cloning might occur if we allow cloning for research or therapy is hardly a sufficient basis for denying persons the present ability to use safe and effective [embryonic-stem-cell-derived] treatments,” as Professor Robertson has argued, the same cannot necessarily be the said about the research that leads to the development of those treatments. Yet, although “[s]lippery slope appeals may rationally serve present values[,] . . . they do so at a cost in both present and future interests,” according to Professor Robertson, accounting for the value of this cost leads to the conclusion that “the fear of a slippery slope to reproductive cloning provides neither a compelling nor even a substantial basis for denying people safe and effective [embryonic stem cell] treatments.” However, even if a court would find the slippery slope argument cognizable in support of a restriction on embryonic stem cell research, the law would likely be overbroad or insufficiently tailored to the State’s objective. To be sure, as Steve Goldberg has suggested: “It is no great feat to write legislation that bans reproductive cloning while allowing therapeutic cloning; indeed, some States have passed laws that do just that. If our society remains committed to prohibiting reproductive cloning, it can prohibit it without stamping out therapeutic cloning as well.” In this light, given the lack of available alternatives to embryonic stem cell research and the therapies derived from it, the state interests in support of laws restricting this research seem considerably weaker.

291 See Goldberg, supra note 25, at 307.
292 See id. at 311–13.
293 Robertson, supra note 19, at 16.
294 Id. at 28 (emphasis added).
295 Id. at 29.
296 Id. at 30.
297 Goldberg, supra note 25, at 311.
than the individual interests implicated by them, thus supporting the contention that such laws unduly burden the right to therapeutic medical treatment.

C. The Survival of Exacting Scrutiny in Assessing the Need for a Life Exception in Laws Implicating the Therapeutic Abortion Right

In Northland Family Planning Clinic, Inc. v. Cox,298 handed down by the Sixth Circuit a few months after Carhart II, the court observed, “it is not apparent how and whether [Carhart II] diminishes the rule requiring an exception to protect the woman’s life that does not impose upon her an increased medical risk,” considering the life exception went unchallenged in Carhart II.299 However, the court concluded that Carhart II “suggests that the Supreme Court’s precedent pertaining to the life exception remains unchanged.”300

The Supreme Court’s traditional application of exacting scrutiny in analyzing the need for a life exception derives from Thornburgh v. American College of Obstetricians and Gynecologists.301 In Thornburgh, the Court invalidated a Pennsylvania statute requiring physicians, in any post-viability abortion, to use the procedure that would provide the best opportunity for the fetus to be born alive unless the procedure would pose “a significantly greater medical risk to the life or health of the pregnant woman.”302 According to the Court, the statute’s life exception provided inadequate protection because it required the “mother to bear an increased medical risk in order to save her viable fetus,” and was thus unconstitutional.303

Carhart II did not consider the applicability of the Thornburgh rule “requiring an exception to protect the woman’s life that does not impose upon her an increased medical risk” because the Partial-Birth

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298 487 F.3d 323 (6th Cir. 2007), cert. denied, 128 S. Ct. 873 (2008) (invalidating a Michigan law that prohibited the D&E procedure on the ground that the law posed an undue burden on women’s nontherapeutic abortion right, and refusing to decide whether the law was also invalid for lack of an adequate life exception).
299 Id. at 340 (citing Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747, 769 (1986), which rejected a “‘trade-off’ between the woman’s health and additional percentage points of fetal survival”).
300 Id.
301 476 U.S. 747.
302 Id. at 768 (quoting 18 PA. CONS. STAT. § 3210(b) (2000)).
303 Id. at 769 (quoting Am. Coll. of Obstetricians and Gynecologists, Pa. Section v. Thornburgh, 737 F.2d 283, 300 (3d Cir. 1984)).
Abortion Act of 2003 already included an adequate life exception.\footnote{Northland Family Planning Clinic, Inc. v. Cox, 487 F.3d 323, 339–40 (6th Cir. 2007) (indicating that the federal Partial Birth Abortion Ban Act of 2003 included a life exception that went unchallenged in Carhart II).} However, the Carhart II Court did note that “[n]o as-applied challenge need be brought if the prohibition in the Act threatens a woman’s life,”\footnote{Carhart II, 127 S. Ct. 1610, 1639 (2007).} because the Act specified that its prohibition “does not apply to a partial-birth abortion that is necessary to save the life of a mother.”\footnote{18 U.S.C. § 1531(a) (2003).} Given the limited opportunities the Court has had to evaluate abortion regulations lacking life exceptions, it is not apparent how the government could overcome a challenge to such a regulation. Under current law, however, suffice it to say that an abortion regulation that does not provide an exception where necessary to save the life of the mother is presumably invalid, despite Carhart II.\footnote{See Cox, 487 F.3d at 339–40.}

