

NORMALIZING REPRODUCTIVE GENETIC INNOVATION

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Many societally accepted techniques were quite controversial at inception and for decades after. For example, historically, dialysis was “unnatural,” vaccination was “the poisoned quill,” and artificial insemination was akin to adultery. Despite social and cultural hurdles, the aforementioned medical techniques have today attained overall public acceptance, permissive legal treatment, and even health insurance coverage in some cases.

Unlike many now-routine treatments like in vitro fertilization (IVF), egg freezing, and organ transplantation, which flourished without significant governmental intervention, today’s controversial medical treatments, especially those involving reproductive genetic innovation, face intense regulatory barriers. Reproductive genetic innovation, which is the combination of IVF and genetic substitution or modification, is also notable for being accompanied by the continued call of scientists, regulators, and individuals for a “societal discourse.”

Yet, despite the repeated calls, there is still no clarity as to the concrete structure of a “societal discourse” or how it could be fostered. This Article adapts the tools of American and comparative administrative law and public participation to prescribe methods for a societal consultation on reproductive genetic innovation. Specifically, it draws on notice-and-comment rulemaking, agency public meetings, the recent rollout of COVID-19 vaccines, the “Consensus Development Review” used in the normalization of liver transplantation, and citizens’ juries to provide substantive suggestions for the societal discourse that scientists, commentators, and federal employees have been requesting for decades.

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INTRODUCTION

Sensationalism is often connected to medical and scientific innovation, especially as it relates to reproduction.¹ In the 1930s, babies created using artificial insemination by donor sperm were referred to as “eugenic babies.”²

1. June Carbone & Naomi Cahn, *Embryo Fundamentalism*, 18 WM. & MARY BILL RTS. J. 1015, 1032 (2010) (noting the sensational news coverage that accompanies assisted reproduction).

2. Kara W. Swanson, *Adultery by Doctor: Artificial Insemination, 1890-1945*, 87 CHI-KENT L. REV. 591, 607 (2012).

Sensationalism has also been criticized as being responsible for the early stigmatization of babies born as a result of in vitro fertilization (IVF).³ The term “designer babies” has been used to refer to children who are or will be selected for sex, eye color, or for traits that could involve genetic modification, rendering a “superior” child who could form the foundation for a “brave new world” full of children created through IVF with pre-ordained roles in furtherance of social stability.⁴ Assisted reproduction technologies (ARTs) that would involve the creation and storage of embryos, as well as techniques whose research would involve destroying embryos, like gene editing, rarely escape the debates about the origins of life, embryo destruction, and abortion in the United States.⁵ Further, conversations about gene editing, especially “reproductive genetic innovation” like human germline gene editing, often trend towards iterations of a debate related to fears of the potential enhancement possibilities posed by these new technologies instead of the potential therapeutic uses. This is despite potential enhancement targets like athletic ability, height, or intelligence being hard to manipulate or even define.⁶

In a *New England Journal of Medicine* article that has been cited almost 500 times, physician Eric Cassel noted “[t]he obligation of physicians to relieve human suffering stretches back into antiquity.”⁷ Techniques involving reproductive genetic innovation could alleviate suffering and improve fertility outcomes.⁸ In this Article, the term reproductive genetic innovation encompasses cytoplasmic

3. See Alison Murdoch, *IVF and The Prevention of Mitochondrial DNA Disease: The Moral Issues*, BIONEWS (May 3, 2011), https://www.bionews.org.uk/page_92949; Carbone & Cahn, *supra* note 1.

4. See Aldous Huxley, *A BRAVE NEW WORLD* 6–8 (Harper Collins 2006) (1932); Michael Sandel, *The Case Against Perfection*, ATLANTIC (Apr. 2004), <https://www.theatlantic.com/magazine/archive/2004/04/the-case-against-perfection/302927>; Eric S. Lander, *Brave New Genome*, 373 *NEW ENG. J. MED.* 5, 5 (2015).

5. See, e.g., Mary Ziegler, *Beyond Balancing: Rethinking the Law of Embryo Disposition*, 68 *AM. U. L. REV.* 515, 518 (2018).

6. See *infra* Part IV.C. See, e.g., Eric S. Lander, *What We Don't Know*, in *NAP COMMISSIONED PAPERS* 20, 27 (2015) (observing that traits like height, intelligence, and athletic ability are “very complex traits—often influenced by hundreds of genes.”).

7. Eric J. Cassell, *The Nature of Suffering and the Goals of Medicine*, 306 *NEW ENG. J. MED.* 639, 639 (1982). As of August 2022, Google Scholar notes that Cassell’s 1998 book of the same title and general subject matter has been cited over 5,000 times. See *Eric Cassell*, *GOOGLE SCHOLAR*, <https://scholar.google.com/citations?user=-dNjzPgAAAAJ&hl=en> (last visited Aug. 16, 2022).

8. See *NAT'L ACADS. SCIS., ENG'G & MED., HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE* 188 (2017) [hereinafter *SCIENCE, ETHICS, AND GOVERNANCE*]; *NAT'L ACAD. MED., NAT'L ACAD. SCIS & ROYAL SOC'Y, HERITABLE HUMAN GENOME EDITING* 88–89 (2020) [hereinafter *HERITABLE HUMAN GENOME EDITING*].

transfer, mitochondrial transfer, and germline gene or genome editing; although for many, germline gene editing is considered far more controversial than cytoplasmic or mitochondrial transfer due to its potential ramifications.⁹ All of the aforementioned reproductive genetic innovation techniques combine genetic modification or substitution with IVF in an effort to improve fertility outcomes, prevent the inheritance of harmful genetic disease, or both. Also, in spite of the varying amounts of genetic modification involved with these individual techniques, all of these promising techniques are now deemed “experimental” in the United States and are also prohibited by a budget rider that has been added to every Appropriations Act since 2015, after years of *de facto* prohibition by federal administrative agencies.¹⁰

In the meantime, scientists and observers have been calling for a societal consensus on reproductive genetic innovation, especially the appropriateness of the use of germline, or heritable, gene editing in certain instances.¹¹ Similarly, federal administrative agency employees, including the Director of the National Institutes of Health (NIH), have called for or mentioned societal discourse or consensus.¹² While scientists

9. For technical background on these techniques, *see infra* Part I.

10. For characterizations of these techniques as “experimental,” see Jason Barritt, Steen Willadsen, Carol Brenner & Jacques Cohen, *Cytoplasmic Transfer in Assisted Reproduction*, 7 HUM. REPROD. UPDATE 428, 433–34 (2001); NAT’L ACADS. SCIS., ENG’G & MED., MITOCHONDRIAL REPLACEMENT TECHNIQUES: ETHICAL, SOCIAL, AND POLICY CONSIDERATIONS 120 (2016) [hereinafter MITOCHONDRIAL REPLACEMENT TECHNIQUES]; David Cyranoski, *What CRISPR-Baby Prison Sentences Mean for Research*, 577 NATURE 154, 155 (2020). For more on the budget rider, see Russell A. Spivak, I. Glenn Cohen & Eli Y. Adashi, *Germ-line Gene Editing and Congressional Reaction in Context: Learning from Almost 50 Years of Congressional Reactions to Biomedical Breakthroughs*, 30 J.L. & HEALTH 20, 20, 22–23 (citing Consolidated Appropriations Act of 2016, Pub. L. No. 114-92, § 749, 129 Stat. 2242, 2283 (2015)). For more on the *de facto* prohibition on techniques involving genetic modification, see Myrisha S. Lewis, *How Subterranean Regulation Hinders Innovation in Assisted Reproductive Technology*, 39 CARDOZO L. REV. 1239, 1241–47 (2018) [hereinafter Lewis, *Subterranean Regulation*].

11. *See* SCIENCE, ETHICS, AND GOVERNANCE, *supra* note 8, at 7, 13; David Baltimore, Paul Berg, Michael Botchan, Dana Carroll, R. Alta Charo, George Church et al., *A Prudent Path Forward for Genomic Engineering and Germline Gene Modification*, 348 SCIENCE 36, 37–38 (2015); Robert K. Naviaux & Keshav K. Singh, *Need for Public Debate About Fertility Treatments*, 413 NATURE 347, 347 (2001); Eric S. Lander, Françoise Baylis, Feng Zhang, Emmanuelle Charpentier, Paul Berg, Catherine Bourgain et al., *Adopt a Moratorium on Heritable Genome Editing*, 567 NATURE 165, 165 (2019); *Broad Scientists and Geneticists Discuss Issues Raised by Clinical Germline Genome Editing*, BROAD INST. (Nov. 26, 2018), <https://www.broadinstitute.org/news/broad-scientists-and-geneticists-discuss-issues-raised-clinical-germline-genome-editing> (referring to statements by Feng Zhang); *infra* Part II.

12. *See* Robert M. Califf & Ritu Nalubola, *FDA’s Science-Based Approach to Genome Edited*

have continued to meet to discuss the appropriateness of germline gene editing, the federal administrative state has yet to facilitate that discourse.

Part of the reason for the lack of progress on that societal discourse is that it remains unclear what the suggested societal discourse would look like, how it would work, and what it would reasonably be expected to accomplish. Further, calls for a societal consensus or discourse may substitute for an intentional delay as structuring a societal discourse might not be a legislative or regulatory priority, despite scientists' and policymakers' calls for one. Similarly, I do not argue for a domestic or global societal *consensus* (which is unlikely), but a societal *discourse*, at least within the United States is certainly possible.¹³ While much of the literature and media coverage has focused on sensational aspects of gene modifying technologies and the potential slippery slope from therapy to enhancement, the future American societal discourse should be one that focuses on “normalization,” meaning the “mainstreaming” of techniques involving reproductive genetic innovation, instead of sensationalism.¹⁴ In prior articles, I have argued that new techniques that involve genetic modifications should not be prevented due to the possibility of future eugenics uses, line crossing, slippery slopes, or other views that stem from or signify the yuck factor or moral panic that often accompanies genetic

Products, FDA: FDA VOICES (Jan. 18, 2017), <http://blogs.fda.gov/fdavoices/index.php/2017/01/fdas-science-based-approach-to-genome-edited-products/> (“Even as FDA implements necessary steps for effective regulation to ensure the safety of products, the role of broader, inclusive public discussion involving multiple constituencies . . . to address the larger societal considerations should not be overlooked.”); HERITABLE HUMAN GENOME EDITING, *supra* note 8, at 3 (“Extensive societal dialogue should be undertaken before a country makes a decision on whether to permit clinical use of heritable human genome editing.”); Francis Collins, *Experts Conclude Heritable Human Genome Editing Not Ready for Clinical Applications*, NAT’L INST. HEALTH: NIH DIR.’S BLOG (Sept. 17, 2020), <https://directorsblog.nih.gov/2020/09/17/experts-conclude-heritable-human-genome-editing-not-ready-for-clinical-applications/>.

13. Currently, experts (including scientists who have developed germline gene editing technologies) cannot come to a consensus on whether there should be a moratorium on these techniques. *See, e.g.*, Bryan Cwik, *Revising, Correcting, and Transferring Genes*, AM. J. BIOETHICS, Aug. 2020, at 7, 9–10 (contrasting various positions of scientists, bioethicists, and non-governmental organizations on the future legal treatment of germline gene editing, whether it should continue, and at what pace innovation should occur); Lander et al., *supra* note 11, at 167 (calling for “broad societal consensus” before any “clinical germline editing”); *see also* Eli Y. Adashi, Michael M. Burgess, Simon Burall, I. Glenn Cohen, Leonard M. Fleck, John Harris et al., *Heritable Human Genome Editing: The Public Engagement Imperative*, 3 CRISPR J. 434, 434–37 (2020).

14. The term “enhancement,” which is often mentioned as a possible outcome of reproductive genetic innovation, is not clearly defined. *See* discussion *infra* Part IV.C.

modification.¹⁵ This Article builds on that argument by identifying useful public consultation tools that could shift the discourse related to these techniques from one that focuses on sensationalism, social opposition, or fear to one that focuses on medical practice.

This Article unites the scientific and legal literatures by linking scientists' calls for a societal discourse with administrative legal structures that could be adapted to create that discourse.¹⁶ The Article also highlights how reproductive genetic innovation upends some common critiques that administrative law and public engagement hinder innovation, as it appears a discourse may be critical to moving reproductive genetic innovation techniques forward.¹⁷ Further, there is a literature on the value of deliberative or participatory democracy, which this article applies to a potential future discourse on reproductive genetic

15. See Myrisha S. Lewis, *Is Germline Gene Editing Exceptional?*, 51 SETON HALL L. REV. 735, 735 (2021) [hereinafter Lewis, *Is Germline Gene Editing Exceptional?*]; Myrisha S. Lewis, *How Analogizing Socio-Legal Responses to Organ Transplantation Can Further the Legalization of Reproductive Genetic Innovation*, 74 SMU L. REV. 665 (2021) [hereinafter Lewis, *Socio-Legal Responses*]; Charles W. Schmidt, *The Yuck Factor: When Disgust Meets Discovery*, 116 ENV'T. HEALTH PERSPS. A524, A525 (2008) ("Generally speaking, 'yuck factor' has become a catchall phrase to describe technophobic sentiments that vary by what triggers them."). For more information on the term "eugenics" and how it has developed over time, see Seema Mohapatra, *Politically Correct Eugenics*, 12 FIU L. REV. 51, 53–58 (2016) (citing FRANCIS GALTON, *INQUIRIES INTO HUMAN FACULTY AND ITS DEVELOPMENT* 17 n.1 (Gavan Tredoux ed., 2d ed. 1907), <http://galton.org/books/human-faculty/text/galton-1883-human-faculty-v4.pdf>); Sonia M. Suter, *A Brave New World of Designer Babies?*, 22 BERKELEY TECH. L.J. 897, 902–05 (2007); Osagie K. Obasogie, *More Than Love: Eugenics and the Future of Loving v. Virginia*, 86 FORDHAM L. REV. 2795, 2796–99 (2018); Julia Mahoney & Gil Siegal, *Beyond Nature? Genomic Modification and the Future of Humanity*, 81 LAW & CONTEMP. PROBS 195, 208 (2018) ("The most emotionally charged criticism of heritable genome editing is that it threatens to usher in a new era of 'eugenics.'" (citation omitted)).

16. See Baltimore et al. *supra* note 11, at 37 ("Given these rapid developments [in CRISPR-Cas9 technology, a technology which could be used for germline gene editing], it would be wise to begin a discussion that bridges the research community, relevant industries, medical centers, regulatory bodies, and the public to explore responsible uses of this technology."); Edward Lanphier, Fyodor Urnov, Sarah Ehlen Haecker, Michael Werner & Joanna Smolenski, *Don't Edit the Human Germ Line*, 519 NATURE 410, 411 (2015); *Broad Scientists and Geneticists Discuss Issues Raised by Clinical Germline Genome Editing*, BROAD INST. (Nov. 26, 2018), <https://www.broadinstitute.org/news/broad-scientists-and-geneticists-discuss-issues-raised-clinical-germline-genome-editing> (referring to statements by Feng Zheng).

17. See Mahoney & Siegal, *supra* note 15, at 212; Nicholas Parrillo, *Should the Public Get to Participate Before Federal Agencies Issue Guidance? An Empirical Study*, 71 ADMIN. L. REV. 57, 59 (2019) (observing that processes mandated by the Administrative Procedure Act in connection with legislative rules are "costly [and] time-consuming"); *id.* at 102.

innovation.¹⁸ Normatively, the Article identifies, critiques, and adapts several administrative law tools and also other tools that could facilitate outcomes that embody the public participatory goals of administrative law and the public participatory goals of scientists and commentators in the realm of reproductive genetic innovation. More broadly, the Article contributes to the literature on the value of process and public deliberation.¹⁹

The Article proceeds as follows. Part I begins by providing background on IVF and reproductive genetic innovation. Part II discusses federal administrative agency decisions applicable to reproduction, the budget riders applicable to reproduction and innovation in the United States, the relationship between calls for public discourse and federal regulation, and the societal and ethical concerns that can impact administrative agency and Congressional actions. Part III focuses on regulatory and societal responses (including sensationalized responses) to commonly accepted techniques like organ transplantation and vaccination and more societally and legally contested techniques like assisted reproduction and techniques involving reproductive genetic innovation. Part IV provides guidance on how to frame issues of reproductive genetic innovation in the realm of medical treatment; in doing so, it fosters a hands-off societal approach instead of one in which members of society, federal agency employees, and certain legislators impose their own social and religious views on other individuals' reproductive decisions without public deliberation.²⁰

In the United States, the NIH used Consensus Development Review in the lead up to the addition of organ transplantation to Medicare's covered treatments, as were public hearings, which were supported by inquiries (as

18. See Nina A. Mendelson, *Foreword: Rulemaking, Democracy, and Torrents of E-mail*, 79 GEO. WASH. L. REV. 1343, 1343 (2011) (citing Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1515 (1992)); Angela M. Banks, *Expanding Participation in Constitution Making: Challenges and Opportunities*, 49 WM. & MARY L. REV. 1043, 1046 n.12 (2008); Nicole Curato, John S. Dryzek, Selen A. Ercan, Carolyn M. Hendriks, & Simon Niemeyer, *Twelve Key Findings in Deliberative Democracy Research*, DÆDALUS, Summer 2017 at 28, 28–29.

19. See Giulia Cavaliere, *Genome Editing and Assisted Reproduction: Curing Embryos, Society or Prospective Parents?*, 21 MED. HEALTH CARE & PHILOS. 215, 222 (2018); H. Holden Thorp, *Public Debate is Good for Science*, 371 SCIENCE 213, 213 (2021); Alan I. Leshner, *Public Engagement with Science*, 299 SCIENCE 977, 977 (2003).

20. For more on religious views related to assisted reproductive technology and regulation in general, see Ariana Eunjung Cha, *How Religion Is Coming to Terms with Modern Fertility Methods*, WASH. POST (Apr. 27, 2018), <https://www.washingtonpost.com/graphics/2018/national/how-religion-is-coming-to-terms-with-modern-fertility-methods/>; see also *Fertility Issues*, BBC, <https://www.bbc.co.uk/bitesize/guides/z2jmyrd/revision/4> (last visited Aug. 16, 2022); NUFFIELD COUNCIL ON BIOETHICS, *GENOME EDITING AND HUMAN REPRODUCTION: SOCIAL AND ETHICAL ISSUES 1*, 53 (2018) [hereinafter *GENOME EDITING & HUMAN REPRODUCTION*].

conducted by Congressional subcommittees) into the designation of organ transplantation as “established” instead of experimental.²¹ Additionally, administrative law in general involves public outreach procedures, including notice-and-comment rulemaking and agency meetings where agency employees interface with the public.²² Other countries, namely the United Kingdom, have held a societal discourse on the topic of mitochondrial transfer, a reproductive genetic technique that has been legalized in the United Kingdom but not the United States.²³ Part IV draws on all of these practices and analyzes methods of public participation that could facilitate a shift from sensationalism or political arguments to discussions that emphasize medical practice. Ultimately, this Article draws on these deliberative methods to construct a blueprint for the societal discourse on reproductive genetic innovation that scientists, commentators, and patient groups have been requesting for years.

