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Choosing the Genetics of Our Children: Options for Framing Public Policy

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Abstract

This paper examines the controversial topic of choosing our children's genes through human germ-line manipulation otherwise known as Inheritable Genetic Modification (IGM) with current Assisted Reproductive Technologies (ARTs) and future Reproductive Genetic Biotechnologies (RGBs) such as genetic engineering. The purpose of the paper is to examine these potentially revolutionary biotechnologies and the emerging social, and bioethical perspectives advanced by both proponents and opponents—in the context of the legal and regulatory policies impacting ARTs and RGBs. Lastly, the paper recommends new public policy and regulatory frameworks to support future research and development of RGBs by providing legislative guidance to policymakers to ensure responsible oversight.

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INTRODUCTION

As research and development continues to advance humankind's understanding of the human genome, our biology, and ultimately our biological potential as a species, new biotechnologies will emerge that may soon enable parents to choose the future genetics and traits of their children. Normal sexual reproduction supports genetic variation in gametes, expressed through changes in alleles located at specific locations on the chromosome that pass dominant traits from parent to offspring.[1] This process of Mendelian inheritance is expressed in two laws: the Law of Segregation and the Law of Independent Assortment, whereby each of the 46 chromosomes segregates during meiosis, each with a 50 percent chance of segregating to a particular cell.[2] These fundamental principles of classical genetics frame Humankind's pragmatic abstraction of evolution—that genetic determinism produces children born with distinct biological advantages or desired phenotypic traits. Proponents of genetic engineering technologies argue that if pursued, such advancements could one day enable parents to choose the genes of their children, and if presented with the opportunity, humankind should seize control of its own destiny.[3] Humanity, according to such proponents, should transcend the draconian and arguably prehistoric practice of random genetic variation through sexual reproduction and natural selection to begin a new era of human self-design. This ideology is predicated on the belief that Humankind is running twenty-first century software (our knowledge) on Stone Age hardware (our bodies) that have not changed in the last 50,000 years.[4]

However, opponents of genetic engineering technologies argue that biologically altering humankind is such a radical choice, that its consequences could have the potential to destroy humanity itself, leaving behind an unrecognizable species, far removed from morality.[5] This ideology advanced by opponents emphasizes several

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1. *See* CECIE STARR ET AL., BIOLOGY: THE UNITY AND DIVERSITY OF LIFE 154-200 (12th ed. 2009).

2. *See id*. at 156-57, 173-74.

3. *See* GREGORY STOCK, REDESIGNING HUMANS: CHOOSING OUR GENES, CHANGING OUR FUTURE 2 (2003).

4. *See* SURVIVING PROGRESS (Cinemaginaire and Big Picture Media Corporation, in Coproduction with the National Film Board of Canada 2012).

5. *See* PRESIDENT'S COUNCIL ON BIOETHICS (U.S.), REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES xii (2004) [hereinafter REPRODUCTION AND RESPONSIBILITY].

issues including: the safety risks imposed,[6] feasibility of the science and technology,[7] and precautionary principle.[8] Opponents' precaution is predicated on the principle that some technologies are so inherently dangerous to humankind; they should be considered a Pandora's Box that should never be pursued, regardless of the potential benefits.[9]

A. Thesis

First, this paper will attempt to elucidate both sides of the controversial debate of enabling parents, by means of current Assisted Reproductive Technologies (ARTs) and future Reproductive Genetic Biotechnologies (RGBs), to choose the genes or genetic traits of their children. The paper will examine current genetic engineering and future genetic modification technologies by evaluating their scientific feasibility, applicability, and development towards enabling parents to choose the genetics of their children. Technologies such as: Gene Therapy, Germline engineering, and Human Artificial Chromosomes (HACs) will be discussed. In addition, the advancement and impact of the Human Genome Project (HGP) will be examined in the context of its impact on the progression of past, present, and future genetic modification technologies.[10]

Second, the social and bioethical implications of genetic modification will be examined in the context of the complex and diverse range of ideologies and perspectives from both prominent proponents and opponents of genetic modification. Prolific proponents—such as Gregory Stock, Julian Savulescu, Lee Silver, and Ray Kurzweil—argue genetic engineering is a promising and desirable technology that could potentially revolutionize and transform humankind by improving our body and our minds.[11] Visceral opponents—such as Leon Kass, Francis Fukuyama, and Bill McKibben—argue inevitable genetic engineering technologies would radically redefine the definition of humankind by manipulating inheritable genetic and epigenetic traits such as: intelligence, athletic

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6. *See id*. at xi.

7. *See* FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION 82 (2002).

8. *See* Bill Joy, *Why the Future Doesn't Need Us*, WIRED (Apr. 2000), http://www.wired.com/wired/archive/8.04/joy_pr.html.

9. *See id*.

10. STOCK, *supra* note 3, at 42.

11. *See generally* STOCK, *supra* note 3; RAY KURZWEIL, THE SINGULARITY IS NEAR: WHEN HUMANS TRANSCEND BIOLOGY (2005); JULIAN SAVULESCU ET AL., ENHANCING HUMAN CAPACITIES (2011); LEE M. SILVER, REMAKING EDEN (1998).

ability, and longevity.[12] These opponents express deep concern of its potential destructive impact on the social, ethical, and philosophical framework of society.[13]

Finally, the paper describes the current regulatory frameworks of governmental and nongovernmental agencies that exercise limited regulatory authority over genetic engineering technologies. In addition, the paper examines the possible future regulations of genetic engineering technologies. Lastly, the paper attempts to balance the costs and benefits of the relevant technologies against the social and bioethical implications in order to recommend guidelines for legislators to consider when seeking practical and prudent public policy solutions.

I. UNDERSTANDING GENETIC ENGINEERING TECHNOLOGIES

A. Assisted Reproductive Technologies (ARTs)

ARTs include a wide range of medical treatments and procedures involving the manipulation of human eggs and sperm inside and outside the human body.[14] ARTs such as, In Vitro Fertilization (IVF), and Pre-implantation Genetic Diagnosis (PGD) have been gateway technologies to all the advanced reproductive technologies now emerging, in addition to prospective technologies such as germline engineering. Moreover, as humankind's understanding of our genomic information and genes that correspond to disease linked genetic markers increase as a result of the Human Genome Project (HGP), the intersection of IVF, PGD, and genomics may potentially form the requisite catalyst needed to enable parents to choose the *positive* genetic traits and characteristics of their offspring.[15]

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12. *See generally* PRESIDENT'S COUNCIL ON BIOETHICS (U.S.), BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF HAPPINESS (2003) [hereinafter BEYOND THERAPY]; FUKUYAMA, *supra* note 7; BILL MCKIBBEN, ENOUGH: STAYING HUMAN IN AN ENGINEERED AGE xi-xiii (2003).

13. *Id.*

14. *See* 42 U.S.C. § 263a-7(1) (2006) ("The term "assisted reproductive technology" means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies.").

15. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 102; *see also* Susannah Baruch, *Preimplantation Genetic Diagnosis and Parental Preferences: Beyond Deadly Disease*, 8 HOUS. J. HEALTH L. & POL'Y 245, 251 (2008).

B. The Human Genome Project (HGP)

Until the HGP was proposed, scientists had to work with small portions of genetic material, usually consisting of only a few genes as they struggled to understand how genetic mutations caused diseases.[16] Although the HGP offers great promise for humankind to gain control of our evolution, this is far from the minds of scientists working toward understanding the genome. Scientists are more focused on disease prevention: "identifying disease-related genes, developing diagnostic tests, finding effective new drugs, understanding cancer and other diseases."[17] The ambitious goals of the HGP included two revolutionary outcomes: (1) "the genome was mapped at a relatively high level. This means that researchers systematically determined the linear order of genes on each chromosome using applied genomics to identify and localize genes in a process known as transcript mapping,"[18] and (2) "[t]he Messenger RNA transcripts from expressed genes are converted to complementary DNAs (cDNAs), which are then sequenced and mapped to sites on particular chromosomes."[19] This revolutionary work in genomic analysis and gene mapping was completed with the announcement in 2003 of the completion of sequencing the 3-billion-base pairs of Human DNA.[20] The project reinvigorated the aspirations of those seeking to improve the human race through genetic engineering and reproductive technologies. With the completion of sequencing the human genome, researchers are more able to quickly and easily diagnose genetic diseases and identify life-threatening prenatal genetic abnormalities.[21]

Since its completion in 2003, remarkable innovations in genetic mapping and computational power have increased the speed, accuracy, and efficiency of sequencing the human genome with recent techniques demonstrating rapid and non-invasive Whole-Genome Sequencing (WGS) of a human fetus for genetic diagnosis.[22] Gregory

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16. *See* John Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439-40 (2003).

17. STOCK, *supra* note 3, at 42.

18. ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 568 (2010).

19. *Id*.

20. *See* U.S. Dep't of Energy, *About the Human Genome Project*, HUMAN GENOME PROJECT INFORMATION ARCHIVE 1990–2003, http://web.ornl.gov/sci/techresources/Human_Genome/project/index.shtml.

21. *See* Maxwell J. Mehlman, *The Law of Above Average: Leveling the New Genetic Enhancement Playing Field*, 85 IOWA L. REV. 517, 521-22 (2000).

22. *See* Jacob O. Kitzman et al., *Non-Invasive Whole Genome Sequencing of a Human*

Stock, a proponent of genetic engineering technologies and futurist recognizes the HGP as an "extraordinary accomplishment, [where] humanity took a giant step toward unraveling its biology and manipulating it in profound ways."[23] Stock envisions that "[t]he immediate consequence of uncovering the more than thirty thousand human genes and their variants will be better identification of our genetic susceptibilities to various diseases and better treatments for them."[24] However, Stock also anticipates that with the completion of the HGP, and a better understanding of our gene related traits and characteristics, future RGBs will be developed to purposely manipulate our genes with somatic cell therapy.[25] In contrast, others have expressed concerns about the completion of the HGP, and the consequences of the future use of genomic sequencing in reproduction, because it raises important social and ethical questions about people deciding to procreate based on their genetic makeup, or that of their embryo or fetuses.[26]

1. Genome Sequencing

Since the completion of the HGP, several companies have capitalized on the opportunity to provide consumers with a confidential, fast, and relatively inexpensive detailed analysis of their genetic information. These services genotype an individual's genetic information and compare it against the probabilities that other individuals who share the same specific genetic traits or genomic markers may have previously experienced medical complications.[27]

Fetus, 4 SCI. TRANSLATIONAL MED. 1 (June 6, 2012); s*ee also* Ying-Ming Zheng et al., *Whole Genome Amplification in Preimplantation Genetic Diagnosis*, 12 J. ZHEJIANG U.-SCI. B (BIOMEDICINE & BIOTECHNOLOGY) 1 (2011); *cf.* Greer Donley et al., *Prenatal Whole Genome Sequencing: Just Because We Can, Should We?*, HASTINGS CENTER REP. July-Aug. 2012, 28, 42 (raising important ethical concerns surrounding the application of pre-natal WGS for trait selection). Next-Generation Screening (NGS) is poised to transform IVF and PGD by enabling whole genome sequencing of an embryo prior to implantation—thereby enabling parents to accept or reject an otherwise healthy embryo based on its pre-disposition of developing specific diseases later in life.

