PURSUING A RIGHT TO GENETIC HAPPINESS

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ABSTRACT

With the continued expansion of assisted reproductive technology (ART), and society's inability to regulate it, complex medico-legal issues and ethical and social dilemmas are arising. Although the desire to prevent or limit genetic disease by, for example, gene editing and mitochondrial transfer is noble, what has been termed the "customization" of birth, raises the fundamental issue of procreative liberty, and, more specifically, the extent to which the state is obligated to assist in the use of ART which, in turn, validate the quest for genetic happiness. There is a current notion that reproductive freedom includes, within it, a right to a genetically connected child free from disease or, in other words, one who has benefitted from positive eugenics. Presently, there is no right, qua right, to genetic happiness, nor is there any obligation of the state to assure that progeny born have good genes. Today, when medical errors occur during usages of ART, the eponymous tort of negligence is available as the most traditional approach to recovery of money damages. The inherent weaknesses of this practice are explored critically and suggestions made for new strategies – especially through recognition of the new torts of Reproductive Negligence or Wrongful Genetic Manipulation.

INTRODUCTION AND HISTORICAL OVERVIEW

With the continuing scientific and biotechnological discoveries which are proving conclusively to be the genetic bases for a plethora of medical disorder and illnesses,[1] a newfound legitimacy for examining heredity has been established.[2] This prominence, in turn, has raised the stature of a field of science that has had a troubling past – the field of human genetic engineering.[3] Since the time of Plato, there have been efforts to study and

1. George P. Smith, II, *Manipulating the Genetic Code: Jurisprudential Conundrums*, 64 GEO. L. J. 697 (1976) [hereinafter Smith*, Manipulating the Genetic Code*]; *see* George P. Smith, II, *Genetic Enhancement Technologies and the New Society*, 4 MED. L. INT'L 85 (2000) [hereinafter Smith, *Genetic Enhancement and the New Society*]; *see also* George P. Smith, II, & Thaddeus J. Burns, *Genetic Determination or Genetic Discrimination*, 11 J. CONTEMP. HEALTH L. & POL'Y 23 (1994).

2. Sheila Jasanoff, *Biology and The Bill of Rights: Can Science Reframe the Constitution?*, 13 AM. J. L. & MED. 249, 269 (1990).

3. Smith, *Manipulating the Genetic Code*, *supra* note 1, at 699.

improve the medical state of eugenics in order to manage, if not alleviate, genetic disease pathologies and thereby secure reasonable public health accommodations.[4]

Tragically, Adolf Hitler corrupted Platonian idealism with his implementation of a state-directed negative eugenics program aimed at ridding the German Nation of negative genetic weakness or strains by conducting a genocide of Jews, those he considered medically "defective" and undesirable, together with others whom he considered impure genetically.[5] Today, it is genetically at-risk couples who seek to control their genetic load and prevent, when possible, the statistical probability of passing deleterious genes to their progeny and thereby adversely compromising the health of their issue.[6] The couples seek to manage their reproductive options through, for example, gene editing while also limiting genetic diseases or correcting genetic anomalies.[7] Accepting the reality of barren love is not a popular alternative, nor is adoption.[8]

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4. Clyde Haberman, S*cientists Can Design 'Better' Babies. Should They?*, N.Y. TIMES (June 10, 2018), https://www.nytimes.com/2018/06/10/us/11retro-baby-genetics.html; *see* Rob Stein, A *Boy for You, and a Girl for Me. Technology Allows Choices*, WASH. POST, Dec. 14, 2004, at A1; *see also* Maher v. Roe, 432 U.S. 464, 478 (1977) (discussing the state's interest in "encouraging [healthy] childbirth" (quoting Beal v. Doe, 432 U.S. 438, 446 (1971)).

5. Smith*, Manipulating the Genetic Code*, *supra* note 1, at 698-99; *see generally* ROBERT WISTRICH, HITLER AND THE HOLOCAUST (2001); *see generally* George J. Annas, *Mengele's Birthmark: The Nuremberg Code in United States Courts*, 7 J. CONTEMP. HEALTH L. & POL'Y 17 (1991); *see* ELIZABETH CATTE, PURE AMERICA: EUGENICS AND THE MAKING OF MODERN VIRGINIA (2020).

6. Jasanoff, *supra* note 2, at 269; *see also* Robert A. Wilson, *Eugenics: Positive vs Negative*, EUGENICS ARCHIVE (Sept. 14, 2013), http://eugenicsarchive.ca/database /documents/5233c3ac5c2ec50000000086#! (stating that historically, eugenics has been divided into positive and negative eugenics. The goal of positive eugenics "refers to efforts aimed at increasing desirable traits." Negative eugenics are "efforts aimed at decreasing undesirable [genetic] traits" selecting for example, "designer babies" or "engaging in some kind of transhumanism").

7. Smith*, Manipulating the Genetic Code*, *supra* note 1, at 699; *see* Adrienne Asch, *Disability Equality and Prenatal Testing: Contradictory or Compatible?*, 30 FLA. ST. U. L. REV. 315 (2003).

8. George P. Smith, II, *Through a Test Tube Darkly: Artificial Insemination and the Law*, 67 MICH. L. REV. 127, 130 (1968); *see also US Adoption Statistics,* ADOPTION NETWORK, https://adoptionnetwork.com/adoption-statistics (last visited Feb. 16, 2020) (stating that only some 140,000 children are adopted each year by American families).

Artificial donor insemination[9] and surrogation remain more "traditional" alternatives.[10]

The animating spirit of the "new" eugenics is drawn from the Platonic notion that by improving the health of all citizens, the opportunities for a "better" life apply not only to individuals but to the common good of society as a whole.[11] Both individual health costs – social and economic – and public health expenses are better managed when citizens are of sound genetic strength. The new eugenics allows genetic illness to be addressed *in utero* and *in vivo* before birth ever occurs.[12]

In 1776, when the Declaration of Independence was written, the government was originally called upon to provide conditions in which "happiness" – understood as material well-being – could be pursued.[13] Ideally, this pursuit delivers happiness: a fundamental right to pursue life in a way that affords one happiness which is legal and does not violate the rights of others.[14] Perhaps a state of happiness may be thought of being achieved when health, wealth, safety, and security are in equilibrium.[15]

There can be little doubt that exploring both the parameters and the perimeters of procreativity, liberty, and determining which restrictions are reasonable to impose upon its exercise is "the most politically divisive domestic legal issue of our time."[16] This divisiveness arises from a societal effort to promote reproductive technologies in order to accommodate

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9. *See generally* Smith, *supra* note 8; *see Swimming Freestyle: The Sperm and Egg Business*, THE ECONOMIST, Mar. 6, 2021, at 27 (discussing anonymity of sperm donors and the need for fertility clinics to require comprehensive screening of donors for their health conditions).

10. *See* George P. Smith, II, *Assisted Noncoital Reproduction: A Comparative Analysis*, 8 B. U. INT'L L. J. 21 (1990) [hereinafter Smith, *Assisted Noncoital Reproduction*); *see also* George P. Smith, II & Roberto Iraola, *Sexuality, Privacy and The New Biology*, 67 MARQ. L. REV. 263 (1984); *see also* Jenna Casolo et al., *Assisted Reproductive Technologies*, 20 GEO. J. GENDER & LAW 313, 315 (2019) (stating that technically, artificial insemination and surrogation are not acknowledged as assisted reproductive technologies).

11. *See* PHILIP KITCHER, THE LIVES TO COME, ch. 8 (1996).

12. Jasanoff, *supra* note 2, at 269-70; *see* James M. Gustafson, *Genetic Theory: Ethical and Religious Reflections*, 8 J. CONTEMP. HEALTH L. & POL'Y 183 (1992).

13. GEORGE F. WILL, THE CONSERVATIVE SENSIBILITY, Introduction (2019).

14. *Id.*

15. *See generally,* Rafael Di Tella, Robert J. MacCulloch & Andrew J. Oswald, *The Macroeconomics of Happiness*, 85 REV. ECON. & STATISTICS 809 (2003).

16. Webster v. Reprod. Health Servs., 492 U.S. 490, 559 (1989) (Blackmun, J., concurring in part and dissenting in part); *see* Skinner v. Oklahoma, 316 U.S. 535, 541 (1942); *see also*, JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGY 93, 221 (1994) (affirming that procreation is a "basic right" and "dominant value in modern society").

those unable to procreate otherwise.[17] Noble though this therapeutic goal is, its clinical use is being complicated all too often by desires for customizing a child's birth so that it will have the strongest genetic profile possible.[18] The purposeful act of creating human life – and the consequences of this depersonalizing and remaking of it – frame the central ethical issue of this undertaking: namely, the extent to which it is ethical to manipulate genetic knowledge in order to achieve a specific goal of sound genetic health of an offspring.[19]

It has been posited that contemporary reproductive freedoms include a specific "right to a genetically connected child free from disease."[20] In 2016, the National Academies of Sciences, Engineering, and Medicine issued a report on one type of gene editing, mitochondrial replacement therapy (MRT), and concluded that wishing to beget children with "significantly reduced risks" of gene disease was a "justifiable" and legitimate motivation to use gene editing.[21] It remains for the genetic parents to determine for themselves "what happens to their bodies."[22] For some, there is value to having children who are related genetically;[23] for others, having children – regardless of a strong genetic profile – is relevant and controlling.[24]

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17. Kaiponanea T.Matsumura, *Public Policing of Intimate Agreements*, 25 YALE J. L. & FEMINISM 159, 161 (2013).

18. *See* Ariana Eun Jing Cha, *From Sex Selection to Surrogates, American IVF Clinics Provide Services Outlawed Elsewhere*, WASH. POST (Dec. 30, 2018), https://www.washingtonpost.com/national/health-science/from-sex-selection-to-surrogates-american-ivf-clinics-provide-services-outlawed-elsewhere/2018/12/29/0b596668-03c0-11e9-9122-82e98f91ee6f_story.html; *See also Maher*, 432 U.S. at 478.

19. Smith, *Manipulating the Genetic Code*, *supra* note 1, at 730; *See* Gustafson, *supra* note 12.

20. G. Owen Schaefer & Markus K. Labude, *Genetic Affinity and the Right to 'Three-Parent IVF,'* 34 J. ASSISTED REPROD. & GENETICS 1577, 1577-78 (2017). If the United States had ratified the International Covenant on Economic, Social, and Cultural Rights (which includes Art. 15(b) and is taken as conferring a human right to enjoy "the right to participate and to enjoy the benefits from scientific progress and its applications"), an argument might be developed which recognizes the right of citizens to the use of germline editing in order to assure that the nascent life of progeny would be free of any genetic disease and consequent discrimination and thus be allowed to lead a dignified life. 993 U.N.T.S. at 3; *see* GEORGE P. SMITH, II, DIGNITY AS A HUMAN RIGHT? Appendix C, at 97, Art. 15, at 103 (2019); *see generally* Andrea Boggio et al., *The Human Right to Science and the Regulation of Human Germline Engineering*, 2 THE CRISPR J. 134 (2019); *see* Audrey R. Chapman, *Towards an Understanding of the Right to Enjoy the Benefits of Science*, 8 J. HUM. RIGHTS 1, 11 (2009).

21. Raymond C. O'Brien, *The Immediacy of Genome Editing and Mitochondrial Replacement*, 9 WAKE FOREST J. L. & POL'Y 419, 480 (2019).