I. THE SCIENCE OF REPRODUCTIVE GENETIC INNOVATION

The term reproductive genetic innovation, as used in this Article, encompasses techniques involving the combination of IVF and genetic substitution or modification, including cytoplasmic transfer, mitochondrial transfer, and germline genetic modification.²⁴ This Part provides background on IVF and forms of reproductive genetic innovation.

21. See *infra* Part IV.C; *National Organ Transplant Act: Hearings before the Subcomm. on Health and the Env't of the Comm. on Energy and Commerce*, 98th Cong. 125 (1983) (statement of Rep. Albert Gore Jr.).

22. See 5 U.S.C. § 553 (2006); Catherine M. Sharkey, *Federalism Accountability: “Agency-Forcing” Measures*, 58 DUKE L.J. 2125, 2163 (2009) (“Notice-and-comment rulemaking is the means by which federal agencies solicit and incorporate the views of all ‘interested persons’ before issuing final rules.”); Nicholas Bagley, *The Procedure Fetish*, 118 MICH. L. REV. 345, 368 (2019) (noting that “administrative law is fond of imposing judicially enforceable procedural rules on agencies to facilitate the ability of outside groups to influence agency decisionmaking, to monitor agency activities, and to check agency overreach[.]” including notice-and-comment rulemaking); Lars Noah, *Doubts About Direct Final Rulemaking*, 51 ADMIN. L. REV. 401, 427 (1999) (“According to some commentators, notice-and-comment rulemaking procedures were designed primarily to facilitate the development of an administrative record in anticipation for judicial review.”).

23. See *infra* Part IV.D.2.

24. See *supra* note 9 and accompanying text. The term “reproductive genetic innovation” does not draw a line based on heritable or non-heritable genetic modification. Not only is the definition of heritability contestable for some, but more importantly, the FDA treats all of these techniques similarly by prohibiting their use without the existence of an investigational new drug (IND) application. In prior works, I have noted why this regulatory treatment is surprising in light of the state-based and hands-off treatment of assisted reproductive technology, including in vitro fertilization, in general. See, e.g., Lewis, *Subterranean Regulation*,

A. Assisted Reproduction: In Vitro Fertilization

At least eight million babies have been conceived using IVF, including the children of celebrities like Chrissy Teigen, Khloe Kardashian, Celine Dion, and Michelle Obama.²⁵ IVF is a treatment that can be used to help women who are experiencing fertility limitations conceive children and also to create embryos for those who may want to use ART for other reasons, such as the desire to select for embryos that are free of disease or other traits.²⁶

IVF involves the fertilization of an egg with sperm in a laboratory, which is then implanted into a woman's uterus with the aim of producing a healthy pregnancy and child.²⁷ IVF was first used to produce a successful human pregnancy and birth in 1978 in the United Kingdom.²⁸ Louise Brown, who was sensationally referred to as the world's "first test tube baby" in 1978, is now forty-four years old and has given birth to her own children.²⁹ The first child born as a result of IVF in the United States has also given birth to her own child.³⁰ In 2010, when awarding Robert G. Edwards the Nobel Prize for his contributions to the development and use of IVF, the Nobel Prize committee noted that "[h]is contributions represent a milestone in the development of modern medicine."³¹

supra note 10, at 1258–59; Myrisha S. Lewis, *Halted Innovation: The Expansion of Federal Jurisdiction over Medicine and the Human Body*, 2018 UTAH L. REV. 1073, 1096, 1101 (2018).

25. See, e.g., Danielle Fowler, *11 Celebrities Who Have Opened Up About Their IVF Experiences: From Amy Schumer to Michelle Obama*, MARIE CLAIRE (Nov. 17, 2020), <https://www.marieclaire.com.au/celebrities-spoken-about-ivf/>; Susan Scutti, *At Least 8 Million IVF Babies Born in 40 Years Since Historic First*, CNN (July 3, 2018, 6:04 AM), <https://www.cnn.com/2018/07/03/health/worldwide-ivf-babies-born-study/index.html>.

26. See SCIENCE, ETHICS, AND GOVERNANCE, *supra* note 8, at 129.

27. *In Vitro Fertilization*, MAYO CLINIC (Sept. 10, 2021), <https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716>.

28. *World's First "Test Tube" Baby Born*, HISTORY (July 23, 2020), <https://www.history.com/this-day-in-history/worlds-first-test-tube-baby-born>.

29. See *id.*; Scutti, *supra* note 25; Cole Moreton, *World's First Test-Tube Baby Louise Brown Has a Child of Her Own*, INDEPENDENT (Jan. 14, 2007, 1:00 AM), <https://www.independent.co.uk/life-style/health-and-families/health-news/world-s-first-test-tube-baby-louise-brown-has-a-child-of-her-own-432080.html>; Ciara Nugent, *What It Was Like to Grow Up as the World's First "Test-Tube Baby"*, TIME (July 25, 2018, 5:00 AM), <https://time.com/5344145/louise-brown-test-tube-baby>.

30. Aina Hunter, *U.S. First Test Tube Baby Elizabeth Carr Gives Birth, Tells Her Story*, CBS NEWS (Aug. 9, 2010), <https://www.cbsnews.com/news/us-first-test-tube-baby-elizabeth-carr-gives-birth-tells-her-story>.

31. *The Nobel Prize in Physiology or Medicine 2010*, NOBEL PRIZE (Oct. 4, 2010), <https://www.nobelprize.org/prizes/medicine/2010/press-release/>.

IVF largely enjoys a hands-off treatment by the U.S. legal system despite religious and bioethical objections, and safety concerns about the potential negative impacts of the fertility drugs and ARTs on egg donors, women implanted with embryos, and children conceived by IVF.³²

B. Reproductive Genetic Innovation: Advanced Assisted Reproductive Technologies

In recent years, IVF has been combined with genetic substitution or modification. This Section provides background on two reproductive genetic innovation techniques involving the combination of IVF and the substitution of genetic material: cytoplasmic transfer and mitochondrial transfer. Previously, I have referred to these techniques collectively as “advanced assisted reproductive technologies” (AARTs).³³ AARTs combine IVF with the modification of non-nuclear DNA.³⁴

In short, cells contain a nucleus, which is surrounded by cytoplasm.³⁵ Contained within that cytoplasm are mitochondria, the organelles targeted in mitochondrial transfer.³⁶ Cytoplasmic, or ooplasmic transfer, was created for the purpose of improving fertility and can assist individuals who have trouble conceiving genetically related children.³⁷ On the other hand, most uses of mitochondrial transfer are intended to prohibit the passage of devastating genetic conditions, although improved fertility outcomes are also possible.³⁸ Mitochondrial disease varies in its severity, but mitochondrial disease affects organs that require the most energy, such as the brain, heart, and kidneys.³⁹ Mitochondrial transfer and cytoplasmic transfer have been treated similarly by the regulatory system, as will be detailed in Part II.⁴⁰

32. See, e.g., Michele Goodwin, *Prosecuting the Womb*, 76 GEO. WASH. L. REV. 1657, 1693 (2008).

33. See Lewis, *Subterranean Regulation*, *supra* note 10, at 1241.

34. *Id.*

35. See NUFFIELD COUNCIL ON BIOETHICS, NOVEL TECHNIQUES FOR THE PREVENTION OF MITOCHONDRIAL DNA DISORDERS: AN ETHICAL REVIEW 1, 36–38 (2012) [hereinafter PREVENTION OF MITOCHONDRIAL DNA DISORDERS].

36. *Id.* at 18.

37. See Sara Darbandi, Mahsa Darbandi, Hamid Reza Khorram Khorshid, Mohammad Reza Sadeghi, Ashok Agarwal, Paullav Sengupta et al., *Ooplasmic Transfer in Human Oocytes: Efficacy and Concerns in Assisted Reproduction*, 15 REPROD. BIOLOGY & ENDOCRINOLOGY, Oct. 2017, at 1, 5; PREVENTION OF MITOCHONDRIAL DNA DISORDERS, *supra* note 35, at 1, 34–38. This Article will use the term “cytoplasmic transfer.”

38. See PREVENTION OF MITOCHONDRIAL DNA DISORDERS, *supra* note 35, at 37; Lynsey Cree & Pasqualino Loi, *Mitochondrial Replacement: From Basic Research to Assisted Reproductive Technology Portfolio Tool—Technicalities and Possible Risks*, 21 MOLECULAR HUM. REPROD. 3–4 (2015).

39. PREVENTION OF MITOCHONDRIAL DNA DISORDERS, *supra* note 35, at 21.

40. See Mauro Cozzolino, Diego Marin, & Giovanni Sisti, *New Frontiers in IVF: mtDNA and*

C. Reproductive Genetic Innovation: Heritable Gene Editing

There are two forms of gene editing: gene therapy and germline gene editing.⁴¹ Heritable genetic modification involves germ cells (sperm and egg cells), whereas somatic modification, or gene therapy, is expected to affect only an individual's cells and not the cells of future offspring.⁴² Somatic cell gene editing has been used to cure leukemia and treat blindness;⁴³ however, one significant disadvantage of somatic cell gene editing is that it can only be used to treat or cure individuals *after* they are born, as opposed to preventing the inheritance of certain diseases, some of which are not curable.

Germline gene or genome editing is not included in the aforementioned category of AART because germline gene editing involves the modification of nuclear DNA.⁴⁴ Non-nuclear DNA, in contrast to nuclear DNA, is generally not associated with a person's individual identity or characteristics that manifest in a physical manner like hair and eye color.⁴⁵ Germline gene editing can prevent harmful genetic disease from occurring before a child is born.⁴⁶ Gene editing technologies "allow genetic material [including nuclear genetic material]

Autologous Germline Mitochondrial Energy Transfer, REPROD. BIOLOGY & ENDOCRINOLOGY, no. 55, July 2019, at 1, 4–5.

41. SCIENCE, ETHICS, AND GOVERNANCE, *supra* note 8, at 218.

42. See *What is Gene Therapy?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy> (July 25, 2018) (describing common methods of gene therapy that do not qualify as ART); *Somatic Cells*, NAT'L HUMAN GENOME RESEARCH INST., <https://www.genome.gov/genetics-glossary/Somatic-Cells> (Aug. 18, 2022).

43. See, e.g., *Kymriah (tisagenlecleucel)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/kymriah-tisagenlecleucel> (July 7, 2022) (treating acute lymphoblastic leukemia and relapsed or refractory large B-cell lymphoma); *Luxturna*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/luxturna> (June 9, 2022) (treating biallelic *RPE65* mutation-associated retinal dystrophy).

44. See Henry T. Greely, *CRISPR'd Babies: Human Germline Genome Editing in the 'He Jiankui Affair'*, 6 J.L. & BIOSCIENCES 111, 115 (2019) (explaining why the author uses the term "genome" instead of "gene" editing); Rosamund Scott & Stephen Wilkinson, *Germline Genetic Modification and Identity: The Mitochondrial and Nuclear Genomes*, 37 OXFORD J. LEGAL STUD. 886, 914 (2017); Bryan Cwik, *Revising, Correcting, and Transferring Genes*, AM. J. BIOETHICS, Aug. 2020, at 7, 11–12; MITOCHONDRIAL REPLACEMENT TECHNIQUES, *supra* note 10, at 106–08. *But see* Erik Parens & Eric Juengst, *Inadvertently Crossing the Germ Line*, 292 SCIENCE 397, 397 (2001); Lucía Gómez-Tatay, José M. Hernández-Andreu & Justo Aznar, *Mitochondrial Modification Techniques and Ethical Issues*, J. CLINICAL MED., Feb. 2017, at 1, 3.

45. For more on the dispute over the definition of the germline, see Lewis, *Socio-Legal Responses*, *supra* note 15, at 679 n.80.

46. See GENOME EDITING & HUMAN REPRODUCTION, *supra* note 20, at 21 (2018); *infra* Part II.

to be added, removed, or altered at particular locations in the genome.⁴⁷ Nevertheless, germline gene editing, as a regulatory matter, is treated similarly to AARTs, and it raises many of the same bioethical objections and concerns as AARTs; these include concerns for future persons, disparities and inequality, and the appropriate role of humans, although objections to germline gene editing are intensified due to the extent of its modification possibilities.⁴⁸ Germline gene editing is analyzed from the perspectives of innovation, health law, Food and Drug Administration (FDA) regulation, and bioethics.⁴⁹

Pre-implantation genetic testing (PGT), a term which encompasses pre-implantation genetic diagnosis (PGD) as well as pre-implantation genetic screening (PGS), is often suggested as a substitute for germline gene editing; however, PGT is not perfect, and it can lack the precision and selectivity that germline gene editing could offer.⁵⁰ More specifically, PGT cannot screen for all abnormalities or mitochondrial defects, which can lead to mitochondrial disease.⁵¹ Also, fertility limitations such as advanced maternal age can result in

47. *What are Genome Editing and CRISPR-Cas9?*, NAT'L LIB. OF MED., <https://medlineplus.gov/genetics/understanding/genomicresearch/genomeediting> (Mar. 22, 2022).

48. Some of the bioethical concerns that accompany germline gene editing include concerns related to the consent of future persons, parental autonomy, health disparities, and inequalities. See, e.g., Lewis, *Is Germline Gene Editing Exceptional?*, *supra* note 15.

49. See, e.g., Paul Enriquez, *Editing Humanity: On the Precise Manipulation of DNA in Human Embryos*, 97 N.C. L. REV. 1147, 1156–57 n.27–28 (2019) (providing bioethical scholarship related to germline gene editing, cloning, and non-heritable gene therapy); Myrisha S. Lewis, *Innovating Federalism in the Life Sciences*, 92 TEMP. L. REV. 383 (2020).

50. Recently, the field of reproductive medicine has shifted away from using the term pre-implantation genetic diagnosis (PGD) in favor of the broader term, pre-implantation genetic testing (PGT). See, e.g., Filipa Carvalho, Edith Coonen, Verrle Goossens, Georgia Kookali, Carmen Rubio, Madelon Meijer-Hoogveen et al., *ESHRE PGT Consortium Good Practice Recommendations for the Organisation of PGT*, HUM. REPROD. OPEN, Feb. 2020, at 1, 2, <https://doi.org/10.1093/hropen/hoaa021> (“The previous terms of preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) have been replaced by the term preimplantation genetic testing (PGT), following a revision of terminology used in infertility care.” (internal citation omitted)). See also Joris Robert Vermeesch Thierry Voet & Koenraad Devriendt, *Prenatal and Pre-Implantation Genetic Diagnosis*, 17 NATURE REVS. 643, 646, 649 (2016); *PGT Q&A*, CTR. FOR ADVANCED REPROD. SERVS., <https://www.uconnfertility.com/family-building-programs/genetic-testing/pgt-qa/> (last visited Aug. 16); Shoukhrat Mitalipov, Paula Amato, Samuel Parry & Marni J. Falk, *Limitation of Preimplantation Genetic Diagnosis for Mitochondrial DNA Diseases*, 7 CELL REPS. 935 (2014); Sozos J. Fasouliotis & Joseph G. Schenker, *Preimplantation Genetic Diagnosis Principles and Ethics*, 13 HUM. REPROD. 2238, 2239 (1998).

51. See MITOCHONDRIAL REPLACEMENT TECHNIQUES, *supra* note 10, at 44–46, 59; June Carbone, *CRISPR and the Future of Fertility Innovation*, 23 SMU SCI. & TECH. L. REV. 31, 36 (2020); Paul R. Brezina & William H. Kutteh, *Clinical Applications of Preimplantation Genetic*

fewer embryos that are even suitable for PGT.⁵² Germline gene editing could be combined with PGT and used to correct otherwise unsuitable embryos by removing the traits that harm them.⁵³ This could allay concerns about the negative impacts of fertility drugs on women as combining PGT with germline gene editing could minimize the number of rounds of follicle stimulation and ovarian retrieval that women might need to undergo in order to use ART in furtherance of a healthy pregnancy.⁵⁴

Gene editing, especially germline gene editing, is also accompanied by several safety concerns, such as the possibility that the technology can also lead to “off-target” changes which are changes to genetic code that were not initially intended, which is generally undesirable.⁵⁵ Scientists who work in the realm of germline gene editing are largely opposed to using the technology

Testing, BRITISH MED. J., Feb. 2015, at 1, 5; Peter Braude, Susan Pickering, Frances Flinter & Caroline Mackie Ogilvie, *Preimplantation Genetic Diagnosis*, 3 NATURE REV. 941, 942 (2002); Mitalipov, Amato, Parry & Falk, *supra* note 50. *But see* J. Poulton & A.L. Bredenoord, *Applying Pre-Implantation Genetic Diagnosis to mtDNA Diseases: Implications of Scientific Advances*, 20 NEUROMUSCULAR DISORDERS 559 (2010); Evrim Unsal, Yasemin Aktas, Oazge Uner, Sarp Ozcan, Feriba Turhan & Volkan Baltaci, *Successful Application of Preimplantation Genetic Diagnosis for Leigh Syndrome*, 90 FERTILITY & STERILITY 2017.e11 (2008).

52. *See* Filippo Maria Ubaldi, Danilo Cimadomo, Alberto Vaiarelli, Gemma Fabozzi, Roberta Venturella, Roberta Maggiulli et al., *Advanced Maternal Age in IVF: Still a Challenge? The Present and the Future of Its Treatment*, FRONTIERS ENDOCRINOLOGY, Feb. 2019, at 1, 1–2.

53. *See* Lander, *Brave New Genome*, *supra* note 4, at 6; George Q. Daley, Robin Lovell-Badge & Julie Steffann, *After the Storm—A Responsible Path for Genome Editing*, 380 NEW ENG. J. MED. 897, 899 (2019).

54. *See* Daley, Lovell-Badge & Steffann, *supra* note 53, at 899; Lindsay Kroener, Dumesic Daniel & Al-Safi Zain, *Use of Fertility Medications and Cancer Risk: A Review and Update*, 29 CURRENT OP. OBSTETRICS & GYNECOLOGY 195, 196 (2017); *see, e.g.*, Marte Myhre Reigstad, Ritsa Storeng, Tor Age Kyklebust, Nan Birgitte Oldereid, Anne Katerine Omland, Trude Eid Robsahm et al., *Cancer Risk in Women Treated with Fertility Drugs According to Parity Status: A Registry-Based Cohort Study*, 26 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 953, 959–60 (2017).

