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Cover Page Footnote
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THREE'S COMPANY: A CONSTITUTIONAL ANALYSIS OF PROHIBITING ACCESS TO THREE-PARENT *IN VITRO* FERTILIZATION

J. Ravindra Fernando*

I. Introduction

I belonged to a new underclass, no longer determined by social status or the color of your skin. No, we now have discrimination down to a science.[1]

The 1997 science-fiction film *Gattaca* tells the story of Vincent Freeman, a "God-child," "de-gene-erate," "faith birth." The film unfolds in a not-too-distant future where genetic modification is commonplace and children's characteristics and predispositions are routinely decided before birth. A rarity in this world, Vincent is conceived without any genetic modification and, consequently, is born with myopia and a congenital heart defect. His inferior genetic profile has banished him to a new subclass of society, so the only way to achieve his lifelong dream of becoming an astronaut is by impersonating a "valid"—a person with a healthy, genetically-engineered DNA.[2]

A hypothetical future? Recent developments suggest not. In June of 2013, the United Kingdom drafted regulations that green-light a new genetic technology: three-parent *in vitro* fertilization ("three-parent IVF").[3] Genetic material from an egg's nucleus is transferred into the egg of a second, enucleated egg, and then the resulting, hybrid egg is fertilized.[4] This "pioneering" genetic technique promises to eradicate diseases caused by mitochondrial mutations in cells, such as heart and liver diseases, muscular dystrophy, and respiratory problems.[5] If the British Parliament approves these regulations, the United Kingdom would become the first country in the world to permit this genetic technique.[6]

But with such promise, why do many urge caution?[7] Three-parent IVF is a therapeutic form of human germ line genetic modification

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1. Gattaca (Columbia Pictures Corp. 1998).
2. *See id.*
3. Laura Smith-Spark, *UK Takes Step Toward "Three-Parent Babies,"* CNN.com (June 28, 2013), http://www.cnn.com/2013/06/28/health/uk-health-dna-ivf/index.html.
4. *Id.*; *see also* Part II.A, *infra.*
5. Smith-Spark, *supra* note 3.
6. The British Parliament is scheduled to vote on these regulations in 2014. *Id.*
7. *See, e.g.*, *id.* ("University of Notre Dame law professor O. Carter Snead, a bioethicist, who specializes in the governance of science, medicine and biotechnology,

("HGGM"),[8] a category of genetic modification characterized by manipulation of either the human sex cells or a fertilized egg.[9] If the embryo is brought to term, the genetic modifications are irreversible—they will propagate throughout the rest of that person's hereditary line.

Naturally this rouses the ire of the pro-life movement, which recognizes personhood at the moment of conception.[10] This camp understandably opposes HGGM because it involves the creation, testing, and likely destruction of many embryos.[11] But detractors and supporters of three-parent IVF are not necessarily pro-life and pro-choice, respectively, because HGGM raises ethical questions distinct from those in the abortion debate. As one pro-choice writer warned, "[I]t doesn't, and shouldn't necessarily, follow that any ethical issue raised by the modifi-

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urged the United Kingdom to 'proceed slowly and cautiously' given the 'unresolved safety and ethical questions' around the new technique."); *IVF 'Designer Babies' and "Three-Parent Babies" Raise Serious Ethical Questions*, INFOWARS.COM (July 8, 2013), http://www.infowars.com/ivf-designer-babies-and-three-parent-babies-raise-serious-ethical-questions/; Hilary White, *Stop 'Eugenic' Creation of 3-Parent Embryos: Council of Europe Members to Britain*, LIFESITENEWS.COM (Oct. 28, 2013), http://www.lifesitenews.com/news/stop-eugenic-creation-of-3-parent-embryos-council-of-europe-members-to-brit.

8. Marcy Darnovsky, *A Slippery Slope to Human Germline Modification*, 499 NATURE 127 (2013). The acronym is borrowed, with thanks, from Nancy Pham. *See* Nancy Pham, *Choice v. Chance: The Constitutional Case for Regulating Human Germline Genetic Modification*, 34 HASTINGS CONST. L.Q. 133 (2006).

9. Pham, *supra* note 8, at 134.

10. *See, e.g.*, Rebecca Taylor, *Creation of Human Embryos With Three Parents Facing Massive Opposition*, LIFENEWS.COM (Oct. 27, 2013, 5:38 PM), http://www.lifenews.com/2013/10/27/creation-of-human-embryos-with-three-parents-facing-massive-opposition/; Isobel Losseff, *Three-parent Embryo Technique is 'Unethical and Macabre', Says Pro-Life Group*, CATHOLICHERALD.CO.UK (June 28, 2013), http://www.catholicherald.co.uk/news/2013/06/28/three-parent-embryo-technique-is-unethical-and-macabre-says-pro-life-group/. For a powerful argument that life and personhood begins at the moment of conception, see Maureen L. Condic & Richard John Neuhaus, *When Does Human Life Begin?: A Scientific Perspective*, THE WESTCHESTER INSTITUTE (Oct. 2008), http://bdfund.org/wordpress/wp-content/uploads/2012/06/wi_whitepaper_life_print.pdf.

11. In March 2004, the President's Council on Bioethics released *Reproduction and Responsibility*, a comprehensive report that investigated recent advances in biomedical technology and explored "the ethical and policy questions related to these developments." PRESIDENT'S COUNCIL ON BIOETHICS, REPROD. & RESPONSIBILITY, at xxvii (2004). There, the Council admitted that while embryo research has the potential to benefit millions of lives, it is still connected to a number of basic ethical issues.

> The chief ethical concerns raised by the practice of human embryo research arise from the fact that such research generally necessitates the use and destruction of human embryos. Many people regard embryos as human beings at the earliest stage of life, and thus worthy of the same respect and protections that we afford all human persons. Even among many who do not assign human embryos the moral standing of "full persons," intentional destruction of developing human life is a cause for some ethical disquiet. To regard developing human life as a mere means—even a means to a noble end, such as the alleviation of suffering—presents a moral problem with potentially serious consequences for society as a whole.

Id. at 126–27.

cation of human genetic material is A-OK, part of the pro-choice package."[12]

To begin with, three-parent IVF is a nascent technology. It is still in development, and many children conceived through the procedure could very well suffer health defects.[13] Not only is it difficult to manipulate genetic material with precision, but it is nigh impossible to determine what effects those changes will have.[14] A single modification could cause a ripple effect with destructive consequences.

Moreover, HGGM might alter the parent-child relationship in unhealthy ways.[15] As the products of choice—not chance—children might experience decreased autonomy because "a parent's determination of what constitutes the 'best' characteristics may not be the ideal characteristics for the child."[16] Children might also experience increased pressures to meet parental expectations,[17] and failure to meet those standards might lead the child to suffer damaging psychological effects.[18] Meanwhile, parents might begin to view children resulting from HGGM as "more like products of a designed manufac-

12. Zoe Williams, *Are Three-Parent Babies the First Step Towards a Blade Runner Future?*, THE GUARDIAN (June 28, 2013), http://www.theguardian.com/commentisfree/2013/jun/28/three-parent-babies-blade-runner.

13. Not only could the direct products of three-parent IVF be harmed, but their heirs might be as well. "[T]he impact of tinkering with cells at that level may not be completely evident for years or even generations . . . ." Ariana Eunjung Cha & Sandhya Somashekhar, *FDA Panel Debates Technique that Would Create Embryos with Three Genetic Parents*, WASH. POST (Feb. 25, 2014), http://www.washingtonpost.com/national/health-science/fda-panel-debates-technique-that-would-create-embryos-with-three-genetic-parents/2014/02/25/60371c58-9e4d-11e3-b8d8-94577ff66b28_story.html.

14. HGGM is extremely risky because researchers are still unable to precisely control how they are actually modifying the human genome. *See* Michael J. Reiss, *What Sort of People Do We Want? The Ethics of Changing People Through Genetic Engineering*, 13 NOTRE DAME J.L. ETHICS & PUB. POL'Y 63, 80–81 (1999). As a result, modification might end up damaging the genetic material, leading the born person to suffer from unforeseen diseases or disorders. *Id.* Though improvement in the technology might eventually reduce this concern, many are likely to suffer until then.

15. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 11, at 95 (arguing against practices that might normalize "the idea that a child's particular genetic make-up" lies within the ambit of parental reproductive choice).

16. Sarah M. Markwood, *Creating a Perfect Human Is Not So Perfect: The Case for Restricting Genetic Enhancement Research*, 110 PENN ST. L. REV. 473, 483 (2005) (predicting that this would jeopardize the child's "individual personhood"); *see also* Maxwell J. Mehlman, *How Will We Regulate Genetic Enhancement?*, 34 WAKE FOREST L. REV. 671, 681 (1999) (characterizing personal autonomy as threatened because traits—which will last into adulthood—are foisted upon the child without her consent).

17. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 11, at 96. The President's Council on Bioethics further weighed in on this possible shift in parental perspective:

> The introduction of rigorous genetic screening into childbearing might set a new standard for what counts as an acceptable birth. The attitude of parents toward their child may be subtly shifted from unconditional acceptance toward critical scrutiny: the very first act of parenting could become not the unreserved welcoming of an arriving child, but the judging of his or her fitness, while still an embryo, to become one's child, all by the standards of contemporary genetic screening.

Id. at 98.

18. Markwood, *supra* note 16, at 483. Michael J. Reiss predicts some of the tension between a child resulting from HGGM and her parents:

turing process than 'gifts' whom their parents are prepared to accept as they are."[19]

There are also broader concerns. For one thing, access to modification could artificially increase the "average" level of achievement.