22. Shaefer & Labude, *supra* note 20, at 1579.

23. O'Brien, *supra* note 21, at 474.

24. *Id.*

Today, all too often a wish becomes a want, then a need, then an entitlement, and proceeds to morph into a right. Indeed, for many, their reach exceeds their grasp.[25] The law should be leery of inventing new rights[26] merely because there is a personal want for an interest or a prerogative to be recognized and protected as an entitlement or as a right.[27]

The test for recognizing a right should not be tied to the extent to which "political power and cultural influences are willing to tolerate,"[28] but, rather, a framework for conferral should be based on determinations of law [29] rather than "reasoned judgments," on social or cultural norms.[30] When a right is distended too far and is unreasonable, it results in injustice[31] and further compromises individual self-respect.[32]

The second section of this Essay examines the concept of happiness and the "responsibilities" of the State to work assiduously to assure that its citizens live and prosper in an environment conducive to securing their material well-being.[33] Additionally, this section will examine the origins and use of the notion of a unilateral "social contract" between the government and its citizens to assure this "right."[34]

The third section of this Essay investigates the scope of new assisted reproductive technologies – particularly MRT[35] –with the "obligation" of the State to promote fecundity and assist those seeking a level of genetic happiness by having children.[36] This section also critically examines the issues and the policies which, at one level or another, guide the extent of use given the new reproductive technologies.[37] Fundamental to this analysis is consideration of the fear that negative, as opposed to positive,

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25. Robert Browning, *Andrea del Sarto*, *in* MEN AND WOMEN 184, 187 (Boston, Ticknor & Fields 1855).

26. Obergefell v. Hodges, 576 U.S. 644, 741 (2015) (Alito J., dissenting).

27. *Id.* at 703 (Roberts, C. J., dissenting).

28. *Id.* at 741 (Alito J., dissenting).

29. *Id.* at 720 (Scalia J., dissenting).

30. *Id.*

31. Frank I. Michelman, *In Pursuit of Constitutional Welfare Rights: One View of Rawls' Theory of Justice*, 121 UNIV. PA. L. REV. 962, 1015 (1973).

32. *Id.* at 990-991.

33. *See generally*, WILL, *supra* note 13.

34. ALFRED COBBAN, ROUSSEAU AND THE MODERN STATE 113-150 (1964).

35. O'Brien, *supra* note 21, at 419; *See* Remah Moustafa Kamel, A*ssisted Reproductive Technology After the Birth of Louise Brown*, 14 J. REPROD. INFERTILITY 96 (2013).

36. George P. Smith, II, *Procreational Autonomy v. State Intervention: Opportunity or Crisis for a Brave New World?*, 2 NOTRE DAME J. L., ETHICS & PUB. POL'Y 635 (1987) [hereinafter Smith, *Autonomy v. State Intervention*]; *See* Smith, *Manipulating the Genetic Code*, supra note 1.

37. GEORGE P. SMITH, II, LAW AND BIOETHICS: INTERSECTIONS ALONG THE MORTAL COIL (2012) [hereinafter SMITH, LAW AND BIOETHICS].

social values associated with genetic engineering will eclipse the parental and societal goals of raising the healthiest children and citizens.[38]

There is an abundant level of vexing confusion surrounding the establishment and extent of reproductive rights as the remedies to be pursued when harm results from abridgement of these rights.[39] The traditional legal responses to injuries incurred during the prenatal and birthing process are actions for negligence and specifically for wrongful birth,[40] wrongful life,[41] wrongful conception,[42] or wrongful death.[43] Thus, although there is no legally protectable, recognizable right to be born with genetic "purity," or protection guaranteeing life without physical or mental impairment, the law nevertheless allows cases to proceed when medical malpractice occurs owing to the negligence of a health care provider.[44]

In an effort to both clarify and thereby "unify" the law of negligence,[45] two new, or perhaps reconfigurations of this tort, have been put forward: reproductive negligence[46] and wrongful genetic manipulation (WGM).[47] It is well beyond the scope of this Essay to undertake an exegesis of these proposals. Suffice it to observe that while both remedies are intriguing and even admirable, it will no doubt take time for the common law to recognize

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38. *See generally* JONATHAN GLOVER, CHOOSING CHILDREN: GENE DISABILITY AND DESIGN (2006); *see generally* George P. Smith, II, *Genetics, Eugenics, and Public Policy*, 1985 SO. ILL. L. REV. 435 [hereinafter Smith, *Genetics, Eugenics, and Public Policy*]; *see generally*, George P. Smith, II, *Limitations on Reproductive Autonomy for the Mentally Handicapped*, 4 J. CONTEMP. HEALTH L. & POL'Y 71 (1988).

39. *See infra* Section IV.

40. DAN DOBBS, ET AL., HORNBOOK ON TORTS Ch. 27 (2d ed. 2016).

41. *See generally* Melinda A. Roberts, *Distinguishing Wrongful from "Rightful" Life,* 6 J. CONTEMP. HEALTH L. & POL'Y 59 (1990) (discussing "rightful life principles" in the context of wrongful life cases and focusing on the issue of harm in the wrongful life cause of action); *see generally* Bonnie Steinbock, *The Logical Case for "Wrongful Life,"* 16 HASTINGS CTR. REP. 15 (1986); *see generally* Barbara Pfeffer Billauer, *Wrongful Life in the Age of CRISPR-CAS: Using the Legal Fiction of "The Conceptual Being" to Redress Wrongful Gamete Manipulation*, 124 PA. ST. L. REV. 435 (2020).

42. GEORGE P. SMITH, II, GENETICS, ETHICS, AND THE LAW, Ch. 4 (1981).

43. *See* Becker v. Schwartz, 386 N.E.2d 807 (1978); *see also* DOBBS, ET AL., *supra* note 40, at 669.

44. SMITH, *supra* note 42.

45. *See generally,* Dov Fox, *Reproductive Negligence*, 117 COLUM. L. REV. 149 (2017).

46. *Id* at 172 (under this tort, disruption of reproductive plans are bundled into three classifications which have the effect of disrupting family planning and "control over their reproductive lives").

47. Billaurer, *supra* note 41, at 497 (this tort is grounded primarily in the law of negligence but also in theories of unjust enrichment and nuisance and would be applicable, for example, to misclassifications of genes for gene editing and to improper use of IVF procedures).

and utilize them.[48] Just as a miasma of judicial lethargy and suspicion exist over the need and effectiveness of change in the law of assisted reproductive technology (ART) is present, so too is the practicing bar's "intellectual conformism."[49] This conformism serves as yet another major roadblock to acceptance and use of new approaches to resolving legal conflicts in the field or ART. This type of conformism is seen as "a ubiquitous tendency to premise any action for a medical mishap on tort law in general and the tort of negligence is particular."[50] Considered together, these two attitudes present serious obstructions to professional acceptance of new approaches to resolving legal conflicts in the field of assisted reproduction. Until there are additional changes by the bench and the practicing bar regarding the scope of tortious conduct during the process of artificial reproduction and acknowledgement that the "failure of the common law to consistently provide adequate remedies,"[51] for harms committed, the recognizable law of ART will remain inequitable, unjust, and mired in a field of bramble.

The fourth section of this Essay examines the constitutional[52] and judicial responses thus far to legal issues arising when harm occurs as a consequence of negligence in the administration of assisted reproductive procedures.[53]

The conclusion drawn from this Essay is that even though the new ARTs prompt a legislative and judicial response balancing the reasonable individual wishes for parenthood with the attendant economic and social costs required to realize this wish or "right" of genetic happiness, through

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48. *See Becker,* 386 N.E.2d at 410-11 (holding (1) that the complaints alleging wrongful life due to a physician's alleged negligence when they failed to accurately inform the parents of risks involved in pregnancy did not state "legally cognizable causes of action" and (2) that the infants born with genetic abnormalities did not suffer any "legally cognizable injury" because there is not a fundamental right for infants to be born whole and functioning, and therefore, recovery of damages for the infants were not calculable).

49. Ronen Perry, *It's a Wonderful Life*, 93 CORNELL L. REV. 329, 398-399 (2008).

50. *Id*.; *but see generally*, RICHARD VAUGHN & STEPHANIE M. BRINKLEY, DEVELOPING A SUCCESSFUL ASSISTED REPRODUCTIVE TECHNOLOGY LAW PRACTICE (2017) (discussing how to start a specialized law practice and the unique needs of a practice focusing on ART).

51. Meghan Boone, *Reproductive Due Process,* 88 GEO. WASH. L. REV. 511, 564 (2020).

52. *See generally* Jasanoff, *supra* note 2 (analyzing potential conflicting intersections between science and the law).

53. *See generally* Smith, *Manipulating the Genetic Code*, *supra* note 1; *see generally* George P. Smith, II, *Judicial Decision-Making in the Age of Biotechnology*, 13 NOTRE DAME J. L., ETHICS & PUB. POL'Y 93 (1999) [hereinafter Smith, *Judicial Decision-Making*]; *see generally*, Smith & Iraola, *supra* note 10 (arguing that (1) there is no fundamental right protecting unmarried women's access to artificial insemination and (2) statutes restricting married women's access to artificial insemination reflect reasonable public policy considerations).

any and all available means for procreation, there is no such "right," *qua* right, to genetic happiness. While the courts have shown a cautious concern and sympathy for those seeking enhanced opportunities to expand fecundity, the State must judge the ethics and the morality of such efforts on a situational case-by-case basis as cases arise rather than seek to impose an unyielding *a priori* standard at all times.[54] The present efforts to recognize expanded bases of liability for pre-conception errors through, principally, the common law acceptance of the newly proposed torts of reproductive negligence and WGM, bear careful scrutiny and restricted use as they are tested in the judicial marketplace of ideas.

I. THE SEARCH FOR HAPPINESS

A. Noble Beginnings

In 1789, Jeremy Bentham asserted that happiness is the greatest good to be achieved in life, that qualitative differences do not exist, and that differences are seen only as qualitative.[55] John Stuart Mill built upon part of this utilitarian proposition in 1859 with the publication of his essay, *On Liberty*, where, under the guiding principle of utility, he held that achieving the greatest amount of happiness for the greatest number of people in life activities should be both a personal and a societal goal of the State.[56] The only limitation to the quest for happiness is tied to the principle of harm which limits conduct when harm to another will result from it.[57]

In 1762, Jean-Jacques Rousseau put forward a utopian theory for legitimatizing political authority and order which is tied to the notion of a social contract between a government and its citizens.[58] Rousseau hypothesized that the contract would both promote and safeguard the general will, or the common good, by finding a common interest uniting all citizens.[59] In order for the contract to be efficacious, self-centered

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54. *See* Smith, *Manipulating the Genetic Code, supra* note 1, at 729-732.

55. *See generally* JEREMY BENTHAM, INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION (1789).

56. JOHN STUART MILL, ON LIBERTY (Batoche Books 2001) (1859) [hereinafter MILL, ON LIBERTY]. This Principle was reanalyzed in John Stuart Mill's book, UTILITARIANISM (1863); *see generally*, D. G. Brown, *What is Mill's Principle of Utility*, 3 CANADIAN J. PHIL. 1 (1973).

57. MILL, ON LIBERTY, *supra* note 56, at 16.

58. *See generally,* JEAN-JACQUE ROUSSEAU, THE SOCIAL CONTRACT (Maurice Cranston trans., Penguin Books 1968) (1762).

59. *Id.*; *see* Thomas E. Mann & Norman Ornstein, *Finding the Common Good in an Era of Dysfunction of Governance*, J. AM. ACAD. & SCI. 15, 15 (2013); *see also* Brian

motives are to be eschewed over supporting the common good.[60] "Fair terms of co-operation" are seen as essential to assuring the integrity[61] of the contract and the maintenance of civil order.[62]

The establishment and then maintenance of economic equality by an all-responsive and protective state is not a purpose of the theory of social contract.[63] Rather, for Rousseau, the foundation upon which individual success is to be measured derives from the very social contract itself. In turn, the framers of the American Constitution embraced this notion when they crafted the Constitution.[64] Modernly, it has been argued that the notion of an American social contract is in need of a renegotiation to include structuring a template for achieving social justice and preventing discrimination.[65] As a normative standard, social justice should be used by individuals for advocating for the public good.[66]

As seen, the founding fathers of the United States were concerned with the achievement of the goal of happiness when, in 1776, in the Declaration of Independence, they declared that all citizens were entitled to the unalienable rights of life and of liberty and to the pursuit of happiness.[67] For the founders, the pursuit of happiness involved neither a chase nor a search for happiness but rather a state of affairs where happiness is practiced.[68] In a way, happiness is as much attitudinal positivism as a "natural right"[69] that the State is obligated to promote and secure for its citizens.[70]

Gilmore, *American Rousseau: Barack Obama and the Social Contract*, 35 T. MARSHALL L. REV. 9, 43 (2009).