55. For more on on-target mutations resultant from CRISPR gene editing technology, *see* Sharon Begley, *Potential DNA Damage from CRISPR Has Been ‘Seriously Underestimated,’ Study Finds*, STAT NEWS (July 16, 2018), <https://www.statnews.com/2018/07/16/crispr-potential-dna-damage-underestimated/>. For more on incomplete editing and unintended consequences from on-target mutations, *see* Haoyi Wang & Hui Yang, *Gene Edited Babies: What Went Wrong and What Could Go Wrong*, PLOS BIOLOGY, Apr. 30, 2019, at 1, 3. The safety concerns that would accompany germline gene editing would play a minimal role in a public consultation, as outlined in Part IV as the public consultation would aim to address social and moral concerns. Nevertheless, safety concerns would be included in an overview of the technology, especially when drawing on the “UK case.” *See* Katrine S. Bosley, Michael Botchan, Annelien L. Bredenoord, Dana Carroll, R. Alta Charo, Emmanuelle Charpentier et al., *CRISPR Germline Engineering—The Community Speaks*, 33 NATURE BIOTECH. 478, 485 (2015).

before a societal discourse and improvement in the techniques, although there are “rogue” scientists who have used the technique in embryos, notably Dr. He Jiankui in China, and others who plan to use the technology.⁵⁶

II. MORALITY, SOCIETAL DISCOURSE, AND REGULATION

Reproductive genetic innovation can transform medical practice by truly moving from treatment to prevention.⁵⁷ Each of the treatments discussed in this Article began with controversy, with some involving more controversy than others. This Part considers the role of sensationalism in the regulatory system, societal discourse, Congressional responses to reproduction in general, the bioethical concerns that accompany ART and reproductive genetic innovation, and scientists’ calls for public consultation in relation to germline gene editing and other controversial medical techniques.

A. Regulation, Appropriations Riders, and Reproduction

Both administrative agencies and Congress have targeted reproduction for restrictions. Even though the NIH is a research agency, historically, both the NIH and the FDA were involved in the regulation and approval of genetic modification.⁵⁸ Yet, the NIH announced in the 1980s that “[the Recombinant

56. See R. Alta Charo, *Rogues and Regulation of Germline Editing*, 380 *NEW ENG. J. MED.* 976, 976–78 (2019); Alisa Opar, *CRISPR-Edited Babies Arrived, and Regulators Are Still Racing to Catch Up*, *SCI. AM.* (Jan. 27, 2020), <https://www.scientificamerican.com/article/crispr-edited-babies-arrived-and-regulators-are-still-racing-to-catch-up/>; Lander et al., *supra* note 11, at 166 (statement of eighteen prominent scientists calling for a halt to CRISPR use); Julia Belluz, *Is the CRISPR Baby Controversy the Start of a Terrifying New Chapter in Gene Editing?*, *VOX* (Jan. 22, 2019, 12:40 PM), <https://www.vox.com/science-and-health/2018/11/30/18119589/crispr-gene-editing-he-jiankui>.

57. The ability to prevent disease leads to debates over what traits or diseases can or should be eliminated in society. See, e.g., Elizabeth F. Emens, *Framing Disability*, 2012 *U. ILL. L. REV.* 1383, 1395, 1410–18 (2012); Mohapatra, *supra* note 15, at 69–70; Leon R. Kass, *The Wisdom of Repugnance*, *NEW REPUBLIC*, June 1997, at 17, 24; Radhika Rao, *Assisted Reproductive Technology and the Threat to the Traditional Family*, 47 *HASTINGS L.J.* 951, 952–54 (1996).

58. See, e.g., *Who We Are*, *NAT’L INSTS. HEALTH*, <https://www.nih.gov/about-nih/who-we-are> (last visited Apr. 16, 2022); Francis S. Collins & Scott Gottlieb, *The Next Phase of Human Gene-Therapy Oversight*, 379 *NEW ENG. J. MED.* 1393 (2018); Statement of Policy for Regulating Biotechnology Products, 51 *Fed. Reg.* 23,309, 23,311, (June 26, 1986); Points to Consider in the Design and Submission of Human Somatic-Cell Gene Therapy Protocols, 50 *Fed. Reg.* 33,463, 33,464 (Aug. 19, 1985); Proposed Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), 80 *Fed. Reg.* 62,543 (Oct. 16, 2015); *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, *NAT’L INSTS. HEALTH* (Apr. 28, 2015), <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos> [hereinafter NIH Director Statement].

DNA Advisory Committee] and its working group will not at present entertain proposals for germ line alterations but will consider for approval protocols involving somatic cell gene therapy.”⁵⁹ Now, the NIH’s role in the regulation of genetic modification has been gradually reduced, although the NIH continues to not fund proposals involving germline gene editing and the FDA continues to not consider applications involving reproductive genetic innovations.⁶⁰

Beyond funding, the federal legal system discourages the use of mitochondrial transfer in the United States as evidenced by the (1) issuance of Untitled Letters to providers of AARTs, (2) the addition of AARTs and germline gene editing to the FDA’s Advisory listening techniques which are subject to burdensome investigational new drug (IND) application requirements, unlike other forms of ART and natural reproduction.⁶¹ Cytoplasmic transfer, which requires IVF, occurred in the United States before the FDA became aware of it and sent Untitled Letters informing physicians that if they wished to continue providing the technique to their patients, they would have to submit an IND application.⁶² An American company that provided a technique involving mitochondrial transfer, Ovascience, was targeted by the FDA for regulation; the company received an Untitled Letter from the FDA and eventually stopped providing mitochondrial transfer to patients in the United States.⁶³ While scientific advances in mitochondrial transfer have been made in the United States, they have been subjected to the same regulatory treatment as cytoplasmic transfer; thus, the technique is, as a practical matter, unavailable in the United States.⁶⁴

59. Points to Consider in the Design and Submission of Human Somatic-Cell Gene Therapy Protocols, 50 Fed. Reg. 33,463, 33,464 (Aug. 19, 1985).

60. See Collins & Gottlieb, *supra* note 58; NIH Director Statement, *supra* note 58.

61. See Lewis, *Subterranean Regulation*, *supra* note 10.

62. For a comprehensive accounting of the FDA’s targeting of cytoplasmic transfer and similar forms of assisted reproductive technology involving genetic modification by Letter, see *id.* at 1241–47, 1253–62. For the FDA’s perspective on the distinctions between Untitled Letters and Warning Letters, see U.S. FOOD & DRUG ADMIN., MAN-000007, REGULATORY PROCEDURES MANUAL, CHAPTER 4: ADVISORY ACTIONS 37 (2022), <https://www.fda.gov/media/71878/download>.

63. See Lewis, *Subterranean Regulation*, *supra* note 10, at 1242–45.

64. See FDA Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P’s) Product List, FDA Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P’s) Product List, U.S. FOOD & DRUG ADMIN. (Feb. 1, 2018), <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/fda-regulation-human-cells-tissues-and-cellular-and-tissue-based-products-hctps-product-list> (regulating cytoplasmic and mitochondrial transfer as “human cells used in therapy involving the transfer of genetic material”); see, e.g., Brittany Shoot, *3-Parent IVF: Why Isn’t It Available in the United States?*, GUARDIAN (Feb. 27, 2015, 8:22 PM), <https://www.theguardian.com/sustainable-business/2015/feb/27/3-parent-ivf-us-mitochondria-dna-babies>.

Somatic cell gene therapy is legal, used in FDA-approved products, and results in presumably non-heritable genetic changes. Nonetheless, a budget rider prevents the FDA from considering INDs involving heritable genetic modification, which the agency currently interprets as including mitochondrial transfer and germline gene editing.⁶⁵ This budget rider, which has been renewed each fiscal year since it was approved in 2015 (and with little discussion) reads:

None of the funds made available by this Act may be used to notify a sponsor or otherwise acknowledge receipt of a submission for an exemption for investigational use of a drug or biological product under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)) in research in which a human embryo is intentionally created or modified to include a heritable genetic modification. Any such submission shall be deemed to have not been received by the Secretary, and the exemption may not go into effect.⁶⁶

The budget rider prohibits FDA from using its funds to consider applications involving “heritable genetic modification,” which the FDA has interpreted to include not only germline genetic modification (which is clearly heritable), but also techniques like mitochondrial and cytoplasmic transfer, AART techniques, which many scholars consider non-heritable genetic modification.⁶⁷

B. Administrative Agency Decisionmaking and the Role of Societal Discourse

In prior Articles related to certain techniques that fall within the ambit of reproductive genetic innovation, I have inquired as to what the practical implication or goal of a societal discourse is. Some groups think that a discourse should be a prerequisite to the introduction of a technique, whereas others do

65. Consolidated Appropriations Act of 2016, H.R. 2029, 114th Cong. § 749 (2015) (prohibiting the FDA from considering applications involving heritable genetic modification). I have previously argued that the idea that AARTs and germline genome editing fall within the FDA’s jurisdiction is surprising and unsupported. See, e.g., Myrisha S. Lewis, *The American Democratic Deficit in Assisted Reproductive Technology Innovation*, 45 AM. J. L. & MED. 130, 131–32, 149–55 (2019) [hereinafter Lewis, *The American Democratic Deficit*]; Lewis, *Subterranean Regulation*, *supra* note 10, at 1273–74; see also, e.g., Sarah Polcz & Anna Lewis, *CRISPR-Cas9 and the Non-Germline Non-Controversy*, 3 J. L. & BIOSCIENCES 413, 413–14 (2016).

66. H.R. 2029 § 749.

67. See, e.g., Radhika Viswanathan, *3 Biological Parents, 1 Child, and an International Controversy*, VOX (July 28, 2018, 10:00 AM), <https://www.vox.com/2018/7/24/17596354/mitochondrial-replacement-therapy-three-parent-baby-controversy> (quoting Eli Adashi) (“[Mitochondrial replacement therapy] can technically be construed as germline modification, so mitochondrial replacement got swept up into that [Congressional budget] rider. . . . It was caught up in the gene editing concerns, and I think it’s sort of an unfortunate linkage.”); Eli Y. Adashi & I. Glenn Cohen, *Going Germline: Mitochondrial Replacement as a Guide to Genome Editing*, 164 CELL 832, 833 (2016).

not explain how the debate would be instrumental to regulation.⁶⁸ While that answer may not be clear, it is possible that such a discourse could serve to address the underlying moral and ethical issues that accompany techniques involving reproductive genetic innovation.⁶⁹ Moreover, there is a scholarship that focuses on the value of deliberative democracy as a good in and of itself.⁷⁰ Beyond the “good” of deliberative democracy, to the extent that agency employees include their own moral, religious, or ethical views into agency decisionmaking, what they think are the moral and ethical views of the American public, or what they think are the views of the Executive Branch, a discourse could identify those views, and hopefully make clear when such views might be included in regulatory decisions (as well as debate whether those views should be included in regulatory decisions). Thus, in case a societal discourse would serve to further these techniques beyond their current regulatory standstill, this Article proffers a potential structure to answer those recurrent calls for a societal discourse.⁷¹

The United States has effectively banned reproductive genetic innovation within its borders but that does not prohibit individuals from traveling abroad in an effort to skirt that prohibition.⁷² Nevertheless, for those inclined to apply such a ban to their activities regardless of location, the current regulatory sphere largely mirrors the moratorium on germline gene editing that many have requested.⁷³ While some would like a moratorium forever, other innovators, like the Broad Institute’s Feng Zhang, would like a moratorium on the use of germline gene editing of limited duration, such as for five years, during which time a public discussion would occur.⁷⁴

68. See GENOME EDITING & HUMAN REPRODUCTION, *supra* note 20, at 87–88 (2018); Mahoney & Siegal, *supra* note 17, at 212.

69. See Alessandro Blasimme, *Why Include the Public in Genome Editing Governance Deliberation?*, 21 AMAJ. ETHICS E1065, E1067 (2019) (“The value of including a plurality of views in democratic deliberation about controversial science is that it enables dissent and provides opportunities to frame what’s at stake. Expert committees can succeed in coordinating temporary solutions that avoid premature research or clinical applications. However, only inclusive deliberation can confer democratic legitimacy on decisions that can affect the future of humanity.”).

70. Nina A. Mendelson, *Rulemaking, Democracy, and Torrents of E-mail*, 79 GEO. WASH. L. REV. 1343, 1343 (2011) (citing Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1515 (1992)).

71. See *infra* Part IV.

72. Mohapatra, *supra* note 15, at 64 (“Dr. Zhang was quoted in the press as having said Mexico was chosen ‘because there are no rules there.’”).

73. Alice Park, *Experts Are Calling for a Ban on Gene Editing of Human Embryos. Here’s Why They’re Worried*, TIME (Mar. 13, 2019, 2:22 PM), <https://time.com/5550654/crispr-gene-editing-human-embryos-ban/>.

74. See Pam Belluck, *How to Stop Rogue Gene-Editing of Human Embryos?*, N.Y. TIMES (Jan.

Scientists continue to engage in open and public international discussions, such as the International Gene Editing Summits.⁷⁵ Commentators and scientists, including those responsible for the creation of CRISPR-Cas9 gene editing, have been calling for public consultations related to the technology in assorted fora.⁷⁶ For example, the twelve-member Organizing Committee for the First International Gene Summit released a statement noting that human gene editing should not proceed until safety and efficacy issues were resolved and “there is broad societal consensus about the appropriateness of the proposed application.”⁷⁷ Yet, with the exception of Human Gene Editing Summits involving mostly scientists and participants in the field, such a larger societal consensus has yet to occur.⁷⁸

This Article focuses on societal discourse instead of on consensus for two reasons. First, broad societal consensus in the United States is unlikely.⁷⁹ The U.S. has yet to achieve broad societal consensus on far less controversial topics including IVF, let alone abortion, an issue that lurks beneath many actions related to reproduction.⁸⁰ Second, broadening the scope of consensus to include

23, 2019), <https://www.nytimes.com/2019/01/23/health/gene-editing-babies-crispr.html>; see also Jon Cohen, *The Latest Round in the CRISPR Patent Battle Has an Apparent Victor, but the Fight Continues*, SCIENCE (Sept. 11, 2020), <https://www.sciencemag.org/news/2020/09/latest-round-crispr-patent-battle-has-apparent-victor-fight-continues>. For more on the patent dispute related to CRISPR-Cas9, see, for example, *id.*

75. See, e.g., *International Summit on Human Gene Editing*, NAT'L ACADS. SCIS., ENG'G & MED. (2015), <https://www.nationalacademies.org/our-work/international-summit-on-human-gene-editing>; *The Second International Summit on Human Gene Editing*, NAT'L ACADS. SCIS., ENG'G & MED. (2018), <https://www.nationalacademies.org/our-work/the-second-international-summit-on-human-gene-editing>.

76. See, e.g., Daley, Lovell-Badge & Steffann, *supra* note 53, at 898; Misha Angrist, Rodolphe Barrangou, Françoise Baylis, Carolyn Brokowski, Gaetan Burgio, Arthur Caplan et al., *Reactions to the National Academies/Royal Society Report on Heritable Human Genome Editing*, 3 CRISPR J. 333, 334 (2020) (referencing Jennifer Doudna's comments); *Broad Scientists and Geneticists Discuss Issues Raised by Clinical Germline Genome Editing*, BROAD INST. (Nov. 26, 2018), <https://www.broadinstitute.org/news/broad-scientists-and-geneticists-discuss-issues-raised-clinical-germline-genome-editing> (quoting Feng Zheng); Lander et al., *supra* note 11; GENOME EDITING & HUMAN REPRODUCTION, *supra* note 20, at 87–88, 87 n. 299.

77. See New Release, Nat'l Acads. Scis., Eng'g & Med., *On Human Gene Editing: International Summit Statement* (Dec. 3, 2015), <https://www.nationalacademies.org/news/2015/12/on-human-gene-editing-international-summit-statement>; see also FRANÇOISE BAYLIS, *ALTERED INHERITANCE: CRISPR AND THE ETHICS OF HUMAN GENOME EDITING* 8 (2019) (arguing for societal consensus).

78. See *supra* note 76 and accompanying text.

79. See GENOME EDITING & HUMAN REPRODUCTION, *supra* note 20, at 87 n.299 (highlighting the difference between social discourse and consensus).

80. See, e.g., Carbone & Cahn, *supra* note 1, at 1016–18 (2010).

other countries presents an even larger challenge; there is nearly endless literature on international approaches to issues of health care, health insurance (more broadly), and, more specifically, the legality of reproductive genetic innovation techniques.⁸¹ This Article expects that a global societal consensus, whatever “consensus” means, on heritable genetic modification—and, relatedly, non-heritable techniques like cytoplasmic and mitochondrial transfer—is impossible. As such, this Article focuses on an American public discourse.

There has been ample opportunity to discuss reproductive techniques involving genetic modification or substitution. Cytoplasmic transfer, for example, has existed since the 1990s.⁸² Thus, we have had approximately thirty years to discuss these techniques, yet we have not done so. Moving forward, it is worth considering how to facilitate that discussion. Interestingly, structured societal discussion did not accompany previous “controversial” techniques that involve DNA transfer, such as blood donation, bone marrow transplantation, or IVF.

The closest that a federal administrative agency has come to incorporating *public* ethical views (instead of the views of its employees) into the regulatory process related to reproductive genetic innovation was in 2014. In 2014, the FDA Cellular, Tissue, and Gene Therapies Advisory Committee held a meeting on the topic of mitochondrial transfer. At that meeting, an FDA employee stated that, “[t]he FDA recognizes [that there are] moral, ethical, and social policy issues related to genetic modification of eggs and embryos, and that these issues have the potential to affect regulatory decisions. However, these issues are outside of the scope of this advisory committee meeting.”⁸³

81. See, e.g., John A. Robertson, *Reproductive Technology in Germany and the United States: An Essay in Comparative Law and Bioethics*, 43 COLUM. J. TRANSNAT'L L. 189, 191–94, 203 (2004); I. Glenn Cohen, Eli Y. Adashi, Sara Gerke, César Palacios-González, & Vardit Ravitsky, *The Regulation of Mitochondrial Replacement Techniques Around the World*, 21 ANN. REV. GENOMICS & HUM GENETICS 565, 577–79 (2020); Roosa Tikkanen & Melinda K. Abrams, *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?*, THE COMMONWEALTH FUND: ISSUE BRIEFS (Jan. 30, 2020), <https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019>; I. Glenn Cohen, *Regulating Reproduction: The Problem with Best Interests*, 96 MINN. L. REV. 423, 424–25 (2011); Adashi & Cohen, *supra* note 67, 832, 834–35; Sonia M. Suter, *Giving in to Baby Markets: Regulation Without Prohibition*, 16 MICH. J. GENDER & L. 217, 262–63 (2009); Carbone & Cahn, *supra* note 1, at 1034–35, 1049 (2010); Ruqaiyah Yearby, *Good Enough to Use for Research, But Not Good Enough to Benefit From the Results of that Research: Are the Clinical HIV Vaccine Trials in Africa Unjust?*, 53 DEPAUL L. REV. 1127, 1129 (2004).