23. STOCK, *supra* note 3, at 41.

24. *Id*.; *but cf.* International Human Genome Sequencing Consortium, *Finishing the Euchromatic Sequence of the Human Genome*, 431 NATURE 931, 945 (2004) (stating that in the initial analysis of the draft sequence, scientists estimated approximately 30,000 human protein coding genes, which was later discovered to be in the range of 20,000-25,000).

25. *See* STOCK, *supra* note 3, at 42.

26. *See* Robertson, *supra* note 16, at 440-41.

27. *See* MIKE MACPHERSON ET AL., ESTIMATING GENOTYPE-SPECIfiC INCIDENCE FOR ONE OR SEVERAL LOCI (2007), *available at* https://23andme.https.internapcdn.net/res/pdf/HIC-SXIYiYqXreldAxO5yA_23-01_Estimating_Genotype_Specific_Incidence.pdf.

In addition, an individual's "genotype-specific risk" is calculated based on the probabilities those other individuals who share similar genetic markers have the propensity to develop, or have developed, diseases such as diabetes expressed through different clinical research studies.[28] These new genetic genotyping services essentially formulate their analysis based upon two layers of abstraction; probabilities on top of probabilities. However inherently abstract these probabilities may seem at first glance, these testing services are continuously refining their formulations, which have been found to be surprisingly accurate for not sequencing an individual's complete genome. These direct-to-consumer genome-testing services only examine an individual's exome, or the 1% of an individual's genome variants and phenotypes most likely to contain information relating to specific markers for genetic traits or diseases.[29] Although these services are still developing as a result of the completion of the HGP, the speed and price required to sequence an individual's genome is falling rapidly, and in the foreseeable future complete genome sequencing, (not just the exome) may become as routine as a blood test in facilitating genetic modification.[30]

2. Genomic Therapy and Enhancement

As genomic sequencing becomes more ubiquitous, and public perception becomes more aware of genetic deficiencies or undesirable traits of an individual's genome, public attitudes towards funding genetic modification research may change. Proponents of genetic engineering argue the distinction between "therapy" and "enhancement" may one-day ultimately merge as a result of the HGP's transformation of ubiquitous whole genome screening.[31] As a result, public attitudes may shift the public debate of "therapy" towards support of genetic engineering technologies that could cure an individual's potential disposition towards genetic mutations or epigenetic cancer causing abnormalities in their genome. Proponents would likely agree such a shift in societal attitudes will come as more and more individuals have their genome analyzed, and learn that they may be more likely to develop genetic complications such as: coronary heart disease, atrial fibrillation, or even debilitating

28. *See id*.

29. *See* Adam Kiezun et al., *Exome Sequencing and the Genetic Basis of Complex Traits*, 44 NATURE GENETICS 623 (2012).

30. *See* STOCK, *supra* note 3, at 46.

31. *Cf. id*.

conditions such as diabetes, Alzheimer's or Parkinson's disease.[32] Such a dramatic shift in genetic knowledge may shift public perception to redefine therapy to include "preventable therapies," which would support RGBs.

On the other hand, since the completion of the HGP, opponents of genetic research take a precautionary approach towards the discussion of the HGP's role in genetic engineering because it may lead to enhancement that goes beyond correcting predisposition to disease.[33] Proponents argue in support of going beyond therapy for enhancement, because if such improvement of human performance becomes feasible it could begin a "golden age" for humankind's quality of life.[34] It is no surprise then, that the sensationalized term "designer babies"[35] has gained recent attention in the media in respect to this "golden age" of genomic research with coming prospects such as: "children born with improved genetic endowments, the result either of careful screening and selecting of embryos carrying desirable genes, or of directed genetic change ('genetic engineering') in gametes or embryos."[36] Opponents understand "directed genetic change" or genetic engineering to go beyond what random reproductive chance has provided, by improving embryos directly by introducing better genes.[37] Futurists such as Stock, acknowledge that "[t]he media has hyped many recent gene discoveries, but there is no question that our genes do shape our predisposition and vulnerabilities. The complexity of most of these influences remains to be determined, but a few are surprisingly simple."[38] However, proponents of genetic engineering contend that these futuristic claims of "designer babies" may not be as sensationalized as they may first appear. Genetic engineering technologies such as gene transfer, germline engineering, and Human Artificial Chromosomes (HACs)—in conjunction with current ARTs—have already shown success with

32. *See* Robertson, *supra* note 16, at 461; *see also* MARK S. FRANKEL & AUDREY R. CHAPMAN, HUMAN INHERITABLE GENETIC MODIFICATIONS (2000), *available at* http://srhrl.aaas.org/projects/human_enhance/reports/germline.pdf.

33. *See* BEYOND THERAPY, *supra* note 12, at 4.

34. NATIONAL SCIENCE FOUNDATION, CONVERGING TECHNOLOGIES FOR IMPROVING HUMAN PERFORMANCE 6 (2002).

35. *See* Bonnie Steinbock, *Designer Babies: Choosing Our Children's Genes*, 372 THE LANCET 1294, 1294 (2008).

36. BEYOND THERAPY, *supra* note 12, at 29.

37. *See id*. at 31.

38. STOCK, *supra* note 3, at 43.

directed genetic change in non-human animal embryos in primates.[39] These experiments include revolutionary gene-editing techniques called Crispr and intracytoplasmic sperm injection (ICSI) to produce genetically modified non-human primates for research, which resulted in the birth of a healthy rhesus monkey male, named "George."[40]

C. Genetic Modification Technologies

Genomic genotyping and the development of ARTs currently being used to treat genetic illnesses could eventually be applied to identify and enhance a person's non-disease genetic characteristics or traits. This broad term of genetic modification includes genetic engineering, which is "the genetic alteration of embryos before implantation in the womb, or, more radically, the genetic alteration of sperm or ova before conception. In theory scientists could add genes that produce desirable traits (such as health, beauty, and intelligence) or subtract genes that produce undesirable traits (such as disease)."[41] There are several methods of trying to produce children naturally with superior genetic endowments, such as: "somatic enhancements in adults and children, pre-conception enhancement, selective abortion, embryo selection, and germline enhancement."[42] However, this paper will focus primarily on the direct manipulation of genes such as gene insertion or deletion. These techniques, otherwise known as RGBs constitute a genetic intervention: "(1) when it is undertaken for the purpose of improving a characteristic or capability that, but for the enhancement, would lie within what is generally accepted as 'normal' range for humans; or (2) when it installs a characteristic or capability that is not normally present in humans."[43] These interventions are still futuristic in many respects and do not currently allow parents to screen or enhance characteristics such as height, eye color, intelligence, or a myriad of other traits; however, the technology is advancing rapidly and as one scientist and futurist observes the time

39. *See* BEYOND THERAPY, *supra* note 12, at 29.

40. *See* Anthony W.S. Chan et al., *Foreign DNA Transmission by ICSI: Injection of Spermatozoa Bound with Exogenous DNA Results in Embryonic GFP Expression and Live Rhesus Monkey Births*, 6 MOLECULAR HUM. REPROD., no. 1 26-33 (2000); Yuyu Niu et al., *Generation of Gene-Modified Cynomolgus Monkey via Cas9/RNA-Mediated Gene Targeting in One-Cell Embryos*, 156 CELL 836 (2014) (stating that researchers in China have created genetically modified monkeys using a new method of precise gene targeting known as Crispr, which can alter a DNA sequence at a specific location within a genome).

41. KERRY L. MACINTOSH, ILLEGAL BEINGS: HUMAN CLONES AND THE LAW 41 (2005).

42. Mehlman, *supra* note 21, at 524.

43. *Id*. at 523.

to address these challenges has arrived:

> The coming challenges of human genetic enhancement are not going to melt away; they will intensify decade by decade as we continue to unravel our biology, our nature, and the physical universe. Humanity is moving out of its childhood and into a gawky, stumbling adolescence in which it must learn not only to acknowledge its immense new powers, but to figure out how to use them wisely. The choices we face are daunting, but putting our heads in the sand is not the solution.[44]

The social, ethical, and legal challenges of genetic enhancement require acknowledgement, but more importantly, recent advancements in biotechnologies such as germline engineering represent a paradigm shift—an early-stage embryo that can be genetically enhanced prior to IVF implantation will likely have profound implications that will redefine humanity. Three such technologies will be discussed in the context of genetic engineering: (1) gene transfer or somatic gene therapy, (2) germline engineering or Inheritable Genetic Modification (IGM), and (3) Human Artificial Chromosomes (HACs).

1. Somatic Gene Therapy

Research and development in somatic gene therapy has responded to inheritable genetic diseases in existing adults that have been identified as a result of the completion of the HGP. Currently, first generation gene therapy technology targets cells other than embryo or sperm cells and works by targeting common monogenic diseases such as Duchenne muscular dystrophy and cystic fibrosis.[45] The process involves transferring normal or healthy cells into the somatic cells or tissue of the patient, producing genetic changes that are restricted to the individual and not inheritable to future offspring.[46] More specifically, the process "involves physical (microinjection), chemical (charged lipid carriers of DNA), and viral methods to introduce the normal gene in chosen target cells."[47] Once the injection has replaced the abnormal or missing gene, the gene is expressed by "viral 'vectors' containing the inserted therapeutic DNA

44. STOCK, *supra* note 3, at 17.

45. *See* S. M. Selkirk, *Gene Therapy in Clinical Medicine*, 80 POSTGRADUATE MED. J. 560, 560-70 (2004); *see also* Donald B. Kohn & F. Candotti, *Gene Therapy Fulfilling its Promise*, 360 NEW ENG. J. MED. 518, 518-21 (2009).

46. *See* STOCK, *supra* note 3, at 38.

47. MERGES ET AL., *supra* note 18, at 612.

[which] are attenuated or modified versions of viruses that are incapable of replicating in the patient, but retain the ability to efficiently deliver DNA to the cell. These 'vectors' also contain promoters that turn the normal gene on and off."[48] Past gene therapy clinical trials have achieved little success, primarily because the human body is made up of trillions of cells and for the gene therapy to be effective, millions of cells need to be altered.[49] Furthermore, with the death of Jesse Gelsinger in 1999, while participating in a gene-transfer clinical trial, greater regulatory oversight of gene therapy has been imposed by the U.S. Food and Drug Administration (FDA).[50]

However, second generation gene therapy technologies may prove more successful, because they target the incorporation of genes into the cell nucleus using a Trojan horse approach, where "[i]nstead of using a cellular virus to transfect the cells, this approach would introduce gene sequences by 'disguising' them as a molecule recognized by the cell and passing them through the cell membrane."[51] Gene transfer techniques face two principal obstacles to their safe and effective use: "[F]irst, the exact locations in the host DNA into which new genetic information is inserted and, second, the extent to which the new genes are expressed in the right cells at the correct developmental time (without inducing other unwanted gene expression or altered regulation of resident genes)."[52] These obstacles have led researchers to experiment with other methods of gene transfer, such as anti-genes and germline engineering that, unlike somatic cell therapy, only requires gene modification once to the reproductive cells of the embryo.[53]

2. Germline Engineering or Inheritable Genetic Modification (IGM)

Germline engineering or the term "germline" refers to the "germ" or "germinal" cells of the eggs and sperm that are targeted for genetic modification.[54] Advances in biotechnology raise the possibility that ARTs such as PGD may move beyond simply

48. *Id*.; *see* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 105.