60. CHRISTOPHER D. WRAIGHT, ROUSSEAU'S THE SOCIAL CONTRACT: A READER'S GUIDE 17 (2008).

61. CHRISTOPHER BERTRAM, ROUSSEAU AND THE SOCIAL CONTRACT 131-32 (2004).

62. ROUSSEAU, *supra* note 58.

63. BERTRAM, *supra* note 61, at 203.

64. MARK HULLIUNG, THE SOCIAL CONTRACT IN AMERICA 173 (2007); *see* ALFRED COBBAN, ROUSSEAU AND THE MODERN STATE 113-150 (1964) (examining the very purpose of the social contract).

65. *See generally* ROUSSEAU, *supra* note 58.

66. GEORGE P. SMITH, II, DISTRIBUTIVE JUSTICE AND THE NEW MEDICINE 17 (2008) [hereinafter SMITH, DISTRIBUTIVE JUSTICE]; *See* George P. Smith, II, *Distributive Justice and Health Care*, 18 J. CONTEMP. HEALTH L. & POL'Y 421, 421-424 (2002) [hereinafter Smith, *Distributive Justice and Health Care*].

67. THE DECLARATION OF INDEPENDENCE, pmbl (U.S. 1776).

68. Arthur M. Schlesinger, *The Lost Meaning of "The Pursuit of Happiness,"* 21 WM. & MARY Q. 325, 325 (1964).

69. *Id*. at 326.

70. Rejecting the philosophy of John Locke that the sole purpose of government is to secure, and then protect, the rights of all citizens to "life, liberty and property." David Brooks, *The Pursuit of Happiness*, HUFFPOST: THE BLOG https://www.huffpost.com /entry/the-pursuit-of-happiness_b_54827 (last updated May 25, 2011) (Thomas Jefferson codified in The Declaration of Independence, his own notion that every American has a

In today's contemporary society, it has been said that America is presently facing "a crisis of governability and legitimacy."[71] For there to be any honest hope for a correctional change to this state of dysfunction, "an informed and strategically focused" citizenry must become involved.[72] Within this climate, there can be no sustaining effort to effect any type of bilateral social contract[73] between the state and the citizenry because of the lethargy exhibited by the average citizen.[74] The will of the people – if there is a dominant will – is central to any effective workable notion of a social contract.[75] Discerning this is found, "less from the number of voices than from the common interest in uniting them."[76] Once determined, provisions within any form of a social contract should, ideally, "not burden some members in order to confer benefits on others,"[77] and, thus, have "fair terms of co-operation."[78]

Complex socio-economic issues infuse American culture.[79] The ability of the State to meet and resolve these societal complexities is limited, both economically and socially, because the social networks of support are frayed and very inefficient. Civil order is challenged by rampant crime,[80] and intolerance for cultures not in conformance with American "norms" is found everywhere.[81] These uncertainties have warped cultural constructs for decision-making.[82] In reality, attempting to

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God-given right to pursue happiness, and it remained for the central government to guarantee this right).

71. Mann & Ornstein, *supra* note 59, at 15.

72. *Id.*; *see generally* PHILIP K. HOWARD, THE DEATH OF COMMON SENSE: HOW LAW IS SUFFOCATING AMERICA (1994); *see generally*, WILLIAM LEDERER, A NATION OF SHEEP (1961).

73. *See* COBBAN, *supra* note 64, at 42-43 (detailing the essential purpose of the classic historic notion of a social contract which first originated in 1762 as a blueprint for establishing a political community and/or social order); *see generally* ROUSSEAU, *supra* note 58.

74. Thom File, U.S.CENSUS BUREAU (May 10, 2017), https://www.census.gov/newsroom/blogs/random-samplings/2017/05/voting_in_america.html (in the presidential election in 2016, only some 64% of the citizen voting-age population reported voting).

75. ROUSSEAU, *supra* note 58, 76.

76. *Id.*

77. *Id.*

78. BERTRAM, *supra* note 61, at 131-132; *see generally* JEAN JACQUES ROUSSEAU, POLITICAL WRITINGS (Frederick Watkins, trans., 1953).

79. *See generally* DANIEL ZIBLATT & STEVEN LEVITSKY, HOW DEMOCRACIES DIE (2018).

80. *See generally* BARRY LATZER, THE RISE AND FALL OF VIOLENT CRIME IN AMERICA (2016).

81. *See generally* MARK NATHAN COHEN, CULTURE OF INTOLERANCE: CHAUVINISM, CLASS, AND RACISM IN THE UNITED STATES (1998).

82. *See generally* THOMAS SOWELL, DISCRIMINATION AND DISPARITIES (2018).

find any reasonable point of balance in today's affluent society becomes nothing more than a search for "the satisfaction of private and public needs" – especially so in effectuating a "right" to enjoy good health and medical care.[83]

B. Roosevelt's Social Contract

In President Franklin D. Roosevelt's second State of the Union address to Congress in 1944, eight rights were put forth by the President as being central to the government's obligation to its citizens.[84] Central to these rights was a "right to adequate medical care and the opportunity to achieve and enjoy good health."[85] In this regard, President Roosevelt can rightly be acknowledged as the progenitor of the social contract for America. However, it remained for President Barack Obama, in 2009, to enhance and seek to effectuate President Roosevelt's "right" to medical care and good health by working with the Congress in 2010 to enhance the Patient Protection and Affordable Care Act,[86] which could be seen as the last piece in the social contract originated by President Roosevelt.[87]

What is viewed as the evolution of the "old social contract" has led to calls for a re-design of the very contract itself.[88] Essentially, the call is for redesigning the economy in such a way to makes its operational structure more equitable and inclusive and one that focuses on addressing issues of equality across social groups.[89] Among the specific proposals for actions to be undertaken to achieve this goal are adoption of a universal basic income,[90] an expansion of new labor laws, reduction of income polarization and other economic challenges,[91] and achieving inclusive outcomes which may achieve a revised social safety net for all citizens.[92]

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83. JOHN KENNETH GALBRAITH, THE AFFLUENT SOCIETY 233 (1998).

84. *See* CASS R. SUNSTEIN, THE SECOND BILL OF RIGHTS: FDR'S UNFINISHED REVOLUTION AND WHY WE NEED IT MORE THAN EVER 9-10, 12-13 (2004).

85. Paul B. Cornely, *National Planning for Health: Structure and Goals,* 48 BULL.OF THE N.Y. ACAD. MED. 53, 53 (1972); HOWARD, *supra* note 72, at 171, 186 (observing that the breadth and the complexity of national goals precludes them from ever becoming aspirational).

86. The Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010).

87. *See generally* Gilmore, *supra* note 59.

88. JAMES MANYIKA ET AL., THE SOCIAL CONTRACT IN THE 21ST CENTURY 1 (2020).

89. *Id.* at 117-127.

90. *Id.* at 120.

91. *Id.* at 26, 118-127.

92. *Id.* at 2, 32.

1. A Bilateral Contract?

The notion of the federal government as the promisor in today's unilateral social contract[93] is in great need of being converted to a bilateral contract where the promisee-citizens enter into promises or performance obligations.[94] An awareness of the responsibility to maintain and advance the common good[95] is limited severely and evidenced by two practical indicators: voting and payment of taxes. If these two responsibilities are not met, there is little hope for a robust, participatory democracy. Both in 2016 and in 2012, the citizen voting-age population showed stability with 61.4% of this age group voting in the 2016 federal election and 61.8% of this same group voting in 2012.[96] A little more than forty-four percent of all Americans pay no federal income taxes each year but may well pay local property and sale taxes.[97] Seventy percent of all federal taxes are paid for by the top ten percent of wage earners.[98] Sadly, these statistics do not present a vital and socially balanced profile. It is only equitable for more Americans to participate more actively in maintaining a new notion of bilateral obligations within the principle of federalism.

Today, happiness for the average American is rather elusive – with only thirty-three percent of citizens surveyed by the Harris Poll in 2017 declaring they were happy.[99] Interestingly, the majority of Americans did express hopefulness, and seventy-two percent went so far as to declare their optimism.[100] While optimism is not necessarily happiness, it is a positive value or attitude to be incorporated into the American psyche.[101] Even with an acceptance of the fact that genetic dispositions influence

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93. JOSEPH M. PERILLO, CONTRACTS 61 (7th ed. 2014) (in a unilateral contract, only one party or, here entity, makes a promise and is subject to legal obligations under that promise).

94. *Id.* (a contract with more than two parties, or entities, is bilateral).

95. *See* B. J. Diggs, *The Common Good as Reason for Political Action*, 83 ETHICS 283, 284 (1973); *see also* DONELSON R. FORSYTH & CRYSTAL HOYT, FOR THE GREATER GOOD OF ALL: PERSPECTIVES ON INDIVIDUALISM, SOCIETY, AND LEADERSHIP (2011).

96. File, *supra* note 74. Interestingly, in the 2020 Presidential election, sixty-seven percent of all Americans voted with this being the highest percentage ever achieved. *See generally United States Election Project, 2020 Presidential Nomination Contest Turnout Rates*, ELECTPROJECT, http://www.electproject.org/2020p (last visited Jan. 22, 2022).

97. Quentin Fottrell, *More than 44% of Americans Pay No Federal Income Tax*, MARKETWATCH (Aug. 28, 2019, 3:42 AM), https://www.marketwatch.com/story/81-million-americans-wont-pay-any-federal-income-taxes-this-year-heres-why-2018-04-16.

98. Demian Brady, *Who Pays Income Taxes?,* NAT'L TAXPAYERS UNION FOUND. (Dec. 7, 2020), https://www.ntu.org/foundation/tax-page/who-pays-income-taxes.

99. Alexander Sifferlin, *Here's How Happy Americans Are Right Now*, TIME (July 26, 2017, 1:46 PM), http://time.com/4871720/how-happy-are-americans/.

100. *Id.*

101. *Id.*

abilities to accept happiness,[102] individuals may "learn" ways to gain happiness simply by blocking negativism from their thinking and living a life with value.[103]

C. Cultural Influences on Happiness

There are four principal social factors affecting society which, in turn, diminish the responsibility of the State to facilitate the pursuit of happiness.[104] Grave socio-economic issues permeate the very fiber of modern America.[105]

Economic stability is central to any goal of happiness. When salaries stagnate and living costs are not managed, the "American Dream" is lost because the notion that hard work translates into achievement is lost.[106] Inasmuch as a sound work ethic does not necessarily provide economic security, daily worries regarding health care, housing, and food become dominant and inevitably lead to chronic stress.[107] Dubbed the "Era of

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102. *See* Eric Barker, *Happy Thoughts: Here Are the Things Proven to Make You Happier*, TIME (Apr. 4, 2014, 12:11 PM), time.com/49947/happy-thoughts-here-are-the-things-proven-to-make-you-happier; *see also Understanding Human Happiness and Well-Being*, SUSTAINABLE SCALE PROJECT, http://www.sustainablescale.org/Attractive Solutions/UnderstandingHumanHappinessandWellBeing.aspx (last visited Jan. 23, 2022) (concluding, concluded that non-material life factors are among the most important determinants of both subjective reports of human happiness and objective indices of well-being – with, for example, ecological sustainability and social justice ranking high as important life factors).

103. Tchiki Davis, *How to be Happy: 23 Ways to be Happier*, PSYCH. TODAY (Jan. 1, 2018), https://www.psychologytoday.com/us/blog/click-here-happiness/201801/how-be-happy-23-ways-be-happier. In America, a "happiness gap" is due, in very large part, to differences (and sometimes clashes) in both social and cultural value systems. It has been said that certain values – individual liberty, hard work and optimism, together with faith and charity, promote levels of happiness for most. *See generally* ARTHUR C. BROOKS, GROSS NATIONAL HAPPINESS: WHY HAPPINESS MATTERS FOR AMERICANS AND HOW WE CAN GET MORE OF IT (2008). In June 2007, the University of Chicago held a conference on "Legal Implications of the New Research on Happiness" and studied methodologies – especially the "happiness approach" – which measures happiness on scales which include wealth, income, family relationships, etc. Econometric analysis is then used to find correlations from these scales which are most determinative of attaining levels of individual happiness. *See generally* LAW AND HAPPINESS (Eric A. Posner & Cass R. Sunstein eds., 2010) (discussing "hedonics", the study of happiness, from the perspective of various disciplines).