82. See *supra* Part I; see also Parens & Juengst, *supra* note 44, at 397 (noting that ooplasmic transfer, another reproductive technique, emerged in the 1980s).

83. U.S. FOOD & DRUG ADMIN., CTR. FOR BIOLOGICS EVALUATION & RSCH.,

Since that acknowledgment that “moral, ethical, and social policy issues . . . [could] affect regulatory decisions[.]” there has been no further identification of or discussion of those “moral, ethical, and social policy issues.”⁸⁴

Thus, because the budget rider has stymied the regulatory consideration of reproductive genetic innovation, these techniques may never obtain insurance coverage or will face substantial regulatory hurdles in doing so. Further, both the budget rider and the imposition of IND requirements substantially curtail the societal discourse.⁸⁵ In light of the potentially expansive application of techniques involving genetic modification, especially germline gene editing, the lack of a societal discourse or regulatory consideration is particularly impactful as it is possible that agency-specific views of the appropriateness of a technology are affecting regulation without potentially useful democratic inputs.⁸⁶ Arguments in favor of the usefulness of democratic inputs include (1) if agency employees are going to make decisions based on their own societal and ethical views, then we should ensure that they have a more comprehensive accounting of those views, and (2) if a democratic process includes an acknowledgment that such societal and ethical views can affect the regulatory process, then the public should have a clear process to proffer those views in a transparent way.⁸⁷

While Congress has barely discussed reproductive genetic innovation, even with the budget rider, scientists and commentators continue to request a societal discourse.⁸⁸ This Article is also opposed to budget riders related to reproductive genetic innovation. First, doing so treats reproductive genetic innovation differently than natural reproduction. Second, budget riders are tools that lack the democratic inputs that more substantive legislation entails.⁸⁹ Third, while some would argue that a “ban could always be reversed,” the trajectory of budget riders in the sphere of reproductive

TRANSCRIPT OF CELLULAR, TISSUE, AND GENE THERAPIES ADVISORY COMMITTEE MEETING #59 13 (2014) [hereinafter MEETING #59 TRANSCRIPT].

84. See *id.*; Lewis, *Subterranean Regulation*, *supra* note 10, at 1271–74.

85. See generally *Investigational New Drug Application*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application> (describing the types of INDs and explaining the FDA’s application process) (July 20, 2022).

86. Organ transplantation was accompanied by public hearings on the appropriateness of including the techniques to the list of Medicare-covered procedures. See *infra* Part IV.D.4.

87. Cf. MEETING #59 TRANSCRIPT, *supra* note 83, at 13 (acknowledging ethical concerns but nonetheless limiting the scope of the meeting).

88. See, e.g., *supra* notes 13–14 and accompanying text; Mary Todd Bergman, *Perspectives on Gene Editing*, HARV. GAZETTE (Jan. 9, 2019), <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/> (quoting I. Glenn Cohen on the legal implications of gene editing).

89. See Richard J. Lazarus, *Congressional Descent: The Demise of Deliberative Democracy in Environmental Law*, 94 GEO. L.J. 619, 656–57, 660 (2006).

genetic innovation indicates that they are not so easily reversible.⁹⁰ Further, many of the budget riders related to reproduction are funding restrictions as opposed to restrictions on legality altogether.⁹¹

Many scholars (and some court cases) have highlighted instances where the FDA has incorporated political or ethical concerns into its decisionmaking process.⁹² Some scholars argue that administrative agencies should include political concerns in their rulemaking or that the FDA specifically should include ethical views in its decisionmaking.⁹³ Others disagree and argue for the removal of political and ethical concerns from FDA decisionmaking.⁹⁴ It

90. Lander, *Brave New Genome*, *supra* note 4, at 7.

91. For example, the Hyde Amendment limits abortion access by restraining federal funding of abortions, not the abortions themselves. *See generally* Harris v. McRae, 448 U.S. 297 (1980) (allowing states participating in Medicaid to decline to fund medically necessary abortions “for which federal reimbursement is unavailable under the Hyde Amendment”). *See also* NAT’L INST. HEALTH, NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES I-C, I-D (2019); R. Alta Charo, *Rogues and Regulation of Germline Editing*, 380 NEW ENG. J. MED. 976, 977–78 (2019) (discussing the consequences of funding restrictions on the development of IVF and stem cell research); George J. Annas, *Resurrection of a Stem-Cell Funding Barrier—Dickey–Wicker in Court*, 363 NEW ENG. J. OF MED. 1687, 1687–89 (2010); I. Glenn Cohen & Eli Y. Adashi, *Human Embryonic Stem-Cell Research Under Siege—Battle Won But Not the War*, 364 NEW ENG. J. OF MED. e48, e48 (2011); JUDITH A. JOHNSON & ERIN D. WILLIAMS, 21 CONG. RSCH. SERV., RL31358, HUMAN CLONING 1, 3–10 (2006).

92. *See generally* Lisa Heinzerling, *The FDA’s Plan B Fiasco: Lessons for Administrative Law*, 102 GEO. L.J. 927 (2014).

93. *See, e.g.*, Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, 2005 MICH. ST. L. REV. 1135, 1191–97 (2005); Richard M. Cooper, *Science, Ethics and Economics in FDA Decision-Making: The Legal Framework*, 61 FOOD & DRUG L.J. 799, 800–01 (2006); Kathryn A. Watts, *Proposing A Place for Politics in Arbitrary and Capricious Review*, 119 YALE L.J. 2, 5 (2009). *See generally* Craig J. Konnoth, *Drugs’ Other Side Effects*, 105 IOWA L. REV. 171 (2019) (analyzing scenarios in which the FDA considered, ignored, and/or incorporated political and ethical concerns in rulemaking).

94. *See* Tummino v. Von Eschenbach, 427 F. Supp. 2d 212, 228 (E.D.N.Y. 2006) (“In his resignation letter, Dr. Davidoff [an FDA official] stated that ‘I can no longer associate myself with an organization that is capable of making such an important decision so flagrantly on the basis of political influence, rather than the scientific and clinical evidence.’” (citation omitted)). Many have argued for or considered whether the FDA should have more independence. *See, e.g.*, Dorit R. Reiss, *Is it Time For The FDA To Be Independent?*, STAT NEWS (Nov. 30, 2020), <https://www.statnews.com/2020/11/03/should-fda-be-independent/>; Robert Califf, Scott Gottlieb, Margaret Hamburg, Jane Henney, David Kessler, Mark McClellan et al., *7 Former FDA Commissioners: The Trump Administration Is Undermining The Credibility of the FDA*, WASH. POST (Sept. 29, 2020, 5:16 PM), <https://www.washingtonpost.com/opinions/2020/09/29/former-fda-commissioners-coronavirus-vaccine-trump/>.

is also possible that one will never be able to remove political, ethical, or social views from administrative agency decisionmaking. Yet, here, I argue (as I have argued in other works) for the removal of those views from decisionmaking, or at the very least, a clear statement of when ethical views impact administrative agency decisionmaking.⁹⁵ A societal discourse furthers that goal by offering a structure for identifying potentially impactful ethical views, increasing transparency in decisionmaking, and reducing the politicization of science.⁹⁶

III. A CONTINUUM OF ACCEPTANCE: FROM SOCIETALLY ACCEPTED TO SENSATIONALIZED (LEGAL) TREATMENTS

Reproductive genetic innovation techniques are viewed by many as controversial, and that view, for many, is based not on science but rather on ethical and moral views that are ultimately incorporated into political decisions.⁹⁷ Each of the commonly accepted techniques studied in this Article, as compared to reproductive genetic innovation, faced early controversy and skepticism. Notably, the commonly accepted techniques discussed in this Part generally achieved societal acceptance or consensus *after* the techniques were already in use as opposed to before, which thus far appears to be the prospective path to any legalization of reproductive genetic innovation. The Article takes a cumulative approach and draws on the legal frameworks and societal views that have fostered the acceptance of these techniques. This Part identifies the societal and legal responses that have accompanied each of the techniques explored in this article respectively: (1) organ transplantation, (2) vaccination, (3) ART, and (4) reproductive genetic innovation. The treatments are organized in order from currently most accepted (and less controversial) to least accepted (and more controversial). Each Section provides the necessary scientific background on the technique, before moving onto society and the regulatory system's reactions to those techniques.

95. See generally Lewis, *Subterranean Regulation*, *supra* note 10; Lewis, *The American Democratic Deficit*, *supra* note 65.

96. See Watts, *supra* note 93, at 33 (advocating for a transparent discourse on political influences in agency decisionmaking); Konnoth, *supra* note 93, at 176 (arguing for the FDA to take a "broader range of concerns and harms" into consideration in its rulemaking).

97. See, e.g., Interview by Christina Lingham with Peter Marks, Dir., Ctr. for Biologics Evaluation & Resch., Food & Drug Admin., <https://www.triconference.com/transcripts/peter-marks-transcript> (last visited Aug. 16, 2022) (providing an FDA employee's characterization of the area of "heritable genetic modifications" as "a tremendously controversial area."). For a discussion of how political, ethical, and social views can affect regulatory decisionmaking in the realm of techniques involving genetic modification, see generally Lewis, *Subterranean Regulation*, *supra* note 10. For a discussion of the ethical objections to techniques involving genetic modification and their

In previous works, I have emphasized (1) the four commonalities that exist between organ transplantation and techniques involving genetic modification;⁹⁸ (2) the commonalities between FDA-approved gene therapy treatments (similar to and categorized as pharmaceuticals) and AARTs, like cytoplasmic and mitochondrial transfer (which fall within the category of reproductive genetic innovation);⁹⁹ and (3) AARTs and traditional ART.¹⁰⁰ This Article briefly draws upon those previously explored commonalities before further exploring the historical and societal development of commonly accepted treatments. Part IV then draws on the experiences with these medical techniques to propose a path for the normalization of reproductive genetic innovation.

A. Organ Transplantation

Organ transplantation encompasses procedures that replace defective or non-functioning organs with functioning ones.¹⁰¹ Today, public and private insurance cover organ transplantation.¹⁰² Organ transplantation, while previously accompanied by the yuck factor, is now a technique that has obtained societal acceptance.¹⁰³ Examining the early history of organ transplantation shows that reproductive genetic innovation may also cease to be accompanied by the yuck factor, or the moral panic that accompanies such innovations early in their inception, as a technique becomes more effective and more common.¹⁰⁴

similarities to other forms of assisted reproductive technology, see Lewis, *Is Germline Gene Editing Exceptional?*, *supra* note 15; see also *infra* Part III.

98. See Lewis, *Socio-Legal Responses*, *supra* note 15, at 690–705.

99. Lewis, *Is Germline Gene Editing Exceptional?*, *supra* note 15, at 795–804.

100. *Id.* at 743, 749–51.

101. *The Organ Transplant Process*, HEALTH RES. SERVS. ADMIN., <https://www.organ-donor.gov/about/process/transplant-process.html> (last visited Aug. 16, 2022).

102. See, e.g., Melissa Wong, Note, *Coverage for Kidneys: The Intersection of Insurance and Organ Transplantation*, 16 CONN. INS. L.J. 535 (2010); *Covering Transplant Costs*, UNOS, <https://transplantliving.org/financing-a-transplant/covering-costs/> (last visited Aug. 16, 2021).

103. See also Charles W. Schmidt, *The Yuck Factor: When Disgust Meets Discovery*, 116 ENV'T HEALTH PERSPS. A524, A525 (2008) (“Generally speaking, ‘yuck factor’ has become a catchall phrase to describe technophobic sentiments that vary by what triggers them.”); Katherine Purvis, *‘Yuck Factor’ Puts Off Eye Donors, Leaving Vital Transplants at Risk*, GUARDIAN (May 7, 2019, 9:00 AM), <https://www.theguardian.com/society/2019/may/07/eye-donors-transplant-risk-corneas>; Tiffanie Wen, *Why Don't More People Want to Donate Their Organs?*, ATLANTIC (Nov. 10, 2014), <https://www.theatlantic.com/health/archive/2014/11/why-dont-people-want-to-donate-their-organs/382297/>; Claire Stubber & Maggie Kirkman, *The Persistence of the Frankenstein Myth: Organ Transplantation and Surrogate Motherhood*, 99 SOUNDINGS: AN INTERDISCIPLINARY J. 29, 34, 37 (2016).

104. See, e.g., Kieran Healy, *Sacred Markets and Secular Ritual in the Organ Transplant Industry*, in THE

Looking at the path through which organ transplantation achieved acceptance in the U.S. could provide a roadmap for the future acceptance of gene modifying techniques. In a recent article, I outlined the four commonalities between organ transplantation and techniques involving genetic modification that weigh in favor of shifting the discourse: (1) the use of foreign biological material, (2) genetic transfer, (3) allocation concerns, and (4) controversy at inception.¹⁰⁵ Much of the discourse related to reproductive genetic innovation today is similar to the rhetoric used in the 1970s to voice opposition to organ transplantation.¹⁰⁶

Transplantation is moving further into the issues that have accompanied reproduction, including debates over whether transplants are therapy or enhancement and issues related to reproduction. Kidney transplantation was considered life enhancing for many years before society started to see it as life-saving.¹⁰⁷ Some recent innovations in face, uterine, and penis transplants have reignited, albeit less intensely, historical controversy related to organ transplantation.¹⁰⁸ Face and penis transplants, which are currently

SOCIOLOGY OF THE ECONOMY 308, 310 (Frank Dobbin ed., 2004); Memorandum from Surgeon General to the Assistant Secretary for Health, Subject: Liver Transplantation (Feb. 3, 1982), <https://collections.nlm.nih.gov/ext/document/101584930X170/PDF/101584930X170.pdf>.

105. Lewis, *Socio-Legal Responses*, *supra* note 15, at 690–705.

106. See Pope Warns of Danger in Organ Transplants and Genetic Testing, N.Y. TIMES, Oct. 28, 1980, at A1; Didier A. Mandelbrot & Martha Pavlakis, *Living Donor Practices in the United States*, 19 ADVANCES IN CHRONIC KIDNEY DISEASE 212, 212 (2012); Fox Butterfield, *Massachusetts' Opposition to Heart Transplant Eases*, N.Y. TIMES, Jan. 7, 1984, at 1.7.

107. Todd E. Pesavento, *Kidney Transplantation in the Context of Renal Replacement Therapy*, 4 CLINICAL J. AM. SOC'Y NEPHROLOGISTS 2035, 2036 (2009).

108. See Arthur Caplan & Duncan Purves, *A Quiet Revolution in Organ Transplant Ethics*, 43 J. MED. ETHICS 797 (2017) (discussing shifting risks and benefits of transplants aimed at improving recipients' quality of life). For more on face transplants, see Brendan Parent, *Informing Donors About Hand and Face Transplants: Time to Update the Uniform Anatomical Gift Act*, 10 J. HEALTH & BIOMED. L. 309 (2015) (arguing that the Uniform Anatomical Gift Act should encourage states to educate people about donating uniquely expressive organs, like hands or faces). For more on uterine and penile transplants, see Michelle J. Bayefsky & Benjamin E. Berkman, *The Ethics of Allocating Uterine Transplants*, 25 CAMBRIDGE Q. HEALTHCARE ETHICS 350, 350, 351 (2016) (discussing uterus transplants ethics); John A. Robertson, *Other Women's Wombs: Uterus Transplants and Gestational Surrogacy*, 3 J.L. BIOSCIENCES 68, 70–71 (2016) (examining ethical issues, including burden shifting caused by surrogacy); Gennaro Selvaggi & Sean Aas, *New Frontiers in Surgery: The Case of Uterus and Penis Transplantation*, in FREEDOM SCI. RSCH. 71, 77 (Simona Giordano ed., 2019) (noting that penis and uterus transplants are currently dangerous and expensive, and the benefits do not always outweigh the risks); Arthur Caplan, Laura L. Kimberly, Brendan Parent, Michael Sosin, & Eduardo Rodriguez, *The Ethics of Penile Transplantation: Preliminary Recommendations*, 101 TRANSPLANTATION 1200, 1201–02 (2016) (noting immunosuppressive and psychosocial costs associated with penile

being pioneered, will raise similar identity-related questions as the other techniques in this Article.¹⁰⁹ For example, using the therapy-enhancement dichotomy that often surfaces in the context of genetic modification and historically in organ transplantation, face and penis transplants could be categorized as life-enhancing as opposed to life-saving although some physicians would categorize penis transplants as life-saving in light of the psychological impacts of genitourinary injury.¹¹⁰ At the same time, at a news conference related to the transplant of “a penis, scrotum, and portion of the abdominal wall” to a man who had lost his during military service, “the chairman of plastic and reconstructive surgery at Johns Hopkins, said the goal of this type of transplant is ‘to restore a person’s sense of identity and manhood’”; identity is one of the areas of ethical discussion that often arises in the context of germline gene editing and reproductive genetic innovation, although certainly in a different manner.¹¹¹ Compared to many other developed countries, the American system of regulation pays little

transplantation); Denise Grady, *Penis Transplants Being Planned to Help Wounded Troops*, N.Y. TIMES (Dec. 6, 2015) [hereinafter Grady, *Wounded Troops*], <https://www.nytimes.com/2015/12/07/health/penis-transplants-being-planned-to-heal-troops-hidden-wounds.html>.

109. See *Changing identity – Face Transplant Ethics*, NHS ROYAL FREE LONDON, <https://www.royalfree.nhs.uk/services/services-a-z/plastic-surgery/facial-reconstruction-and-face-transplants/changing-identity-face-transplant-ethics/> (last visited Aug. 16, 2022) (“Altered or changing identity is often the first issue raised when face transplant ethics are discussed with health professionals, patients and the general public.”); *Face Transplant Benefits and Risks*, BRIGHAM & WOMEN’S HOSP., <https://www.brighamandwomens.org/surgery/plastic-surgery/restorative-surgery/benefits-and-risks-facial-transplant> (last visited Aug. 16, 2022). See generally Jennifer S. Swindell, *Facial Allograft Transplantation, Personal Identity and Subjectivity*, 33 J. MED. ETHICS 449 (2007).