> If a child's intellect could be enhanced through [HGGM], the average level of intellectual capability would continue to increase, genetic enhancement procedures would become increasingly refined, and parents would use the procedures to ensure that their children were at the highest possible level of intellect.[20]

And at the outset, "ordering" a genetically "ideal" child will likely carry a steep price tag.[21] As the average increases, those unable to afford the fruits of HGGM will be left behind, and income inequality may yield to a new achievement inequality. This could magnify social disparity and prejudice between the affluent, genetically-modified rank and the lower-income, naturally-conceived file,[22] eventually ushering in a new era of eugenics.[23]

Current regulation of HGGM is sparse. No federal or state legislation specifically governs this advanced reproductive technology, and federal oversight through the National Institute of Health ("NIH") and

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> [O]ne can imagine arguments between genetically engineered children and their parents, with great unhappiness sometimes resulting: "We didn't pay for you to be musically gifted just to have you spend all your time playing baseball" or "We didn't pay for you to be an outstanding baseball player just to have you spend all your time in a rock band."

Reiss, *supra* note 14, at 85.

19. PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY, at xxix (2002). However, Prof. Sonia M. Suter believes that these concerns are overblown:

> The mere fact that individuals are interested in "improving" the birth of their children does not in and of itself mean that reproduction and the child will be commodified, or worse, that they will be *solely* viewed as a commodity. Simply because parents try to control the outcome of reproduction, rather than to allow things to happen "naturally," does not preclude them from viewing their children as a gift.

Sonia M. Suter, *A Brave New World of Designer Babies?*, 22 BERKELEY TECH. L.J. 897, 961 (2007) [hereinafter Suter, *A Brave New World*].

20. Markwood, *supra* note 16, at 484 (citing Cynthia B. Cohen & LeRoy Walters, *Gene Transfer for Therapy or Enhancement*, *in* A CHRISTIAN RESPONSE TO NEW GENETICS 68 (David B. Smith & Cynthia B. Cohen eds., 2003)).

21. Even *in vitro* fertilization—which has been available for decades—is still out of reach for many Americans. The American Society of Reproductive Medicine lists the average price of an IVF cycle at $12,400, and this cost is usually not covered by insurance. *The Costs of Infertility Treatment*, RESOLVE: THE NATIONAL INFERTILITY ASSOCIATION, http://www.resolve.org/family-building-options/insurance_coverage/the-costs-of-infertility-treatment.html.

22. *See* Mehlman, *supra* note 16, at 687 ("[U]nequal access to genetic enhancement will divide society into the enhanced and the un-enhanced. Germ cell enhancement will perpetuate enhancements from generation to generation, creating a hereditary aristocracy or 'genobility.'").

23. *See, e.g.*, Markwood, *supra* note 16, at 485–86. However, not all necessarily see this as undesirable. *See* Suter, *A Brave New World*, *supra* note 19, at 898 (distinguishing what Prof. Suter calls "neoeugenics"—the use of reproductive technologies to create "good births"—from the horrors of classic eugenics).

the Food and Drug Administration ("FDA") is limited.[24] Of these, the FDA's regulatory power is relatively more potent[25] because developers of HGGM techniques must receive the FDA's approval, a process that includes searching review of the method's safety and efficacy as well as satisfactory completion of human trials.[26]

Furthermore, approval of three-parent IVF in the United States appears imminent as researchers place increasing pressure on the FDA.[27] In October 2013 the FDA met in Silver Spring, Maryland to discuss the ethical, health, and safety issues implicated by three-parent IVF.[28] And in February 2014 an FDA panel considered whether to allow researchers to proceed with human trials.[29]

Given the lack of meaningful regulation and escalating pressure, Congress cannot remain silent for long—it must decide both whether and how to regulate HGGM. And when it does, one option is to prohibit access to both therapeutic and non-therapeutic HGGM.[30] Assuming that such legislation has passed, this Note looks ahead to the inevitable constitutionality challenges. It asserts that courts should (1) analyze a right of access to HGGM as a substantive due process right; (2) review the legislation under the rational basis test; and (3) uphold the restriction.[31] Part II provides background information on the relevant reproductive techniques and reviews the legal framework for judicial review. Part III (1) argues that a right of access to HGGM finds its strongest support in the doctrine of substantive due process; and (2)

24. PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 11, at 110; *Germline Gene Transfer*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (Mar. 2006), http://www.genome.gov/10004764.

25. Operating within the NIH is the Recombinant DNA Advisory Council (RAC), which considers the ethical implications of novel genetic modification techniques. The RAC, which makes recommendations to the NIH's director about which genetic modification methods should receive federal funding, has "ruled it would not evaluate germ-line engineering proposals and would only consider approving proposals that involved somatic gene engineering." Markwood, *supra* note 16, at 479; *see also* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 11, at 114–16. However, this control is worth little because researchers can be privately funded. Markwood, *supra* note 16, at 479.

26. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 11, at 112.

27. Erika Check Hayden, *Regulators Weigh Benefits of 'Three-Parent' Fertilization*, 502 NATURE 284, 284 (2013). As a practical matter, though, three-parent IVF is still in its infancy—Mitalipov detected genetic abnormalities in about half of the created embryos. *Id.*

28. *Id.*

29. Cha & Somashekar, *supra* note 13.

30. This Note does not delve into whether Congress has authority to pass such legislation. But all indications are that this prohibition would likely be upheld as a constitutional exercise of the Commerce Clause power. *See* Jason C. Glahn, *I Teach You the Superman: Why Congress Cannot Constitutionally Prohibit Genetic Modification*, 25 WHITTIER L. REV. 409, 422–23 (2003).

31. Though others have discussed the constitutionality of a prohibition on HGGM, this Note more forcefully advocates a certain mode of analysis and a particular result. In contrast, Nancy Pham's thoughtful article considers what the Court is *likely* to do but takes no position on what the Court *should* do. *See* Pham, *supra* note 8; *compare id.* at 148 (concluding that a prohibition on non-therapeutic HGGM is most likely to survive a constitutionality challenge) *with* Glahn, *supra* note 30, at 411 (arguing that the Constitution protects access to both therapeutic and non-therapeutic HGGM).

charts the proper analysis. Applying this analysis, Part IV then concludes that the hypothetical legislation should be upheld because there is no fundamental right of access to HGGM. Finally, Part V concludes.

I. Background

A. *Human Germ Line Genetic Modification (HGGM)*

We humans are considered multicellular eukaryotes because our bodies are composed of trillions of cells, each cell housing a nucleus with our genetic material.[32] These cells are grouped into two primary categories: somatic cells, which form body parts and organs; and germ cells (gametes), which are reproductive cells—in humans, egg and sperm cells.[33] Both types of cells contain a variety of organelles, or structures that allow the cell to survive and carry on the processes of life.[34] One such organelle is the mitochondrion, which is known as a "miniature power plant" because it uses oxygen to break down substances and create energy for the cell.[35]

Somatic and germ cells store most genetic material within the nucleus.[36] There, deoxyribonucleic acid ("DNA") is gathered into tightly-packed bunches known as chromosomes.[37] Generally, the number of chromosomes is the same for all somatic cells in each organism of a species—for instance, all human somatic cells contain forty-six chromosomes.[38] An organism's germ cells typically contain half the number of chromosomes as the somatic cells—in humans, twenty-three.[39] Thus, when two germ cells (i.e., the sperm and the egg) combine in the process of fertilization, the resultant cell—called a zygote[40]—has that organism's required number of chromosomes. This zygote is neither a somatic nor germ cell; it remains an undifferentiated, totipotent cell—or, once it divides, a clump of totipotent cells called an embryo—for several weeks into pregnancy.[41] But while an

32. *See* Elaine Johansen Mange & Arthur P. Mange, Basic Human Genetics 16–17 (2d ed. 1999).

33. *Id.* at 17.

34. *Id.* Organelles comprise cells; cells comprise organs; organs comprise organ systems; organ systems comprise the human body.

35. *See id.*

36. *See id.* at 16.

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.* at 34.

41. *See* President's Council on Bioethics, Monitoring Stem Cell Research: A Report of the President's Council on Bioethics 157–80 (2004). Some maintain that a zygote should not be considered an embryo until at least one cell division has occurred. *See, e.g.*, J.K. Findlay et al., *Human Embryo: A Biological Definition*, 22 Human Reprod. 905 (2007). Yet Maureen Condic has presented strong evidence that accepted scientific conventions demand that a zygote be considered an embryo from the moment of fertilization. *See* Maureen L. Condic, *When Does Human Life Begin? The Scientific Evidence and Terminology Revisited*, 8 U. St. Thomas J.L. & Pub. Pol'y 44 (2013) (arguing that the zygote is a unicellular human embryo—a viable human life).

organism's nuclear DNA is a combination of its parents' germ cell DNA, that organism's mitochondrial DNA is not.

Compared to all other organelles, mitochondria are unique in that they contain a small amount of their own genetic material[42] called mitochondrial DNA ("mtDNA").[43] All mtDNA in an embryo comes from the egg only—though the tail section of sperm cells contain mitochondria, the father's mtDNA is excluded during the zygote's formation.[44] In other words, individuals inherit mtDNA directly—and exclusively—from their mothers.[45]

Mutations in either nuclear or mitochondrial DNA can lead to disease,[46] and certain mutations can be passed on to offspring. Accordingly, there has recently been an explosion in research on genetic modification, or gene therapy, which promises to treat these inherited and acquired diseases.[47] The underlying principle is simple: to "introduce into target cells a piece of ['fixed'] genetic material that will result in either a cure for the disease or a slowdown in the progression of the disease."[48] Rather than alleviating the symptoms or damage of the genetic disease, gene therapy seeks to cure the basic defect.[49]

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42. NEIL A. CAMPBELL & JANE B. REECE, BIOLOGY 124 (6th ed. 2002). A single cell contains many mitochondria, and each mitochondrion may house dozens of copies of its own DNA. Heidi Chial & Joanna Craig, *mtDNA and Mitochondrial Diseases*, NATURE (2008), http://www.nature.com/scitable/topicpage/mtdna-and-mitochondrial-diseases-903.