49. *See* FUKUYAMA, *supra* note 7, at 76.

50. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 113.

51. MERGES ET AL., *supra* note 18, at 612.

52. REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 107.

53. *See* LEE M. SILVER, REMAKING EDEN 273 (1998).

54. *See* ASS'N OF REPRODUCTIVE HEALTH PROFESSIONALS, HUMAN CLONING AND GENETIC MODIFICATION: THE BASIC SCIENCE YOU NEED TO KNOW, *available at* http://www.arhp.org/uploadDocs/cloning.pdf [hereinafter ARHP].

diagnosing or selecting embryos for particular traits, to genetic modification or engineering embryos for desired characteristics by changing the genes in a progenitor's gametes.[55] Current germline engineering technology represents such a shift in human reproduction as it incorporates normal cells into the germline or reproductive cells, essentially becoming part of the permanent genome of the offspring, which unlike somatic gene therapy would be passed onto the next generation through reproduction.[56] This multistep germline modification process includes: (1) using IVF to create a single-cell embryo or zygote that develops into the blastocyst stage; (2) embryonic stem cells are removed from the blastocyst, and the stem cell genes are modified using viral vectors; (3) modified stem cells colonies are tested for successful incorporation of the new genes; (4) a cloning process transfers the modified stem cell nucleus into an enucleated egg cell; and finally (5) the newly constructed embryo would then be implanted into a woman's uterus and after gestation would produce a genetically modified child.[57]

Although the science and technology required to enable parents to choose the genetic traits and characteristics of their children continues to remain speculative, researchers involved in recent genetic modification studies of mice and primates[58] believe scientific breakthroughs are inevitably pushing us closer to germline modification in humans.[59] Recent experimental breakthroughs demonstrating the technological feasibility of germline modification in mice have shown researchers can use sperm and eggs grown from Induced Pluripotent Stem Cells (iPSCs) for reproduction—a breakthrough theorized by some scientists involved in the project that could be applied not just to mice, but in other mammals as well, including humans.[60] In a second recent scientific breakthrough in germline modification, a new generation of genetically modified mice were developed using Haploid Embryonic Stem Cells (haESCs); a technique that researchers speculated could be used in the future to correct genetic diseases in germ cells not just of mice, but of humans,

55. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 106.

56. *See* ARHP, *supra* note 54; *see also* MERGES ET AL., *supra* note 18, at 612.

57. *See* ARHP, *supra* note 54.

58. *See* Anthony W.S. Chan et al., *Transgenic Monkeys Produced by Retroviral Gene Transform into Mature Oocytes*, 291 SCIENCE 309, 309-12 (2001).

59. *See* Katsuhiko Hayashi et al., *Offspring from Oocytes Derived from in Vitro Primordial Germ Cell–Like Cells in Mice*, 338 SCIENCE 971, 971 (2012).

60. *See id*.

too.[61] Finally, biologists have recently succeeded in cloning human stem cells by reprogramming somatic cells into pluripotent embryonic stem cells (ESCs) through somatic cell nuclear transfer (SCNT).[62] This groundbreaking technique produces human stem cells without the ethical implications that accompany the creation and destruction of human embryos—which could have significant implications for research of pluripotent stem cell regenerative medicines.[63] These scientific breakthroughs illustrate proponents' arguments that IGM is not only scientifically feasible, but could also be used to allow couples to avoid passing on serious genetic diseases, and have healthy offspring that is genetically related to both parents.[64]

Proponents of IGM such as Stock, reiterate that "[g]ermline engineering represents a shift in human reproduction, but as effective somatic therapies become common, reduced public concern about genetic interventions in general will smooth the way for a move from screening and selecting embryos to actually manipulating them."[65] However, critics of human germline manipulation "frequently point to the risks of passing on genetic errors to future generations. But even if errors are entirely preventable, making our early genetic modifications permanent parts of the human genome pool would be foolish."[66] Opponents such as Fukuyama are in limited agreement with Stock's perspective that germline engineering represents potentially the most consequential development in biotechnology. "The reason for this is that human nature is fundamental to our notions of justice, morality, and the good life, and all of these will undergo change if this technology becomes widespread."[67] Yet, both proponents and advisory agencies recognize the many shortcomings of germline engineering, and recommend that even if such genetic

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61. *See* Hui Yang et al., *Generation of Genetically Modified Mice by Oocyte Injection of Androgenetic Haploid Embryonic Stem Cells*, 149 CELL 605, 605-17 (2012); *see also* Wei Li et al., *Androgenetic Haploid Embryonic Stem Cells Produce Live Transgenic Mice*, 490 NATURE 407 (2012), *available at* http://dx.doi.org/10.1038/nature11435. *From Embryonic Stem Cells, a Sperm Replacement and Easier Path to Genetic Modification*, PHYS.ORG (Apr. 26, 2012), http://phys.org/news/2012-04-embryonic-stem-cells-sperm-easier.html.

62. *See* Masahito Tachibana, et al., *Human Embryonic Stem Cells Derived by Somatic Cell Nuclear Transfer*, 153 CELL 1228, 1228-38 (2013).

63. *See* Thomas A. Rando, *Stem Cells, Ageing and the Quest for Immortality*, 441 NATURE 1080, 1080-86 (2006); Katharine Brown et al., *SIRT3 Reverses Aging-Associated Degeneration*, 3 CELL REP. 319, 319-27 (2013).

64. *See* STOCK, *supra* note 3, at 56; *see also* BEYOND THERAPY, *supra* note 12, at 5.

65. STOCK, *supra* note 3, at 39.

66. *Id*. at 69.

67. FUKUYAMA, *supra* note 7, at 82-83.

errors could be reversed, safer alternatives should be pursued that minimize potential germline risks.[68]

3. Human Artificial Chromosomes (HACs)

The discussion surrounding current somatic gene therapy and germline genetic engineering technologies looks to minimize the safety risks, complexity, and costs associated; while maximizing flexibility, general application, and future technological adaptation. Researchers looking beyond current genetic engineering developments believe an answer has emerged in the form of a technology called Human Artificial Chromosomes (HACs). Scientists predict HACs could be the archetypal futuristic answer to all the problems of expensive, complex, and risky gene transfer technologies. However, HACs are not a relatively new technology, but rather were introduced in 1997, in a research article that first described the process of "combined long synthetic arrays of alpha satellite DNA with telomeric DNA and genomic DNA to generate artificial chromosomes in human HT1080 cells."[69] This fascinating introductory research claimed that, "[t]his first-generation system for the construction of human artificial chromosomes should be suitable for dissecting the sequence requirements of human centromeres, as well as developing constructs useful for therapeutic application."[70] Research has developed slowly over the last decade, and focused primarily on gene delivery and transfer into stem cells.[71] However, recent scientific advancements have stirred excitement with breakthroughs in gene therapy that have found HACs "exhibit several potential characteristics desired for an ideal gene delivery vector, including stable episomal maintenance and the capacity to carry large genomic loci with their regulatory elements, thus allowing the physiological regulation of the introduced gene in a manner similar to that of native chromosomes."[72] These breakthroughs with HAC research in animals highlight the technology's potential maturity and future development, in contrast to several aforementioned genetic

68. *See* FRANKEL & CHAPMAN, *supra* note 32.

69. John J. Harrington et al., *Formation of De Novo Centromeres and Construction of First-Generation Human Artificial Microchromosomes*, 15 NATURE GENETICS 345, 345, 355 (1997).

70. *Id*.

71. *See* Xianying Ren et al., *Human Artificial Chromosome Vectors Meet Stem Cells*, 2 STEM CELL REV. 43, 43-50 (2006).

72. Y. Kazuki et al., *Refined Human Artificial Chromosome Vectors for Gene Therapy and Animal Transgenesis*, 18 GENE THERAPY 384, 384-93 (2011).

engineering technologies.[73]

Proponents of genetic modification technologies propose widespread adoption will require generalized methods for germline modification and insertion, a problem in which the introduction of HACs could be the answer researchers have been searching for. The process would involve inserting a new chromosome pair (numbers 47 and 48) into our genome that would act as framework or platform in which to add or remove genetic modules, instead of trying to modify the genes on one of our present 46 chromosomes.[74] Compared to previous unreliable genetic modification techniques such as gene therapy, an artificial chromosome would provide a generalized and reproducible framework for adding and removing genetic material to cells, that could produce a reliable and potentially "safe" human germline technology. Proponents argue that such a technology would revolutionize the conception of reproduction, and create a marketplace where:

> Parents will want the most up-to-date genetic modifications available. Were these prospective parents' own modifications scattered through their chromosomes, cleaning them out and upgrading them would be tricky, but with changes confined to an auxiliary chromosome, a parent could simply discard the entire thing and give his or her child a new version.[75]

An advantage of such a technique could provide for "gene-packs" that could allow for hundreds, if not thousands of unique gene modifications to an embryo.[76] Based on proponents' futuristic predictions, HACs could solve many of the problems plagued by current genetic engineering technologies, and provide parents the option of passing on their chromosomal genetic upgrades to their children or discarding them.[77] Futurists predict this technological advancement if successful, would result in a profound transformation of the human condition, because ultimately "it is a convergence of the processes that will bring us as well as machines into being and shape our natures. Human conception is shifting from chance to conscious design."[78]

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[73] *See* Yuwna Yakura et al., *An induced pluripotent stem cell-mediated and integration-free factor VIII expression system*, 431 BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS 336 (2013).

74. *See* STOCK, *supra* note 3, at 66.

75. *Id*. at 69-70.

76. *See* SILVER, *supra* note 53, at 271.

77. *See* STOCK, *supra* note 3, at 70.

78. *Id*. at 75.

However, opponents of genetic modification such as Leon Kass, Chair of the President's Council on Bioethics, concede that such futuristic artificial chromosomal genetic modifications such as HACs, would be a safer alternative to the known risks of gene therapy or inheritable alternatives such as IGM.[79] Kass concedes that HACs (assuming a hypothetical agreement on their perceived safety), would have greater benefits over current genetic engineering technologies, because the creation and injection of artificial chromosomes would essentially enable "the new 'better' genes [to] be packaged in small, manufactured chromosomal elements that, on introduction into cells, would not integrate into any of the normal forty-six human chromosomes. Such artificial chromosomes could, in theory, be introduced into ova or zygotes without fear of causing new mutations."[80] In realizing the potential benefits of HACs, Kass is careful to recognize the technology is far from practical, and there exist significant challenges to overcome, such as the fact that genes introduced on an artificial chromosome "would now be present in three copies (one from mother, one from father, and one on the extra chromosome) instead of the usual two, throwing off the normal balance of gene copies among all the genes. The consequences of such 'triploidy' [could] be deleterious . . . ."[81] Therefore, Kass's superficial support of HACs over alternative genetic engineering technologies may simply be in response to the current unavailability of the technology, and belief that the safety risks will always pose a barrier to its adoption. However, as research and development of HACs continues, only time will tell if the technology materializes into the futuristic visions proposed by proponents of genetic engineering, or as suggested by opponents, into another unrealized speculative technology with promise, but with far too many practical hurdles to overcome to become a reality.[82]

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79. BEYOND THERAPY, *supra* note 12, at 37.