104. Tchiki Davis, *4 Ways American Culture is Influencing Happiness*, PSYCH. TODAY (May 17, 2018), https://www.psychologytoday.com/us/blog/click-here-happiness/201805/4-ways-american-culture-is-influencing-happiness;

105. *See generally*, JOSEPH E. STIGLITZ, THE PRICES OF INEQUALITY: HOW TODAY'S DIVIDED SOCIETY ENDANGERS OUR FUTURE (2012).

106. Davis, *supra* note 104.

107. *Id.*

Uncertainty," many do not have access to traditional social security support networks which, in turn, is a prescription for unproductiveness.[108] Job security, affordable education, retirement benefits, and health care are additional worries which attack the very ideal of an American Dream.[109] No longer having any sustained level of financial security results in limited options for use of social resources simply because local communities are severely strained and cannot meet the support needs of the impoverished.[110] Because of the diminished social networks relied upon previously, even more levels of significant stress arise because of these limitations.[111] Social inequalities give rise to prejudice and discrimination which often result in social injustice.[112] Optimizing government services is truly a Herculean task.

Government action is restrained by both economic and social limitations. Thus, for every right asserted as fundamental, there must be a corresponding responsibility which directs that right be exercised not only reasonably and effectively but also within the economic strictures of cost/benefit reasoning.[113]

A fundamental truth and a caveat in trying to manage social policy was suggested by Charles Murray:

…. social programs in a democratic society tend to produce net harm in dealing with the most difficult problems. They will inherently tend to have enough of an inducement to produce bad behavior and not enough of a solution to stimulate good behavior; and the more difficult the problem, the more likely it is that this relationship will prevail. The lesson is not that we can do no good at all, but that we must pick our shots.[114]

II. ASSISTED REPRODUCTIVE TECHNOLOGIES

A. The Fertility Industry

Over the last decades, the redefining of family relationships and its creation has been witnessed.[115] More people are not only utilizing

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108. *Id.*; *See generally,* JOHN KENNETH GALBRAITH, THE AGE OF UNCERTAINTY (1977).
109. Davis, *supra* note 104..
110. *Id.*
111. *Id.*
112. *See generally* SOWELL, *supra* note 82.
113. *See* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW, Chs. 1-2 (8th ed. 2011) (analyzing the nature of economic reasoning, the economic approach to the law and its impact on social theories and policies).
114. CHARLES MURRAY, LOSING GROUND: AMERICAN SOCIAL POLICY 218 (1984).
115. *See generally* Michael Boucai, *Is Assisted Procreation an LBGT Right?*, 2016 WIS. L. REV. 1065 (2016).

surrogacy arrangements but are now also availing themselves of the technological options for parenting available by assisted reproduction technologies and are beginning to explore mitochondrial transfer (MRT) in their quest for genetically healthy children.[116] Fifteen states have enacted legislation requiring private insurance coverage be provided to cover either all or some of the expenses for infertility treatment.[117] Largely unregulated, the U.S. fertility industry – together with Cyprus and the United Arab Emirates – are perhaps the only three countries where *in vitro* fertilization is used for screening embryos for gender.[118] Additional fertility services in U.S. clinics include "commercial surrogacy, anonymous sperm donation and screening for physical characteristics such as eye color."[119] It is estimated that in 2018, the fertility industry was worth as much as $5.8 billion.[120]

B. Underwriting The Costs – Economic, Cultural and Social

Worldwide, fertility clinics have come into vogue and now offer a variety of services from embryo testing for genetic abnormalities to even "surgically wounding the womb to encourage the embryo to implant itself."[121] It has been predicted that the global fertility market will rise from twenty-five million in dollar sales to forty-one billion dollars by 2026.[122]

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116. Raymond C. O'Brien, *Accessing Assisted Reproductive Technology*, 27 CATH. UNI. J. L. & TECH. 1, 8-12 (2018).

117. *Id.* at 20; *see generally* George P. Smith, II, *Intimations of Life: Extracorporeality and the Law*, 21 GONZ. L. REV. 395 (1986); *see also* Access to Infertility Treatment and Care Act of 2018, H.R. 5965, 115th Cong, 2nd Sess. §1720J (2018) (under this proposed legislation, any health group plan or health insurer, must provide treatment coverage for iatrogenic infertility determined as such by a treating physician. For the armed services, the Secretary of Defense will establish cost-sharing requirements for the coverage and diagnostic treatment of fertility and is, furthermore, required to furnish fertility treatment to "a veteran or a spouse or partner of a veteran").

118. Cha, *supra* note 18; *see* Boone, *supra* note 51, at 533 (referring to the U.S. governmental approval to regulating ART as being *laissez-faire*); *see also* Myrisha S. Lewis, *Is Germline Gene Editing Exceptional?* 51 SETON HILL L. REV. 735 (2021) (calling for regulation of ART).

119. Cha, *supra* note 18; *see generally* Sarah M. Capelouto et al., *Sex Selection for Non-Medical Indications: A Survey of Current Pre-Implantation Genetic Screening Practices Among U.S. ART Clinics*, 35 J. ASSISTED REPROD. GENETICS 409 (2018); *see generally* Noah Geldberg, *Zygote Zeitgeist: Legal Complexities in the Expanding Practice of Embryo Donation*, 49 LOY. L.A. L. REV. 813 (2016); *see also* ZIMMER, GLOWING GENES: A REVOLUTION IN BIOTECHNOLOGY (2005).

120. Cha, *supra* note 18.

121. *The Fertility Business is Booming*, THE ECONOMIST, Aug. 8, 2019, (available online at https://www.economist.com/business/2019/08/08/the-fertility-business-is-booming).

122. *Id.*

Egg freezing, in America alone, is now covered by one in twenty corporations as a part of regular employee benefits.[123]

Since the efforts of Apple and Facebook in 2014 to underwrite fertility options for their employees, today it is commonplace to find between one in four large American corporations paying for various types of fertility treatments,[124] with egg-freezing being one of the most common treatment coverages being offered.[125] Surrogacy and *in vitro* fertilization (IVF) treatments are particularly appealing to LGBT employees and underscore corporate efforts "to promote 'diversity and inclusion.'"[126] One in twenty of all American companies pay for this treatment.[127] Interestingly, Tesla, the automobile corporation, pays for unlimited IVF treatment cycles.[128]

C. New Beginnings in The Laboratory

It has been predicted that within the next twenty to forty years, the laboratory will become the focus and, indeed for many, the point of creation for birthing new human life.[129] From conception to the selection of gestation periods, sex, health strengths, social traits, and the birth itself, a significant number of children will be processed.[130] Sexual intercourse will remain the fundamental process for procreation, but the severance of sex and reproduction will be considered the preferred route when genetic uncertainties are a concern when a normal pregnancy is followed to term.[131]

1. Biological Parenting v. Reproductive Technology

The notion of biological parenting as the central or controlling tenet of reproduction is being challenged by advances in reproductive

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123. *More Employers Want to Help Workers Make Babies,* THE ECONOMIST, Aug. 8, 2019, (available online at https://www.economist.com/business/2019/08/08/more-employers-want-to-help-workers-make-babies).

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. HENRY T. GREELY, THE END OF SEX AND THE FUTURE OF HUMAN REPRODUCTION 1 (2016).

130. *Id.* at 2; *see generally* Tara T. Melillo, *Gene Editing and The Rise of Designer Babies*, 50 VAND. J. TRANSNAT'L L. 757 (2017); *see also* Cha, *supra* note 18.

131. GREELY, *supra* note 129, at 1; *see generally* Naomi Cahn, *The New "ART" of Family: Connecting Assisted Reproductive Technologies and Identity Rights*, 2018 ILL. L. REV. 1443 (2018).

technology.[132] Presently, the legal process is very slowly accommodating a conferral of parenthood and of parental rights upon same-sex couples who seek to establish a parent-child relationship as significant as those who are biological parents.[133] Even with this nascent legislative and judicial "movement" toward expanded validation of parental status, there is no uniformity of action with a number of courts in fact refusing to countenance a uniformity of private agreements to both create and to sever parental relationships.[134]

2. Pre-Implantation Genetic Diagnosis

As a form of prenatal diagnosis, preimplantation genetic diagnosis (PGD) derives from the process of IVF which is used as a method to select embryos for implant – not only free of the statistical probability of carrying disease, but also to particular characteristics as sex or intelligence.[135] Since the refinement of IVF during the late 1970s and the 1980s, embryos are able to be created outside the body and subsequently implanted in a gestational or surrogate carrier.[136] Today, the availability of PGD is restricted because of the high costs for its use as well as the inconvenience in completing the diagnosis and the risks associated with it.[137] Usually, the process costs between $15,000 and $30,000 per cycle for the basic IVF procedure (with several cycles often being required before success) while PGD costs upwards of an additional $5,000.[138]

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132. Cahn, *supra* note 131, at 1446; Casolo et al., *supra* note 10, at 315 ("ART procedures include in vitro fertilization ('IVF'), gamete intrafallopian transfer ('GIFT'), zygote intrafallopian transfer ('ZIFT'), and intracytoplasmic sperm injection ('ICSI')").

133. Douglas NaJaime, *Marriage Equality and the New Parenthood*, 129 HARV. L. REV. 1185, 1208-1213 (2016) (the scope of legal issues confronting same sex couples expressing a wish for intentional parenthood through the use of artificial reproductive technology is analyzed by referencing pertinent provisions within the Uniform Status of Children by Assisted Conception Act. Additional support for this notion is found in case law in California where the judicial position is advanced that much as a "traditional" married couple, with intent, deliberate to initiate the procreative process, so too should same-sex couples be credited within initiating the process of procreation by choosing an artificial reproductive technology to actualize their intent to have a child); O'Brien, *supra* note 21, 439-441 (discussing functional versus de facto parenting).

134. *See* Matsumura, *supra* note 17, at 203.

135. GREELY, *supra* note 129, at 86-88; *see* DOV FOX, BIRTH RIGHTS AND WRONGS 21 (2019); *see also* Smith, *Genetic Enhancement and the New Society*, *supra* note 1, 91-98.

136. GEORGE P. SMITH, II, FAMILY VALUES AND THE NEW SOCIETY: DILEMMAS OF THE 21ST CENTURY Ch. 5 (1998); *See* GEORGE P. SMITH, II, THE NEW BIOLOGY: LAW, ETHICS AND BIOTECHNOLOGY Chs. 1, 4, 9 (1989) [hereinafter SMITH, THE NEW BIOLOGY]; *see also* Smith, *Assisted Noncoital Reproduction, supra* note 10, at 25-26.

137. GREELY, *supra* note 129, at 88.

138. *Id.*; Marissa Conrad, *How Much Does IVF Cost?*, FORBES (Sept. 28, 2021, 9:44 AM), https://www.forbes.com/health/family/how-much-does-ivf-cost/; *see generally* B. C.

As genetic sciences become even more refined and sophisticated, it is speculated that "Easy PGD" will largely resolve the cost, discomfort, and risks of this IVF procedure.[139] Easy PGD could well become a standard practice for couples planning their pregnancies.[140] Between 2006 and 2010, 62.9% of births were planned in the United States.[141] It is to be remembered that PGD does not allow potential parents a *carte blanche* to select genetic and physical features which they do not have nor to edit out those features that they do not want their progeny to retain.[142] Rather, Easy PGD provides a procedure for selecting embryos for subsequent implantation, from a number with multiple characteristics,[143] ranging from serious genetic disease to combinations of positive and negative traits.[144]

Perhaps the most notable aspect of embryonic science is the prospect that, over time, an artificial embryo could be developed from embryonic cells – built from reprogrammed adult human cells requiring no fertilization or ordinary embryonic development.[145] Dr. John D. Aach stated that the broader goal of this investigative research is to engineer these cells into types of both tissue and organs termed "synthetic human entities with embryonic features" or "sheefs" for short.[146]

3. New Ethical Dilemmas

A critical rethinking of the scheme of the universe and of the significance or the role of humanity is prompted by the startling advances

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L. Rev. Staff, *The Price Tag on Designer Babies: Market Share Liability*, 59 B.C. L. Rev., 319 (2018).