110. See Nancy M.P. King, *Human Gene-Editing Research: Is the Future Here Yet?*, 97 N.C. L. REV. 1051, 1077 (2019) (“Discussion of the similarities and differences among prevention, treatment, and enhancement is a debate that is older and broader than genetics . . .”); *infra* Part IV.C; Denise Grady, *Cancer Survivor Receives First Penis Transplant in the United States*, N.Y. TIMES (May 16, 2016), <https://www.nytimes.com/2016/05/17/health/thomas-manning-first-penis-transplant-in-us.html>; Dorota J. Hawksorth, Damon S. Cooney, Arthur L. Burnett, Trinity J. Bivalacqua, & Richard J. Redett, *Penile Allotransplantation: Pushing the Limits*, 5 EUR. UROLOGY FOCUS 533, 534 (2019); *Face Transplant*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/face-transplant/about/pac-20394037> (last visited Aug. 16, 2022); Alexandra Sifferlin & Diane Tsai, *What Life Looks Like After the World’s Most Extensive Face Transplant*, TIME (Aug. 25, 2016, 6:30 AM), <https://time.com/4463200/face-transplant-the-first-family-vacation/> (noting that a face transplant recipient had a 50% chance of surviving the procedure); Michael Freeman & Pauline A. Jaoudé, *Justifying Surgery’s Last Taboo: The Ethics of Face Transplants*, 33 J. MED. ETHICS 76, 77–79 (2007) (examining identity challenges encountered by face transplant recipients).

111. See Denise Grady, *‘Whole Again’: A Vet Maimed by an I.E.D. Receives a Transplanted Penis*, N.Y. TIMES (Apr. 23, 2018), <https://www.nytimes.com/2018/04/23/health/soldier-penis-transplant-ied.html>; see also Grady, *Wounded Troops*, *supra* note 108.

attention to issues of ART, unlike other countries' systems like the U.K.'s which has methods of connecting gamete donors with donor-conceived children and donor-conceived children with each other.¹¹² Ultimately, while the controversies over donor death and other ethical issues in organ allocation have yet to be resolved, the existence of these controversies does not prohibit the legality of transplant techniques.¹¹³

B. Vaccination

Some have made the explicit analogy between germline gene editing and vaccination, like Dr. Dan McArthur, who tweeted during the National Academies of Sciences and Medicine Germline Gene Editing Summit in December 2019: "Prediction: my grandchildren will be embryo-screened, germline-edited. Won't 'change what it means to be human'. It'll be like vaccination."¹¹⁴ Vaccines are a recurring part of American and international society from school-age to adulthood.¹¹⁵ Edward Jenner's 1796 smallpox vaccination has been characterized as "the first major vaccine-related advance."¹¹⁶ The 1951 Nobel Prize in Physiology or Medicine was awarded to Max Theiler for his research on Yellow Fever which led to a vaccination.¹¹⁷ Most recently, COVID-19 vaccines based on mRNA technology have received significant attention.¹¹⁸ Further, states impose vaccination requirements on school children including common vaccinations against illnesses like tetanus, diphtheria, pertussis, Hepatitis B, and polio.¹¹⁹ Vaccines have also been cited as

112. See, e.g., *Donor Sibling Link (DSL)*, HUM. FERTILISATION & EMBRYOLOGY AUTH. (Nov. 3, 2020), <https://www.hfea.gov.uk/donation/donor-conceived-people-and-their-parents/donor-sibling-link-dsl/>; *Donor-Conceived People and Their Parents*, HUM. FERTILISATION & EMBRYOLOGY AUTH. (Nov. 3, 2020), <https://www.hfea.gov.uk/donation/donor-conceived-people-and-their-parents/>.

113. See, e.g., *The Urgent Need to Reform the Organ Transplantation System to Secure More Organs for Waiting, Ailing, and Dying Patients, before the H. Comm. on Oversight & Reform*, 117th Cong. (2021); Arthur Caplan, *Bioethics of Organ Transplantation*, COLD SPRING HARBOR PERSPS. MED., Mar. 2014, at 4–6.

114. Erika Check Hayden, *Should You Edit Your Children's Genes?*, 53 NATURE 402, 405 (2016).

115. For more on vaccine development, see Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 734–747 (2019); see also *infra* notes 124–126 and accompanying text.

116. Angela Desmond & Paul A. Offitt, *On the Shoulders of Giants — From Jenner's Cowpox to mRNA Covid Vaccines*, 385 N. ENGL. J. MED. 1081, 1081 (2021) (citing EDWARD JENNER, AN INQUIRY INTO THE CAUSES AND EFFECTS OF THE VARIOLAE VACCINAE: A DISEASE DISCOVERED IN SOME OF THE WESTERN COUNTIES OF ENGLAND, PARTICULARLY GLOUCESTERSHIRE, AND KNOWN BY THE NAME OF THE COW POX (London: Ashley & Brewer, 1801)).

117. See *Max Theiler Facts*, THE NOBEL PRIZE, <https://www.nobelprize.org/prizes/medicine/1951/theiler/facts/> (last visited Aug. 16, 2022); Desmond & Offitt, *supra* note 116, at 1082.

118. Desmond & Offitt, *supra* note 116, at 1081–82.

119. See *Recommended Vaccines Needed by Age*, CTRS. FOR DISEASE CONTROL &

“... occupy[ing] a liminal position between pure treatment and straightforward enhancement, appearing at first to serve as preventative treatment, but then forcing us to grapple with the question of where treatment ends and enhancement begins.”¹²⁰ Using the terms somatic and germline, the two terms describing the two types of gene editing, Shawna Benston notes that vaccines “make up for a somatic deficit” by conferring a non-naturally occurring protection against disease by including cellular changes.¹²¹ Vaccines, similar to somatic and germline gene editing aim to minimize human suffering although through different mechanisms: vaccines aim to prevent transmission of diseases, whereas gene editing aims to “reverse” disease-causing traits or illnesses.¹²² Thus, the two are certainly not the same, but they do have similar end goals.

Vaccination engenders controversy and “vaccine hesitancy” today with individuals being resistant to taking vaccines, including the well-covered trend in which many parents aim to opt out of giving their children vaccines based on perceptions that vaccines have some connection to autism.¹²³ In the past, vaccination also engendered controversy based on concerns such as efficacy, safety, and parental rights.¹²⁴ Many individuals suffered harms as a result of vaccinations, which has led to anti-vaccination views for those affected and those who knew of those adverse reactions.¹²⁵

PREVENTION, <https://www.cdc.gov/vaccines/vpd/vaccines-age.html> (Nov. 22, 2016); Y. Tony Yang & Vicky Debold, *A Longitudinal Analysis of the Effect of Nonmedical Exemption Law and Vaccine Uptake on Vaccine-Targeted Disease Rates*, 104 AM. J. PUB. HEALTH 371, 371–73 (2014); CTRS. FOR DISEASE CONTROL & PREVENTION, GROWING UP WITH VACCINES: WHAT SHOULD PARENTS KNOW? (2018), <https://www.cdc.gov/vaccines/growing/images/global/CDC-Growing-Up-with-Vaccines.pdf>.

120. Shawna Benston, *Everything in Moderation, Even Hype: Learning from Vaccine Controversies to Strike a Balance with CRISPR*, 43 J. MED. ETHICS 819, 820 (2017).

121. *Id.*

122. *Id.*

123. *See id.* at 821; Lois A. Weithorn & Dorit Rubinstein Reiss, *Providing Adolescents with Independent and Confidential Access to Childhood Vaccines: A Proposal to Lower the Age of Consent*, 52 CONN. L. REV. 771, 773–74 (2020).

124. *See* Benston, *supra* note 120, at 820–21; Robert M. Wolfe & Lisa K. Sharp, *Anti-Vaccinationists Past and Present*, 325 BRITISH MED. J. 430, 430–32 (2002); James G. Hodge & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 834–35, 846, 876 (2001/2002); Dorit Rubenstein Reiss & Lois A. Weithorn, *Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal*, 63 BUFFALO L. REV. 881, 935, 937–39 (2015); Jason L. Schwartz, *New Media, Old Messages: Themes in the History of Vaccine Hesitancy and Refusal*, 14 AMA J. ETHICS 50, 52 (2012); Dorit Rubenstein Reiss, *Litigating Alternative Facts: School Vaccine Mandates in the Courts*, 21 U. PA. J. CONST. L. 207 (2018).

125. *See, e.g., National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN. ,

Current legal analysis of vaccination tends to start with the Supreme Court case *Jacobson v. Massachusetts*,¹²⁶ which upheld the right of the states to use their police powers to enact compulsory vaccination laws, before discussing exceptions to those state police powers.¹²⁷ Before institutions make vaccines compulsory, for example, they are subject to review and approval or authorization by the FDA.¹²⁸ Safety and effectiveness are the hallmarks of the FDA's assessment of medical tools.¹²⁹ Often these two concepts are shown by animal trial data (with the acknowledgment that safety and efficacy are not absolutely achievable).¹³⁰ Part IV.D.5 argues for a stronger emphasis on animal trials and scientific education related to reproductive genetic innovation when a public discourse occurs.

C. Assisted Reproductive Technology

Assisted reproductive technology is becoming increasingly prevalent in American society.¹³¹ As early as 1997, Professor Leon Kass—who is known for, amongst other works, his role as the head of President George W. Bush's Bioethics Commission—noted that society had “become accustomed to new

<https://www.hrsa.gov/vaccine-compensation/index.html> (Nov. 2020); Benston, *supra* note 120, at 820; Mary S. Holland, *Liability for Vaccine Injury: The United States, the European Union, and the World*, 67 EMORY L.J. 415, 419–20 (2018); Efthimios Parasidis, *Recalibrating Vaccination Laws*, 97 B.U. L. REV. 2153, 2189, 2197–98, 2201, 2204 (2017); Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 389–90 (2004); Reiss & Weithorn, *supra* note 124, at 886–87.

126. 197 U.S. 11, 35 (1905).

127. See Lindsay F. Wiley & Stephen I. Vladeck, *Coronavirus, Civil Liberties, and the Courts: The Case Against “Suspending” Judicial Review*, 133 HARV. L. REV. F. 179, 180–84, 190–94 (2020); Lindsay F. Wiley, *Public Health Law and Science in the Community Mitigation Strategy for Covid-19*, 7 J.L. & BIOSCIENCES. 1, 18 (2020); Erwin Chemerinsky & Michele Goodwin, *Compulsory Vaccination Laws Are Constitutional*, 110 NW. U.L. REV. 589, 595 (2016). For more on the controversy that has accompanied compulsory vaccination and vaccination in general, see, e.g., Schwartz, *supra* note 124, at 51–52.

128. See, e.g., *Emergency Use Authorization for Vaccines Explained*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained> (Nov. 20, 2020); *Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/understanding-regulatory-terminology-potential-preventions-and-treatments-covid-19> (Oct. 20, 2020).

129. See 21 U.S.C. §§ 355(a), 393(b)(2)(B), 360bbb-2(a); 42 U.S.C. § 262(i)(1).

130. See Barbara Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME L. REV. 419, 434–35, 473 (2010).

131. Gretchen Livingston, *A Third of U.S. Adults Say They Have Used Fertility Treatments or Know Someone Who Has*, PEW RSCH. CTR. (July 17, 2018), <https://www.pewresearch.org/fact-tank/2018/07/17/a-third-of-u-s-adults-say-they-have-used-fertility-treatments-or-know-someone-who-has/>.

practices in human reproduction,” including IVF, “embryo manipulation, embryo donation[,]” and surrogacy.¹³² Today, in addition to insurance coverage in some states and egg freezing as an employee incentive, there is an increasing openness in American society to acknowledging the uses of assisted reproductive technology.¹³³ Further, the consequences of the use of ART, namely parentage, have been resolved by state family law.¹³⁴

In the United States, IVF is societally accepted and legal, yet it still elicits controversy. Assisted reproductive technology generates assorted debates, including those related to the appropriateness of sex selection or selection of certain other traits and in some cases, analyses of IVF in general.¹³⁵

Beyond the baseline legality, acceptance can extend to include societal encouragement as signified by insurance coverage, employer benefits, and overall cultural acceptance.¹³⁶ Even when a technique has garnered

132. Kass, *supra* note 57, at 17.

133. See *id.*; Benjamin J. Peipert, Shelun Tsai, Melissa N. Montoya, Ryan C. Ferrante & Tarun Jain, *Analysis of State Mandated Insurance Coverage for Infertility Treatment and Fertility Preservation in the United States*, 114 FERTILITY & STERILITY E4, E4–E5 (2020); Julia Carpenter, *Planning Your Fertility—With Your Company’s Help*, CNN MONEY (Mar. 19, 2018, 4:09 PM), <https://money.cnn.com/2018/03/19/pf/fertility-planning-benefits/index.html>; Staci Zaretsky, *Top Biglaw Firm Wows All Employees With New Fertility And Family-Planning Benefits*, ABOVE THE LAW (Feb. 3, 2020, 11:15 AM), <https://abovethelaw.com/2020/02/top-biglaw-firm-wows-all-employees-with-new-fertility-and-family-planning-benefits/?rf=1>.

134. See generally JUDITH AREEN, MARC SPINDELMAN & PHILOMILA TSOUKALA, FAMILY LAW: CASES AND MATERIALS 600–48 (6th ed. 2012); Sonia Bychkov Green, *Interstate Intercourse: How Modern Assisted Reproductive Technologies Challenge the Traditional Realm of Conflicts of Law*, 24 WIS. J.L. GENDER & SOC’Y 25, 50, 58–87 (2009).

135. See DOV FOX, BIRTH RIGHTS AND WRONGS: HOW MEDICINE AND TECHNOLOGY ARE REMAKING REPRODUCTION AND THE LAW 147 (2019) (noting medical reasons for sex selection); Ethics Committee of the American Society for Reproductive Medicine, *Use of Reproductive Technology for Sex Selection for Nonmedical Reasons*, 103 FERTILITY & STERILITY 1418, 1419 (2015); Radhika Rao, *Equal Liberty: Assisted Reproductive Technology and Reproductive Equality*, 76 GEO. WASH. L. REV. 1457, 1483, 1486–87 (2008); David McCarthy, *Why Sex Selection Should be Legal*, 27 J. MED. ETHICS 302, 306 (2001); Obasogie, *supra* note 15, at 2796–99.

136. See, e.g., *Busy Women Lawyers Are Freezing Eggs and Embryos to Manage Careers*, YAHOO! (Feb. 27, 2019), <https://www.yahoo.com/now/busy-women-lawyers-freezing-eggs-074924236.html>. But see William Levada, *Congregation for the Doctrine of the Faith, Instruction Dignitas Personae on Certain Bioethical Questions*, VATICAN (Sept. 8, 2008), https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html; John M. Haas, *Begotten Not Made: A Catholic View of Reproductive Technology*, U.S. CONF. OF CATHOLIC BISHOPS (1998), <http://www.usccb.org/issues-and-action/human-life-and-dignity/reproductive-technology/begotten-not-made-a-catholic-view-of-reproductive-technology.cfm> (last visited Aug. 16, 2022); Ariana Eunjung Cha, *Fertility Frontiers: Gifts from God*, WASH. POST (Apr. 27, 2018),

scientific acceptance, it may not automatically become routine and commonplace, as illustrated by the general lack of insurance coverage for fertility treatment, including procedures involving assisted reproductive technology and fertility preservation by insurance plans.¹³⁷

* * *

Clinical trials, including animal trials, have been a large part of progress in techniques involving reproductive genetic innovation.¹³⁸ Before AARTs like mitochondrial transfer are available for clinical use, the National Academies of Sciences recommended scientists demonstrate the “[l]ikelihood of efficacy . . . by preclinical research using in vitro modeling, animal testing, and testing on human embryos as necessary.”¹³⁹ Yet, the National Academies of Science’s recommendations on human testing are stymied by the Congressional budget rider.¹⁴⁰

While ART has generally developed without governmental oversight, techniques involving genetic modification have been subject to substantial governmental interference, through the imposition of IND requirements and Congressional budget riders.¹⁴¹ This substantial governmental interference has been largely devoid of democratic inputs.¹⁴² As will be emphasized in Part IV.D.5, physicians developing

<https://www.washingtonpost.com/graphics/2018/national/how-religion-is-coming-to-terms-with-modern-fertility-methods/> (noting that “[m]ost major religions have indeed come to tolerate—and even embrace—IVF, which was originally viewed with equal alarm. But the increasingly commonplace procedure is still condemned at the highest levels of the Catholic Church.”).

137. For more on why ART is not covered by insurance in some states in the U.S. and in other countries, even though infertility is recognized as a disease by many, including the World Health Organization, see Hane Htut Maung, *Is Infertility A Disease and Does It Matter?*, 33 *BIOETHICS* 43, 43–45 (2019); Peipert, Tsai, Montoya, Ferrante, Jain, *supra* note 133 (discussing insurance coverage and ART). There are many unresolved issues that would surround a discussion of mandating insurance coverage for forms of ART involving genetic modification and that would fall outside of the scope of this Article.

138. THOMAS STARZL, *THE PUZZLE PEOPLE: MEMOIRS OF A TRANSPLANT SURGEON* 138, 164 (U. of Pitt. Press 1992) (“The clinical trial of new therapeutic methods is based more firmly than ever on prior animal experimentation. Virtually all practices in cardiac as well as in transplantation surgery have been transferred, almost without change, from the laboratory to the clinical ward or operating room.”).

139. MITOCHONDRIAL REPLACEMENT TECHNIQUES, *supra* note 10, at 10.

140. Cohen et al., *supra* note 81, at 442. See Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 749, 129 Stat. 2283 (2015).

141. See *supra* Part II; R. Alta Charo, *Rogues and Regulation of Germline Editing*, 380 *NEW ENG. J. MED.* 976, 977 (2019); David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 *FERTILITY & STERILITY* 932, 932 (2002).

142. See, e.g., Lewis, *The American Democratic Deficit*, *supra* note 65.

ART and AARTs have also used extensive animal trials, a hallmark of pharmaceutical and biologic (vaccine) development.

IV. NORMALIZATION: REDUCING SENSATIONALISM RELATED TO REPRODUCTIVE GENETIC INNOVATION

Normalizing reproductive genetic innovation could (1) facilitate the approval of techniques involving reproductive genetic innovation, (2) ascertain opposition to reproductive genetic innovation that is based on morality or politics instead of science or medicine, and (3) serve as part of scientists' calls for a public discussion of techniques involving heritable genetic modification. This discourse is significant to regulation because political, ethical, and social issues can impact regulation.¹⁴³ Having a discourse on these techniques brings those ethical and social issues to the fore and could be a first step towards lifting the regulatory standstill that currently accompanies techniques involving reproductive genetic innovation.