80. *Id.*

81. *Id*. Proponents would likely argue any reproductive safety concerns from opponents in respect to the feasibility of RGBs such as HACs, could simply be solved by removing or disabling the HACs, or inserting an anti-germline birth-control or sterilization module to prevent an inadvertent 'triploidy' or IGM.

82. *See* FUKUYAMA, *supra* note 7, at 77; *cf.* Def. Advanced Research Projects Agency (DARPA), *ST13B-001: Advanced Tools for Mammalian Genome Engineering*, SBIR/STTR (July 26, 2013), https://www.sbir.gov/node/411230 (defining DARPA's objective to "[i]mprove the utility of Human Artificial Chromosomes (HACs) by developing new selectable metabolic markers for use in human cells, new high-fidelity methods for inserting DNA constructs of at least 50,000 base pairs (bp) in length into defined genomic loci, and new methodologies for facile intercellular genome transplantation").

II. THE SOCIAL AND BIOETHICAL IMPLICATIONS

There are numerous social and ethical concerns proposed by both proponents and opponents of Reproductive Genetic Biotechnologies (RGBs) that form the extensive and varied controversial public debate surrounding reproductive technologies. The public debate put forward by both proponents and opponents of genetic modification span a broad range of contentious issues that are beyond the scope of this paper which include: constitutional reproductive issues, gender selection, eugenics, cloning, and abortion. Therefore, the following discussion will be divided into two sections. First, proponents' principle arguments in support of genetic engineering will be briefly introduced. Second, opponents' arguments against genetic engineering will be discussed, followed by corresponding rebuttals from proponents.

A. Proponents of Genetic Engineering

Proponents of RGBs have advanced numerous social, ethical, legal, and philosophical justifications. Yet, many of these arguments advocating support of genetic engineering are articulated in rebuttals to opponents' arguments against RGBs—discussed later in the paper in response to opponents' various arguments. However, for the purposes of lucidity, the following discussion will focus narrowly on only four of proponents' most salient points: evolution, inevitability, defining life, and feasibility.

First, proponents argue that humans have always acted in ways that affect the evolution of our species. "Human action has shaped human biology and altered the genome as long as there have been human beings: a series of non-biomedical enhancements of human capacities, from the agrarian revolution . . . has trigged processes of natural selection and mixed previously isolated gene pools."[83] From this perspective, RGBs are just the next step along a path long since taken. Moreover, a case can be made that humankind's modern day socio-technological progress has exceeded its outdated biology, rendering it necessary to accelerate our biological evolution. Gregory Stock articulates this point stating, "It is rather poignant that we cannot yet apply technology more directly to our biological selves, because the advances in transportation, telecommunications, and other areas that enable us to transcend some of our bodily limits give

83. ALLEN E. BUCHANAN, BEYOND HUMANITY?: THE ETHICS OF BIOMEDICAL ENHANCEMENT 1-2 (2011).

us the idea that we should also be able to stay our eventual aging and decay."[84]

Second, prominent proponents such as Julian Savulescu, argue in addition to Stock that "[g]enetic selection to determine how our children look, think and act isn't recklessly playing God . . . . It's a gift to future generations."[85] Savulescu articulates this modernist ideology of inevitability, an argument often posited by proponents, that "[i]f we have the power to intervene in the nature of our offspring—rather than consigning them to the natural lottery—then we should. Surely trying to ensure that your children have the best, or a good enough, opportunity for a great life is responsible parenting?"[86] This argument is founded on the conceptualization that if humankind has the ability to better our children, such improvements will be an inevitable consequence of providing for our offspring. Whether the improvement occurs pre-gestation or post gestation is irrelevant, because society is still trying to care for their children. This distinction of improvement analyzed from proponents' perspective, lends credibility to the inevitability argument that, "[w]hether we like it or not, the future of humanity is in our hands now. Rather than fearing genetics, we should embrace it. We can do better than chance."[87]

Third, futurist proponents such as Lee Silver argue opponents maintain a controversial defect in their definition in human life, and that there is a serious flaw in the logical progression that leads people to adopt the idea that the "essence" of human life is contained within our genetic material.[88] According to Silver, the flaw is caused by the inability of opponents to separate the different meanings of the word "life" at the level of the individual embryo and at the level of human consciousness.[89] This extremely important, yet controversial and complex discussion of attempting to define exactly when life begins, from either a theological or scientific perspective, is far beyond the scope of this paper. However, this important principle remains a fundamental differentiation between proponents and opponents, and provides further context to understanding justifications for or against

84. STOCK, *supra* note 3, at 33.

85. Julian Savulescu, *The Maverick: It's Our Duty to Have Designer Babies*, READER'S DIGEST (2012) (on file with Santa Clara High Technology Law Journal).

86. *Id.*

87. *Id.*

88. *See* SILVER, *supra* note 53, at 276.

89. *See id.*

RGBs. Silver and other proponents recognize the difficulty and futility of influencing opponents' definition of human life. As a result, proponents typically avoid advancing such arguments in favor of focusing on the benefits RGBs can bring to existing human life and the feasibility of the technology for prevention of genetic disease.

Fourth, proponents reject assertions that genetic modification is still highly speculative and thus not deserving of rational discourse. The crucial enabling technology for germline engineering was discovered in 1980,[90] and since then has seen advancements in "knocking out" or silencing genes.[91] These advancements were discovered in 2001, which include a new classification of ribo-nucleic acids (RNAs) that selectively silence genes after transcription.[92] Researchers introduce a specific germline modification in a mouse gene by injecting the mouse's fertilized eggs with DNA and grow embryonic stem cells encoding the intended change.[93] Researchers then inject the selected embryonic stem cells into a blastocyst, which is implanted in the foster mother mouse.[94] After gestation, the mother gives birth to chimeric mice that when mated with normal mice can give birth to mice with the targeted gene, thereby producing a "knock-out strain" in the subsequent mouse generation.[95] Some proponents have considered this development of knocking-out genes in the next generation of mice as a cornerstone of germline engineering research that will one day enable parents to select and manipulate the genetics of their children.[96] Moreover, proponents often synthesize these four main arguments when predicting future research and development in genetic engineering will inevitably lead to human genetic manipulation. Therefore, it's argued that "inevitability" of RGBs defeat opponents' arguments of feasibility, because such advancements are the logical conclusion of our ongoing evolution in reproductive biology.[97]

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90. *See* Jon W. Gordon et al., *Genetic Transformation of Mouse Embryos by Microinjection of Purified DNA*, 77 PROC. NAT'L ACAD. SCI. no. 12 7380, 7380-84 (1980).

91. *See* Goran K. Hansson, *Advanced Information: Gene Modification in Mice*, NOBELPRIZE.ORG (2007), http://www.nobelprize.org/nobel_prizes/medicine/laureates/2007/advanced.html [hereinafter Nobel].

92. *See* Jennifer Couzin, *Breakthrough of the Year*, 298 SCIENCE 2296, 2296 (2002).

93. *See* Nobel, *supra* note 91; *see also* STOCK, *supra* note 3, at 50.

94. *See* Nobel, *supra* note 91.

95. *See id.*; *see also* STOCK, *supra* note 3, at 50.

96. *See* STOCK, *supra* note 3, at 50.

97. *See id.* at 61.

1. Procreative Liberty and Genetic Engineering

Some proponents of RGBs argue that parents should be free to choose the genetic disposition of their children. John Robertson, who takes a moderate perspective on genetic engineering,[98] classifies procreative liberty proponents of RGBs as either radical libertarians or modern traditionalists.[99] Modern traditionalists hold "reproductive choice in a liberal, rights-based society is a basic freedom, including the use of genetic and reproductive technologies that are helpful in having healthy, biologically related offspring."[100] Radical libertarians would arguably support any form of genetic modification regardless of its purpose,[101] based on the fundamental principles of individual liberty, autonomy, and freedom, whereas modern traditionalists' "acceptance of reproductive and genetic technologies . . . exists only insofar as they aid the task of successful reproduction, and do not directly harm offspring, families, women, society, or others."[102] This perspective balances the benefits of non-medical genetic selection against the perceived costs and safety risks involved in such a selection. Therefore, justification for positive genetic modification of our children's genes, from a modern traditionalist perspective, would depend on the parent's reasons and whether it occurs as a result of therapeutic alteration or non-therapeutic alteration.[103]

a. Therapeutic Alteration

First, arguments advanced in support of IGM for therapeutic purposes focus on allowing couples to avoid passing on serious genetic diseases, such as "sickle cell anemia, Tay Saches disease, or cystic fibrosis."[104] However, opponents in rebuttal, claim other less risky methods already exist to accomplish the same goal, such as PGD that requires no manipulation of the germline.[105] Secondly, proponents posit that IGM can allow couples that both share a

98. *See* John A. Robertson, *Symbolic Issues in Embryo Research*, HASTINGS CENTER REP., Jan.-Feb. 1995, at 37.

99. Robertson, *supra* note 16, at 446, 474.

100. *Id*. at 446.

101. *See id.* at 474. Eisenstadt v. Baird, 405 U.S. 438, 453 (1972) ("If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.").

102. Robertson, *supra* note 16, at 446.

103. *See id.*

104. *See id.* at 476.

105. *See id.*

defective gene to have a healthy child that is related to both of them, rather than produce no child at all.[106] Yet, opponents still reject such assertions, because such cases are likely to be a very rare and small percentage to warrant IGM.[107] Lastly, proponents conclude that human IGM clinical trials need to continue in order to establish that the science and process behind therapeutic modification becomes safe and effective.[108] Therefore, any inherent risk or harm to the child, if minimized, would be a generally acceptable risk of medical progress.[109]

b. Non-therapeutic Alteration or Enhancement

First, proponents argue that if IGM could allow couples to "enhance" their children to be healthier, more athletic, intelligent, or attractive, such enhancement is supported by procreative liberty whether it occurs pre-birth or post-birth.[110] However, opponents refute such claims, because non-therapeutic enhancement would likely be permanent and affect future generations, and because genetic modifications are very different in quality and kind than post-birth enhancements.[111]

Second, proponents recognize the inherent threat to equality if genetic enhancement becomes so essential for reproduction it would require parents to engage in a genetic arms race for their children.[112]

> Many think that it is inherently unfair for some people to have access to technologies that can provide advantages while others, less well-off, are forced to depend on chance alone. I would agree. It is inherently unfair. But American society adheres to the principle that personal liberty and personal fortune are the primary determinants of what individuals are allowed and able to do. Anyone who accepts the right of affluent parents to provide their children with an expensive private school education cannot use 'unfairness' as a reason for rejecting the use of reprogenetic technologies.[113]

Therefore, proponents and opponents would likely agree that there exist serious risks of genetic social stratification, but it is unclear

106. *See id.*
107. *Id.*
108. *See* Robertson, *supra* note 16, at 476-77.
109. *Id.*
110. *See id.* at 478-79.
111. *Id.*
112. *See id.* at 479.
113. SILVER, *supra* note 53, at 10-11.

at what point proponents agree such risks warrant government regulation. In order to understand these complex issues and frame solutions to these future genetic societal problems, risks must also be examined in the context of post-humanism.