43. *Mitochondrial DNA*, GENETICS HOME REFERENCE (May 2013), http://ghr.nlm.nih.gov/mitochondrial-dna. One of the leading theories for mitochondrial DNA was first advanced by Russian biologist C. Mereschkovsky. He theorized that mitochondria were originally bacteria living within single-celled organisms. The bacteria probably entered the cell first as undigested prey or as internal parasites, but over time the two formed a symbiotic relationship. *See* CAMPBELL & REECE, *supra* note 42, at 549–50.

44. MANGE & MANGE, *supra* note 32, at 262.

45. Chial & Craig, *supra* note 42.

46. *See, e.g.*, Jordan S. Orange et al., *Human Disease Resulting from Gene Mutations that Interfere with Appropriate Nuclear Factor-kB Activation*, 203 IMMUNOLOGICAL REVIEWS 21 (2005) (nuclear DNA disease); Robert W. Taylor & Doug M. Turnbull, *Mitochondrial DNA Mutations in Human Disease*, 6 NATURE REVIEWS 389, 389 (2005) (mitochondrial DNA disease). Note that most diseases are caused by polygenic mutations—mutations in more than one gene. But there are a handful of genetic diseases that are caused by a single mutation on the chromosome. Chial & Craig, *supra* note 42. For a non-exhaustive list of nuclear genetic disorders, see *Genetic Disease Related Diseases & Conditions*, MEDICINENET.COM, http://www.medicinenet.com/genetic_disease/related-conditions/index.htm. A list of known mitochondrial diseases can be found at *Conditions Related to Mitochondrial Genes*, GENETICS HOME REFERENCE (May 2013), http://ghr.nlm.nih.gov/mitochondrial-dna/show/Conditions.

47. Inder M. Verma & Matthew D. Weitzman, *Gene Therapy: Twenty-First Century Medicine*, 74 ANNU. REV. BIOCHEMISTRY 711, 711 (2005).

48. *Id.* at 712. Introducing genetic material occurs through the use of vectors—delivery "vehicles" which ferry snippets of genetic material into a strain of DNA. *Id.*; *Gene Delivery: Tools of the Trade*, LEARN.GENETICS, http://learn.genetics.utah.edu/content/genetherapy/gttools/ (last visited Sept. 20, 2014). Along with identifying the genes that are responsible for various traits and diseases, one of the largest challenges to widespread use of HGGM is the development of safe, effective vectors. Verma & Weitzman, *supra* note 47, at 712.

49. MANGE & MANGE, *supra* note 32, at 443.

Corresponding to the two types of cells, there are two types of genetic modification: somatic and germ line modification.[50] The former, which naturally involves manipulation of somatic cells, affects only the modified cells and any other cells that descend from them.[51] Thus, somatic gene therapy is noninheritable: "A recipient does not pass the genetic correction to offspring."[52] Contrast human germ line genetic modification (HGGM), where the DNA of a germ cell or fertilized ovum is altered. The *defining characteristic* of germ line modification is that any changes made to the DNA are passed to offspring.[53]

Germ line genetic modification can be further subdivided into therapeutic modification and non-therapeutic modification. Therapeutic genetic modification refers to any alteration of the human genome that is intended to eliminate negative traits such as genetic abnormalities and disease.[54] Non-therapeutic genetic modification would include any other use of gene-altering technology,[55] including enhancement modifications that add helpful traits like improved intelligence or athleticism.[56]

Abnormalities in mtDNA are associated with certain heritable diseases, affecting an estimated one in four thousand children.[57] Though rare, these diseases can often be fatal.[58] And if a mother's mitochondria carry the mutation, then her offspring will certainly receive it.[59]

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50. *Id.*

51. RICKI LEWIS, HUMAN GENETICS: CONCEPTS AND APPLICATIONS 402 (8th ed. 2008).

52. *Id.* at 395.

53. *Id.*; Maxine F. Singer, *Genetics and the Law: A Scientist's View*, 3 YALE L. & POL'Y REV. 315, 329 (1985) ("A critical difference between them is that changes made in germline manipulation will be passed on to future generations while somatic changes are lost when the recipient individual dies.").

54. Pham, *supra* note 8, at 148.

55. *Id.* The National Institute of Health (NIH) sheds further light on the concept of genetic enhancement:

> In general, genetic enhancement refers to the transfer of genetic material intended to modify nonpathological [non-disease-related] human traits. The term commonly is used to describe efforts to make someone not just well, but better than well, by optimizing attributes or capabilities—perhaps by raising an individual from standard to peak levels of performance.

Genetic Enhancement, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (2006), http://www.genome.gov/10004767.

56. Pham, *supra* note 8, at 148; *see also Genetic Enhancement*, *supra* note 55 ("[G]enetic enhancement refers to the transfer of genetic material intended to modify nonpathological human traits. The term commonly is used to describe efforts to make someone not just well, but better than well, by optimizing attributes or capabilities.").

57. David Cyranoski, *DNA-Swap Technology Almost Ready for Fertility Clinic*, NATURE (Oct. 24, 2012), http://www.nature.com/doifinder/10.1038/nature.2012.11651. Note, though, that both mitochondrial and nuclear DNA can be mutated through the process of cell division. However, this natural mutation is 100 times more likely for mtDNA than for nuclear DNA. Moreover, it is typically not passed on to offspring. Chial & Craig, *supra* note 42.

58. Cyranoski, *supra* note 57.

59. In humans, mtDNA is always inherited from a person's mother. Chial & Craig, *supra* note 42.

Researchers developed three-parent *in vitro* fertilization ("three-parent IVF"), a form of therapeutic HGGM,[60] to eliminate these defects.[61] The principle is simple: increase the number of healthy pregnancies by replacing defective egg cell mitochondria with healthy mitochondria.[62] This has been accomplished with at least two different techniques.[63]

The first technique begins with two unfertilized eggs—one with mutated mitochondria and one with healthy mitochondria. First, the egg with mutated mitochondria is enucleated—its nucleus, which contains that mother's nuclear DNA, is removed. Along with its abnormal mtDNA, the cell remainder is destroyed. Second, an unfertilized egg with healthy mitochondria is enucleated. Here, though, the nucleus is destroyed and the cell remainder, including the healthy mtDNA, is retained. Third, the nucleus from the first cell is inserted into the remains of the second cell. This produces a unique cell housing the genetic material from two mothers: the nuclear DNA of the first mother and the mtDNA of the second mother. Fourth, the hybrid egg cell is fertilized with sperm, contributing the genetic material of a third parent. Finally, since all prior steps are conducted *in vitro*, the fertilized zygote is implanted in a woman's uterine wall.[64]

The second method is similar but *begins* with fertilization of both eggs (one egg with mutated mitochondria and one egg with healthy mitochondria). Next, the embryo with healthy mitochondria is enucleated, and the nucleus is destroyed. Then the embryo with mutated mitochondria is enucleated, the nucleus is retained, and the embryo remains and mtDNA is destroyed. After that, the retained nucleus is inserted into the remains of the embryo with healthy mitochondria. Again, the procedure ends when the composite embryo is implanted in a woman's uterine wall.[65]

A team led by Shoukhrat Mitalipov, a reproductive biologist at Oregon Health and Science University in Beaverton, has already used the first technique to create healthy rhesus monkeys.[66] Tracked throughout their lives, these monkeys exhibited no long-term health issues.[67] Mitalipov's team has also begun researching the use of three-parent IVF to create viable human embryos.[68] Initial results are less than promis-

60. Darnovsky, *supra* note 8, at 127.

61. Smith-Spark, *supra* note 3.

62. Cyranoski, *supra* note 57.

63. *See* James Gallagher, *Three-Person Babies "In Two Years" – Says Science Review*, BBC NEWS (June 3, 2014, 8:11 AM), http://www.bbc.com/news/health-27678464.

64. *See* Cyranoski, *supra* note 57; Gallagher, *supra* note 63.

65. *See* Gallagher, *supra* note 63. This method raises even more ethical issues than the first because it involves the creation and destruction of two viable embryos.

66. Cyranoski, *supra* note 57.

67. *Id.*

68. David Cryanoski explains that though the research is not currently conducted with public funds, three-parent IVF might change this:

> The US National Institutes [sic.] of Health (NIH) restricts funding for research that destroys human embryos, so Mitalipov had to do his work with money from private sources, and in a "mirror laboratory" that shared no resources with his NIH-funded research. However, work in the clinic will create eggs that are not

ing, though—half of the fertilized hybrid egg cells were unfit for implantation.[69]

Seeking to refine the technique, Mitalipov has led the charge for clinical trials of three-parent IVF in the United States.[70] Approval for these trials must come from the U.S. Food and Drug Administration (FDA), which has asserted authority over reproductive technology research.[71] In January of 2013, Mitalipov submitted an application seeking this approval, but he has thus far been met with silence. Says Mitalipov, "The ball is on their side of the court. We just want their guidance. Unfortunately the patients are waiting."[72]

B. *The Legal Framework for Judicial Review*

The Bill of Rights entitles individuals to certain protections. In addition to the rights expressly protected, the Supreme Court has recognized that there are unenumerated, yet equally fundamental, rights protected by the Constitution.[73] Through the power of judicial review, courts can, under certain circumstances, strike down legislation that impermissibly violates those rights.[74] Thus, courts must carefully consider whether the challenged regulation burdens an express or unenumerated right. The significance of this threshold issue cannot be overstated because it affects the level of scrutiny that courts apply. Fundamental rights are not absolute; they can be burdened by government action. But if so, courts review the constitutionality of that action under a more rigorous standard of review.