Section A defines normalization. Section B argues that viewing reproductive genetic techniques through the lenses of commonly accepted treatments such as vaccinations, organ transplantation, gene therapy, and to a lesser extent, IVF, instead of the lens of moral panic could facilitate the use of life-saving gene-modifying techniques by reducing the yuck factor or moral panic that accompanies these techniques. Section C builds on the paths to societal acceptance outlined in Part III to address objections based on enhancement and "slippery slopes." Section D offers substantive suggestions for a societal discourse, based on other methods of public deliberation used in the United States and abroad.

143. See generally Kathryn A. Watts, *Proposing A Place for Politics in Arbitrary and Capricious Review*, 119 YALE L.J. 2, 18 (2009) (identifying instances in which administrative agencies, including agencies that are part of the U.S. Department of Health & Human Services, have incorporated political influences into their decisionmaking).

A. Normalization

When I use the term “normalize” as applied to reproductive genetic innovation, I mean to frame techniques as medical treatments as opposed to an unnatural occurrences that should be prohibited based on the yuck factor or sensational reactions that might accompany them.¹⁴⁴ By including reproductive genetic innovation within the sphere of medical discussion instead of dystopian fears, political debates, or religious debates, it is possible to separate social or moral views from scientific views and to have an informed dialogue about these techniques.¹⁴⁵

The term normalization in this Article is connected to the idea of medicalization, which is the concept of including naturally occurring natural phenomena within the ambit of the medical field, but “normalization” goes beyond the meaning of “medicalization.”¹⁴⁶ First, reproductive genetic innovation is automatically “medicalized,” as the techniques currently fall within the authority of medical institutions due to the involvement of physicians or scientists.¹⁴⁷ Positive results of medicalization include improved life expectancy, better medical treatment, and improved quality of life.¹⁴⁸ Medicalization is theoretically a neutral term, although it is often analyzed negatively; the scholarship on the negative impacts of medicalization spans many issues, including the impact of medicalization on the right to an abortion, increased surveillance of women, and forced medical

144. See *supra* notes 1–6 and accompanying text.

145. See *supra* Part II.B.

146. See, e.g., Diana C. Parry, “*We Wanted a Birth Experience, Not a Medical Experience*”: Exploring Canadian Women’s Use of Midwifery, 29 HEALTH CARE FOR WOMEN INT’L, 784, 785 (2008); Erik Parens, *On Good and Bad Forms of Medicalization*, 27 BIOETHICS 28, 28 (2013); Rabia Belt & Doron Dorfman, *Reveighing Medical Civil Rights*, 72 STAN. L. REV. ONLINE 176, 183 (2020); Allison K. Hoffman, *How Medicalization of Civil Rights Could Disappoint*, 72 STAN. L. REV. ONLINE 165, 168–69 (2020).

147. See Parry, *supra* note 146; Parens, *supra* note 146, at 28–30; Drew Halfmann, *Recognizing Medicalization and Demedicalization: Discourses, Practices and Identities*, 16 HEALTH 186 (2012); Craig Konnoth, *Medicalization and the New Civil Rights*, 72 STAN. L. REV. 1165 (2020); Dayna Bowen Matthew, *Health and Housing: Altruistic Medicalization of America’s Affordability Crisis*, 81 L. & CONTEMP. PROBS. 161, 161–70 (2018); William Sage & Jennifer Laurin, *If You Would Not Criminalize Poverty, Do Not Medicalize It*, 46 J.L., MED. & ETHICS 573, 573–80 (2018); Peter Conrad, *The Shifting Engines of Medicalization*, 46 J. HEALTH & SOC. BEHAV. 3, 10 (2005); Michelle Oberman, *Motherhood, Abortion, and the Medicalization of Poverty*, 46 J. L. MED. & ETHICS 665, 665 (2018); Peter Conrad, Thomas Mackie & Ateev Mehrotra, *Estimating the Costs of Medicalization*, 70 SOC. SCI. & MED. 1943, 1943 (2010).

148. See Parry, *supra* note 146, at 800; Shah Ebrahim, *The Medicalisation of Old Age*, 324 BMJ 861, 862 (2002); Parens, *supra* note 146, at 28–29; Conrad, Mackie & Mehrotra, *supra* note 147.

treatment of women.¹⁴⁹ These concerns about medicalization and reproduction exist regardless of whether reproduction is natural or assisted, as would occur with reproductive genetic innovation.

This Article builds on prior scholarship related to the medicalization of natural occurrences, with a focus on pregnancy and childbirth, and the cultural and legal acceptance of previously objectionable but now accepted techniques, in order to reduce the sensationalism that accompanies reproductive genetic innovation.¹⁵⁰ Medicalization can help remove some of the stigma that accompanies a technique, although it can also increase stigmatization.¹⁵¹ Thus, the Article draws on the literature related to medicalization, particularly regarding de-stigmatizing controversial techniques, in structuring a societal discourse on techniques involving reproductive genetic innovation. Stigma matters because stigmatized or sensationalized techniques are often targeted for legal restraints. By focusing on normalization, this Article emphasizes de-sensationalizing reproductive genetic innovation and avoids the (often childbirth-focused) debate on the implications of medicalizing reproduction.

149. See, e.g., Julia Bandini, *The Medicalization of Bereavement: (Ab)normal Grief in the DSM-5*, 39 DEATH STUD. 347, 347 (2015); Khiara Bridges, *Racial Disparities in Maternal Mortality*, 95 N.Y.U. L. REV. 1229, 1245 n.57–58 (2020); Michelle Oberman, *Mothers and Doctors' Orders: Unmasking the Doctor's Fiduciary Role in Maternal-Fetal Conflicts*, 94 NW. U. L. REV. 451, 452–53 (2000); AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *Approaches to Limit Intervention During Labor and Birth*, ACOG Committee Opinion, Num. 766, 133 OBSTETRICS & GYNECOLOGY e164, e166–67 (2019); Jessica Martucci, *Beyond the Nature/Medicine Divide in Maternity Care*, 20 AMAJ. ETHICS 1168, 1171 (2018); Reva B. Siegel, *Roe's Roots: The Women's Rights Claims That Engendered Roe*, 90 B.U. L. REV. 1875, 1878–83 (2010); April L. Cherry, *Roe's Legacy: The Nonconsensual Medical Treatment of Pregnant Women and Implications for Female Citizenship*, 6 U. PA. J. CONST. L. 723, 726, 728–43 (2004); In re A.C., 573 A.2d 1235 (D.C. 1990); Sylvia A. Law, *Childbirth: An Opportunity for Choice that Should Be Supported*, 32 N.Y.U. REV. L. & SOC. CHANGE 345, 345–62 (2008); Elizabeth Kukura, *Obstetric Violence*, 106 GEO. L.J. 721 (2018).

150. See, e.g., Courtney Megan Cahill, *Reproduction Reconceived*, 101 MINN. L. REV. 617, 654 (2016); Gaia Bernstein, *The Socio-Legal Acceptance of New Technologies: A Close Look at Artificial Insemination*, 77 WASH. L. REV. 1035 (2002); Kara Swanson, *Adultery by Doctor: Artificial Insemination, 1890-1945*, 87 CHI.-KENT L. REV. 591, 591–95 (2012); Law, *supra* note 149, at 376 (citing George J. Annas, *Homebirth: Autonomy vs. Safety*, 8 HASTINGS CTR. REP. 19, (Aug. 19, 1978)); Parry, *supra* note 146, at 788–90, 795–801.

151. *But see* INST. MED. NAT'L ACADS., *THE HEALTH OF LESBIAN, GAY, BISEXUAL, AND TRANSGENDER PEOPLE; BUILDING A FOUNDATION FOR BETTER UNDERSTANDING* 34 (2011) (“Nevertheless, after Freud, the division of people into ‘heterosexuals’ and ‘homosexuals’ involved stigmatization of the latter.”).

B. *Sensationalism, Ethics, and the Regulatory System*

Several sensational terms, often stemming from science fiction motivated concerns or yuck-based responses, regularly appear in media coverage of discussions related to mitochondrial transfer and genome editing.¹⁵² The technique of mitochondrial transfer has commonly been referred to as “three-parent[IVF],” a characterization that scientists oppose.¹⁵³ Similarly, children born as a result of IVF have been subjected to sensational terminology and media coverage for years.¹⁵⁴ While reproductive genetic innovation techniques are often examined through the lens of bioethics or ART, this Article adds to that analysis and shows how discussions surrounding organ and tissue donation and other commonly accepted medical treatments could be both a useful lens and the basis for a helpful analogy to use while examining gene-modifying techniques.¹⁵⁵

There are also some differences that support viewing germline gene editing as less sensational. First, efforts at human germline gene editing focus on modifying, adding, or deleting human DNA, not animal DNA.¹⁵⁶ This differs from previous attempts in the history of organ transplantation to transplant animal organs into humans.¹⁵⁷ While it is certainly possible that efforts might shift to xenotransplantation in the future, the potential that reproductive genetic innovation could one day be used for negative purposes

152. See Marc Thiessen, *Gene Editing is Here. It's an Enormous Threat*, FOX NEWS (Nov. 30, 2018, 4:00 AM), <https://www.foxnews.com/opinion/marc-thiessen-gene-editing-is-here-its-an-enormous-threat> (referring to gene editing as a potential “death blow to the American dream” due to the potential for wealth-based inequalities in access); Michael Guillen, *Sketchy Genetic Engineering Practices Could Spell the End of the World as We Know It*, FOX NEWS (Oct. 19, 2018, 5:08 PM), <https://www.foxnews.com/opinion/michael-guillen-its-the-end-of-life-as-we-know-it>; Sarah Gurev, *CRISPR in Popular Media: Sensationalism of Germline Editing in Human Embryos*, 10 INTERSECT 1, 6–8 (2017).

153. See, e.g., Rob Stein, *Clinic Claims Success In Making Babies With 3 Parents' DNA*, NPR (June 6, 2018, 5:11 AM), <https://www.npr.org/sections/health-shots/2018/06/06/615909572/inside-the-ukrainian-clinic-making-3-parent-babies-for-women-who-are-infertile>; Rebecca Jacobson, *Why the Term ‘Three-Person Baby’ Makes Doctors Wince*, PBS NEWS HOUR (Feb 10, 2015, 2:31 PM), <https://www.pbs.org/newshour/science/term-three-person-baby-makes-doctors-wince>; Françoise Baylis, *The Ethics of Creating Children with Three Genetic Parents*, 26 REPROD. BIOMEDICINE ONLINE 531, 531 (2013), <https://www.rbmojournal.com/action/showPdf?pii=S1472-6483%2813%2900132-6> (arguing for the continued use and “legitimacy” of the terms like “‘three-parent embryos’ ‘three-parent babies’ and ‘three-person IVF.’”).

154. See *supra* notes 1–4 and accompanying text.

155. See *supra* note 16 and accompanying text.

156. *What Are Genome Editing and CRISPR-Cas9?*, *supra* note 47.

157. David K.C. Cooper, *Experimental Development of Cardiac Transplantation*, 4 BRITISH MED. J. 174, 180 (1968).

should not preclude its use for existing humans and their potential children. If the safety and efficacy concerns related to germline gene editing are resolved and only moral and social concerns remain, germline gene editing and AARTs (which are accompanied by fewer safety and efficacy concerns) may remain only available to the wealthy, who have the means to access these techniques abroad or through hard-to-find domestic options.¹⁵⁸

C. *Normalization Instead of Sensationalism: Therapy Instead of Enhancement*

One goal of normalizing techniques involving reproductive genetic innovation is to move the techniques from experimental to established. Currently, many controversial techniques have managed to develop in a way that has permitted them to become established instead of experimental. The first child born of a cryopreserved egg was born in 1986.¹⁵⁹ Decades later, in 2012, the American Society for Reproductive Medicine Practice Committee removed the experimental label from the description of egg freezing.¹⁶⁰

Some concerns related to eugenics or enhancement-based uses pertain to concerns about the yuck factor that accompanies reproductive genetic innovation.¹⁶¹ Yet these same societally- and ethically-based concerns about “unnatural” processes accompanied organ transplantation, which is now commonly accepted in the United States and around the world.¹⁶² Reducing that yuck factor or moral panic and addressing issues of therapy versus enhancement could cause legislators and agency staff to be less opposed to the techniques and reduce the impact of panic-based views, which can often evince religious opposition, on regulation.

158. See David Orentlicher, *Discrimination Out of Dismissiveness: The Example of Infertility*, 85 IND. L.J. 143, 181 (2010); see also Tarun Jain, Bernard L. Harlow & Mark D. Hornstein, *Insurance Coverage and Outcomes of In Vitro Fertilization*, 347 NEW ENG. J. MED. 661, 661 (2002); Dorothy E. Roberts, *Race and the New Reproduction*, 47 HASTINGS L.J. 935, 946 (1996).

159. ETHICS COMMITTEE OF THE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, *Planned Oocyte Cryopreservation for Women Seeking to Preserve Future Reproductive Potential: An Ethics Committee Opinion*, 110 FERTILITY & STERILITY 1022, 1022 (2018).

160. *Id.*

161. See Kass, *supra* note 57, at 24 (“We do indeed already practice negative eugenic selection, through genetic screening and prenatal diagnosis.”); Tony McGleenan, *Human Gene Therapy and Slippery Slope Arguments*, 21 J. MED. ETHICS 350, 350 (1995); Melissa Murray, *Race-ing Roe: Reproductive Justice, Racial Justice, and the Battle for Roe v. Wade*, 134 HARV. L. REV. 2025, 2036–40 (2021). For more on positive and negative eugenics, see Suter, *supra* note 15, at 905.

162. But see Michele Goodwin, *Deconstructing Legislative Consent Law: Organ Taking, Racial Profiling & Distributive Justice*, 6 VA. J.L. & TECH. 2, 8 n.25 (2001).

Normalization can remove moral concerns from medical decisionmaking. For example, today, artificial insemination is a technique that individuals undertake on their own.¹⁶³ Some no longer consider artificial insemination a technique of ART due to its simplicity; yet, at its inception, it was extremely controversial and most assuredly outside of the realm natural reproduction as were other forms of ART.¹⁶⁴ As a matter of socio-legal acceptance, “[t]he participation of a doctor did the cultural work of transforming what some considered a variation of adultery into a treatment for infertility, that is, ‘sin into therapy.’”¹⁶⁵ Similarly, reproductive genetic innovation techniques currently would involve physicians.¹⁶⁶

Many individuals avail themselves of medical treatments that others would reject, such as prenatal testing and selective abortion.¹⁶⁷ While ART may face concrete legal threats in the aftermath of the U.S. Supreme Court’s decision in

163. See, e.g., Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 608 (2003); Christopher YY. v. Jessica ZZ., 159 A.D.3d 18, 20–21 (N.Y. App. Div. 2018); Steve Almasy, *Mother Loses Appeal in Turkey Baster Pregnancy Case*, CNN (Apr. 22, 2015, 2:22 AM), <https://www.cnn.com/2015/04/21/us/turkey-baster-pregnancy-legal-ruling>; Bruce v. Boardwine, 770 S.E.2d 774, 776–77 (Va. Ct. App. 2015).

164. For various definitions of ART, including differences as to whether artificial insemination constitutes ART, see Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 608 n.16 (2003); *What is Assisted Reproductive Technology?*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/art/whatis.html> (Oct. 8, 2019); see also Kara W. Swanson, *Adultery by Doctor: Artificial Insemination, 1890–1945*, 87 CHI.-KENT L. REV. 591 (2012).

165. Courtney Megan Cahill, *Reproduction Reconceived*, 101 MINN. L. REV. 617, 654 (2016) (citing KARA W. SWANSON, *BANKING ON THE BODY: THE MARKET IN BLOOD, MILK, AND SPERM IN MODERN AMERICA* 225 (2014)).

166. See *supra* Part I (describing reproductive genetic innovation, which uses ART and genetic substitution or modification).

167. See *State-Specific Assisted Reproductive Technology Surveillance*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/art/state-specific-surveillance/index.html> (Dec. 27, 2021) (“Nationally, ART accounted for 2.1% of all infants born in the United States.”); Laura C. Colicchia, Cynthia L. Holland, Jill A. Tarr, Doris M. Rubio, Scott D. Rothenberger & Judy C. Chang, *Patient-Health Care Provider Conversations About Prenatal Genetic Screening: Recommendation or Personal Choice*, 127 OBSTETRICS & GYNECOLOGY 1145, 1145, 1148 (2016) (cohort study finding that “[h]ealth care providers offered genetic screening at 90% of visits; 78% of women chose genetic screening.”); Marsha Michie, *Is Preparation a Good Reason for Prenatal Genetic Testing? Ethical and Critical Questions*, 112 BIRTH DEFECTS RSCH. 332, 332–33 (2020) (estimating that “74% of [U.S.] women with a prenatal diagnosis of Down syndrome—the most commonly prenatally diagnosed chromosomal condition—choose to terminate.”); see also Jamie L. Natoli, Deborah L. Ackerman, Suzanne McDermott, & Janice G. Edwards, *Prenatal Diagnosis of Down Syndrome: A Systematic Review of Termination Rates (1995–2011)*, 32 PRENATAL DIAGNOSIS 142, 142 (2012).

Dobbs, it is unlikely to be prohibited in the entirety of the United States.¹⁶⁸ Some parents combine pre-implantation genetic testing with ART, while many other parents reproduce naturally and do not use ART techniques or prenatal testing.¹⁶⁹ ART is seemingly in no danger of prohibition. Currently, some parents use PGD to identify embryos suitable for transplantation, based on parameters provided by those parents to scientists and physicians who can screen embryos for desirable and undesirable traits.¹⁷⁰ Beyond uses of ART, prenatal testing, and PGD, some vaccinate their children (and themselves) while many do not.¹⁷¹ All of these reflect individual decisions about medical techniques and interventions.

While there is a focus on the debate over germline gene editing and the potential related “slippery slope” from therapy to enhancement, this issue is not unique to germline gene editing. Instead, the debate over therapy and enhancement is well engrained in the practice of medicine. The possibility of enhancement should not prohibit the legality of germline gene editing. The therapy versus enhancement debate that is cited by some as a reason not to permit germline gene editing accompanies many forms of medicine.¹⁷² Concerns related to “enhancement” are often the basis for the slippery slope arguments that lead opponents of gene modifying technologies to assume that the potential perils of gene modifying techniques should outweigh more imminent disease-curing uses.¹⁷³

168. *Dobbs v. Jackson Women’s Health Organization*, 597 U.S. ___ (2022); I. Glenn Cohen, Melissa Murray & Lawrence O. Gostin, *The End of Roe v. Wade and New Legal Frontiers on the Constitutional Right to Abortion*, 328 JAMA 325, 326 (2022).