2. Our Post-Humanism Future

Many proponents of genetic engineering suggest if humankind were to adopt genetic engineering technologies that enable parents to choose the genetic characteristics of their children, and were to take the science a step further—to choose desirable genetic enhancements and abilities, such as sharper eyesight, better hearing, stronger immune systems, or greater intelligence—would the child still be considered human?[114] When framing humankind's existence and identity in this continually evolving context, one must accept that due to constantly changing somatic and germ-line mutations, the genetic composition of who we are today, is not who we were yesterday. This reconceptualization of existence is necessary to understand the post-humanist movement's principles as humankind looks to new frameworks to define life. Ray Kurzweil attempts to answer the question of identity in that, "I am rather like the pattern that water makes in a stream as it rushes past the rocks in its path. The actual molecules of water change every millisecond, but the pattern persists for hours or even years."[115] This poignant example forces us to re-examine the importance of our ideological belief that we define our existence not by the atoms or particles that make our bodies, but rather the pattern of our life form that existentially creates the essence of our being. In that sense, if we were to alter our physical bodies with futuristic RGBs such as those proposed, after such radical genetic modifications, would we continue to exist or simply be replaced by somebody or something else? "At bare minimum, even if enhancement brings such goodies as superhuman intelligence and radical life extension, it must not involve the elimination of any of your essential properties. For in that case . . . they would not be experienced by you—they would be experienced by someone else."[116] This quintessential point illustrates that this reconceptualization of

114. *See generally* GREGORY STOCK & JOHN CAMPBELL, ENGINEERING THE HUMAN GERMLINE: AN EXPLORATION OF THE SCIENCE AND ETHICS OF ALTERING THE GENES WE PASS TO OUR CHILDREN (2000).

115. KURZWEIL, *supra* note 11, at 383.

116. SCIENCE FICTION AND PHILOSOPHY: FROM TIME TRAVEL TO SUPERINTELLIGENCE 244 (Susan Schneider, ed., 2009).

human existence as a result of the ultimate genetic enhancements, could lead to enhancing our children beyond their essential properties, which would be tantamount to suicide. It is precisely these types of complex philosophical issues surrounding autonomy and existence that require the social and ethical implications of this post-humanism movement to be considered as equally important as the progression of the technologies themselves. If humankind ever chooses to adopt the benefits of this transformation, how it chooses to define the human condition and its impact on society will ultimately determine if RGBs are considered good or bad.[117] The salience of this post-humanism, and evolutionary genetic prospective has also been articulated from philosophers such as Friedrich Nietzsche:

> All beings so far have created something beyond themselves; and do you want to be the ebb of this great flood and even go back to the beasts rather than overcome man? What is the ape to man? A laughingstock or a painful embarrassment. And man shall be just that for the overman: a laughingstock or a painful embarrassment. You have made your way from worm to man, and much in you is still worm. Once you were apes, and even now, too, man is more ape than any ape.[118]

Whether man is in fact still an ape in the context of our current evolutionary perspective, or has already achieved natural evolutionary perfection is one of the fundamental dichotomies between proponents and opponents of RGBs. This divergence of ideologies is further explored by the following arguments advanced by opponents through their justifications of rejecting genetic modification technologies.

B. Opponents of Genetic Engineering

First, opponents of RGBs argue that public perception based on the pre-existing safe and successful biotechnological results of ARTs such as PGD, "may already be shifting parental and societal attitudes toward prospective children: from simple acceptance to judgment and control, from seeing a child as an unconditionally welcome gift to seeing him as a conditionally acceptable product."[119] However, such

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117. *See generally* JAMES HUGHES, CITIZEN CYBORG: WHY DEMOCRATIC SOCIETIES MUST RESPOND TO THE REDESIGNED HUMAN OF THE FUTURE (2004) (Advocating a moderate perspective of democratic post-humanism, where genetic engineering technologies will radically improve humankind, but only if we can democratically regulate their use, and make them equally available in free societies).

118. FRIEDRICH NIETZSCHE, THE PORTABLE NIETZSCHE 124 (Walter Kaufmann, ed. trans., Penguin Books 1977).

119. BEYOND THERAPY, *supra* note 12, at 35.

"child product" arguments against PGD hold little weight in public perception. The technology has already proven the procedure safe and effective; more than 1,000 babies have born worldwide[120] without any noticeable impact on social attitudes toward children. Opponents' perceptions may be accurate that public attitudes in support of PGD are shifting away from prevention of genetic diseases, to the selection of desired traits as the number of PGD procedures performed is increasing.[121] However, proponents respond that regardless of whether PGD is becoming a normative technology in society, and whether that transformation is perceived as a positive or negative, both parties agree that the earlier screening occurs, the more likely it is that prospective parents will have healthy offspring.[122]

Second, John Robertson characterizes many opponents of RGBs as strict traditionalists.[123] A strict traditionalist "holds that reproduction is a gift from God, resulting from the loving intimacy of two persons. They receive the gift of an embryo, fetus, and then child who is to be unconditionally cherished for its own sake."[124] A leading contemporary of strict traditionalism is Leon Kass, who postulates, "[w]hat's at issue is not the crude old power to kill the creature made in God's image but the attractive science-based power to remake ourselves after images of our own devising."[125] Kass uniquely articulates the social, ethical, and philosophical implications surrounding the debate of genetic modification from a strict traditionalist perspective and argues strenuously against genetic enhancement primarily because of its enormous potential to interfere with and diminish the purity of human nature.[126] As he explains:

> In a word, one major trouble with biotechnical (especially mental) 'improvers' is that they produce challenges in us by disrupting the normal character of human being-at-work-in-the-world, what Aristotle called *energeia psyches*, activity of soul, which when fine and full constitutes human flourishing. With biotechnical interventions that skip the realm of intelligible meaning, we cannot really own the transformations nor experience them as genuinely ours. And we will be at a loss to attest whether the resulting

120. *See* JUDITH F. DAAR, REPRODUCTIVE TECHNOLOGIES AND THE LAW 305 (2006).
121. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 90.
122. *See* Robertson, *supra* note 16, at 460.
123. *See id.*
124. *Id.* at 442.
125. BEYOND THERAPY, *supra* note 12, at 10.
126. *See id.*

> conditions and activities of our bodies and our minds are, in the fullest sense, our own as human.[127]

In this passage, Kass characterizes genetic enhancement biotechnologies as transformations that are not our own and, therefore, not human. Thus, Kass frames the quintessential question, "'What is biotechnology for?' but also, 'What should it be for?'"[128] The term biotechnology is understood to be "bigger than its processes and products; it is a form of human empowerment. By means of its techniques (for example, DNA sequences), biotechnology empowers us human beings to assume greater control over our lives, diminishing our subjection to disease and misfortune, chance and necessity."[129] It is precisely this enthusiasm for biotechnology that attempts to answer the question what biotechnology is for, with the knowledge that the "discoveries of biologists and the inventions of biotechnologists are steadily increasing our power ever more precisely to intervene into the workings of our bodies and minds and to alter them by rational design."[130] The public debate surrounding these emerging technologies, from the perspective of strict traditionalists, has already provided unwanted answers to these rhetorical questions expressed simply by the "[v]ast numbers of people and their families [who] ardently await cures for many devastating diseases and eagerly anticipate relief from much human misery. We will surely welcome . . . new technological measures that can bring us healthier bodies, decreased pain and suffering, peace of mind, and longer life."[131]

1. Going Beyond "Therapy" for "Enhancement"

In contrast to proponents' enthusiasm of biotechnology, opponents express caution in adopting these new biotechnologies that promise to usher in an era of healthier bodies, simply because "the prospect of genetic engineering, though welcomed for treatment of inherited genetic diseases, raises for some people fears of eugenics or worries about 'designer babies.'"[132] These fears form the crux of the strict traditionalist perspective and Kass's argument—a perspective which is predicated on the concern of the emerging juxtaposition of

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127. Leon R. Kass, *Ageless Bodies, Happy Souls: Biotechnology and the Pursuit of Perfection*, 1 NEW ATLANTIS 9, 24 (2003).

128. BEYOND THERAPY, *supra* note 12, at 1.

129. *Id.* at 2.

130. *Id.* at 5.

131. *Id.*

132. *Id.*

biotechnology applications in traditional medicinal use for healing, and those that go "beyond therapy," thus improving the human condition for enhancement purposes. Kass suggests that these broad concerns, "attach especially to these uses of biotechnology that go 'beyond therapy,' beyond the usual domain of medicine and the goals of healing, uses that range from the advantageous to the frivolous to the pernicious."[133] Kass's concerns justifiably find support in the public debate, primarily because his ideologies resonate with society's cultural and historical understanding that enhancement for enhancement sake, goes beyond the purpose of healing and raises important theological concerns that "[n]ot everyone likes the idea of 'remaking Eden' or of 'man playing God.'"[134]

Kass bemoans the tendency to dismiss these issues. In his words, "questions raised by efforts to 'improve on human nature' seem abstract, remote, and overly philosophical, unfit for public policy; indeed, many bioethicists and intellectuals believe either that there is no such thing as 'human nature' or that altering it is not ethically problematic."[135] However, Kass notes that the distinction between therapy and enhancement is not too remote or abstract—technologies that alter "human nature," such as cosmetic surgery and performance enhancing drugs, are already pervasive in our society.[136] Public attention is warranted now, before a wave of new and more extreme technologies alter human nature and human society.[137]

a. Seeking Perfection

For these reasons strict traditionalists narrowly focus on the implications of the "well-meaning and strictly voluntary uses of biomedical technology through which the user is seeking some improvement or augmentation of his or her own capacities, or, from similar benevolent motives, of those of his or her children."[138] The different motivations behind therapeutic alterations and non-therapeutic enhancements form an important cornerstone of opponents' arguments, because in effect they form the guideposts between moral justification and condemnation.[139] Strict

133. BEYOND THERAPY, *supra* note 12, at 6.
134. *Id.* at 7.
135. *Id.*
136. *See id.* at 8.
137. *See id.* at 10.
138. BEYOND THERAPY, *supra* note 12, at 10.
139. *See* MICHAEL J. SANDEL, THE CASE AGAINST PERFECTION: ETHICS IN THE AGE OF

constructionists perceive "[s]uch use of biotechnical powers to pursue 'improvements' or 'perfections,' whether of body, mind, performance, or sense of well-being, is at once both the most seductive and the most disquieting temptation."[140]

Differentiating between these two ideologies of therapy and enhancement arguably distinguish opponents' Kantian philosophy, where the ends do not justify the means. This moral perspective on self-augmenting capabilities, or the idea of enhancement, is understood as seeking something "better than normal" or human perfection itself.[141] This reflection illustrates the "perfectionist" strict constructionist argument against RGBs, because such perfection or enhancement can only be seen as a means to an end. Thus, those in pursuit of perfection must distort the modern day intended purpose of ARTs and RGBs, which is the prevention and curing of disease, in order to alleviate suffering.[142]

b. Seeking Normality

Kass rejects proponents' arguments that support RGBs based on genetic inequality in order to pursue human normality.[143] This controversial idea of normality is defined by the libertarian argument that the human condition and its capacities acquired at birth are no more than a product of pure chance. As a result "[m]ost human capacities fall along a continuum, or a 'normal distribution' curve, and individuals who find themselves near the lower end of the normal distribution may be considered disadvantaged and therefore unhealthy in comparison with others."[144]

Predictably, Kass simultaneously acknowledges and dismisses the normality argument advanced by proponents of enhancement, because even though normality may not be driven by "perfection," those who unluckily fall on the low-end of the culturally-relative spectrum, exist as a result of human nature; therefore, "[a]lthough less radical than the quest for 'perfection,' the quests for happiness, success, and self-esteem, especially in our society, may prove to be more powerful motives for an interest in using biotechnical power for

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GENETIC ENGINEERING 8-18 (2007).