139. GREELY, *supra* note 129, at 102-103.

140. *Id.* at 197-198.

141. *Id.*

142. *Id.* at 193-196.

143. *Id.*

144. *Id.* at 193

145. Carl Zimmer, *A New Form of Stem-Cell Engineering Raises Ethical Questions*, N.Y. TIMES (Mar. 21, 2017), https://www.nytimes.com/2017/03/21/science/embryonic-stem-cells-synthetic-embryos-sheefs.html.

146. *Id.*; *see generally* Thomas Douglas & Julian Savulescu, *Synthetic Biology and The Ethics of Knowledge*, 36 J. MED. ETHICS 687 (2010); *see also*, Julia Dalzell, *The Impact of Artificial Womb Technology on Abortion Jurisprudence*, 25 WM. & MARY L. RACE, GENDER & SOC. JUST. 327, 327-332 (2019); *see generally* SCOTT GELFAND & JOHN R. SHOOK, ECTOGENESIS: ARTIFICIAL WOMB TECHNOLOGY AND THE FUTURE OF HUMAN REPRODUCTION (2006); *The Engineering of Living Organisms Could Soon Start Changing Everything*, THE ECONOMIST, Apr. 4, 2019, (available online at https://www.economist.com/technology-quarterly/2019/04/04/the-engineering-of-living-organisms-could-soon-start-changing-everything).

being achieved in molecular science and specifically in ART.[147] Consequently, new ethical issues arise from these scientific advances, such as distributive justice, the extent of determinism and of free will, and the components of personhood.[148] Rather than being tied to dogmatic assertions, what is needed is a return to a standard of fundamental wisdom which acknowledges those traits that we all share as humans.[149] In developing a medico-legal and ethical framework for utilizing the wonders of the New Biology, it must be remembered that the constant companion to explorative opportunity is risk in both the *micro* and the *macro* levels of society.[150]

The polemics of fecundity have become common play in today's dystopian society – a society both intrigued and frightened by the vast potential for "good" and for "evil" that new ARTs present as vexatious options for decision-making and action.[151] One of the most exciting and ethically challenging biotechnological advances to be found is the new process of gene editing which allows for germline modification of the embryo.[152] Although proposed as a means for treating genetic disease before it occurs, if perfected for human use, this procedure would have far reaching socio-medical effects, not the least of which would be the charge that such actions were eugenic in character and capable of creating a caste system where genetic inferiorities or disadvantages would not be allowed or tolerated.[153] For some, governmental attempts to identify and to correct

147. AUDREY R. CHAPMAN, UNPRECEDENTED CHOICES: RELIGIOUS ETHICS ON THE FUTURE OF SCIENCE 168 (1999); *see The Sheep of Things to Come*, THE ECONOMIST, Feb. 18, 2017, at 16 (discussing cloning, an advancement in molecular science); *see also*, Paige Winfield Cunningham, *'Designer Babies' Worry Both Parties*, WASH. EXAM'R (Nov. 30, 2015, 12:01 AM) (discussing "designer babies", another advancement in molecular science).

148. *See generally*, SMITH, THE NEW BIOLOGY, *supra* note 136.

149. *See* MICHAEL D. KIRBY, THROUGH THE WORLD'S EYE, Ch. 4 (2000).

150. *See generally* SMITH, DISTRIBUTIVE JUSTICE, *supra* note 66**;** *see generally*, SMITH, THE NEW BIOLOGY, *supra* note 136 (discussing the major areas of concern/study as ways to expand artificial fecundity, asexual reproduction, birth surrogacy, genetic privacy and screening, and the extent of government regulation of these areas).

151. *See generally* SMITH, LAW AND BIOETHICS, *supra* note 37; *see also* GEORGE P. SMITH, II, BIOETHICS AND THE LAW: MEDICAL, SOCIO-LEGAL AND PHILOSOPHICAL DIRECTIONS FOR A BRAVE NEW WORLD (1993).

152. *See generally* Matthew D. Hebert, *Opening a Can of Genetically-Modified Worms: Funding and Regulating CRISPR Technology*, 52 VAL. UNIV. L. REV. 505 (2018); *see generally*, O'Brien, *supra* note 21.

153. *See* Hebert, *supra* note 152; *see also* Ben Merriman, *"Editing": A Productive Metaphor for Regulating CRISPR*, 15 AM. J. BIOETHICS 62 (Dec. 2, 2015); *See generally*, *Sex and Science; Reproductive Technologies*, THE ECONOMIST, Feb. 18, 2017, at 9.

genetic disadvantages borders on eugenics[154] and has been long regarded as "politically suspect, if not unthinkable."[155] Yet, the reality of the present, evolving societal character toward accessing the assisted reproductive biological technologies is becoming voracious.[156]

The foundational issues arising from the inevitability of genetic enhancements is how society will act in order to curb what is seen as "genetically produced unfairness."[157] Rather than becoming mired in a psychological quagmire regarding the fairness or unfairness of genetic enhancements and the reality that some individuals will be given an opportunity for a more privileged social position than un-enhanced individuals,[158] perhaps it would be better to promote an ideal which affords "equality of opportunity."[159] Alternatively, a recognition could be given to the eventuality that unequal holdings will occur, but they must be acquired justly.[160]

4. Challenging the Freedom of Scientific Investigation

The scientific ethic of investigation all too often becomes ensnared by the inconclusiveness over the role law plays in scientific decision-making.[161] While some would, analytically, separate law from morality, others assert that they are inseparable.[162] In whatever capacity or role law is cast, it is confronted with a dilemma: whether to reach out to "science and medicine," or be restrained as a reaction to "social needs and

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154. *See generally* Smith, *Genetics, Eugenics and Public Policy*, *supra* note 38; *see generally*, Smith & Burns, *supra* note 1.

155. Maxwell J. Mehlman, *The Law of Above Averages: Leveling the New Genetic Enhancement Playing Field*, 85 IOWA L. REV. 517, 557 (2000).

156. Cha, *supra* note 18.

157. Mehlman, *supra* note 155, at 576; *see generally* NATHANIEL C. COMFORT, THE SCIENCE OF HUMAN PERFECTION: HOW GENES BECOME THE HEART OF AMERICAN MEDICINE (2012); *see generally*, ZIMMER, *supra* note 119.

158. Mehlman, *supra* note 155, at 576; *see generally*, Deborah Zalesne, *The Intersection of Contract Law, Reproductive Technology and the Markets: Families in the Age of ART*, 51 RICH. L. REV. 419 (2017).

159. Michel Rosenfeld, *Substantive Equality and Equal Opportunity: A Jurisprudential Appraisal*, 74 CALIF. L. REV. 1687, 1702 (1986).

160. ROBERT NOZICK, ANARCHY, STATE, AND UTOPIA 151-152 (1974); ALLEN BUCHANAN, DAN W. BROCK & NORMAN DANIELS, FROM CHANGE TO CHOICE: GENETICS AND JUSTICE 315-321 (2001).

161. *See generally* Julius Stone, *Knowledge, Survival, and The Duties of Science*, 23 AM. U. L. REV. 231 (1973); *see generally* George P. Smith, II, *Biotechnology and the Law: Social Responsibility or Freedom of Scientific Inquiry*, 39 MERCER L. REV. 437 (1988).

162. Ronald Reagan, *Politics and Morality Are Inseparable*, 1 NOTRE DAME J. L. ETHICS & PUB. POL'Y 7, 10 (1984); *see generally* E. D. Pellegrino, *Balancing Science, Ethics and Politics: Stem Cell Research, a Paradigm Case*, 18 J. CONTEMP. HEALTH L. & POL'Y 591 (2002).

demands."[163] Law should not be considered an end in and of itself. Rather, it should be seen as a means[164] to achieve a just and equitable resolution of a legal conflict. Accordingly, "…tools are not ordinarily made to hammer out solutions to hypothetical problems but for real problems, which means that the problem must arise, exist, and be recognized before the law reacts to provide a solution."[165]

D. Mitochondrial Transfer

1. Advancing Gene Repair and Editing: CRISPR

In 2016, the first recorded success of a mitochondrial transfer was recorded with a baby being born having genetic affinity with three parents: two mothers and one father.[166] Mitochondrial replacement therapy (MRT) is presently only legal in the United Kingdom,[167] but it has been approved in the United States provisionally.[168] MRT is an *in vitro* fertilization procedure involving the removal of the nucleus from one egg and its transfer "into the remnants of a different donated egg (which had its nucleus removed and discarded)."[169] Consequently, the new resulting egg contains the nucleus from the nuclear mother and the "mitochondrial DNA from a donor ("the mitochondrial mother")."[170] The newly assembled egg

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163. Warren E. Burger, *Reflections on Law and Experimental Medicine*, 15 UCLA L. REV. 436, 436 (1968); *see generally* Stephen G. Breyer, *The Interdependence of Science and Law*, 280 SCI. 537 (1998).

164. Breyer, *supra* note 163, 537.

165. Burger, *supra* note 163, at 436.

166. Daniel Green, *Assessing Parental Rights for Children with Genetic Material from Three Parents*, 19 MINN. J. L. SCI. & TECH. 251, 251-55 (2018); *see generally* Ainsley J. Newson et al., *Ethical and Legal Issues in Mitochondrial Transfer*, 8 EMBO MOLECULAR MED. 589 (2016).

167. Garry Hamilton, *The Mitochondria Mystery*, 525 NATURE 444, 444 (2015); E. Owen Schaefer & Markus K. Labude, *Genetic Affinity and the Right to Three Parent IVF*, 34 J. ASSISTED REPROD. GENETICS 1597, 1577 (2017).

168. NAT'L ACAD. SCI. ENG'G & MED., MITOCHONDRIAL REPLACEMENT TECHNIQUES: SOCIAL AND POLICY CONSIDERATION 20 (Ann Claiborne, Rebecca English & Jeffrey Kahn eds., 2016) (the National Academy of Sciences, Engineering and Medicine concluded in 2016 that it was permissible, ethically, for MRT clinical investigations to continue so long as the study is limited to women "who are otherwise at risk of transmitting mtDNA disease, where mutation's pathogencity is undisputed"); *see* Jocelyn Kaiser, *U.S. Panel Gives Yellow Light to Human Embryo Editing*, SCI. (Feb. 14, 2017), http://www.sciencemag.org/news/2017/02/us-panel-gives-yellow-light-human-embryo-editing.

169. Green, *supra* note 166, at 255; *see* Boggio et al., *supra* note 20, at 138-139.

170. Green, *supra* note 166, at 255; *see also* Bob Zhao, *Mitochondrial Replacement Therapy and The Regulation of Reproductive Genetic Technologies in the United States*, 15 DUKE L. & TECH. REV. 121 (2017).

is then fertilized by the genetic father's sperm and is then "…implanted in the nuclear mother in order to begin the pregnancy."[171]

In 2015, Jennifer A. Doudna, Emmanuel Charpentier, Martin Jinels, and Krzystof Chylinski first disclosed a new groundbreaking technology for editing and repairing genes which they termed Clustered Regularly Interspaced Short Palindromic Repeats, or CRISPR.[172] CRISPR-Cas9 technology is an engineered version of that system and is a type of protein associated with CRISPR.[173] This new technology not only holds great promise in treating and eradicating human monogenic diseases *in vitro*[174] – said to be the cause of some five thousand disorders[175] – but also in being a catalyst for the wider use of assisted reproduction.[176] There is also great promise for this MRT technology to alter the production of agricultural crops which are resistant to herbicides and can grow in changing world ranges.[177]

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171. Green, *supra* note 166, 255.