169. See *State-Specific Assisted Reproductive Technology Surveillance*, *supra* note 167; see also Jeani Chang, Sheree L. Boulet, Gary Jeng, Lisa Flowers & Dmitry M. Kissin, *Outcomes of In Vitro Fertilization with Preimplantation Genetic Diagnosis: An Analysis of the United States Assisted Reproductive Technology Surveillance Data, 2011–2012*, 105 FERTILITY & STERILITY 394, 395 (2016) (reporting that in 2012 approximately 4% of patients that used IVF used PGD as well); Michie, *supra* note 167. For an overview of prenatal testing and PGD, see HENRY T. GREELY, *THE END OF SEX AND THE FUTURE OF HUMAN REPRODUCTION* 86–88, 102 (2016).

170. See Chang et al., *supra* note 168, at 395 (noting increased use of PGD in connection with IVF); Susannah Baruch, David Kaufman & Kathy L. Hudson, *Genetic Testing of Embryos: Practice and Perspectives of US In Vitro Fertilization Clinics*, 89 FERTILITY & STERILITY 1053, 1054 (2008) (estimating that “4%-6% of all IVF cycles in the United States include PGD”).

171. Sara Novak, *The Long History of America’s Anti-Vaccination Movement*, DISCOVER MAG. (Nov. 26, 2018, 7:00 PM) <https://www.discovermagazine.com/health/the-long-history-of-americas-anti-vaccination-movement>; Allison L. Hargreaves, Glen Nowak, Paula M. Frew, Alan R. Hinman, Walter A. Orenstein, Judith Mendel et al., *Adherence to Timely Vaccinations in the United States*, 145 PEDIATRICS 48, 49, 51 (2020); Schwartz, *supra* note 124, at 50–52.

172. See, e.g., Bryan Cwik, *Revising, Correcting, and Transferring Genes*, 20 AM. J. BIOETHICS 7, 7 (2020).

173. See King, *supra* note 110, at 1077 (discussing the difficulty in defining the term “enhancement”); Suter, *supra* note 15, at 933–34; NAT’L HUM. GENOME RSCH. INST., *supra* note 42.

A larger discussion of therapy versus enhancement, in addition to including face transplants and the changed characterization of kidney transplants, could also focus on tissues such as corneas, which are tissues that could be categorized as “enhancements,” but whose transplantation continues in the United States.¹⁷⁴ Physicians also use harvested human tissues in procedures such as knee replacements.¹⁷⁵ In the past, corneal transplants have been accompanied with some of the controversy of organ transplantation, including controversy related to consent for donation and the sale of human tissue.¹⁷⁶ Further, reminding the public that issues of therapy and enhancement accompany many existing medical procedures can reduce the sensationalizing of reproductive genetic innovation.

One potential counterargument is that one does not need to address the issue of therapy versus enhancement at all. Plastic surgeons offer services such as the treatment of victims of car accidents and other issues that are deemed “therapeutic,” while at the same time also offering enhancements such as face lifts, rhinoplasty, breast augmentation, breast reduction, and other treatments that are not life-saving.¹⁷⁷ Plastic surgery as a specialty is still available even though it can be used in enhancement.¹⁷⁸ Similarly, there is a societal approach to organ transplantation and gene therapy where many individuals accept it, reject it, or do not think about it at all, but do not aim to prevent it for others.¹⁷⁹ To a lesser extent, some individuals take this approach to abortion and the use of ART.¹⁸⁰ Some people use medicines that were developed as therapies for severe diseases for preventive reasons, such as statins to lower cholesterol.¹⁸¹ Reproductive genetic innovation could benefit from a similar treatment.

174. Michele Goodwin, *Empires of the Flesh: Tissue and Organ Taboos*, 60 ALA. L. REV. 1219, 1223 (2009).

175. *Id.*

176. *Id.* at 1223–24.

177. *Cosmetic Surgery vs. Plastic Surgery*, AM. BD. COSM. SURGERY, <https://www.americanboardcosmeticsurgery.org/patient-resources/cosmetic-surgery-vs-plastic-surgery/> (last visited Aug. 16, 2022).

178. *Id.*

179. *See, e.g.*, Katie Hafner, *Once Science Fiction, Gene Editing Is Now a Looming Reality*, N.Y. TIMES (July 22, 2020), <https://www.nytimes.com/2020/07/22/style/crispr-gene-editing-ethics.html>.

180. *See* Karlyn Bowman, *Ambivalent on Abortion*, FORBES (Jan. 22, 2010, 3:47 PM), <https://www.forbes.com/2010/01/22/abortion-roe-v-wade-anniversary-opinions-columnists-karlyn-bowman.html>; *see also* Chelsea Fortin & Susanne Abele, *Increased Length of Awareness of Assisted Reproductive Technologies Fosters Positive Attitudes and Acceptance Among Women*, 9 INT’L J. FERTILITY & STERILITY 452, 459 (2016) (depicting the correlation between one’s political identity and attitude towards ART).

181. *See, e.g.*, Amy Dockser Marcus, *Crispr’s Next Frontier: Treating Common Conditions*, WALL

D. Structuring a Societal Discourse Using Administrative Law

While consensus may never be possible on reproductive genetic innovation, a discourse is likely worth undertaking. This Article proceeds based on that assumption even though other options include having (1) no societal discourse at all, with decisions left to individuals in a permissive regime, or no one, in the current regulatory standstill; (2) limited discourse only in connection with issues like governmental funding or insurance coverage; or (3) discourse only *after* the technique is societally available or undergoing larger human clinical trials, as occurred with the innovations discussed in Part II of the Article. Yet, the current trajectory is toward a societal discourse *before* the use of reproductive genetic innovation, at least in the United States, if the techniques encompassed by the term are ever to be legalized in the United States. Thus, this Article works within the confines of the current regulatory expectation even though as a matter of efficiency, the most expedient method of normalizing reproductive genetic innovation would be to lift the current budget rider and allow the market to operate in the way it usually does for medical innovation, whether that is the hands-off regulation of medical procedures, like with IVF, or the operation of the federal approval process that reproductive genetic innovation currently cannot proceed through due to the budget rider. As the hands-off option seems unlikely and the lifting of the budget rider will still encounter other hurdles, to include the public, the federal government likely needs to follow the lead of the United Kingdom, directly facilitating those discussions about the use and legality of these technologies.¹⁸² Yet, participation could have disadvantages. For example, those who would participate in a deliberative mechanism may not represent society at large but rather extremely interested stakeholders who would not constitute a cross-section of society.¹⁸³ While some would consider federal advisory

St. J. (May 5, 2021, 11:00 AM), <https://www.wsj.com/articles/crisprs-next-frontier-treating-common-conditions-11620226832>.

182. See *supra* Part IV.C; *supra* note 95 and accompanying text (discussing the possibility that political and social decisions impact regulatory decisionmaking); *infra* Part IV.D.4 (discussing the Congressional hearings that weighed covering certain transplants under Medicare); Richard A. Rettig, *Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972*, in *BIOMEDICAL POLITICS* 176, 181 (Kathi E. Hanna ed., 1991) (“The Gottschalk Committee report, in 1967, sanctioned dialysis and transplantation as established therapies, thus resolving the conflict between clinicians who wished to treat patients and researchers who thought dialysis experimental.”).

183. See Dorit Rubinstein Reiss, *Tailored Participation: Modernizing the APA Rulemaking Procedures*, 12 N.Y.U. J. LEGIS. & PUB. POL’Y 321, 345 (2009); Gary E. Marchant & Andrew Askland, *GM Foods: Potential Public Consultation and Participation Mechanisms*, 44 JURIMETRICS J. 99, 123–24 (2003) (discussing bias in the selection and participation of citizen jurors).

committees as a type of participatory decisionmaking, the same concerns about bias could apply to federal advisory committees, as the advisory committee members tend to be experts in the field who would, perhaps, be better placed as witnesses in a citizens' jury process instead of as jurors.¹⁸⁴ Ultimately, however, based on the trajectory of the societal and regulatory treatment of reproductive genetic innovation, any negative participation would simply result in the preservation of the status quo, where traditional ART in the U.S. is available but ART involving genetic substitution or modification is not. Consensus-based methods, in which deliberative public views form a part of regulation, are commonly used in Europe, Australia, and the U.K.¹⁸⁵ Thus, this Article is largely focused on processes that involve the government, but the government can be a hindrance to progress and stakeholder conversations, as illustrated by the many medical innovations that have flourished without federal government involvement, as well as occurrences outside of the realm of health and medicine, namely environmental law, where consensus has been used to resolve disputes.¹⁸⁶

1. *Inadequacies of Familiar Structures*

There are a number of options that can increase public participation in the scientific process. Referenda and ballot initiatives, like the California ballot initiatives on stem cell funding, can indicate public perspectives on scientific matters, although they are not used on a federal level.¹⁸⁷ However, referenda are not seen as deliberative as the only options are “yes” or “no.”¹⁸⁸ Surveys,

184. See Marchant & Askland, *supra* note 183, at 119–20; Matthew D. Adler, *Welfare Polls: A Synthesis*, 81 N.Y.U. L. REV. 1875, 1878 (2006) (“A variety of concrete formats have been proposed for civic republican citizen deliberation, including citizen advisory committees or review panels, citizen juries, and ‘deliberative polling.’” (citations omitted)); *Advisory Committees Give FDA Critical Advice and the Public a Voice*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/sumer-updates/advisory-committees-give-fda-critical-advice-and-public-voice> (Oct. 20, 2020); FOOD AND DRUG ADMINISTRATION ADVISORY COMMITTEES 88–89, 98 (Richard A. Rettig et al., eds., 1992); Stéphane Lavertu & David L. Weimer, *Federal Advisory Committees, Policy Expertise, and the Approval of Drugs and Medical Devices at the FDA*, 21 J. PUB. ADMIN. RSCH. & THEORY 211, 212 (2011).

185. Tee Rogers-Hayden & Nick Pidgeon, *Reflecting Upon the UK's Citizens' Jury on Nanotechnologies: Nanojury UK*, 3 NANOTECHNOLOGY L. & BUS. 167, 168 (2006).

186. See Karrigan Bork, *Governing Nature: Bambi Law in A Wall-E World*, 62 B.C. L. REV. 155, 204 (2021) (citing Marc B. Mihaly, *Citizen Participation in the Making of Environmental Decisions: Evolving Obstacles and Potential Solutions Through Partnership with Experts and Agents*, 27 PACE ENV'T L. REV. 151, 188 (2010)).

187. See generally Marchant & Askland, *supra* note 183, at 116 (identifying “Referenda and Initiatives” as methods of increasing public participation in science); Nidhi Subbaraman, *California's Vote to Revive Controversial Stem-Cell Institute Sparks Debate*, 587 NATURE 535, 535 (2020).

188. Marchant & Askland, *supra* note 183, at 116.

community meetings, and focus groups have also been characterized as a method of increasing the involvement of individuals in government.¹⁸⁹

Administrative law is known for its notice-and-comment process, by which members of the public submit comments on proposed regulations provided by federal agencies.¹⁹⁰ Administrative agencies routinely engage in public-facing efforts, such as general public meetings.¹⁹¹ Currently, the regulation of reproductive genetic innovation is centered in budget riders, as of 2016, so there would be no regulation to discuss and, the Article does not advocate for those standard administrative law methods such as increased use of notice-and-comment rulemaking.¹⁹²

Agency meetings focus on conveying information to the public or obtaining public comments, so they are inherently less deliberative because agency employees obtain the views of the public and provide arguably non-deliberative responses.¹⁹³ After the agency responds that it agrees, disagrees, or notes that comments are out of the scope of the rulemaking, it often provides scant explanation of its position on the public comments and does not engage in any meaningful back-and-forth after its response.¹⁹⁴ Further, the deliberation involved with agency meetings focuses on the gathering of information from the public and notice-and-comment processes is less deliberative than the other models explored in this Article.¹⁹⁵ This Article does not provide an exhaustive

189. Susan Pickard, *Citizenship and Consumerism in Health Care: A Critique of Citizens' Juries*, 32 SOC. POL'Y & ADMIN. 226, 229 (1998).

190. 5 U.S.C. § 553 (2006); There is an extensive literature devoted to critiquing and analyzing the notice-and-comment process. See, e.g., Roni A. Elias, *The Legislative History of the Administrative Procedure Act*, 27 FORDHAM ENV'T L. REV. 207, 219–20 (2016); see TODD GARVEY, CONG. RSCH. SERV. R41546, A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW (2017); S. DOC. NO. 248 (1944–46), reprinted in LEGISLATIVE HISTORY OF THE ADMINISTRATIVE PROCEDURE ACT, 1946, at 18–20 (1946); Parrillo, *supra* note 17.

191. William R. Sherman, *The Deliberation Paradox and Administrative Law*, 2015 B.Y.U. L. REV. 413, 416–17, 443 (2015) (discussing agency meetings).

192. See *supra* Part II.A; *supra* Part III.

193. See Sherman, *supra* note 191, at 451.

194. See Jonathan Weinberg, *The Right to be Taken Seriously*, 67 U. MIAMI L. REV. 149, 149–50, 158 (2002) (noting the goal of agency comment response); Parrillo, *supra* note 17, at 83.

195. See, e.g., Nina A. Mendelson, *Rulemaking, Democracy, and Torrents of E-mail*, 79 GEO. WASH. L. REV. 1343, 1363–64 (2011) (“Very frequently, a notice of final rule will note the filing of large numbers of public comments, but will pass over those comments lightly, saving detailed responses for more sophisticated or technical comments. In general, rulemaking documents only occasionally acknowledge the number of lay comments and the sentiments they express; they very rarely appear to give them any significant weight.” (citations omitted)). This Article focuses on notice-and-

analysis of all potential administrative legal options. For example, in the realm of bioethics, other scholars have lamented the end of presidential bioethics commissions, although these commissions were designed for expert consultation, not solicitation of public input.¹⁹⁶ Nevertheless, consensus development is often one goal of a bioethics commission.¹⁹⁷ Similarly, the Office of Technology Assessment, a Congressional entity, existed from 1972 until 1995 and provided guidance to Congress on emerging technological issues, ranging from e-mail to biomedical research to nuclear weapons.¹⁹⁸ In 2022, Representatives Mark Takano, Bill Foster, Sean Caster, and Donald Beyer introduced the Office of Technology Assessment Improvement and Enhancement Act, which will revive the Office of Technology Assessment if passed.¹⁹⁹ If the Office of Technology Assessment is reconstituted, it could be part of a broader effort to educate both legislators and the public on issues of reproductive genetic innovation.

2. *Adapting the U.K.'s Public Consultation Methods to the U.S.' Existing Deliberative Process*

The United Kingdom's experience in legalizing mitochondrial transfer is notable for its use of public participation and public education.²⁰⁰ While the United Kingdom has a substantially more centralized system of regulating ART than the United States, there are still some aspects of its regulatory system that could be translated into an American societal discourse.²⁰¹

comment rulemaking; however, there are other methods of rulemaking, that are even less deliberative. See Lars Noah, *Doubts About Direct Final Rulemaking*, 51 ADMIN. L. REV. 401, 402 (1999) (discussing "interim final" or "post-promulgation comment" rulemaking).

196. See generally Alexander M. Capron, *Building the Next Bioethics Commission*, 47 HASTINGS CTR. REP. (SPECIAL REP.) S4 (2017); Jacob M. Appel, Opinion, *Where's Trump's Bioethics Commission?*, Baltimore Sun, (May 31, 2019, 7:40 AM) <https://www.baltimoresun.com/opinion/op-ed/bs-ed-op-0603-bioethics-commission-20190531-story.html>; SCIENCE, ETHICS, AND GOVERNANCE, *supra* note 8, at 172.

197. Capron, *supra* note 196, at S7.

198. See David Malakoff, *House Democrats Move to Resurrect Congress's Science Advisory Office*, SCI. INSIDER (Apr. 30, 2019), <https://www.science.org/content/article/house-democrats-move-resurrect-congress-s-science-advisory-office>. Princeton University maintains an archive of OTA publications. See *The OTA Legacy*, PRINCETON U., <https://www.princeton.edu/~ota/> (last visited Aug. 16, 2022).

199. Office of Technology Assessment Improvement and Enhancement Act, H.R. 4426, 116th Cong. (2019).

200. See, e.g., Lanphier, Urnov, Haecker, Werner & Smolenski, *supra* note 16, at 411; Lewis, *The American Democratic Deficit*, *supra* note 65, at 145–47.

201. The United Kingdom has an "independent regulator," the Human Fertilisation & Embryology Authority, that regulates assisted reproductive technology. Steve P. Calandrillo

The U.K.'s legalization of mitochondrial transfer was a lengthy twelve-year process that included multiple approaches to public consultation.²⁰² In the United Kingdom, the Parliament was responsible for passing regulations to “allow techniques that alter the DNA of an egg or embryo to be used in assisted conception, to prevent the transmission of serious mitochondrial disease.”²⁰³ As part of the lead-up to the legalization of mitochondrial transfer (under particularly limited circumstances), the Human Fertilisation & Embryology Authority (HFEA), the “independent regulator” of ART in the United Kingdom undertook multiple scientific reviews and a five-strand public consultation.²⁰⁴ The HFEA-facilitated five-strand public consultation

& Chryssa V. Deliganis, *In Vitro Fertilization and the Law: How Legal and Regulatory Neglect Compromised a Medical Breakthrough*, 57 ARIZ. L. REV. 311, 333 (2015); *About Us*, HUM. FERTILISATION & EMBRYOLOGY AUTH. (June, 9, 2022), <https://www.hfea.gov.uk/about-us/>; Human Fertilisation and Embryology Act, 1990, c. 37, § 5 (Eng.).

202. Senate Community Affairs References Committee, Parliament of Australia, Science of Mitochondrial Donation and Related Matters (Report of 27 June 2018) 5–7, https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MitochondrialDonation/Report (providing a timeline of the U.K.'s legalization of mitochondrial transfer, including the 2005 licensing of pronuclear transfer); Al Bredenoord & I. Hyun, *The Road to Mitochondrial Gene Transfer: Follow the Middle Lane*, 23 MOLECULAR THERAPY 975 (2015).