140. BEYOND THERAPY, *supra* note 12, at 10.

141. *See id*. at 14.

142. *See id*. at 12.

143. *Id.* at 131-34, 140, 281-82.

144. *Id*. at 18.

purposes that lie 'beyond therapy.'"[145] Kass concedes that, given the opportunity, "many of us might welcome biotechnical assistance in improving our native powers of mind and body, many more people will probably turn to it in search of advancement, contentment, and self-satisfaction—for themselves and for their children."[146] Yet, opponents are careful to differentiate that even though many people would pursue enhancement if available and proven safe, further study is still needed to determine the far-reaching implications, and whether accessibility to these biotechnologies will be equitably distributed. If such genetic enhancements are pursued without regard for its social implications, opponents argue disastrous social consequences could follow.[147]

c. Natural Limits Theory

Kass characteristically poses the quintessential question of genetically engineering our children's genes: "[w]hat parents would not wish to enhance the life of their children, to make them better people, to help them live better lives?"[148] Parents fundamentally strive to improve and better their children by means of clothing, nutrition, education, and support until they become adults. It has been this inherent concept of naturally improving our children that is under scrutiny, argues opponents, because present and projected biotechnologies will provide new and powerful means for improving our children.[149] The moral and philosophical questions raised in response by Kass presuppose the improvement of our children, and the means best suited to accomplish these goals are inherently limited as a design of human nature. Yet opponents recognizes these limitations are in actuality, inequalities placed on human nature itself:

> [N]ature sets limits on what can be accomplished by education and training alone. No matter how much we try to help, the tone-deaf will need more training to learn to carry a tune, the short will be less likely to excel at basketball, the irascible will have trouble restraining their tempers, and the insufficiently smart will remain handicapped for competitive college admissions.[150]

If our children's natural "equipment" is faulty or limited by

145. *Id.* at 19.
146. BEYOND THERAPY, *supra* note 12, at 19.
147. *See id.*
148. *Id.* at 25.
149. *See id.* at 27.
150. *Id.*

means which will prevent them from realizing their true human potential (either by subjective or objective determinism), parents will naturally wish and seek out methods to improve or better their children as they have always done. Improving our children in this context is a socially conditioned maxim that requires no justification, when "[e]ven before the coming of the present age of biotechnology, we have used technological adjuncts to improve upon nature's gifts. We give our children supplementary vitamins, fluoridated toothpaste, and, where necessary, corrective lenses or hearing aids."[151] These culturally normative improvements and adaptations of our children's gifts provide little support to Kass's "natural limits" theory, which is further exacerbated by continued technological developments enabling parents to "use biological means of improving their [children's] limited human capacity to resist disease: we immunize our children against polio, diphtheria, and measles, among other infectious diseases, by injecting them with attenuated viruses and bacteria in the form of vaccines."[152]

2. Safety Risks of Genetic Engineering

Finally, opponents question the post-human agenda on biological and safety grounds. In order for genetic engineering to be done, "one would first need to identify all (or enough) of the specific variants of genes whose presence (or absence) correlates with certain desired traits: higher intelligence, better memory, perfect pitch, calmer temperament, sunnier disposition, greater ambitiousness, etc."[153] These socially normative "desired traits" of parents for their unborn children, even if they were discovered, are genetic traits heavily influenced by the external environment, which "are most certainly polygenic, that is, traits (or phenotypes) that depend on specific genes or their variants at several, perhaps many, distinct loci."[154] The complexity of these polygenic and epigenetic gene interactions would essentially prevent parents from choosing desired traits beyond simple single gene interactions such as height, eye, or hair color.[155] Furthermore, because many of the genes involved in the expression of

151. *Id.* at 28.

152. BEYOND THERAPY, *supra* note 12, at 28*; see* KATHLEEN S. SWENDIMAN, CONG. RESEARCH SERV., RS21414, MANDATORY VACCINATIONS: PRECEDENT AND CURRENT LAWS (2011).

153. BEYOND THERAPY, *supra* note 12, at 35.

154. *Id.*

155. *See id.* at 36.

normal traits are "pleiotropic—that is, they influence many traits, not just one—even a properly inserted gene introduced to enhance a particular trait would often have multiple effects, not all of them for the better."[156] For these reasons, opponents conclude that any attempt to genetically modify or enhance normal "healthy" gametes or embryos would be unsafe, infeasible, and ethically suspect.[157]

In response, proponents recognize that there exist numerous polygenic and epigenetic safety concerns that need to be addressed. However, if the technology is proven to be successful, it would only be introduced if it were possible to block genetic transmission to the next generation.[158] Moreover, proponents understand that proving the technology to be successful will require inherently risky and unpredictable human clinical experimentation. Yet, proponents are careful to argue that all medical progress does entail some risk within generally accepted parameters, and genetic modification could be reversed if problems occur.[159] Furthermore, proponents argue that when viewing RGBs as a form of medical progress, any arguments against the use of medical assistance in reproduction would only be justified if based on a theological or metaphysical perspective of "natural" reproduction; essentially condemning all forms of technological assistance.[160] Unless opponents believe that any interference with the natural process of reproduction is wrong, such an argument against medical progress could not withstand scrutiny, because societal technological advancements currently assist humans with the limitations nature has placed on them. Proponents use this perspective to justify their argument that utilizing ARTs and, potentially, RGBs pre-birth to assist in the creation of life is no more objectionable than using technologies post-birth to sustain or support that life.[161]

In contrast to proponents who are excited that RGBs will usher in a new era of human evolution, opponents such as Bill McKibben argue that it is wrong to alter human nature.[162] According to McKibben, "What makes us unique is that we can restrain ourselves. We can decide not to do something that we are able to do. We can set

156. *Id.* at 37.
157. *See id.*
158. *See* STOCK, *supra* note 3, at 69.
159. *See id.* at 153.
160. *See* SILVER, *supra* note 53, at 275-76.
161. *See* Robertson, *supra* note 16, at 444.
162. *See* MCKIBBEN, *supra* note 13.

limits on our desires. We can say 'Enough.'"[163] McKibben argues we need to preserve humankind's uniqueness before we lose our capacity for restraint. As the availability of genetic enhancement technologies becomes as ubiquitous in society as elective cosmetic surgeries, or pharmaceutical enhancing drugs, the ability for humankind to define and retain its "essential properties" will become increasingly difficult.[164] According to McKibben, we must question not only our desire to improve, but also how we choose to reach that goal.[165]

3. Inequality Concerns of Genetic Discrimination

If the proliferation of RGBs is only available to a select few who can afford them, the consequences will likely divide society and create two related problems: social inequality and unfairness.[166] The division will likely further perpetuate social inequality and further entrench socio-economic stratification, because RGBs will initially only be available to those who can afford the elective procedures involved.[167] IVF alone can cost an average of $37,000 per delivery; the genetic manipulations of embryos required will add further expense.[168] Moreover, most health insurance does not cover IVF[169] and is unlikely to cover add-ons such as the engineering of embryos.[170] Therefore, most people will not be able to afford RGBs. Society could attempt to minimize the threat to equality by providing universal coverage of genetic enhancements, or subsidizing their availability to the genetically disadvantaged. Yet, such "utopian eugenics"[171] would be prohibitively expensive, because such widespread access to enhancements that depended on IVF or PGD would cost $120 billion per year for IVF services alone.[172] Additionally, attempting to subsidize genetic enhancements would require identifying genetically disadvantaged individuals and groups,

163. *Id*. at 205.

164. *See id*. at 109-17.

165. *See* MCKIBBEN, *supra* note 13.

166. *See* Mehlman, *supra* note 21, at 533-34.

167. *See* FUKUYAMA, *supra* note 7, at 81.

168. *See* Mehlman, *supra* note 21, at 530-31.

169. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 154-55; *see also* Judith F. Daar, *Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms*, 23 BERKELEY J. GENDER L. & JUST. 18, 36-37 (2008).

170. *See* Mehlman, *supra* note 21, at 531.

171. *See* SILVER, *supra* note 53, at 261.

172. *See* Mehlman, *supra* note 21, at 532.

which raise serous practical, moral, and political concerns.[173] Furthermore, because society will not be able to provide everyone with access to the same genetic enhancements the wealthy can purchase, there would continue to be an inherent inequality.[174]

Employers and educators are an example of a constituency that will likely face new challenges in determining fairness and equitability in regulating standards for enhanced versus unenhanced individuals.[175] For example, studies show that people who are tall and physically attractive are more likely to be hired and promoted than people who are short or unattractive.[176] Genetically enhanced individuals could have an unfair advantage in competition for scarce societal and economic resources such as aptitude-based employment, or academic acceptance, because genetic enhancement could improve characteristics that are arguably suited for success and well-being.[177] Some commenters have even proposed futuristic scenarios in which unequal access to RGBs "eventually create[s] a political system dominated by a genetic aristocracy, or 'genobility,' that possesses a lock on wealth, privilege, and power."[178] As Francis Fukuyama states:

> What the emergence of a genetic overclass will do to the idea of universal human dignity is something worth pondering. . . . [T]o the extent that [bright and successful young people] become "children of choice" who have been genetically selected by their parents for certain characteristics, they may come to believe increasingly that their success is a matter not just of luck but of good choices and planning on the part of their parents, and hence something deserved. They will look, think, act, and perhaps even feel differently from those who were not similarly chosen, and may come in time to think of themselves to be aristocrats, and unlike aristocrats of old, their claim to better birth will be rooted in nature and not convention.[179]

However speculative these concerns of inequality may be, they

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173. *See id*. at 555-56.

174. *See id*. at 555.

175. *See* JOHN E. J. RASKO, GABRIELLE M. O' SULLIVAN & RACHEL A. ANKENY, THE ETHICS OF INHERITABLE GENETIC MODIFICATION: A DIVIDING LINE? 160-61 (2006).

176. *See* Mehlman, *supra* note 21, at 533; *see also* Daniel S. Hamermesh & Jeff E. Biddle, *Beauty and the Labor Market*, 84 AM. ECON. REV. 1174, 1192 (1994) ("Other things equal, wages of people with below-average looks are lower than those of average-looking workers and there is a premium in wages for good-looking people that is slightly smaller than this penalty.").

177. *See* Mehlman, *supra* note 21, at 577.

178. *Id*. at 533.

179. FUKUYAMA, *supra* note 7, at 157.

must be considered in the context of the future development of RGBs, and the public policies and regulatory oversight ensuring their safe and equitable adoption; otherwise opponents' predictions of genetic engineering causing irreparable societal dysfunction may become a reality.

III. POLICY RECOMMENDATIONS

The public policy debate over germline engineering technologies and HACs raises questions about how these technologies are regulated now, or should be regulated in the future. This section will explore the possibilities of regulatory responses to the challenges posed by new RGBs, from adapting current regulation to the creation of a new regulatory institution.