172. JENNIFER A. DOUDNA & SAMUEL H. STERNBERG, A CRACK IN CREATION: GENE EDITING AND THE UNTHINKABLE POWER TO CONTROL xvii (2018). The first actual description of the process which would subsequently be termed CRISPR was set by Yoshizumi Ishino and his colleagues in 1987 *see id.* at Ch. 1 (discussing the early history of CRISPR technology). Interestingly, Jennifer Doudna was a co-recipient with Emanuelle Charpentier, of the 2020 Nobel Prize in Chemistry for their work in developing genetic editing through CRISPR–Cas9. *See* Press Release, The Royal Swedish Acad. of Sci., The Nobel Prize in Chemistry 2020 (Oct. 7, 2020) (https://www.nobelprize.org /prizes/chemistry/2020/press-release/); *Pioneers of CRISPR Gene Editing Win Nobel Prize in Chemistry,* BIOTECHSCOPE (Oct. 7, 2020), https://biotechscope.com/pioneers-of-crispr-gene-editing-win-nobel-prize-in-chemistry/#:~:text=Today%2C%20The%20Royal%20Swedish%20Academy,a%20method%20for%20genome%20editing.

173. The Royal Acad. of Sci., *supra* note 172; *see also*, F. Ann Ran, et al., *In Vivo Genome Editing Using Staphylococcus Aureus Cas9*, 520 NATURE 186 (2015) (showing that Cas9 can successfully edit the cholesterol regulatory gene).

174. O'Brien, *supra* note 21, at 443; *See* Hebert, *supra* note 152.

175. Versha Prakash et al., *Current Progress in Therapeutic Gene Editing for Monogenic Diseases,* 24 MOLECULAR THERAPY 465, 465 (2016); Hebert, *supra* note 152, at 511 (the scope of opportunity and real prospects for treating (and perhaps even curing) Alzheimer's disease and other genetic diseases ranging from muscular dystrophy to even blindness are possible consequences evolving from CRISPR research).

176. O'Brien, *supra* note 21, at 447; *see generally*, HENRY GREELY, CRISPR PEOPLE: THE SCIENCE AND ETHICS OF EDITING HUMANS (2021).

177. Hebert, *supra* note 152, at 510; *See* DOUDNA & STERNBERG, *supra* note 172, at Ch. 2 (discussing the various applications of CRISPR Technology to animals, plants, humans, and other possible groupings).

E. Federal Regulations

1. The Dickey-Wicker Amendment

Federal regulation of the entire field of biotechnology is under the control and the supervision of three agencies: the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).[178] Outdated since the regulations were developed in 1986,[179] the Dickey-Wicker Amendment further complicates continued and vital research in the assisted reproductive technologies.[180] Targeted in 1996 to address the ethical concerns of IVF research and to ban any human research here, this federal legislation acts as a significant roadblock to all embryonic research as well as the funding and regulation of CRISPR.[181] Yet, private laboratory successes by scientists in the U.S. in editing human cell traits occur almost weekly because the Dickey-Wicker Amendment applies only to the disbursement of federal or public funds.[182]

2. Presidential Responses

In March, 2009, President Barack Obama issued an Executive Order allowing the National Institutes of Health (NIH) to conduct and fund research on human embryos to the extent of the law.[183] New guidelines for stem cell research were also required under the Order.[184] The scope of the Order's application was limited, however, since the Dickey-Wicker Amendment defines the extent of the law's application.[185] A subsequent "clarification" by Francis S. Collins, the Director of the NIH, did little to blunt the force of the Dickey-Wicker Amendment as it pledged full respect

178. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23, 304 (June 26, 1986).

179. *See generally id.*

180. *See* Balanced Budget Downpayment Act, Pub. L. No. 104-199, § 128, 110 Stat. 34 (1996) (Section 128 became known as the Dickey-Wicker Amendment).

181. *Id.* (the Amendment states that, in subsequent budget legislative actions, no funds will be available and may not be used for "the creation of a human embryo or embryos for "research purposes" nor may "research in which a human embryo or embryos are destroyed, discarded, or knowingly subject to risk of injury or death greater than that allowed for research under applicable Federal Regulations" under 45 C.F.R 46.208(a)(2) & 42 U.S.C. § 289g(b)); *see* Hebert, *supra* note 152, at 516 (noting the continuing impact of this Amendment since its enactment).

182. Hebert, *supra* note 152, at 515.

183. Proclamation No. 13,505, 74 Fed. Reg. 10,667, 10,667 (Mar. 9, 2009).

184. *See* Hebert, *supra* note 152, at 516.

185. *Id.* at 516.

for the prohibitions on embryonic research set by Congress.[186] Building upon President Obama's Executive Order of 2009, however, the NIH did amend its guidelines in order to accommodate research into CRISPR technology.[187] However, in 2018, President Donald Trump sought to limit fetal tissue research by the FDA and the NIH involving the use of elective abortions and urged experimentations derived from sources other than the present source.[188] Subsequently, in June 2019, the Trump Administration directed the Department of Health and Human Services to impose new restrictions on the NIH, undertaking federally funded research and, thus, vital research on CRISPR using fetal tissue obtained from elective abortions and ordered reviews of government funded research at universities and other scientific centers where fetal tissue remains are used for experimentation; all of which were reversed by President Biden in 2021 allowing a return to fetal research derived from abortion.[189]

3. Congressional Lethargy

To encourage, promote, and accommodate an endorsement of a full scientific inquiry into the untold wonders of genetic improvement from clinical trials of CRISPR research,[190] there needs to be Congressional legislation expanding the authority of the FDA to regulate these trials and determine the treatments or technologies which are safe for public use.[191]

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186. *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos,* NAT'L INST. OF HEALTH (Apr. 29, 2015), https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos (affirming that the NIH would not involve itself with gene editing); *see* Hebert, *supra* note 152, at 539.

187. Final Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, 81 Fed. Reg. 15,315, 15,316 (March 22, 2016).

188. Meredith Wadman & Jocelyn Kaiser, *Trump Officials Move to Limit Human Fetal Tissue Research*, 362 SCI. 1223, 1223 (2018); *see* Denise Grady, *Fetal Tissue Research Is Curtailed by Trump Administration*, N.Y. TIMES (Dec. 12, 2018), https://nytimes.com/2018/12/12/health/fetal-tissue-research-trump.html.

189. Abby Goodnough, *Trump Administration Sharply Curtails Fetal Tissue Medical Research*, N.Y. TIMES (June 5, 2019), https://www.nytimes.com/2019/06/05/us/politics/fetal-tissue-research.html; Sarah McCammon, *Here's What You Should Know About Biden's New Rules For Fetal Tissue Research,* NPR (Apr. 16, 2021, 6:15 PM), https://www.npr.org/2021/04/16/988221424/heres-what-you-should-know-about-bidens-new-rules-for-fetal-tissue-research; *see* Apoorva Mandavilli, *Biden Administration Ends Limits on Use of Fetal Tissue Research*, N.Y. TIMES, https://www.nytimes.com/2021/04/17/health/fetal-tissue-abortion-biden.html (last updated May 27, 2021).

190. Hebert, *supra* note 152, at 533-535.

191. *Id.* at 531. Inasmuch as gene sequencing – and thus CRISPR – are classified as biological products, the FDA controls its regulation, through its Center for Biologies Evaluation Research. *See also* Elizabeth Price Foley & Elizabeth C. Price, *Does the FDA Have Authority to Regulate Human Cloning?* 11 HARV. J. L. & TECH. 619 (1998); *see* Dov

Trials which are sensitive to valid ethical concerns of genetic discrimination being advanced by research of this nature[192] can be justified by the depth of scientific knowledge which can be applied to treating and curing diseases and inherited genetic conditions.[193]

For this ideal of open scientific investigations to be realized, Congress should repeal the Dickey-Wicker Amendment and thus make an unequivocal statement of support for advancing crucial research into CRISPR.[194] This declaration, together with a legislative ban on conducting embryonic research could, in turn, become a cornerstone for establishing a functional pathway for thoughtful dialogue and public involvement in meeting the challenges and in charting the future of genomic editing and mitochondrial transfer.[195]

F. IVG and the Principle of Procreative Beneficence: Toward a New Eugenics?

1. Ethical Concerns

Presently, there is research supporting the possibility of *in vitro* harvesting of both eggs and sperm, or gametes, from human stem cells.[196] This process, termed, *in vitro gametogenesis* (IVG), would not only serve as a model for advanced research into human gametogenesis and associated diseases of the germline but also as a supply source for forming gametes as a possible aid for treatment of fertility and as a process to manipulate the human germline.[197] It is this latter potential for use which raises specific concerns about IVG as an animating force behind, what some fear, is a "new" eugenics.[198]

To contain the fears of a new eugenics which would, as in the past, promote social inequalities and raise complex moral issues, an operative

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Fox, *Safety, Efficiency and Authenticity: The Gap Between Ethics and Law in Decision-Making*, 2005 MICH. ST. L. REV. 1135, 1159-1177 (2005).

192. Hebert, *supra* note 152, at 511; *see generally* Smith & Burns, *supra* note 1.

193. *See generally* Smith & Burns, *supra* note 1.

194. Hebert, *supra* note 152, at 528; *see* Lewis, *supra* note 118, at 758 (describing the Dickey-Wicker Amendment and its effect on research funding).

195. O'Brien, *supra* note 21, at 421, 427, 491, 494; *see* Stone, *supra* note 161, at 240, 250 (observing that scientific research should only be limited when its work is likely to threaten cataclysmic, physical, or psychological survival).

196. Hannah Bourne et al., *Procreative Beneficence and In Vitro Gametogenesis*, 30 MONASH BIOETHICS REV. 29, 30 (2012); Niels Geijsen et al., *Derivation of Embryonic Germ Cells and Male Gametes from Embryonic Stem Cells*, 427 NATURE 148, 149 (2004).

197. Bourne, et al., *supra* note 196, at 30; *see also* Zubin Master, *Embryonic Stem-Cell Gametes: The New Frontier in Human Reproduction*, 21 HUMAN REPROD. 857 (2006).

198. Bourne et al., *supra* note 196, at 40; *see generally,* GLOVER, *supra* note 38.

principle has been posited which has had the very opposite effect of this stated purpose. Indeed, this "principle of procreative beneficence" has – for many – only expanded and fortified their concerns about the feared outreach of continued research and development of human IVG.[199] This principle, and its significance in structuring analysis, debate, and possible application is a controversial vector of force in shaping new public policies for interpreting the scope of application for the new assisted reproductive technologies and particularly IVG.[200]

The principle of procreative beneficence holds, "…that when a couple plans to have a child, they have significant moral reasons to select, of the possible children they could have, the child who is most likely to experience the greatest well-being – that is, the most advantaged child, the child with the best chance at the best life."[201] In order to be "operative," this principle suggests "…using technological means, such as pre-implantation genetic diagnosis."[202] It posits no definitive or absolute moral obligation[203] and does not direct a particular course of action.[204] It is built upon "common sense intuitions"[205] and the universal parental desire to prevent their child from being disabled genetically at birth by selecting traits, *in vitro*, which would fight any disability before the actual birth.[206]

2. Preventing Genetic Disease and Disability

The underlying goal of the principle of procreative beneficence would be to "…prevent disease by erasing genetic mutations in future generations…"[207] Some parents might well select traits to prevent development of diabetes, heart disease, or obesity.[208] Other parents might wish to select for multiple non-disease traits such as a disposition to

199. Julian Savulescu & Guy Kahane, *The Moral Obligation to Create Children with the Best Chance of Life*, 23 MONASH BIOETHICS REV. 274, 288 (2009); *see also* Jacques Testart, *The New Eugenics and Medicalized Reproduction*, 4 CAMBRIDGE Q. HEALTHCARE ETHICS 304 (1995).

200. Bourne et al., *supra* note 196, at 29.

201. *Id*.