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meant to be destroyed, so might be eligible for public money. "Now the questions is: will the NIH fund the clinical research?" asks a somewhat exasperated Mitalipov.

Id.

69. *Id.* It is unclear why this is so. Mitalipov hypothesizes that as compared to rhesus monkeys, human germ cells are more "sensitive" and that the problem may be caused by "incomplete meiosis," a faulty splitting of the cells. He is currently working to alleviate this problem. *Id.*

70. *Id.*

71. B. Jason Erb outlines the basis of the FDA's authority over reproductive technologies:

> On January 20, 1998, in response to the potential physical risks to women and children, the Food and Drug Administration (FDA) announced its intentions to regulate human cloning under section 351 of the Public Health and Service Act (PHSA). . . . The FDA proposal to regulate cell and tissue-based products was intended to: (1) prevent the use of contaminated tissue; (2) prevent mishandling that might contaminate the tissue; and (3) ensure clinical safety for tissue that is more than minimally manipulated.

B. Jason Erb, *Deconstructing the Human Egg: The FDA's Regulation of Scientifically Created Babies*, 5 ROGER WILLIAMS U. L. REV. 273, 274–75 (1999) (citing Rick Weiss, *Human Clone Research Will be Regulated*, WASH. POST, Jan. 20, 1998; FOOD AND DRUG ADMINISTRATION, PROPOSED APPROACH TO REGULATION OF CELLULAR AND TISSUE-BASED PRODUCTS 6 (1997)).

72. Cyranoski, *supra* note 57.

73. GREGORY E. MAGGS & PETER J. SMITH, CONSTITUTIONAL LAW: A CONTEMPORARY APPROACH 615–16 (2d ed. 2011).

74. *Id.* at 102; *see, e.g.*, Griswold v. Connecticut, 381 U.S. 479 (1965) (striking down a Connecticut law which forbade the use of contraceptives because the law violated substantive due process under the 14th Amendment).

Courts generally apply one of three levels of scrutiny when deciding issues of constitutionality. The most deferential standard is rational basis review—"legislation is presumed to be valid and will be sustained" if it is "rationally related to a legitimate state interest."[75] Legislation subjected to this standard is all but certain to be held constitutional.[76] Intermediate scrutiny, the second standard, is usually limited to challenges that invoke the Fourteenth Amendment's Equal Protection Clause.[77] Here there is no colorable Equal Protection argument for a right of access to HGGM, so courts should not apply intermediate scrutiny. Strict scrutiny, the third and most demanding standard of judicial review, is triggered when courts identify a "fundamental right" that is burdened.[78] In order to pass constitutional muster, the government action or regulation must meet three requirements. First, it must serve a "compelling governmental interest"; second, it must be "narrowly tailored" to further that interest; and third, it must be the "least restrictive means" for achieving that interest.[79] Conventional wisdom has it that strict scrutiny is "strict in theory and fatal in fact,"[80] and, even though some have challenged this adage,[81] there is no denying it: when challenged government action is subjected to rational basis rather than strict scrutiny, it is far more likely to survive.

Thus, the constitutionality of prohibiting access to therapeutic and non-therapeutic HGGM hinges, in large part, on whether courts are to

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75. City of Cleburne v. Cleburne Living Ctr., 473 U.S. 432, 440 (1985).

76. MAGGS & SMITH, *supra* note 73, at 528–29 ("[Rational basis] is a highly deferential form of review, and it virtually always results in a conclusion that the challenged regulation is valid."). This is grounded in courts' reluctance to "'substitute their social and economic beliefs for the judgment of legislative bodies, who are elected to pass laws,' regardless of whether the laws are 'wise or unwise.'" *Id.* at 529 (quoting Ferguson v. Skrupa, 372 U.S. 726, 730–32 (1963)).

77. Professors Gregory E. Maggs and Peter J. Smith explain intermediate scrutiny:

> Government decisions that classify on the basis of gender are subject to intermediate scrutiny. This level of scrutiny requires a justification that is "exceedingly persuasive" and will be upheld only if the government can demonstrate that "the [challenged] classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives."

MAGGS & SMITH, *supra* note 73, at 777 (quoting United States v. Virginia, 518 U.S. 515, 516 (1996)).

78. *See, e.g.*, Roe v. Wade, 410 U.S. 113, 155–56 (1973); Griswold v. Connecticut, 381 U.S. 479, 503–04 (1965) (citing Skinner v. Oklahoma, 316 U.S. 535, 541 (1942)). Strict scrutiny is also triggered when government action applies to a "suspect classification," such as laws that discriminate on the basis of race or national origin. MAGGS & SMITH, *supra* note 73, at 776 (citing Hunter v. Underwood, 471 U.S. 222 (1985)).

79. *See Roe*, 410 U.S. at 155–56 ("Where certain 'fundamental rights' are involved, the Court has held that regulation limiting these rights may be justified only by a 'compelling state interest,' . . . and that legislative enactments must be narrowly drawn to express only the legitimate state interests at stake.").

80. Gerald Gunther, *The Supreme Court, 1971 Term—Foreword: In Search of Evolving Doctrine on a Changing Court: A Model for a Newer Equal Protection*, 86 HARV. L. REV. 1, 8 (1972).

81. Adam Winkler, *Fatal in Theory and Strict in Fact: An Empirical Analysis of Strict Scrutiny in the Federal Courts*, 59 VAND. L. REV. 793, 797 (2006) (calling this a "popular myth" because "laws can (and do) survive strict scrutiny with considerable frequency").

review it under rational basis review or strict scrutiny.[82] And this, in turn, depends on whether there is a "fundamental right" of access to this technology. Legislation that prohibits therapeutic and non-therapeutic HGGM affects too broad a swath of activity to be considered "narrowly tailored." So if a court holds that a fundamental right is burdened, then the legislation likely will not pass strict scrutiny. On the flip side, many "legitimate state interests" are conceivably furthered by restricting access to HGGM.[83] Hence, if a court finds no fundamental right encumbered, then the legislation will presumably be upheld.[84]

II. Substantive Due Process and the Right to Genetically Modify

A. *Human Germ Cells*

Those challenging a prohibition on access to HGGM must establish that the legislation deprives them of a fundamental right, a right that might be predicated on a number of bases. One potential source of the right is the First Amendment's protection of free speech.[85] But

82. Indeed, this finding triggers a presumption that is, in truth, more-or-less dispositive:

> [I]f the claimed right ranks as fundamental, courts will apply some form of heightened scrutiny and insist upon a demonstration of exceptional public need for the incursion. By contrast, if the burdened interest is classified merely as an ordinary or non-fundamental aspect of liberty, the state's incursion is presumed to be constitutional, subject only to the minimal demands of rational basis review.

David D. Meyer, *Domesticating Lawrence*, U. Chi. Legal F. 453, 456 (2004) (citation omitted).

83. *See* Pham, *supra* note 8, at 146–49 (insisting that the compelling state interests furthered by a blanket prohibition on HGGM include protection of the physical and psychological health of children and preserving the sanctity of life); Markwood, *supra* note 16, at 489–91 (asserting that regulation of genetic enhancement serves compelling government interests because the technology threatens harm to individual children as well as our society's democratic values at large); Amber Stine, *The Implications of the Due Process Clause on the Future of Human Embryonic Gene Therapy*, 45 Ariz. L. Rev. 507, 525 (2003) (citations omitted) ("There is probably a compelling state interest in preserving genetic diversity given the Court's prior decisions indicating that a state interest in the unborn can be compelling and given authoritative statements that a decrease in the gene pool may interfere with human adaptability to the environment"); *but see* Glahn, *supra* note 30, at 425 (citations omitted) (admitting that a prohibition on genetic modification could serve legitimate government interests like the "desire to ensure genetic diversity" and "the desire to preserve an egalitarian society devoid of a genetic gap between the rich and the poor," but rejecting that these interests are "compelling"). With regard to the genetic diversity interest, Amber Stine believes that while a ban on non-therapeutic HGGM would be rationally related to this interest, a ban on therapeutic HGGM would not. However, this view purports to know what traits will be necessary to survival in the future. The Earth's environment could change dramatically, and some genetic aberrations that cau se disease today may be useful to survival in the future. Rather than pretend that we can separate the necessary from unnecessary genetic modifications, courts should err on the side of caution: they should rule that a prohibition on both therapeutic and non-therapeutic HGGM is rationally related to preserving genetic diversity.

84. Pham, *supra* note 8, at 142 ("[Rational basis] is a very deferential standard which merely questions whether a law is irrational or arbitrary.").

85. *See, e.g.*, Wilson Huhn, *Three Legal Frameworks for Regulating Genetic Technology*, 19 J. Contemp. Health L. & Pol'y 1, 21–22 (2003); *but see* Glahn, *supra* note 30, at 424–25.

even those who reject restrictions on access to HGGM as unconstitutional admit that the First Amendment is a fragile peg on which to hang constitutional protection.[86] Because a right of access to HGGM fails the relevant free speech tests, and because compelling policy reasons counsel against extending free speech protection to cover this scientific research, the First Amendment is a poor source of cover.[87] Therefore, this Note studies two other bases for a constitutionally-protected right of access to HGGM: the Ninth[88] and Fifth/Fourteenth Amendments.[89]

B. *The Ninth Amendment*

One argument justifying access to HGGM is that it is protected by the Ninth Amendment,[90] which states: "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people."[91] In *Griswold v. Connecticut*,[92] Justice Goldberg famously wrote that "[t]he language and history of the Ninth Amendment"—in addition to its text—reveal that it protects certain rights that are fundamental yet unenumerated.[93]

But the Ninth Amendment is the sentinel, not the sire, of these rights. In the same opinion Justice Goldberg explicitly rejected the notion that the Ninth Amendment "constitutes an independent source of rights."[94] Instead, the provision "simply shows the intent of the Constitution's authors that other fundamental personal rights should not be denied such protection or disparaged in any other way simply because they are not specifically listed in the first eight constitutional

86. *See* Glahn, *supra* note 30, at 424–25.