A. Current Regulation

1. Federal Regulation of Gene Transfer Research

Presently, there is no federal law or promulgated regulations directly addressing the genetic modification of gametes or early embryos, likely because the science supporting genetic modification is currently unavailable and regarded as purely speculative.[180] However, gene transfer research is subject to federal regulations.[181] Some commenters believe germline engineering technologies and HACs could fall under the broad definition of "gene transfer" for regulatory purposes.[182] Thus, this section will examine existing regulations and discuss whether they apply.

a. NIH and FDA Oversight

There are currently only two principal sources of federal regulatory oversight of gene-transfer research: the National Institute of Health (NIH) and the FDA.[183] The NIH provides oversight of

180. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 110; *but cf.* Council of Europe Convention on Biomedicine and Human Rights, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Dec. 1, 1999, E.T.S. No. 164 ("An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.").

181. REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 110-13; *see* 21 C.F.R. § 1271 (2012).

182. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 110-13.

183. *Id.*

gene-transfer technologies and funding applications through the Recombinant DNA Advisory Committee (RAC) that considers the social and ethical implications of "novel gene-transfer research protocols that have some funding connection with NIH."[184] Presently, the RAC is "responsible for ethical review of all NIH-funded research proposals that involve putting genes into human beings, [and] is, as a matter of policy, not reviewing any proposals that seek to modify gametes or embryos."[185] This decision not to federally fund such research has created an effective moratorium, except in cases where the research is privately funded.[186]

The FDA is tasked with monitoring the safety and effectiveness of gene-transfer products. The FDA oversees gene-therapy products that are classified as, "any transfer to a human subject . . . that introduce[s] genetic material into the body to replace faulty or missing genetic material (or to alter the regulation of resident genes) for the treatment or cure of disease . . . ."[187] Additionally, the FDA has asserted authority over gene-therapy products which include "biologically based articles, such as a subject's own cells that have been extracted and modified outside the body prior to re-transfer into the human subject, or articles (natural or synthetic) that are directly transferred to the human subject with the intention of genetically altering his or her cells."[188] The FDA's claim to authority over gene-therapy products came from a published Federal Registrar Notice in 1993,[189] which broadly defined its authority and oversight of gene-therapy products that, "'contain genetic materials administered to modify or manipulate the expression of genetic material or to alter the biological properties of living cells.' Such products are subject to the licensing, false labeling, and misbranding provisions for biologics"[190] under the Public Health Service Act (PHSA)[191] and drugs under the U.S. Federal Food, Drug, and Cosmetic Act (FDCA).[192] Furthermore, because the FDA has potentially classified gene-therapy products as

184. *Id.* at 111.

185. BEYOND THERAPY, *supra* note 12, at 37-38.

186. *See* Robertson, *supra* note 16, at 483; *see also* FRANKEL & CHAPMAN, *supra* note 32, at 8.

187. REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 111.

188. *Id.*

189. *See* Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248, 53,248 (Oct. 14, 1993).

190. REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 112.

191. *See* 42 U.S.C.A. § 262(a) (West 2014).

192. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2012).

both biologics and drugs, manufacturers would be required to obtain both a Biologics License Application (BLA) and a New Drug Application (NDA).[193]

However, the FDA's scope of authority is limited in the respect that it only has authority to regulate claims of safety and effectiveness of germline therapy products on human subjects, not the products themselves. The regulations may not legally apply to early embryos or gametes that are not considered legal subjects, because human subject protections only reach embryos once they are implanted through IVF.[194] The Office of Human Research Protections (OHRP) and the FDA under the Common Rule,[195] protect embryos inside a woman's uterus as human subjects for purposes of research on pregnant women and fetuses.[196] If the regulations did apply, presumably the FDA would not approve germline engineering technologies or HACs, because such technologies have not been proven safe or effective.[197]

b. Non-governmental Organization (NGO) Regulation

Numerous professional societies and NGOs have issued statements in response to emerging genetic engineering and gene-therapy technologies, including American Association for the Advancement of Sciences (AAAS),[198] which "urged an immediate block on a wide range of clinical procedures that the group labeled 'inheritable genetic modifications' (IGM);"[199] and the Council for Responsible Genetics (CRG), which strongly opposes the use of germline gene modification in humans based on scientific, ethical, and social concerns.[200] Other influential NGOs include the American

193. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 112 (citing Public Health Service Act 42 U.S.C. § 351(a), 42 U.S.C. § 262(a)).

194. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 111-13.

195. *See* 45 C.F.R. § 46.201 (2001) (specifically Subpart B--Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research).

196. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 131-32, 135.

197. *See id.* at 113.

198. *See generally* ENITA A. WILLIAMS, GOOD, BETTER, BEST: THE HUMAN QUEST FOR ENHANCEMENT (2006) *available at* http://shr.aaas.org/projects/human_enhance/reports/HESummaryReport.pdf; *see also* SCOTT F. GILBERT, DEVELOPMENTAL BIOLOGY (9th ed. 2010) (citing N. Schichor et al., *Should We Allow Genetic Engineering? A Public Policy Analysis of Germline Enhancement*, DEVBIO (2010), http://9e.devbio.com/article.php?id=172.

199. STOCK, *supra* note 3, at 153; *see generally* FRANKEL & CHAPMAN, *supra* note 66.

200. *See* Council for Responsible Genetics, *Position Paper on Human Germline*

Medical Association (AMA), which has stated that "genetic engineering should be conducted safely, no dangerous viruses should be employed, and the safety and effectiveness of any such procedures should be evaluated very closely."[201] Analogous to the CRG's response to genetic engineering, the AMA asserts that germline modification should not be explored because of the "'welfare of future generations and its association with risks and potential for unpredictable and irreversible results.' Nontherapeutic applications of gene-transfer are 'contrary to the ethical traditions of medicine and against the egalitarian values of society.'"[202] While professional societies do not have formal regulatory authority, their influence on constituencies and policy makers could have a significant impact on how current and future genetic engineering legislation is perceived and directed by the general public.

B. Future Regulation

Once RGBs become feasible, or nearly so, the public may demand a legislative or regulatory response. This section will consider four possible policy options.

1. Congress Bans Reproductive Genetic Biotechnologies (RGBs)

First, those who oppose germline engineering on religious, moral, or policy grounds might urge Congress to impose a legislative ban on all pertinent technologies. However, such a ban will likely be ineffective for several reasons. There are hundreds of fertility clinics in the United States. These clinics, and the labs associated with them, offer IVF and related technologies to thousands of clients every day. Doctors harvest eggs and sperm; labs use those gametes to create embryos; and doctors then transfer embryos back into the wombs of women who are anxious to become parents. Throughout all of this activity, medical privacy reigns supreme. In such a setting, it would be easy for physicians to employ unauthorized RGB procedures to alter the gametes or embryos with desired genetic modifications,

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Manipulation, COUNCIL FOR RESPONSIBLE GENETICS [hereinafter *Human Germline Manipulation*], *available at* http://www.councilforresponsiblegenetics.org/ViewPage.aspx?pageId=101# (last visited Oct. 2, 2013).

201. REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 113; *see also Human Germline Manipulation*, *supra* note 200, at 118.

202. REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 111-13.

under the pretense of a normal IVF procedure.[203] As a result, the only effective way to ban such a practice, would be to ban both therapeutic and enhancement procedures.[204]

Moreover, even if RGBs were illegal within the United States, parents could simply travel to other countries with laxer laws, undergo IVF with RGBs, and return to the United States to birth the genetically modified child.[205] Such a scenario would likely be too burdensome for the U.S. to regulate or enforce, because it would require a controversial determination of whether or not a child has been illegally enhanced. In addition, law enforcement would need to establish specific criteria and consequences for illegal "therapy" or "enhancement," and under what circumstances children would be subject to mandatory genetic testing.[206] Creating such an elaborate enforcement scheme would likely prove a complete ban unrealistic, especially if the enhancement would create a social benefit for both the individual and society.[207]

Furthermore, enforcing this Federal-funding ban will likely prove ineffective, as researchers continue to cross thresholds previously considered off limits, by replacing human mitochondrial DNA in embryos to avoid gene mutations that could be epigenetically passed onto the next generation.[208] A similar technique, called ooplasm transfer[209] has produced, to date, thirty children born worldwide, but it has not been approved for clinical testing within the United States.[210] Therefore, for practical reasons, a future ban on

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203. *See* Mehlman, *supra* note 21, at 564-65 ("The FDA presently has no authority to control the prescribing behavior of physicians. Consequently, they are free to prescribe products for unauthorized uses.").

204. *See id.*; *see also* STOCK, *supra* note 3, at 153; *About Us*, EDITAS MEDICINE, http://editasmedicine.com/about.php (last visited Feb. 25, 2014) ("The company's mission is to translate its genome editing technology into a novel class of human therapeutics that enable precise and corrective molecular modification to treat the underlying cause of a broad range of diseases at the genetic level.").

205. *But see* George J. Annas et al., *Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations*, 28 AM. J.L. & MED. 151, 154 (2002).

206. *See* Mehlman, *supra* note 21, at 565-68.

207. *See id.* at 565-70.

208. *See* Masahito Tachibana et al., *Towards Germline Gene Therapy of Inherited Mitochondrial Diseases*, 493 NATURE 627 (2012), *available at* http://dx.doi.org/10.1038/nature11647.

209. *See* Kerry L. Macintosh, *Brave New Eugenics: Regulating Assisted Reproductive Technologies in the Name of Better Babies*, 2010 U. ILL. J.L. TECH. & POL'Y 257, 271 (2010).

210. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 28, 34; *see* Jason A. Barritt et al., *Cytoplasmic Transfer in Assisted Reproduction*, 7 HUM. REPROD. UPDATE 428,

RGBs may prove ineffective.

2. Congress Augments the Regulatory Authority of the FDA

Second, proponents of germline engineering have proposed that Congress might enact legislation to expand the scope of the FDA's authority to cover RGBs. The advantage of this approach is that the FDA already exists and (arguably) is ready to exercise oversight, at least on safety and efficacy grounds.[211] However, the FDA's existing patterns of activity do not regulate RGBs, but rather "drugs, devices, and biologics that are or will be marketed for use in the United States. Its principal purpose is to ensure the safety and efficacy of products according to their approved use."[212] Therefore, in order for the FDA to expand its jurisdiction to include RGBs, "it might be necessary for the FDA to construe an embryo that might be transferred into a uterus as a 'drug,' 'biological product,' or 'device.'"[213] Classifying future genetic engineering technologies under the FDA's definitions of drugs, biologics, or devices will likely present regulatory challenges, because each definition carries its own regulatory frameworks that would require a statutory amendment to define a modified human embryo as a "product."[214] If Congress fails to ban RGBs, the FDA will most likely continue to provide regulatory authority over ARTs and future RGBs, under the auspices of these definitions, as it already understands the complex challenges involved in exercising jurisdiction over these broad definitions.[215] Furthermore, the FDA's unique position distinctively qualifies it to undertake the daunting responsibility of creating regulatory policies and guidelines that

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428-34 (2001).

211. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 188 (The FDA regulates a broad range of consumer products under the Food, Drug, and Cosmetic Act (FDCA), and the Public Health Services Act (PHSA)).

212. *Id.* at 55; *see generally* Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (West 2014); Public Health Services Act, 42 U.S.C. § 201 (West 2014).

213. REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 61.

214. *See* Elizabeth C. Price, *Does the FDA Have Authority to Regulate Human Cloning?*, 11 HARV. J. L. & TECH. 619, 638-41 (1998) (arguing the FDA does not have the statutory authority to regulate embryos as biological products for human cloning).