202. *Id.*

203. *Id.*

204. *Id.*

205. *Id*.

206. *Id.* at 43 (to be noted, there are no laboratory successes which have created functional human eggs or sperm, and genes have not been sequenced simply because they have not been discovered). *But see* FOX, *supra* note 135, at 235-36 (discussing the desire of some deaf parents to have deaf children).

207. Bourne et al., *supra* note 196, at 39-40.

208. *Id.*

cheerfulness or to intelligence.[209] Interestingly, there are 400 possible combination of traits from which parents could choose.[210]

Inasmuch as IVG technology is presently unavailable and may never be possible,[211] it has been suggested that it is premature to create ethical conundrums.[212] Others assert that ethical debate of this issue must precede the future development of IVG now so that an ethical framework can be structured to aid in shaping the limits of these anticipated technological advancements.[213] It would be prudent to begin evaluating the projected scope of the new reproductive technologies presently instead of waiting for their unguided development.[214] Rather than have this evaluative study give rise to perplexing rhetorical questions and vexatious ethical quagmires which would have the effect of either setting unrealistic boundaries on investigation or halting altogether the progress of pure, as opposed to applied, scientific research into the technologies of the new reproduction, a new ethic needs to be shaped. Ideally, this scientific ethic would not only guide continuing explorations of fecundity in today's brave new world with careful and purposeful resolve to minimize human suffering, but it would also maximize the social good.[215]

When there is an openly expressed parental motivation to prevent genetic disability before birth – with the ultimate goal of giving a child the best opportunity for a good, fulfilling life, without major disease and/or disability – the principle of procreative beneficence can be in play and be a positive force in critical decision-making regarding the use of ARTs. Parental choice of this dimension should be respected for they are motivated by parental compassion for a future child and an honest wish to prevent a lifetime of pain and suffering.[216] This conclusion is fortified when it is remembered that the National Academies of Science, Engineering and Medicine found in a 2016 report on gene editing, and specifically the use of MRT, that it is a legitimate and "justifiable" motivation to wish to reduce, if not eliminate, genetic anomalies.[217]

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209. *Id.*
210. *Id.*
211. *Id.* at 29-30.
212. *Id*. at 33-43.
213. *Id.*
214. *See generally* Smith, *supra* note 161.
215. *Id.*; *see generally* George P. Smith, II, *Uncertainties on the Spiral Staircase: Meta-Ethics and The New Biology*, 41 THE PHAROS MED. J. 10 (1978) (analyzing the extent to which metaethics examines normative standards and whether they should be structured and applied to the genetic research community in order to shape a level of social responsibility as well as individually).
216. GLOVER, *supra* note 38, at 28; *see also* COMFORT, *supra* note 160; *see generally* Bourne et al., *supra* note 196.
217. O'Brien, *supra* note 21, at 480.

3. Confronting the Economic Costs of Genetic Disease

Approximately 7.9 million babies are born world-wide with major birth defects.[218] This figure accounts for six percent of the global population.[219] Each year, one in every thirty-three babies is born in the United States with birth defects, and this accounts for approximately three percent of all babies.[220] The leading cause of death among all infants is attributable to birth defects and accounts for twenty percent of the deaths.[221]

It is estimated that eight percent of children under the age of 15 years in the United States suffer from a disability.[222] Of this percentage, nearly half of those disabilities are classified as severe.[223] In 2013, for care of children, $13,000 a year was required.[224] For autism alone, the U.S. spends $137 billion a year.[225] During a lifetime, the care for one typical autistic person can cost anywhere from an estimated $1.4 million to $2.3 million if the person is disabled intellectually.[226] Typically, one year of family expenses for autistic care can run to $60,000.00 or even more.[227]

A study of the financial impact of genetic diseases on one accountable care organization (ACO) in 2014, shows that the total claims in 2014 were $379 million.[228] Insurance claims for pediatric care numbered 258,299 children in this study, and of the amount paid it was determined $161 million (or 42.5% of the total amount) covered care for children diagnosed with a known single gene disorder or chromosomal abnormalities.[229]

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218. Ingrid Lobo & Kira Zhaurova, *Birth Defects: Causes and Statistics*, 1 NATURE EDUC. (2008), https://www.nature.com/scitable/topicpage/birth-defects-causes-and-statistics-863/.

219. *Id.*

220. *Data & Statistics on Birth Defects,* CTR. FOR DISEASE CONTROL AND PREVENTION, cdc.gov/ncbddd/birthdefects/data.html (last visited Oct. 24, 2021).

221. *Id.*

222. Craig Guillot, *The Cost of Raising a Special Needs Child*, INTUIT MINTLIFE BLOG, https://mint.intuit.com/blog/planning/the-cost-of-raising-a-special-needs-child-0713/ (last modified Dec. 15, 2021).

223. *Id.* ("For a special needs child, these expenses can quadruple").

224. *Id.*

225. *Id.*

226. *Id.*

227. *Id*.

228. Katherine F. Miller et al., *The Financial Impact of Genetic Diseases in a Pediatric Accountable Care Organization,* FRONTIERS PUB. HEALTH, Feb. 28, 2020, at 1.

229. *Id.*

III. THE SCOPE OF REMEDIAL RELIEF

A. Constitutional Concerns, Guidance and Protection

If genetic therapy were to be accepted as proper treatment in the field of reproductive technology, the concerns about this process as a medical treatment would be of the same level as that shown to other treatment of this nature which invariably carry degrees of benefits and of risk.[230] The U.S. Supreme Court could equate efforts to control genetic disease with past issues regarding compulsory vaccination.[231] In the 1905 landmark case of *Jacobson v. Massachusetts*, the Supreme Court validated a state policy which was aimed at containing "…the spread of contagious diseases," specifically smallpox.[232] This precedent would fortify any position taken by state or local governments to enforce genetic therapy whose purpose would be acknowledged "…to prevent the vertical transmission of disease from one generation to the next."[233]

Statutes which restrict personal liberties and impose "lifestyle" changes are often allowed to stand when such changes are designed to protect individuals from harming themselves, "promote public health and safety," and serve as protection for the public-at-large from excessive financial awards to accident victims.[234]

B. Judicial Scrutiny

In today's social climate, judicial scrutiny is likely to be given to "protected groups"[235] and to legislative schemes negatively impacting on reproductive freedoms.[236] However, when state actions are viewed as "therapeutic techniques" with goals to "…enable a marked reduction of genetic defects and the burden they impose on their victims and on societal resources," great judicial acceptance may be given to such legislation.[237]

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230. Jasanoff, *supra* note 2, at 276.

231. *Id.* The governmental action of this nature is justified as an exercise of the *parens patriae* power of the state to "protect" its citizens from harm. LAWRENCE GOSTIN & LINDSAY F. WILEY, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 51 (2d ed. 2008); SARAH CONLY, AGAINST AUTHORITY: JUSTIFYING COERCIVE PATERNALISM 10 (2013) (advocating for state interference with individual autonomy under certain circumstances).

232. *See* Jacobson v. Massachusetts, 197 U.S. 11, 35 (1905).

233. Jasanoff, *supra* note 2, at 277.

234. *Id.*

235. *Id.*

236. *Id.*

237. *Id.* at 277 n.130 (citing PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. AND BIOMEDICAL RSCH., SPLICING LIFE 66 (1982)).

Issues which carry constitutional *gravitas* appear when the powers of science are used by the federal government and the states in illegitimate ways.[238] The scope of these actions run the gamut from actions directed toward mass screening for heritable traits and eugenic policies designed to interfere and control reproductive freedoms to regulations which have the effect of regulating knowledge by placing restrictions on research.[239] In all, nine areas have been identified as areas where constitutional issues arise because of intrusive and regulatory governmental conduct.[240]

C. A Living Constitution?

As the scope of science expands and technological capabilities multiply, a level of constitutional concern will undoubtedly be given to the products of the New Biology and their uses.[241] Independent of public concerns, regulatory policies set by legislatures, and judicial supervision, science will continue to progress.[242] For the Constitution to provide guidance and accommodation for social change, some assert that it should be seen as a "Living Constitution" which gives rise to a gradual evolutionary process and thus adapts to the "social circumstances of the day."[243] Inasmuch as no guidance is given to the central issue of how general social changes evolve and how science shapes interpretative efforts to test the extent of constitutional prohibitions versus the guarantees of fundamental rights, others maintain that clarity and certainty can best be achieved by embracing the philosophy of originalism.[244] This philosophy holds that contemporary interpretations of the Constitution must be grounded by the original statements of understanding by the delegates to the Constitutional Convention of 1787[245] or of the populace

238. Jasanoff, *supra* note 2, at 259.

239. *Id.* at 261.

240. *Id.* at 261, tbl. I.

241. *See generally* George P. Smith, II, *Global Health Law: Aspirational, Paradoxical, or Oxymoronic?, in* 16 LAW & GLOBAL HEALTH: CURRENT LEGAL ISSUES 452 (Michael Freeman, Sarah Hawkes & Belinda Bennett eds.) (2014); *see also*, Smith, *Judicial Decision-Making*, *supra* note 53.

242. *See* O'Brien, *supra* note 21, at 452; *see also* George P. Smith, II, *Biomedicine and Bioethics: De Lege Lata, De Lege Ferenda,* J. CONTEMP. HEALTH L. & POL'Y 233 (1993).

243. Jasanoff, *supra* note 2, at 254; *see* Jack M. Balkin, *The Roots of the Living Constitution*, 92 B.U. L. REV. 1129, 1129 (2012).

244. *See* James E. Fleming, *Living Originalism and Living Constitutionalism as Moral Readings of The American Constitution*, 92 B.U.U. L. REV. 1171, 1172 (2012).

245. Richard R. Beeman, *The Constitutional Convention of 1787: A Revolution in Government,* NAT'L CONST. CTR., https://constitutioncenter.org/interactive-constitution/white-papers/the-constitutional-convention-of-1787-a-revolution-in-government (last visited Dec. 1, 2021); Steven G. Calabresi, *On Originalism in Constitutional*

of the time on common and ordinary meanings and usages at the time of ratification.[246]

D. In Search of Balanced Decision-Making

Neither constitutional concern nor protection need be given to "every social dislocation produced" by and from the New Biology.[247] Indeed, as Chief Justice John Roberts cautioned previously in his dissent in *Obergefell v. Hodges* in 2015, not all constitutional liberties can be translated into "positive entitlements" from the State.[248] Robust public debate of what medico-legal norms and evolving social policies entail are pertinent to informed decision-making.[249] These debates can be, and are, shaped by dialogue among professional bodies as well as by state legislatures.[250] Consensus building is often reached without any appeals to the Constitution or the penumbra's found therein.[251] In order to reach sound and fair judgments here by policymakers, ethicists, scientists, physicians, legislators, and by the courts, decision-making is required to be shaped by the attainment of a point of equilibrium where a reasonable balance between risks and social costs – and hoped-for benefits to individuals at the micro level and to society at the macro level, is reflected in deliberative actions taken.[252] Ideally, the benefits and the risks associated with critical policymaking should be shared equally among the participants as well as the recipients.[253]

Interpretation, NAT'L CONST. CTR., https://constitutioncenter.org/interactive-constitution/white-papers/on-originalism-in-constitutional-interpretation (last visited Dec. 1, 2021).

246. Calabresi, *supra* note 245.

247. Jasanoff, *supra* note 2, at 288.

248. *Obergefell*, 576 U.S. at 702 (Roberts, C. J. dissenting).

249. Jasanoff, *supra* note 2, at 288-289; *see e.g.*, Kalina Kamenova, The Public Communication and Biopolitics of Human Embryos Stem Cell Research in the United States and the European Union (Nov. 2011) (Ph.D dissertation, York University) (ResearchGate); *see also,* C.P. SNOW, THE TWO CULTURES (1959); C.P. SNOW, THE TWO CULTURES & A SECOND LOOK: AN EXPANDED VERSION OF THE TWO CULTURES AND THE SCIENTIFIC REVOLUTION 70 (1963) (analyzing the communication gaps between scientists and other societal groups and the need for a third culture – possibly law – to bring cohesion to these misunderstandings).