87. Jason C. Glahn presents two primary reasons. For one thing, the right to genetically modify germ lines solely for that purpose would become subordinate to the pursuit of scientific knowledge. This would send the message that the "state consider[ed] the resultant children merely a means to an end"—that end being the advancement of scientific knowledge. Additionally, notes Glahn, "it would seem odd for the state to deem a right to scientific experiment more important or fundamental than the right of parents to raise their children." *Id.* at 426.

88. *See id.* at 434–38.

89. *Id.*; *see also* Lawrence Wu, *Family Planning Through Human Cloning: Is There a Fundamental Right?*, 98 COLUM. L. REV. 1461, 1463 (1998) (arguing that procreation through human cloning, which raises issues similar to HGGM, is a substantive due process right for married couples).

90. Glahn, *supra* note 30, at 435–38.

91. U.S. CONST. amend. IX.

92. Griswold v. Connecticut, 381 U.S. 479, 487 (1965).

93. *Id.* at 488 (Goldberg, J., concurring). The constitutional protection of unenumerated rights is contested, but Peter J. Smith provides some support for the proposition. First, "there is little dispute that the First Amendment's explicit protections—for speech, religion, and so forth—also imply the existence of a 'freedom of association,' even though the Amendment nowhere mentions such a right." Additionally, most of the provisions that grant express rights are framed at "very high levels of generality," presuming that judicial interpretation will derive secondary rights from them. As an example, Smith cites interpretation of the Due Process Clause to require that the government prove criminal charges "beyond a reasonable doubt." Finally, he notes, the Fourteenth Amendment reference to privileges and the structure of federalism both imply certain restraints on government action that are not explicitly acknowledged within the Constitution. MAGGS & SMITH, *supra* note 73, at 615–16.

94. *Griswold*, 381 U.S. at 492 (Goldberg, J., concurring).

amendments."[95] This interpretation is consistent with the majority opinion in *Roe v. Wade*.[96] There, the Northern District of Texas believed that the unenumerated right of privacy was founded in the Ninth Amendment.[97] But Justice Blackmun, writing on behalf of the majority in *Roe*, decided instead that this right inhered "in the Fourteenth Amendment's concept of personal liberty"[98]—in other words, the Fourteenth Amendment implied the existence of a right while the Ninth Amendment expressly protected that right.

This distinction undermines any argument that the Ninth Amendment provides freestanding protection to a right of access to HGGM.[99] These arguments rely on a faulty premise: the Ninth Amendment protects some "natural" individual rights that do not necessarily inhere in the Bill of Rights.[100] For reasons above, however, this understanding is at odds with *Griswold* and *Roe*, which reveal that unenumerated rights must find basis outside of the Ninth Amendment. Moreover, accepting this premise would lay far more power in the hands of unelected judges. However tenuous the history and tradition analysis is, it at least anchors constitutional interpretation in some earth; the Ninth Amendment premise, though, severs the anchor line and sets the boat adrift. Under guise of interpreting the "natural" rights protected by the Ninth Amendment, judges could essentially write constitutional law. Hence, to jettison the history and tradition analysis is to multiply judicial discretion. Absent more consistent agreement on which—if any—unenumerated rights the Ninth Amendment protects, courts should adopt the narrower approach advocated by Justice Goldberg in *Griswold*.

Alternatively, some have proposed a broader interpretation of the Ninth Amendment that would protect the right to engage in any activity that does not violate the harm principle.[101] The harm principle states that "the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant."[102] Because the Ninth Amendment should be "viewed as protecting individual actions that do not pose a threat of harm to oneself or to others," the argument goes, access to HGGM should be protected.[103] However, even this broad reading does not sustain a right of

95. *Id.*

96. 410 U.S. 113 (1973).

97. Roe v. Wade, 314 F. Supp. 1217 (N.D. Tex. 1970).

98. *Roe*, 410 U.S. at 153.

99. *See, e.g.*, Glahn, *supra* note 30.

100. Glahn, *supra* note 30, at 434 (citations omitted); *but see* Eric M. Axler, Note, *The Power of the Preamble and the Ninth Amendment: The Restoration of the People's Unenumerated Rights*, 24 SETON HALL LEGIS. J. 431, 469–71 (2000) (arguing persuasively that, in addition to rights inherent to the Bill of Rights, the Ninth Amendment was originally intended to protect Lockian natural law rights, which were mentioned in the Declaration of Independence's Preamble).

101. *See* Chase J. Sanders, *Ninth Life: An Interpretive Theory of the Ninth Amendment*, 69 IND. L.J. 759, 806–17 (1994); *see also* Glahn, *supra* note 30, at 435–38.

102. Glahn, *supra* note 30, at 436 n.132 (citation omitted).

103. *Id.* at 437; *see also* Sanders, *supra* note 101, at 806–17.

access to HGGM. According to Chase J. Sanders, "the Ninth Amendment protects the right to engage in any activity which entails no threat of substantive *physical* or *economic* harm to either the actor or others."[104] But genetic modification of the human germ line raises ethical issues—such as unforeseen diseases and increased income inequality—that directly implicate physical and economic harm to the human population, regardless of whether the technology has been perfected or not.[105] Hence, a right of access to HGGM violates the harm principle and cannot be supported by this understanding of the Ninth Amendment.

C. *Alternative Standards of Review*

In addition to the traditional, three-tiered judicial review—comprised of rational basis, intermediate scrutiny, and strict scrutiny[106]—the Supreme Court has employed other standards in its substantive due process analysis. This makes it difficult to pinpoint which might be used.[107] One option is *Planned Parenthood v. Casey*'s "undue burden" standard.[108] The Court explained that an "undue burden" exists when "a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus."[109] On its face this standard seems limited to government restraints on women seeking abortions. Yet, some argue that "access to HGGM [is] a right on par with the right to abortion" because both implicate pre-viability decision-making ability.[110]

Nancy Pham responds that "the language of the Court's decisions to date casts doubt on whether it would equate the two rights."[111] In addition to procreative liberty, she emphasizes that *Roe* and *Casey* were decided on the principle of "bodily integrity."[112] On this basis, Pham distinguishes access to abortion and access to HGGM:

> Unlike the right to abortion, without which a woman would bear the burden of physically carrying her child to term, a woman who chooses HGGM would already have made the decision to bear the burden of physically carrying her child to term. Since HGGM raises no bodily integrity issue, the Supreme Court has less rationale for categorizing access to HGGM as a fundamental right.[113]

104. Sanders, *supra* note 101, at 806 (emphasis added) (citations omitted).

105. *See supra* text accompanying notes 13–22.

106. *See supra*, Part II.B.

107. Pham, *supra* note 8, at 143.

108. Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 874 (1992) ("Only where state regulation imposes an undue burden on a woman's ability to make this decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause.").

109. *Id.* at 877.

110. Pham, *supra* note 8, at 143.

111. *Id.* at 144.

112. *Id.* at 139 (citing *Casey*, 505 U.S. at 857); *see also*, LAURENCE H. TRIBE & MICHAEL C. DORF, ON READING THE CONSTITUTION 73–112 (1991).

113. Pham, *supra* note 8, at 139.

However, Pham gives relatively short shrift to procreative liberty, which arguably does far more work in *Casey*.[114] The reaffirmation of *Roe* lays on a key premise: that in pregnancy, "the *liberty* of the woman is at stake in a sense unique to the human condition and so unique to the law."[115] The woman's place is unique, the Court reasoned, because she alone deals with the physical and emotional consequences of pregnancy.[116] The subtext here is that the state deprives a pregnant woman of the *liberty* to decide whether or not she wants to bear these consequences when it places restrictions on access to abortion.

Prior to *Casey*—specifically, in *Roe*—the Court engaged in classic substantive due process analysis and reviewed these restrictions under strict scrutiny. This form of review is government-centric, examining restrictions on "fundamental rights" relative to legitimate government interests.[117] In contrast, the "undue burden" standard requires courts to analyze government restrictions from the point of view of a woman seeking an abortion. This standard requires courts to strike down legislation that places any "substantial obstacle" between a woman and access to abortion.[118] So, because the *Casey* plurality viewed pregnancy as *divesting* women of liberty, it forged a more exacting standard of review to return some liberty to those women.

This rationale is inapposite to a right of access to HGGM. The parent or couple seeking to genetically modify their germ line is totally unlike the pregnant mother in *Casey*, who is forced to "confront[ ] the reality that, perhaps despite her attempts to avoid it, she has become pregnant."[119] The "undue burden" test at least returns some liberty to pregnant mothers facing these deep "personal decisions."[120] But those seeking access to HGGM have had time to ponder whether to have a child—a decision fully within their control and one that entails no loss of liberty. Thus, courts should not analyze restrictions on access to HGGM under the "undue burden" standard.[121]

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114. *See, e.g.*, *Casey*, 505 U.S. at 846 ("[The Due Process Clause] declares that no State shall 'deprive any person of life, liberty, or property, without due process of law.' The controlling word . . . before us is 'liberty.'"). Emphasis on the ineluctable concept of "liberty" is also evident in Justice Kennedy's well-known "mystery passage": "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life." *Id.* at 851.

115. *Id.* at 852 (emphasis added).

116. *See id.* ("The mother who carries a child to full term is subject to anxieties, to physical constraints, to pain that only she must bear.").

117. *See supra* text accompanying notes 78–81.