215. *See id.* at 55; *cf.* FRANCIS FUKUYAMA & FRANCO FURGER, BEYOND BIOETHICS: A PROPOSAL FOR MODERNIZING THE REGULATION OF HUMAN BIOTECHNOLOGIES 231 (2006) ("Even assuming that by some obscure legal theory the FDA does have the power the adjudicate contentious ethical questions – i.e., to regulate the use of new reproductive technologies and biomedical research not exclusively in terms of safety and efficacy – it would be unsuitable for this task.").

would support successful future regulation of RGBs.[216] The following three classifications: (i) drugs, (ii) biologics, and (iii) devices, are briefly discussed as potential classifications the FDA could expand to include RGBs within its jurisdiction.

a. Drugs

The FDA could exercise its jurisdiction over RGBs under the broad statutory definition of "drug" which is defined according to the Food, Drug, and Cosmetic Act (FDCA), as "encompassing any officially recognized article that is either (1) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, or (2) (excepting foods) intended to affect the structure or any function of the body of man."[217] The definition of a drug or dietary supplement under the FDA currently categorizes pharmaceutical products, or off-label products, which are subject to premarket authorization. However, classifying RGBs as drugs likely encompasses too broad of a definition and offers inadequate regulation for a drug that would change the structure and function of the human body.[218]

b. Biological Products

The FDA under the PHSA has the regulatory authority to regulate "biological products," defined as "'any virus, therapeutic serum, toxin, anti-toxin, vaccine, blood, blood component or derivative, allergenic product or analogous product, applicable to the prevention, treatment or cure of diseases or injuries to humans.'"[219] Similarly, an Investigational New Drug Application (IND) required for drugs, and biologics must also undergo an approval process through a Biologics License Application (BLA), which requires the product be "safe, pure, and potent."[220] In addition, under the FDA's authority to regulate biological products, it oversees the Center for Biologics Evaluation and Research (CBER), which has "undertaken

216. *See* Christine Willgoos, *FDA Regulation: An Answer to the Questions of Human Cloning and Germline Gene Therapy*, 27 AM. J.L. & MED. 101, 119-24 (2001) ("[T]he FDA appears to be a good candidate for the oversight of genetically manipulated reproductive technology.").

217. REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 55-56.

218. *See* JULIAN SAVULESCU ET AL., *supra* note 11, at 511.

219. REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 56 (citing 42 U.S.C. § 262(i) (West 2014)).

220. *Id.* at 57.

regulation of cellular and gene-therapy products," [221] which must meet the same pre-market standards for safety as drugs. Therefore, the FDA could potentially encompass future gene-modification RGB products under a strained biologic definition, but such a classification for enhancement may not be suitable.

c. Devices

According to the FDA, the products that are subject to premarket authorization include drugs, biological products, food additives, and devices that the FDA reviews on a product-by-product basis, and "determines whether the proposed device is substantially equivalent to a product that is already on the market."[222] Similar to the definition of "drug" and "biological product" discussed earlier, a "device" is defined as any "'instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including any component' that is officially recognized, intended for the diagnosis, treatment, cure, mitigation, or prevention of disease in man, or intended to affect the structure and function of the body."[223] The FDA reviewers often require manufactures to provide product related scientific research data and detailed product information when submitting a product to the FDA in order to support their regulatory decisions—those presenting greater safety risks such as RGBs would likely be subject to a more rigorous pre-market approval process for safety and effectiveness.[224] However, because the FDA's regulatory authority only regulates products and claims about products, not the technologies themselves; the FDA may not be aware of the unsanctioned use of RGBs on the market, a safety problem perceived by many as a serious regulatory inadequacy.[225] However, looking at how medical devices are currently regulated and examining their efficacy under the FDA's FDCA may help illustrate the FDA's ability to adequately regulate RGBs as medical devices, rather than drugs, or biologics now and in the future. Devices are regulated in a tiered three level classification system that is based on the relative degree of risk associated with the product:[226] Class I or II devices are

221. *Id.*

222. *Id.* at 59.

223. *Id.* at 58.

224. *Id.* at 59.

225. *See* Robertson, *supra* note 16, at 483; *see also* Mehlman, *supra* note 21, at 564-66 (suggesting the DEA rather then the FDA may be the most appropriate government agency to regulate genetic enhancements).

226. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 59.

considered low risk in which the safety and effectiveness are well established; Class III devices are the most complex and significantly high-risk devices used to sustain or support life, or those implanted in the human body.[227] Therefore, although the FDA's definition of devices could likely incorporate future RGBs as Class III devices, Congress would be required to augment the FDA's regulatory authority beyond its current classification system to adequately consider the moral concerns of RGBs.

3. Congress Creates a New Independent Regulatory Agency

Third, Congress could enact legislation authorizing the creation of a new regulatory agency focused specifically on the oversight of genetic engineering biotechnologies. This ambitious task would require the new agency to be more competent than the FDA to deal with the complex array of social, ethical, and legal issues. In practice, this new independent agency could more effectively decrease bureaucracy currently existing between multiple agencies claiming authority, and provide unified regulatory guidance for research and development funding requirements.[228] Traditionally Congress has established independent regulatory agencies to oversee specific policy-making areas that require extensive expertise and judgment, and provide isolation from political considerations.[229] Currently, many of the emerging issues discussed in assisted reproduction, genetic engineering, and RGBs are new and unprecedented, and do not fall naturally into the jurisdiction of any existing government body or agency.[230] This new agency could be authorized to directly consider policy concerns that extend beyond the FDA's purview of safety and efficacy.

Initially, a new agency tasked with regulatory authority over genetic engineering technologies, would need to be cautious not to expand its authority to include differentiating biotechnologies as either therapy or enhancement. Granting such authority to differentiate between the approval of technologies for therapy and not enhancement purposes, could grant this new governmental regulatory agency an effective monopoly over which future biological traits of its citizens are acceptable; a fear shared by many opponents of IGM

227. *See id.*

228. *See* FUKUYAMA, *supra* note 7, at 215.

229. *See* FUKUYAMA & FURGER, *supra* note 215, at 293-311.

230. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 187.

as a method of eugenics.[231] Opponents such as Fukuyama argue that the "FDA [or a new agency] is not set up to make politically sensitive decisions concerning the point at which selection for characteristics like intelligence and height ceases to be therapeutic and becomes enhancing, or whether these characteristics can be considered therapeutic at all."[232]

Other nations have already created independent agencies to address these challenges such as: the Human Fertilization and Embryology Authority (HFEA) in Britain, and the Assisted Human Reproduction Agency (AHRA) in Canada.[233] In response, some commenters have suggested that the creation of a new regulatory agency would likely resemble Britain's HFEA,[234] and would act with its new federal authority to place greater restrictions on RGBs.[235] However, a new regulatory agency could potentially accelerate future research and development of RGBs, if national attention and focus is brought to the issue through a national conversation that has previously remained largely inaccessible to the general public.[236] Furthermore, creation of an independent agency may be more adept at handling the complex policies required of RGBs, but it could arguably lead to more restrictive regulation if political conflicts over embryo status, federal research funding, and abortion rights shift the focus of its purpose.[237] As several commenters have suggested, if left to free-market forces, "[m]ost regulation will occur informally through the market interactions of willing consumers and providers of these services against a background of common law norms, some professional self-regulation, and occasional state legislative intrusions."[238] Therefore, Congress could decide to give the FDA the power to consider moral and philosophical issues of RGBs, thereby

231. *See* Mehlman, *supra* note 21, at 556-57.

232. FUKUYAMA, *supra* note 7, at 213.

233. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 187; FUKUYAMA & FURGER, *supra* note 215, at 149-79.

234. *See* Letter from the Center for Genetics and Society addressing HFEA's current consultation on Mitochondrial Replacement Research (Nov. 15, 2012) (The HFEA launched a public consultation to gather views on the social and ethical impact of mitochondria replacement techniques. In response the CRG sent a letter to the HFEA, strongly recommending that the current UK law prohibiting germline engineering remain in effect), *available at* http://www.biopoliticaltimes.org/downloads/Letter%20to%20HFEA.pdf.

235. *See* Robertson, *supra* note 16, at 482-84; *see also* REPRODUCTION AND RESPONSIBILITY, *supra* note 5, at 187.

236. *See generally* FRANKEL & CHAPMAN, *supra* note 68.

237. *See* Robertson, *supra* note 16, at 482; *see also*, Macintosh, *supra* note 209, at 292-93.

238. *See* Robertson, *supra* note 16, at 483-84.

expanding its regulatory authority without having to distort its current three-tier classifications. However, such a radical change would require reorganization of the agency and its staffers to address the emerging social, ethical, and philosophical issues of RGBs. If those elements were to be considered by the FDA, it would make more sense for Congress to focus its resources on creating a new independent agency and framework for oversight with new staffers that have the relevant expertise.[239] This new agency should be tasked with promoting a national conversation about the acceptable uses of RGBs for therapeutic and enhancement applications, designing mechanisms for assessing the social, ethical, and safety risks involved, encouraging the creation of public and private policy guidelines, and serving as a single data repository and funding recommendation mechanism for genetic research on animals and humans.[240] An agency tasked with these responsibilities and regulatory authority would be able to adequately perform independent scientific and ethical reviews of all RGB research protocols and procedures.[241]

CONCLUSION

As the biotechnology revolution increases humankind's genomic knowledge, our current abilities using ARTs, and the future possibilities of RGBs, the bioethical, legal, and social challenges of choosing our children's genes will require comprehensive policy frameworks and regulatory oversight of these technologies to ensure their safe and effective development. Public awareness and attitudes of genetic engineering will influence its evolution, and public policy needs to adapt with unique regulations that consider the greater social and moral implications. Scientific advancements may provide the opportunity to fundamentally alter our evolution and biological potential as a species by rejecting the archaic practice of random genetic variation through sexual reproduction and natural selection. However, before we adopt RGBs that go beyond therapy for enhancement of our bodies and our minds, we must promote equality and fairness; otherwise we risk potential social and economic

239. *See* FRANKEL & CHAPMAN, *supra* note 32, at 51.

240. *See id.* at 51-53.

241. *See id.*; FUKUYAMA & FURGER, *supra* note 215, at 297-98 ("This organizational form is a far better match for what may be described as the two main tasks facing a regulatory agency responsible for overseeing reproductive medicine and biomedical research – implementing the Congressional mandate and adjudicating societal disputes – than an executive agency.").

instability where genetic discrimination fragments society into a genetic aristocracy. Rather than continuing to place federal-funding restrictions on technological advances in genetic engineering, policymakers need to recognize such economic mechanisms or temporary bans will likely prove ineffective, and need to be reconsidered. One such proposed solution for policymakers is the creation of a new independent regulatory agency tasked specifically to address these issues, rather than attempting to augment the FDA's existing policy framework and statutory definitions to meet the needs of these emerging challenges. The creation of a new regulatory agency would appropriately balance arguments advanced by both proponents and opponents of genetic engineering technologies used in assisted reproduction. Its creation would support the responsible and safe adoption of RGBs to increase human prosperity, while simultaneously providing adequate regulatory oversight, and enforcement mechanisms if parents one day decide to choose the genetics of their children.