D. The Application of Exacting Scrutiny to Laws Restricting Embryonic Stem Cell Research

Subject to the exacting scrutiny of the life exception, embryonic stem cell research restrictions could only pass constitutional muster if a State could show that existing therapies do not impose upon individuals with life-threatening illnesses an increased risk that they would otherwise not be exposed to if the restrictions were lifted. Given that the medical community generally believes therapies derived from embryonic stem cells could be used to combat life-threatening degenerative conditions,\footnote{See MOONEY, supra note 3, at 195–216.} preventing the development of these therapies inherently increases the medical risks to which individuals with these conditions are exposed. Indeed, the longer laws restricting embryonic stem cell research remain in place, the longer the development of potential therapies is stalled, which in turn subjects individuals with degenerative conditions to medical risks associated with those conditions for a longer period of time. Therefore, application of the Thornburgh rule should warrant striking down laws restricting embryonic stem cell research without question.
IV. CONCLUSION

The purpose of this Comment is to propose a framework for challenging laws restricting embryonic research. This Comment does not attempt to reach a definitive conclusion as to the constitutionality of particular restrictions, considering such a determination largely depends on the circumstances of a given case. Yet, the foregoing framework indicates that those laws which directly prohibit the techniques necessary to perform embryonic stem cell research, such as somatic cell nuclear transfer or in vitro fertilization, are most susceptible to successful constitutional attack, whereas funding restrictions and other laws that incidentally burden the performance of this research are least susceptible.

While there is substantial support to challenge restrictions of embryonic stem cell research, prospective challengers must be wary of the doctrinal and ideological limitations they might confront should they decide to bring such an action. Over the years, courts have tended to shy away from finding new substantive due process rights or expanding the scope of constitutional protection for those already recognized. The Supreme Court’s abortion cases, in particular, constitute “perhaps the most controversial line of decisions in modern constitutional history.” As such, it is arguable that invoking them is “not a promising point of departure to establish a more general right.” While certain courts may not be so inclined to entertain a theory proposing a broader right to therapeutic medical treatment, the Supreme Court continues to recognize new fundamental rights under substantive due process and relies on prior precedent, including its abortion jurisprudence, to justify such protection.

311 Id. To be sure, according to the cynical observer, the status of therapeutic abortion as a fundamental right seems to rest in Justice Kennedy’s hands for the moment. Compare Carhart I, 530 U.S. 914, 956–57 (2000) (Kennedy, J., dissenting) (arguing that the Nebraska law banning D&X does not constitute an undue burden on the therapeutic abortion right), with Carhart II, 127 S. CT. 1610, 1630–59 (2007)) (holding the same with respect to the Federal Partial Birth Abortion Ban Act of 2003).
In his testimony before the Senate in 2004, Irving Weissman, a prominent embryonic stem cell researcher, warned legislators: “Whoever of you acts to ban this research is responsible for the lives it could save.” Since the suffering of so many hangs in the balance, a careful consideration of legal strategy is recommended, if not required, of prospective challengers to therapeutic research restrictions. Indeed, only if they heed this advice will redress come to those presently being deprived of liberty without due process of law.

313 MOONEY, supra note 3, at 201.