118. *Casey*, 505 U.S. at 877.

119. *Id.* at 853.

120. *Id.*

121. This undermines Amber Stine's argument that a ban on therapeutic HGGM would violate substantive due process. *See* Stine, *supra* note 83, at 529. She asserts,

> A total ban on therapeutic gene therapy would likely constitute an undue burden on reproductive liberties because it would result in the government dictating to individual's [sic] that if they are to have children, they must bear an afflicted child with all of the accompanying the [sic] emotional, physical, and financial hardships associated with a special needs child.

Id. Because the "undue burden" standard should not be applied to restrictions on access to HGGM, Stine's argument fails.

The second option for judicial review finds support in *Lawrence v. Texas*.[122] Before this decision, the notorious "footnote four" of *United States v. Carolene Products Co.*[123] instructed lower courts to presume that legislation is constitutional unless it is "within a specific prohibition of the Constitution."[124] In the context of substantive due process, this presumption was translated into a requirement that petitioners who claim a violation of their Fourteenth Amendment rights bear the burden of proving that the challenged statute violates a "fundamental right."[125]

But some suggest that the traditional structure of review has been inverted. They view cases like *Lawrence* and *Casey* as creating a new "autonomy approach,"[126] which asks whether the right, as framed, is "one that 'involve[s] the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy.'"[127] If so, the argument goes, restrictions on that right are presumed invalid, and the government bears the burden of justifying the restriction.[128]

However, Professor David D. Meyer presents compelling reasons to read *Lawrence* more narrowly. An expansive autonomy right could reduce the government's ability to promote normative models of family organization and conduct:

> The danger is that effectively expanding the "family" protected by the Constitution to include *all* conceptions of intimacy that can-

122. 539 U.S. 558 (2003).

123. 304 U.S. 144 (1938).

124. *Id.* at 152–53 n.4; *see also* Philip Chapman, Note, *Beyond Gay Rights:* Lawrence v. Texas *and the Promise of Liberty*, 13 WM. & MARY BILL RTS. J. 245, 247–48 (2004).

125. Chapman, *supra* note 124, at 248.

126. *See* Sonia M. Suter, *The "Repugnance" Lens of* Gonzales v. Carhart *and Other Theories of Reproductive Rights: Evaluating Advanced Reproductive Technologies*, 76 GEO. WASH. L. REV. 1514, 1520 (2007) [hereinafter Suter, *Repugnance*] ("[Under one reading of *Roe*,] [r]eproductive rights . . . protect against state interference with important and intimate decisions central to one's personal identity and self-definition. This notion was . . . explicitly articulated in *Planned Parenthood of Southeastern Pennsylvania v. Casey*."); Meyer, *supra* note 82, at 465–74 (demonstrating that *Lawrence* "can be understood to articulate a grand and expansive right of individual autonomy" termed "a fundamental right of intimate self-realization"); Chapman, *supra* note 124, at 246 (arguing "that the Supreme Court's opinion in *Lawrence v. Texas* is an attempt to move away from the 'fundamental rights' analysis that has characterized the Court's substantive due process jurisprudence since the 1938 case *United States v. Carolene Products Co*"); Note, *Assessing the Viability of a Substantive Due Process Right to In Vitro Fertilization*, 118 HARV. L. REV. 2792, 2798 (2005) [hereinafter *Assessing the Viability*] ("[T]he [*Lawrence*] Court seemed to embrace the autonomy-based inquiry of *Casey* . . . ."); Note, *Last Resorts and Fundamental Rights: The Substantive Due Process Implications of Prohibitions on Medical Marijuana*, 118 HARV. L. REV. 1985, 1987 (2005) [hereinafter *Last Resorts*] (footnote omitted) ("*Lawrence v. Texas* exemplifies the autonomy strand in the substantive due process tradition.").

127. *Assessing the Viability*, *supra* note 126, at 2802 (alteration in original) (quoting Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 851 (1992)).

128. *See* Meyer, *supra* note 82, at 468 ("[This reading of] *Lawrence* . . . seems to reject the idea that an individual's claim to protection for intimate conduct turns on some social validation of the asserted interest. Instead, it implies that private conceptions of intimate conduct are entitled to public deference unless the government can demonstrate some palpable injury to others.").

> not be deemed "harmful" will ultimately sap family of its distinctive value and vitality. If society is disabled from channeling intimate conduct into relationships reflective of durable commitment, the fulfillment of dependency, and other basic aspirational values commonly associated with family, human interaction may drift toward more self-centered, unstable, and transient forms.[129]

Further, the government would be helpless to regulate a vast array of consensual conduct without concrete proof that the conduct causes harm.[130] By this point the harm would already have occurred, and it would be near impossible to put the toothpaste back into the tube. Accordingly, Professor Meyer has questioned the value of *Lawrence*'s "harm" exception as a limitation and predicted that courts will interpret this exception very narrowly.[131]

In light of the above, it is dangerous to apply broad autonomy rights to modification of the human genome. This would tie the federal government's hands behind its back, preventing it from regulating a technology that could have a dramatic impact on the public health. Hence, courts should not apply the autonomy approach to presume that restrictions on HGGM are unconstitutional.

III. Applying Substantive Due Process

Washington v. Glucksberg[132] set forth the traditional two-prong test for identifying those fundamental rights worthy of substantive due process protection:

> First, the Court stated that "the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, '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.'" Second, the Court stated that substantive due process protection requires "a 'careful description' of the asserted fundamental liberty interest," one that

129. *Id.* at 477.

130. *See id.* at 468 ("By this understanding [of *Lawrence*], the 'intimacy' protected by the Constitution is essentially open ended. It is not cabined by tradition or even by modern social consensus; rather, it is expandable with the imagination of the individual pursuit of self-realization, limited only by the duty to avoid injury to others."); *Last Resorts*, *supra* note 126, at 1989 (citation omitted) (claiming that an expansive reading of *Lawrence* "might initially appear to subject virtually all laws to strict scrutiny, for all limitations on conduct burden the self-definitions of those who define themselves in terms of that conduct, it is in fact subject to principled constraints").

131. For instance, David D. Meyer has expressed concern that "in defining the sort of 'injury' contemplated by *Lawrence*, courts may turn to the understanding of 'harm' developed elsewhere in family-privacy caselaw." Meyer, *supra* note 82, at 470. In that area of the law, "courts typically demand that the harm threatened to a child be 'substantial' or even 'severe.'" *Id.* at 471 (citations omitted). So, "[g]iven the courts' reluctance to find cognizable 'harm' in these contexts, there might be reason to expect courts to give a similarly narrow cast to the 'injury' exception suggested by *Lawrence*. In that event, the scope of fundamental 'liberty' relating to family and other intimacy would be significantly enlarged." *Id.* at 471–72 (citation omitted).

132. 521 U.S. 702 (1997).

> "direct[s] and restrain[s] [the Court's] exposition of the Due Process Clause."[133]

Application of this standard, however, has been less than consistent.

To determine whether a statute proscribing access to HGGM violates substantive due process rights, courts must address an issue sunk under grey waters[134]: whether there is a fundamental right of access to HGGM technologies like three-parent IVF. Yet deciding this is anything but straightforward because the Court has neither articulated specific bases on which it bases such fundamental rights nor employed consistent rhetoric in its analysis.[135] Further complicating matters, some have argued that *Casey* and *Lawrence* modified the "history and tradition" approach of *Glucksberg* into a new "autonomy approach"[136]—and the trajectory of the Court's recent decisions suggests that it may be gravitating to this new approach.[137]

Consistent with the description prong of *Glucksberg*, this Part first proffers an appropriate articulation of the asserted right. Then it argues that the articulated right fails both the "history and tradition" prong of *Glucksberg* and the newer "autonomy approach."

A. *Framing the Asserted Right*

Framing the asserted right is the first step in determining whether government action has triggered substantive due process protections. This step of the analysis is vital because the level of generality at which this occurs is often dispositive of whether a fundamental right exists.[138] In general, the analyzed right should be phrased narrowly. But "the precise framing of a right ought not to be conflated with the narrowest and most concrete definition of the conduct the state seeks to punish; the appropriate level of generality may require a broader understanding of the asserted interest."[139] After considering some of the most

133. *Assessing the Viability*, *supra* note 126, at 2797 (alteration in original) (citing *Glucksberg*, 521 U.S. at 720–21).

134. The Supreme Court has not even decided the constitutionality of traditional IVF, a reproductive technology that has been available since the 1970s. *Id.* at 2793–94.

135. *See id.* at 2796–2800 (expounding on the lack of clarity employed by the rhetoric in fundamental rights cases); Joanna Nairn, *Is There a Right to Have Children? Substantive Due Process and Probation Conditions that Restrict Reproductive Rights*, 6 STAN. J. C.R. & C.L. 1, 15 (2010) (citation omitted) ("The right to privacy, the Court [has held], extend[s] to activities surrounding marriage, procreation, contraception, family relationships, child rearing and education. Yet it is often unclear what level of specificity the Court will use to define rights within that group.").

136. *See, e.g.*, *Last Resorts*, *supra* note 126, at 1986 (citing Robert C. Post, *The Supreme Court, 2002 Term—Foreword: Fashioning the Legal Constitution: Culture, Courts, and Law*, 117 HARV. L. REV. 4, 89 (2003)).

137. *See* Nairn, *supra* note 135, at 25–26 ("There appears to be a relatively strong societal consensus in favor of the right to procreate. . . . All evidence points to a movement away from restrictions on procreation in favor of increased freedom in this area.").

138. Pham, *supra* note 8, at 139 (citing LAURENCE H. TRIBE & MICHAEL C. DORF, ON READING THE CONSTITUTION 73–112 (1991)).