250. Jasanoff, *supra* note 2, at 288.

251. *Id.*

252. *See generally* Smith, *Distributive Justice and Health Care*, *supra* note 66; *see also,* George P. Smith, II, *Setting Limits: Medical Technology and the Law,* 23 SYDNEY L. REV. 283 (2001) [hereinafter Smith, *Setting Limits*].

253. *See* Smith, *Setting Limits, supra* note 251; *see also* Smith, *Manipulating the Genetic Code*, *supra* note 1, at 725-733.

E. Discriminating Conduct

Traditionally, unmarried and/or lesbian women have not been given access to the new reproductive technologies[254] primarily because they do not "fit" into the traditional notion of what constitutes a family unit.[255] Indeed, a woman's fundamental right to procreative liberty and its protection against intrusion[256] is not conferred upon single women.[257]

The U.S. Department of Veteran Affairs (DVA) will not cover medical expenses for fertility (IVF) treatments, not only for unmarried veterans but for same sex couples as well.[258] In order for coverage to be provided, the medical need must be proved to be "a service connected condition."[259] Mandated by Congress, in order for veterans to qualify for coverage of fertility treatment, "… they must have suffered a service-connected injury, be married, and be able to supply their own eggs or sperm" – excluding unmarried couples, same-sex couples, and those who are unable to produce eggs or sperm.[260] Accordingly, efforts undertaken by an unmarried veteran, Toni Hockney, to have the DVA cover the costs of IVF treatments so that she could become pregnant, were denied.[261] Similarly, Khris Goins, a transgender man, who served in the army from 2006-2009, was denied coverage for him to have the costs of IVF covered by the DVA.[262] Both Toni and Khris maintained that they wished to "fill a void" and "continue [their] blood line[s]…" by having children rather than seeking to adopt a child.[263]

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254. Smith, *Autonomy v. State Intervention*, *supra* note 36, at 658-659 (in particular, the use of artificial insemination was not recognized as a fundamental right available to unmarried women); Smith & Iraola, *supra* note 10, at 29 (in particular, the use of artificial insemination was not recognized as a fundamental right available to unmarried women).

255. *Reproductive Technology and The Procreation Rights of the Unmarried*, 98 HARV. L. REV. 669, 678-79 (1985) [hereinafter *Reproductive Technology*].

256. Jasanoff, *supra* note 2, at 267; *see* Griswold v. Connecticut, 381 U.S. 479, 488 (1965).

257. Justyn Lezin, *(Mis)Conceptions: Unjust Limitations on Legally Unmarried Women's Access to Reproductive Technology and Their Use of Known Donors*, 14 HASTINGS WOMEN'S L. J. 185, 189 (2003).

258. Amy Sokolow, *The VA Doesn't Cover Fertility Treatments for Unmarried Veterans of Same-Sex Couples. Some Want to Change That*. USA TODAY, https://usatoday.com/story/news/nation/2020/08/21/veterans-groups-say-va-should-offer-ivf-unmarried-same-sex-couples/3371635001 (last updated Aug. 21, 2020, 7:33 PM).

259. *Id.*

260. *Id.*

261. *Id.*

262. *Id.*

263. *Id.*

F. Individual Procreative Liberty

In contemporary society, it is argued by some that the right of procreation should be seen as a "matter of individual reproductive liberty,"[264] and, accordingly, should be exercised as is desired, utilizing any and all ARTs.[265] Further, inasmuch as "a sensitive reading" of pertinent U.S. Supreme Court decisions "implicitly" buttresses this very right of procreative liberty, this right should not be narrowly interpreted by the states as only allowed within the bounds of a traditional family unit.[266] Support for the notion of expanded procreational uses of ARTs was seemingly validated in the amended Uniform Parentage Act of 2017 which allowed a martial presumption to be made "…equally to both male and female spouses of the woman who gave birth."[267] Married, same-sex parents are now recognized legally.[268]

CONCLUSION

Largely unregulated today, as seen,[269] ARTs are being developed and utilized at an exhilarating pace far exceeding what has been anticipated during the 20th century.[270] While affording new reproductive options for those genetically at-risk individuals, the noble desire to prevent or limit genetic diseases or correct genetic anomalies from being passed to their progeny exists as well. These efforts raise ethical concerns that "customizing" birth violates the basic tenets of divine creation by God.[271]

As ART evolves, more complex medical errors are to be expected. Presently, the eponymous tort of negligence is the legal foundation and the framework for relief to plaintiffs harmed as a consequence of errors made

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264. O'Brien, *supra* note 21, at 475.

265. *Id.*; Kenneth L. Karst, *The Freedom of Intimate Association*, 89 YALE L. J. 624, 690 (1980) (expanded uses of ART may also be recognized and "justified" by acceptance of the notion that the right to freedom of association is fundamental to the exercise of procreative liberty)

266. *Reproductive Technology*, *supra* note 255, at 685.

267. O'Brien, *supra* note 21, at 440.

268. *Id.*; *see* Courtney G. Joslin, *Nurturing Parenthood Through the UPA (2017)*, 127 YALE L. J. F. 589, 612 (2018).

269. FOX, *supra* note 135, at 161; *See* Boone, *supra* note 51, at 533 (referring to the *laissez-faire* approach of the United States to regulating ART); Lewis, *supra* note 118, at 752; *see also Tomorrow's World: Two Books Explore a Technology That Could Transform Humanity*, THE ECONOMIST (Mar. 3, 2021), https://www.economist.com/books-and-arts/2021/03/03/two-books-explore-a-technology-that-could-transform-humanity [hereinafter *Tomorrow's World*].

270. *See generally* GREELY, *supra* note 129.

271. *See* O'Brien, *supra* note 21, at 420.

during medical procedures.[272] Legal actions for negligent medical malpractice, wrongful birth, wrongful life, or for wrongful death are the "standardized" remedies.[273] Issues of clarity in separating the evidentiary proofs required under these remedies, especially in computing damages for injuries, have led to calls for a "unitary tort strategy"[274] by reconfiguring the tort of negligence to craft two, new, specific actions to deal with the wide spectrum of liability arising from medical procedures to expand fecundity: specifically, reproductive negligence[275] and wrongful genetic manipulation.[276] Regrettably, until judicial recognition is given to the newly proposed torts, any steps toward reformation of the laws of negligence must be seen as tentative at best. Paramount to adapting the law to the Age of ART and determining a defined level of genetic responsibility is a willingness to act decisively, reasonably, and with common sense rather than continue in a vortex of indecisiveness.

One of the most vexatious issues in contemporary society is determining the extent to which the State is legally "obligated" to reconceptualize the ideal of a right to pursue happiness set forth in the Declaration of Independence to include a basic right to procreate.[277] As early as 1888, the United States Supreme Court declared marriage to be "…the foundation of the family and of society, without which there would be neither civilization nor progress," and, as such, is taken as a basic right.[278] Indeed, it has been postulated that within the right to procreate is an ancillary right to a genetically child free of disease[279] – a right justified fully by the very notion of social contract put forth by President Franklin Roosevelt in 1944.[280] Furthermore, this is a right found within the national health policy which promotes a policy of fostering a healthier society which can only be guaranteed by reproductive security and strong, healthy genes at birth.[281] The prevailing legal view, however, remains that there is no right to be free from genetic disease at birth.[282] However, as has already

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272. Perry, *supra* note 49, at 398-399.

273. *See* FOX, *supra* note 135.

274. Fox, *supra* note 45, at 211.

275. *Id.* at 212.

276. *See generally* Billaurer, *supra* note 41.

277. THE DECLARATION OF INDEPENDENCE, pmbl., para (U.S. 1776).

278. Maynard v. Hill, 125 U. S. 190, 211 (1888); *see generally*, Skinner v. Oklahoma, 316 U.S. 535, 541 (1942) (acknowledging marriage and procreation as "…fundamental to both the very existence and survival of the race").

279. Schaefer & Labude, *supra* note 20; *See generally Park v. Chessin,* 88 Misc. 2d 222, (1976) (holding there is a "legal right to begin life unimpaired").

280. *See generally,* ROUSSEAU *supra* note 58; President Franklin D. Roosevelt, State of the Union Message to Congress (Jan. 11, 1944).

281. O'Brien, *supra* note 21, at 476-477.

282. *Id.* at 477; *See* Billaurer, *supra* note 41, at 477.

been seen, parties harmed during the birthing process are protected by the laws of negligence and medical malpractice.[283]

The overriding goal of the science of genetics should be, simply, to create and support a society with "significantly greater freedom from disease" or, in other words, the "improvement" of heredity.[284] ARTs provide a real opportunity to dramatically limit genetic disease through gene editing *in vitro* and *in vivo* before birth actually occurs. The goal of lessening the heavy burden of genetic disease can only be met by pursuing scientific research into these fields of the genetic technologies and by selective use of gene editing before birth.[285] Mastery of the genetic code must be undertaken with "…a careful resolve to minimize human suffering and maximize the social good" or, in other words, the maintenance of health and prevention of congenital disease.[286] The "hard reality" of gene editing is that it will not be discarded.[287] To the contrary, it will be commonplace.[288]

Genetic manipulation is seen either as heinous and a perverse violation of the laws of nature deemed as sacred, together with the very dignity of existence, or it is viewed, simply, "as a way to fix, clean, update and upgrade faulty genes," by editing and replacing them from the human genome.[289] Indeed, advancing knowledge that the realization of gene manipulation technology means that a virtual eradication of genetic birth defects will be achieved, and, thus, the harms of genetic disease will be blunted, is determinative of which view is controlling.[290]

In order for "open-ended research,"[291] which will promote scientific progress toward assisting those with debilitating genetic diseases to receive curative treatments be allowed to progress, the scientific community must be more honest and forthcoming with the public[292]

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283. *See supra* note 40-57; *See also* SMITH, GENETICS, ETHICS, AND THE LAW, *supra* note 42, at ch. 4.

284. O'Brien, *supra* note 21, at 476.

285. *Id.* at 476-477; *see* Josephine Johnston et al., *Sequencing Newborns: A Case for Nuanced Use of Genomic Technologies*, 48 HASTINGS CTR. REP. 1 (2018) (urging that genomic sequencing be done selectively);.*see generally* ERIN NELSON, LAW POLICY & REPRODUCTION LIBERTY (2013).

286. Smith, *Genetics, Eugenics, and Public Policy*, *supra* note 38, at 453.

287. *Tomorrow's World*, *supra* note 268.

288. *Id.*

289. DOUDNA & STERNBERG, *supra* note 172, at 246; *see generally* Anna Zaret, *Editing Embryos: Considering Restrictions on Genetically Engineering Humans*, 67 HASTINGS L. J. 1805 (2016).

290. DOUDNA & STERNBERG, *supra* note 172, at 218. *see generally* Gustafson, *supra* note 12.

291. DOUDNA & STERNBERG, *supra* note 172, at 246.

292. *Id.* at xix, 7.

concerning the broadest consequences of scientific work in this field.[293] The ethics of experimentation and use of genomic research, together with a regulatory scheme and safety guarantees for its specific applications, are central to a sound program of public education and local involvement.[294] What is called for is an "ethos of discussion without dictation."[295] Such a discussion of this notion becomes problematic when it is realized that an insufficient understanding of this subject area and an ability to deliberate and hopefully make informed decisions is lacking in the populace.[296] Even with this state of affairs, it can be expected that the day may soon arrive when it is considered "unethical not to use germline editing to alleviate human suffering."[297]

293. *Id.* at 244.

294. *Id.* at 220.

295. *Id.* at 244.

296. GOSTIN & WILEY, *supra* note 231, at 51 (explaining that because of the lack of citizen pedantry in ART, it becomes necessary for the government to exercise its *parens patriae* power in this sphere of decision-making); *see generally* JENNY REARDON, THE POSTGENOMIC CONDITION: ETHICS, JUSTICE, AND KNOWLEDGE AFTER THE GENOME (2017).

297. DOUDNA STERNBERG, *supra* note 172, at xix.