139. *Last Resorts*, *supra* note 126, at 1987 (citing Lawrence v. Texas, 539 U.S. 558, 566–67 (2003)); *see also Assessing the Viability*, *supra* note 126, at 2798–99 (describing *Law-*

plausible ways to articulate the right at stake, this section explains which one is the most appropriate.

1. Right of Privacy in Genetically Modifying the Human Germ Line—When framing the asserted right, *Lawrence* instructed courts to see the forest, not the trees. Courts should "not take such a myopic view of the claimed right that [they] lose[ ] sight of the values at stake—the underlying fundamental freedoms that might be endangered if particular conduct is prohibited."[140] In other words, courts err when they view the "claimed right as identical to the conduct that the law prohibits, thereby failing to capture all the relevant values that the 'far-reaching consequences' of the law 'touch[ ] upon.'"[141] It was on this basis that *Lawrence* overruled *Bowers v. Hardwick*,[142] which held that a Texas anti-sodomy statute did not violate substantive due process. The *Bowers* court had erred because it framed the asserted right as the right to engage in homosexual sodomy. Likewise, framing the asserted right here as the right to genetically modify one's own germ line is improper—it describes the precise conduct that will be prohibited.[143] This articulation would run afoul of *Lawrence*.

2. Right of Privacy in Medical Autonomy—Some may argue that access to HGGM is subsumed within a larger "right to medical autonomy," which protects the ability "to choose effective medical treatment pursuant to a doctor's recommendation."[144] The case law suggests that this right is both negative and affirmative: it "protects not only the fundamental right to be free from unwanted medical treatment, but also the freedom to obtain desired medical treatment in consultation with a doctor."[145] But medical autonomy is not as broad as this language suggests. Because "obtaining *necessary* medical treatment may be just as important to an individual's dignity, autonomy, and avoidance of pain, as is rejecting unwanted treatment," the affirmative right of access to desired treatment is limited to situations of necessity.[146]

> Thus, the right to medical autonomy, properly understood, is narrower than a right to choose from among several effective treat-

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rence as having "muddied the meaning of the second *Glucksberg* prong" by departing from the "established tendency to construe asserted rights narrowly").

140. *Last Resorts*, *supra* note 126, at 1988.

141. *Id.* (alteration in original) (citing Lawrence, 539 U.S. at 566–67).

142. 478 U.S. 186 (1986).

143. Nancy Pham has proposed framing the asserted right as "the right to choose the genetic or physical characteristics of one's child using alternate reproductive technology." Pham, *supra* note 8, at 140 (citing Jodi Danis, *Sexism and "The Superfluous Female": Arguments for Regulating Pre-Implantation Sex Selection*, 18 HARV. WOMEN'S L.J. 219, 248 (1995)). But this is functionally identical to "the right to genetically modify a human germ line." Thus, analysis remains the same: because it describes the actual conduct to be prohibited, this framing of the right is too narrow.

144. *Last Resorts*, *supra* note 126, at 1995; *see also* John B. Attanasio, *The Constitutionality of Regulating Human Genetic Engineering: Where Procreative Liberty and Equal Opportunity Collide*, 53 U. CHI. L. REV. 1274, 1288 (1986).

145. *Last Resorts*, *supra* note 126, at 1995 (citing Cruzan v. Dir., Mo. Dep't of Health, 479 U.S. 261, 278 (1990)); Washington v. Harper, 494 U.S. 210, 221 (1990); Whalen v. Roe, 429 U.S. 589, 603 (1977)).

146. *Id.* at 1996 (emphasis added).

> ments the particular treatment the patient desires. The fundamental right is to consult with a doctor and to choose an effective course of treatment; if only one effective treatment exists for a patient, the patient has a fundamental liberty interest in seeking it.[147]

This constraint makes the "right to medical autonomy" an inappropriate way to frame the right at stake. It is easy to see why non-therapeutic HGGM is never necessary—there are few therapeutic justifications for predetermining a child's eye color. But therapeutic HGGM is also not "necessary," as used in this context, because the right to medical autonomy entails a particular breed of necessity.

Therapeutic HGGM seeks to eliminate a potential child's diseases, and the necessity of this technology relies on a key assumption: that it is necessary to have a child. But there is no settled, affirmative right to be a parent,[148] and having a child is never necessary, especially when there is access to abortion. Though many medical diseases, like diabetes, can be the result of personal decisions,[149] contracting a disease is generally beyond human control. In contrast, bearing a diseased child is predicated upon choice. And when it comes to mitochondrial diseases, which parents know with near certainty that their child will inherit, it is easy to isolate the parents' decision to have a child as the first private choice leading to that disease. This discretion precludes parents from arguing necessity—it is their own decision that has put a life in jeopardy and "necessitated" the treatment sought.

Further, the right to medical autonomy implies decision-making ability for oneself.[150] By the time an individual has decided to genetically modify their child, they have already made the decision to have a child. Directing medical treatment for that child is not an exercise in

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147. *Id.* at 1996–97 (citations omitted).

148. However, there may be an established right to retain the *ability* to procreate. In *Skinner v. Oklahoma*, 316 U.S. 535 (1942), the Court invalidated an Oklahoma statute that permitted forced sterilization of convicted felons. But the scope of this procreative right is vague:

> On the one hand, *Skinner* could be read as establishing a broad, generalized right to procreative freedom that would include a fundamental freedom to choose to reproduce. . . . On the other hand, the law struck down in *Skinner* was specifically one that sought to *destroy* a person's ability to procreate. *Skinner* could thus be read as establishing only a negative right against forced destruction of one's procreative capacities, as the Court never explicitly asserted a broader fundamental right to procreate.

Assessing the Viability, *supra* note 126, at 2800. Because the correct reading of *Skinner* is beyond the scope of this Note, it assumes that the narrower interpretation is valid. This is in keeping with the Court's reluctance to recognize broad, affirmative rights under substantive due process. *See* Washington v. Glucksberg, 521 U.S. 702, 720 (1997) (explaining the Court's hesitation in recognizing new substantive due process rights because this "place[s] the matter outside the arena of public debate and legislative action").

149. But this involves many singular choices, and none of those individually can be fairly characterized as the "cause" of the disease. It is impossible to single out one French fry as the cause of heart disease, or to isolate one soda as the cause of diabetes.

150. *See Autonomy*, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/autonomy (last visited March 1, 2014) (defining autonomy as "self-directing freedom").

autonomy; it is a choice of treatment for another person. Therefore, access to HGGM is improperly framed as an exercise in medical autonomy.

3. Right of Privacy in Reproductive Decisions—In its reproductive rights jurisprudence, the Court has identified three substantive due process rights that protect reproductive decisions: the rights to procreation, contraception, and abortion.[151] But each of these rights—and thus the right of privacy in reproductive decisions as a whole—is, in reality, grounded in a right to bodily integrity.[152] This rationale cabins the right,[153] limiting its application to situations in which that integrity is threatened. Consequently, defining the right to HGGM as part of the broader "right to make decisions regarding reproduction" is "a disingenuous classification of HGGM."[154] Because "[HGGM] is radically different from traditional reproduction and does not involve a woman's bodily integrity, which was part of the rationale in *Roe* and *Casey*," the Court should decline to frame the asserted right as a protected part of broader reproductive decision-making.[155]

4. Right of Privacy in Making Parental Decisions—The right of access to HGGM may also be abstracted into a right to parental decision-making, a right with firm roots in substantive due process doctrine. "Indeed, some of the earliest cases to articulate the right to privacy did

151. *See Assessing the Viability*, *supra* note 126, at 2800.

152. *See* Suter, *Repugnance*, *supra* note 126, at 1544 (citation omitted) ("[T]he interest in bodily integrity[ ] is deeply ensconced in our history and common law traditions. The fact that the reproductive decisions that have occupied the Court—sterilization, abortion, and contraception—all directly implicate bodily integrity only reinforces this idea."); B. Jessie Hill, *Reproductive Rights as Health Care Rights*, 18 COLUM. J. GENDER & L. 501, 506 (2009) ("The understanding of reproductive rights as health care rights, which has long been present in reproductive rights jurisprudence, has been downplayed by both courts and reproductive rights advocates in favor of a rhetoric centered on personal autonomy, equality, and dignity."); Pham, *supra* note 8, at 139 (citing Planned Parenthood v. Casey, 505 U.S. 833, 857 (1992)) ("*Roe* and *Casey* were decided not only on values of procreative liberty, but also on rules of bodily integrity. That is, bodily integrity was doing some of the work along with a woman's right to make reproductive decisions."); *see also* Hill, *supra* note 152, at 506–10 (arguing that reproductive rights should be re-conceptualized as part of an overall right to health).

153. *See* Attanasio, *supra* note 144, at 1287 ("[T]he Court itself admits that the protected sphere of liberty does not include all childbearing activity.").

154. Pham, *supra* note 8, at 140 (citation omitted).

155. *Id.* at 141. Jason C. Glahn argues forcefully that HGGM is protected by substantive due process as well as the Ninth Amendment. Glahn, *supra* note 30, at 430–38. But even he concedes that, under extant case law, this is probably an improper way to frame the asserted right:

> Since genetic modification involves the attempt to produce a child with certain phenotypic traits rather than produce a child simpliciter, it is unlikely that it would be viewed by the Court as involving the decision whether to "bear or begat a child." . . . The Court noted in *Casey* that the primary purpose of the reproductive rights line of cases was to ensure the liberty and autonomy interests of women. Such interests probably do not extend to the decision whether to bear a child if, and only if, it is a certain kind of child.

Id. at 428–29 (citation omitted).

so in the context of parental decision[-]making."[156] In a series of cases, "[t]he Supreme Court has generally protected parental autonomy in child-rearing decisions, which includes decisions where children will live, how they will be educated, and what values and morals they will be taught."[157] This right is limited only by the harm principle, which states that it is justifiable to interfere with parental autonomy only when "parental action is likely to cause serious (and avoidable) harm to the child."[158]

Access to HGGM involves the relationship between a potential parent and a future child. Consequently, this Note agrees that restricting access to HGGM is most plausibly seen as burdening parental autonomy to choose the characteristics of their children.[159] Courts should adopt this framing of the asserted right for purposes of substantive due process analysis.

B. *Glucksberg's History and Tradition Prong*

The fundamental right burdened by restrictions on HGGM is the right of parental decision-making. In various decisions the Court has expressed no doubt that this right is "deeply rooted in this Nation's history and tradition," and "implicit in the concept of ordered liberty."[160] The argument that this right includes a right of access to HGGM proceeds thus: Substantive due process safeguards parental control over the child's education in two primary areas—what and how their children learn. "[The Court] has protected the parents' right to choose the school that their child will attend and to influence her education in the public school system. It even has enforced the parental right to choose the child's religious upbringing . . . ."[161] In other words, "[t]he Court . . . should be construed as having articulated a

156. Suter, *Repugnance*, *supra* note 126, at 1548 (citing Pierce v. Soc'y of Sisters, 268 U.S. 510, 534–35 (1925); Meyer v. Nebraska, 262 U.S. 390, 399 (1923); Wisconsin v. Yoder, 406 U.S. 205 (1972)).

157. Pham, *supra* note 8, at 152 (citing *Pierce*, 268 U.S. 510; *Meyer*, 262 U.S. 390; John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 481 (1996)). In general, Pham writes, parents are given this authority so that they can raise children the way they see fit. *Id.* Still, though, parental decision-making can be subject to certain state limitations and regulations. *Id.* "For example, parents cannot abuse their children." *Id.* at 152 n.130.

158. Carson Strong, *Defective Infants and Their Impact on Families: Ethical and Legal Considerations*, 11 J.L. MED. & ETHICS 168, 171 (1983).

159. Even those arguing that substantive due process protects access to HGGM agree that this is the most plausible way to frame the right at stake. *See* Glahn, *supra* note 30, at 430 ("[P]arental rights cases provide the strongest support for a fundamental right to genetic modification."); *see also* Megan Anne Jellinek, *Disease Prevention and the Genetic Revolution: Defining a Parental Right to Protect the Bodily Integrity of Future Children*, 27 HASTINGS CONST. L.Q. 369, 374 (1999) (arguing that "parents have a fundamental right to protect the health and bodily integrity of their children by making crucial decisions at all stages of human development").

160. Washington v. Glucksberg, 521 U.S. 702, 720–21 (1997) (citing Pierce v. Soc'y of Sisters, 268 U.S. 510 (1925); Meyer v. Nebraska, 262 U.S. 390 (1923); Wisconsin v. Yoder, 406 U.S. 205 (1972)).

161. Attanasio, *supra* note 144, at 1291 (citing *Pierce*, 268 U.S. at 534; *Meyer*, 262 U.S. at 400; *Yoder*, 406 U.S. at 213–14).

general right of parents to inculcate positive traits in their children, traits which the state 'can neither supply nor hinder.'"[162] Moreover, modern genetic science has revealed that traits like intelligence, physical ability, and personality "may be influenced to some extent by genetic factors,"[163] and using this technology to enhance positive attributes is analogous to inculcating positive values through education.[164] Since parental autonomy includes discretion to decide whether children will receive the benefits of genetic modification, access to HGGM is protected.[165]

But this reasoning fundamentally re-conceptualizes the parent-child relationship: it assumes that there can be a *parent* before there is yet a *child*.[166] None of the parental decision-making cases address unborn children; none of the reproductive rights cases (purport to) consider "children." Indeed, established substantive due process jurisprudence demonstrates that *different* privacy rights attach to decisions about born, versus potential, life.[167]

Moreover, this distinction is meaningful and should be maintained. There is significant cognitive dissonance in holding that an advanced, cutting-edge technology like HGGM somehow has basis in "history and tradition."[168] Plus, the language of parental autonomy is far broader than the language of reproductive rights. The latter has been limited to situations in which a person's bodily integrity is threatened, while the former is usually limited only by the harm principle.[169] Allowing the right of parental autonomy to extend to control over germ cells and fertilized ova would render the bodily integrity limitation nugatory. This would dramatically expand the scope of substan-

162. Glahn, *supra* note 30, at 431 (quoting Stanley v. Illinois, 405 U.S. 645, 651 (1972)); *see also* Attanasio, *supra* note 144, at 1291 (positing that the doctrine of substantive due process has protected liberty in child rearing and liberty in child bearing, both of which "shield the family from governmental intrusion").

163. Glahn, *supra note 30*, at 430 (citing ELLIOT SOBER, THE MEANING OF GENETIC CAUSATION IN FROM CHANCE TO CHOICE: GENETICS AND JUSTICE 347, 354 (Allen Buchanan, Dan W. Brock, Norman Daniels & Daniel Wikler eds., Cambridge U. Press 2002)).

164. *See* Attanasio, *supra* note 144, at 1291 ("The right to form the body and mind with [HGGM] is analogous to molding the child through education.").

165. Glahn, *supra* note 30, at 430–34.

166. HGGM can occur at one of two times: prior to conception, through modification of a parent's germ cells; or after conception, through modification of the fertilized ovum. *See supra* Part II.A. And according to established reproductive rights jurisprudence, a fertilized ovum is not a legal person. *See* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 839 (1992) (emphasis added) ("[A]bortion involves the purposeful termination of *potential* life . . . ."). Therefore, at neither point in time is the "parent" modifying their "child"; they are modifying a "potential life."

167. *Compare* Pierce v. Soc'y of Sisters, 268 U.S. 510 (1925) (right of privacy in making parental decisions) *and* Wisconsin v. Yoder, 406 U.S. 205 (1972) (right of privacy in making parental decisions) *with* Roe v. Wade, 410 U.S. 113 (1973) (right of privacy in reproductive decision-making) *and* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992) (right of privacy in reproductive decision-making).

168. *See* Suter, *Repugnance*, *supra* note 126, at 1541 ("If physician-assisted suicide is not part of our 'Nation's history and tradition,' it raises a question as to whether advanced reproductive technologies—such as IVF, prenatal testing, PIGD, or reproductive genetic modification—would be.").

169. *See supra* text accompanying notes 157–58.

tive due process rights, permitting state regulation only when "parental action is likely to cause serious (and avoidable) harm to the child."[170] Rather than place such an extreme amount of consensual conduct beyond regulation,[171] courts should hold that HGGM is not protected by the right of parental decision-making.

C. *The "Autonomy Approach"*

The "autonomy approach" was discussed earlier in the context of judicial review.[172] It was argued that this standard is inappropriate for a nascent technology with unknown consequences. But even if a court adopts the "autonomy approach" within the substantive due process context, access to HGGM should not be protected.

Even advocates of the expansive autonomy approach admit that it should have a limit: the harm principle. For instance, John A. Robertson, a fierce proponent of procreative autonomy, supports "a liberty claim-right to use genetic knowledge and techniques to have healthy offspring to nurture and rear."[173] And yet, he believes that this broad access to genetic technology should be limited "if [it] imposed serious harms on the persons most directly affected by them."[174] This makes good sense: without meaningful constraint, individuals could engage in any course of conduct intended to bring self-fulfillment, regardless of the effects on others.

Further, under the autonomy approach rights that have already been identified as fundamental are to be retained. One of these is a right to bodily integrity, recognized by the *Roe* and *Casey* line of cases. And while access to abortion is easily justified under the autonomy approach,[175] access to HGGM is fundamentally different because modification of a "potential life" occurs under the assumption that it will be brought to term. Stated differently, HGGM implicates a human life because the intended result is to produce children. So courts must consider whether the technology threatens the bodily integrity of those children.

Furthermore, HGGM is likely to result in both bodily and psychological harm. Especially while the technology is being developed, there is strong likelihood that children will be born with physical defects.[176] And widespread use of HGGM could lead to a host of psychological issues.[177] Legislation prohibiting access to the technology would pre-

170. Strong, *supra* note 158, at 171.

171. *See* Washington v. Glucksberg, 521 U.S. 702, 720 (1997) (explaining that the Court is hesitant to expand substantive due process rights because this increases the amount of activity that is "outside the arena of public debate and legislative action.").

172. *See supra* text accompanying notes 122–30.

173. John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439, 484 (2003).

174. *Id.*

175. Destroying a fertilized ovum maintains the bodily integrity of a woman and causes no harm to a human person because it is only a "potential life." *See* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 839 (1992).

176. *See* Reiss, *supra* note 14.

177. *See supra* text accompanying notes 15–18.

vent all of this damage. Thus, true commitment to the harm principle[178] means ruling that there is no fundamental right of access to genetic modification technologies.

IV. Conclusion

Three-parent IVF dips our toes into the pool of human germ line modification. Access to this technology would open the door to further manipulation of genetic material, and this could have disastrous effects on society at large. This Note has examined various legal theories that might sustain access to HGGM. But many are inappropriate for such a unique reproductive technology, and even the doctrine of substantive due process is of no avail. Established jurisprudential principles do not guarantee access to HGGM, so legislation that prohibits this access should be reviewed under the rational basis standard. And because many legitimate governmental interests justify such a prohibition, courts should hold that the restriction is constitutional.

178. A contrary conclusion risks justifying the ends by the means—likelihood of harm to even one human life should not justify access to HGGM. This is consistent with the bioethical principle of nonmaleficence, which "asserts an obligation not to inflict harm on others." Patricia A. King, et al., Law, Medicine, and Ethics 47 (2006) (quoting Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics (2001)).