203. HUM. FERTILISATION & EMBRYOLOGY AUTH., MITOCHONDRIA REPLACEMENT CONSULTATION: ADVICE TO GOVERNMENT 9 (2013), https://www.hfea.gov.uk/media/2618/mitochondria_replacement_consultation_-_advice_for_government.pdf [hereinafter ADVICE TO GOVERNMENT]; see Joan Mahoney, *Genome Mapping and Designer Babies: A Comparative Perspective*, 79 UMKC L. REV. 309, 312 (2010) (discussing the scientific and social motivations for the 2008 Amendment to the 1990 Human Fertilisation and Embryology Act, the “enabling statute,” in American parlance for the UK’s Human Fertilisation & Embryology Authority).

204. ADVICE TO GOVERNMENT, *supra* note 203, at 7. For the “three scientific reviews” of mitochondrial transfer (and the 2014 addendum to the “further update in 2014”), see generally HUM. FERTILISATION & EMBRYOLOGY AUTH., THIRD SCIENTIFIC REVIEW OF THE SAFETY AND EFFICACY OF METHODS TO AVOID MITOCHONDRIAL DISEASE THROUGH ASSISTED CONCEPTION: 2014 UPDATE (2014), https://www.hfea.gov.uk/media/2614/third_mitochondrial_replacement_scientific_review.pdf; HUM. FERTILISATION & EMBRYOLOGY AUTH., SCIENTIFIC REVIEW OF THE SAFETY AND EFFICACY OF METHODS TO AVOID MITOCHONDRIAL DISEASE THROUGH ASSISTED CONCEPTION: UPDATE (2013), https://www.hfea.gov.uk/media/2612/mito-annex_viii-science_review_update.pdf; HUM. FERTILISATION & EMBRYOLOGY AUTH., REVIEW OF THE SAFETY AND EFFICACY OF POLAR BODY TRANSFER TO AVOID MITOCHONDRIAL DISEASE ADDENDUM TO ‘THIRD SCIENTIFIC REVIEW OF THE SAFETY AND EFFICACY OF METHODS TO AVOID MITOCHONDRIAL DISEASE THROUGH ASSISTED CONCEPTION: 2014 UPDATE’ (2014), https://www.hfea.gov.uk/media/2610/2014-10-07_-_polar_body_transfer_review_-_final.pdf; HUM. FERTILISATION & EMBRYOLOGY AUTH., SCIENTIFIC REVIEW OF THE SAFETY AND EFFICACY OF METHODS TO AVOID MITOCHONDRIAL DISEASE THROUGH ASSISTED CONCEPTION (2011),

included a number of information gathering methods, including “deliberative public workshops, . . . [a] public representative survey, . . . [an] open consultation questionnaire, . . . open consultation meetings . . . and patient focus groups.”²⁰⁵ While industry participants and patient groups tend to be organized enough to “capture” the attention of regulatory bodies like the FDA, especially its Advisory Committee Members, the broader public, as noted in the next section on Citizens’ Juries, do not interact with the agency employees as often.²⁰⁶

Of the U.K.’s five methods of public consultation related to the approval of mitochondrial transfer, deliberative public workshops could be especially useful in the United States as the U.K.’s deliberative public workshops focused on educating the public on the science of mitochondrial transfer, the science and scope of mitochondrial disease, and discussing the social and ethical issues related to techniques of mitochondrial transfer.²⁰⁷ Additionally, the U.K.’s open consultation meetings “involved a combination of small group discussions around particular issues, whole group debates, and discussion between and across the panel and the floor.”²⁰⁸ In terms of structuring such debates, citizens’ juries, which are the subject of the next section, could offer one method.

Similarly, the public meetings that are often structured in the context of American agency meetings could be similar to the U.K.’s “open consultation questionnaires.”²⁰⁹ In the “open consultation questionnaire” related to mitochondrial transfer, interested members of the public considered information posted on a public consultation website before submitting responses to seven

<https://www.hfea.gov.uk/media/2613/scientific-review-of-the-safety-and-efficacy-of-methods-to-avoid-mitochondrial-disease-through-assisted-conception.pdf>. See also HUM. FERTILISATION & EMBRYOLOGY AUTH., SCIENTIFIC REVIEW OF THE SAFETY AND EFFICACY OF METHODS TO AVOID MITOCHONDRIAL DISEASE THROUGH ASSISTED CONCEPTION: 2016 UPDATE 4–5 (2016), https://www.hfea.gov.uk/media/2611/fourth_scientific_review_mitochondria_2016.pdf.

205. SARAH BARBER & PETER BORDER, MITOCHONDRIAL DONATION 13 (2015), <https://researchbriefings.files.parliament.uk/documents/SN06833/SN06833.pdf>.

206. See Mendelson, *supra* note 195, at 1357–58 (“Regulated entities tend to be heavily represented in rulemaking, compared with regulatory beneficiaries—those who expect to benefit from a regulatory program.”); Nicholas Bagley, *The Procedure Fetish*, 118 MICH. L. REV. 345, 389–91, 394 (2019) (discussing “agency capture” and the “diffuse public interest”). For more FDA-specific analysis of these issues, see INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 73–74 (Alina Baciu et al., eds., 2007); Fredrick H. Degnan, *An Introduction to FDA Advisory Committees*, 45 FOOD, DRUG, COSMETIC L. J. 709 (1990); Catherine M. Sharkey, *States v. FDA*, 83 GEO. WASH. L. REV. 1609, 1626 (2015).

207. ADVICE TO GOVERNMENT, *supra* note 203, at 10–11, 22.

208. *Id.* at 11.

209. See Sherman, *supra* note 191, at 416–17, 443 (2015).

specific questions through the mail or online.²¹⁰ In the United States, public meetings (which are announced in the Federal Register and agency webpages) are often used to increase public awareness of agency activities and facilitate the submission of comments related to regulatory actions.²¹¹

Questions to be considered in the United States' consultations can include whether specific techniques of reproductive genetic innovation should be permitted and a reminder of the demarcation between state and federal law in issues such as recognizing the parentage of children conceived using ART and reproductive genetic innovation. Further, a discussion of the bioethical considerations that accompany reproductive genetic innovation could be identified and discussed. Thus, if the FDA will continue to be the go-to agency for issues of genetic modification, it could post documents related to the scientific and ethical issues that accompany reproductive genetic innovation on an easy to find website (as it did for each of the authorized COVID-19 vaccines).²¹² Also, while the FDA is the first agency that many scientists consider when addressing issues of reproductive genetic innovation, the Centers for Disease Control and Prevention (CDC) could also play a role in educating the public. The CDC is responsible for maintaining the ART statistics required by the 1992 Fertility Clinic Success Rate Act, a statute that is often criticized for its lack of enforcement mechanism.²¹³ The CDC could aid in the creation of shorter documents that provide the scientific background that members of the public need to understand techniques of reproductive genetic innovation, as it does with many other ailments. Creators of germline gene editing view this education as imperative to the facilitation of a "rational

210. See ADVICE TO GOVERNMENT, *supra* note 203, at 10–11, 22.

211. See, e.g., Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology, 80 Fed. Reg. 60,414 (Nat'l Sci. Tech. Couns. Oct. 6, 2015); Public Meeting Notice, 80 Fed. Reg. 62,538 (FDA Oct. 16, 2015).

212. See, e.g., *Spikevax and Moderna COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine> (July 1, 2022); *Comirnaty and Pfizer-BioNTech COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine> (last updated July 1, 2022). Many scholars have recommended the creation of a separate administrative agency to regulate assisted reproductive technology, similar to the UK's Human Fertilisation and Embryology Authority. Thus far, those recommendations have not been adopted. See, e.g., Jamie King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH L., POL'Y & ETHICS 283, 321 (2008); Michelle Bayefsky, *Who Should Regulate Preimplantation Genetic Diagnosis in the United States?*, 20 AMA J. ETHICS 1160, 1160–64 (2018).

213. See 42 U.S.C. § 263a-1 (2012).

public discourse.”²¹⁴ Thus, reproductive genetic innovation could provide an opportunity for inter-agency cooperation to educate the public and to highlight public views which may impact the regulatory process.²¹⁵

3. *Citizens’ Juries as a Method of Including the Public*

While the definition of the term can vary, citizens’ juries are another form of furthering “deliberative democracy.”²¹⁶ Citizens’ juries use members of the public as quasi-adjudicators who question expert witnesses, deliberate on the issue presented, and then, instead of rendering a verdict, issue one or more recommendations on that issue.²¹⁷ Citizens’ juries, which are also referred to as “citizens’ panels,” are modeled on the juries used in court cases, although they aim to ascertain citizens’ views on scientific methods as opposed to legal controversies.²¹⁸ The “decisions made in citizens’ juries are based on consensus, but do not have to be those of the majority.”²¹⁹ Citizens’ juries have been used to ascertain public views on assorted innovations in science, including nanotechnology, mitochondrial transfer, and genetically modified foods.²²⁰ In the United States, a citizens’ jury was used for public deliberations related to the 1993 Clinton Health Plan.²²¹

214. See Jennifer A. Doudna & Emmanuelle Charpentier, *The New Frontier of Genome Engineering with CRISPR-Cas9*, 346 SCIENCE 1258096-1, 1258096-7 (2014); Matthew C. Nisbet, *The Gene-Editing Conversation*, 106 AM. SCIENTIST 15 (2018) (emphasizing the importance of public participation in dialogue and sharing of knowledge).

215. See Doudna & Charpentier, *supra* note 214, at 1258096-7 (2014) (discussing the importance of educating non-scientists to encourage and facilitate public discourse); INST. MED., NAT’L ACADS., *THE FUTURE OF THE PUB.’S HEALTH IN THE 21ST CENTURY* 163 (2003).

216. Jennifer A. Whitty, Paul Burton, Elizabeth Kendall, Julie Ratcliffe, Andrew Wilson, Peter Little Johns et al., *Harnessing the Potential to Quantify Public Preferences for Healthcare Priorities Through Citizens’ Juries*, 3 INT’L J. HEALTH POL’Y AND MGMT. 57, 58 (2014).

217. Rogers-Hayden & Pidgeon, *supra* note 185, at 168.

218. *Id.*

219. Rachael Goberman-Hill, Jeremy Horwood & Michael Calnan, *Citizens’ Juries in Planning Research Priorities: Process, Engagement and Outcome*, 11 HEALTH EXPECTATIONS 272, 276 (2008).

220. See Rogers-Hayden & Pidgeon, *supra* note 184; Marchant & Askland, *supra* note 183, at 121.

221. See William Raspberry, *A Citizen’s Look at Health Care*, WASH. POST (Sept. 17, 1993), <https://www.washingtonpost.com/archive/opinions/1993/09/17/a-citizens-look-at-health-care/0928cae6-b00b-45ba-b9c5-b1f123c81031/> [hereinafter Raspberry, *A Citizen’s Look*]; William Raspberry, ‘Citizens’ Juries’, WASH. POST (Jan 23, 1993), at A19 [hereinafter Raspberry, *Citizens’ Juries*]; Ned Crosby & John C. Hottinger, *The Citizens Jury Process*, in *THE BOOK OF STATES* 325 (Council of State Gov’ts, 2011 ed.).

Such participatory methods have been used in Denmark, the United Kingdom, and Australia.²²² While not the focus of much of the legal literature on sensationalized innovations, citizens' juries have been used in the United States.²²³ In the United States, citizens' juries are often associated with Ned Crosby, who used them a number of times in different states before being involved with a Citizens' Jury convened to assess the Clinton Health Plan in 1993.²²⁴

Citizens' juries, like civil and criminal juries, should represent a cross-section of society, although there is significant criticism that surrounds how citizens' juries can be unrepresentative.²²⁵ Thus, citizens' juries could involve the views of individuals who are less likely to have made their views known, such as those who lie between patient advocacy groups and those opposed to genetic modification.²²⁶ In citizens' juries, those who are members of special interest or advocacy movements tend to be removed from the jury pool, similar to strikes for cause.²²⁷ Other healthcare related citizens' juries have also excluded individuals employed as healthcare professionals or the government.²²⁸

The size of citizens' juries can vary, as can the method of selecting jurors.²²⁹ The Clinton Health Plan's jury consisted of 24 "jurors" who were

222. Some have noted that citizens' juries are based on a Danish model, whereas others have referenced a German inspiration. See Rogers-Hayden & Pidgeon, *supra* note 185, at 168; see also Dorit Rubinstein Reiss, *Tailored Participation: Modernizing the APA Rulemaking Procedures*, 12 N.Y.U. J. LEGIS. & PUB. POL'Y 321, 339 (2009) (discussing how Denmark has utilized consensus conferences as a representative model for issues of science and technology); Gooberman-Hill, Horwood & Calnan, *supra* note 219, at 274.

223. Rogers-Hayden & Pidgeon, *supra* note 185, at 168.

224. See *supra* note 223 and accompanying text; see also Huma Khan, *Throback to 1993? What's New About Democrats' Health Care Plans*, ABC NEWS (Sept. 25, 2009, 4:17 PM), <https://abcnews.go.com/Politics/HealthCare/health-care-reform-president-obama-path-bill-clinton/story?id=8675596> (recounting the similarities and differences between the Clinton Health Plan and Obamacare/Affordable Care Act); Ben Smith, *Obamacare vs. Clintoncare*, POLITICO (Mar. 23, 2010, 1:49 PM), <https://www.politico.com/blogs/ben-smith/2010/03/obamacare-vs-clintoncare-025991>.

225. See Pickard, *supra* note 189, at 238; Jackie Street, Katherine Duszynski, Stephanie Krawczyk & Annette Braunack-Mayer, *The Use of Citizens' Juries in Health Policy Decision-Making: A Systematic Review*, 109 SOC. SCI. & MED. 1, 5 (2014).

226. Gooberman-Hill, Horwood & Calnan, *supra* note 219 at 276.

227. Devidas Menon & Tania Stafinski, *Engaging the Public in Priority-Setting for Health Technology Assessment: Findings From a Citizens' Jury*, 11 HEALTH EXPECTATIONS 282, 284–85 (2008).

228. Tania Stafinski, Devidas Menon & Yutaka Yasui, *Assessing the Impact of Deliberative Processes on the Views of Participants: Is it In One Ear and Out the Other?*, 17 HEALTH EXPECTATIONS 278, 279 (2012).

229. See *id.* ("Citizens' juries bring together 12–16 individuals selected to be broadly representative of their community. Over a two- to four-day period, they learn about a relevant

selected through a process that was both random and “weighted so as to reflect the ethnic, gender, age, income, geographic, educational and political makeup of the electorate.”²³⁰ The 24 jurors were selected from a “random pool of 2,000 American adults to be a microcosm of the nation in age, gender, race, education (as an income indicator), geographic locale, 1992 presidential preference, and source of healthcare financing. Jurors were paid their expenses and a stipend of \$600 for a week of meetings in Washington, DC.”²³¹

Citizens’ juries in Germany, which are also referred to as “planning cells” when used in an official governmental capacity, have used moderators with a specific knowledge of the topic being discussed, but specialized moderators are not always used for citizens’ juries.²³²

Deliberations can be structured in many ways, including through methods that involve strong direction by moderators or facilitators, or more free form meetings reliant upon the direction of the jurors themselves instead of moderators.²³³ The expertise of moderators also varies.²³⁴ Final outcomes can be reported in different ways. For example, the 1993 Clinton Health Plan citizens jury vote was “[u]nanimous (24-0) for reform of the health care system[,] 19-5 against the Clinton plan[, u]nanimous (24-0) in adopting 25 specific criteria for a health care reform plan to meet[, u]nanimous (24-0) in believing the federal executive, legislative, and judicial branches must live under the same plan adopted for the rest of America[, and] 13-9 against rating any other plans.”²³⁵ The twenty-five specific criteria that the jurors recommended included some aspects that were addressed in the Patient Protection and Affordable Care Act such as coverage for pre-existing conditions, prescriptions, and preventive care.²³⁶

issue, hear from expert ‘witnesses’ who offer different perspectives, engage in deliberations among themselves and arrive at a common ground answer.”); Rachel Krinks, Elizabeth Kendall, Jennifer A. Whitty & Paul A. Scuffham, *Do Consumer Voices in Health-Care Citizens’ Juries Matter?*, 19 HEALTH EXPECTATIONS 1015, 1016 (2015) (noting that “jurors are invited to meet for (usually) 3-5 days”); Gerry King, David J. Heaney, David Boddy, Catherine A. O’Donnell, Julia S. Clark & Francis S. Mair, *Exploring Public Perspectives on E-Health: Findings From Two Citizen Juries*, 14 HEALTH EXPECTATIONS 351, 353–54 (2010) (describing a one-day citizens jury).

230. See Raspberry, *A Citizen’s Look*, *supra* note 221; JEFFERSON CTR. FOR NEW DEMOCRATIC PROCESSES, AM.’S TOUGH CHOICES: CITIZENS JURY ON HEALTH CARE REFORM OCT. 10–14 (1993) [hereinafter AMERICA’S TOUGH CHOICES].

231. AMERICA’S TOUGH CHOICES, *supra* note 230, at 16.

232. Pickard, *supra* note 189, at 240–41.

233. See *id.* at 235, 240; Street, Duszynski, Krawczyk & Braunack-Mayer, *supra* note 223, at 6–7.

234. Pickard, *supra* note 189, at 240 (“In Germany, moderators are required to have a specific knowledge of the topic being discussed, whereas this is not the case in the USA.”).

235. See AMERICA’S TOUGH CHOICES, *supra* note 230, at 10–14.

236. *Id.*

Interestingly, one commentator observed, in relation to the Clinton Health Plan, that the citizens juries “are doing precisely what the House of Representatives ought to be doing but can’t quite seem to.”²³⁷ Applying that same observation to the current situation in relation to germline gene editing, a citizens’ jury could similarly be characterized as doing what Congress should have done but has failed to do. The Clinton Health Plan jury was “videotaped and edited down to a one-hour PBS presentation,” which would allow for the dissemination of some of the expert information used for the citizens’ jury deliberations to the general public.²³⁸

Considering the role of citizens’ juries in the timeline of America’s transition to increased health insurance availability, perhaps there will be an evolution that begins with citizens juries on reproductive genetic innovation, similar to the 1993 experience with the Clinton Health Plan citizens’ jury. Additional Congressional subcommittee hearings would occur along the way, some of which have already occurred in the context of germline genetic modification. All of this could ultimately lead to larger Congressional consideration and potentially legislation, as occurred with the Patient Protection and Affordable Care Act. Even if contemporary society is somewhere on this health insurance access timeline, there is also a use for Congressional hearings. For example, during the debate on cloning (which ultimately did not lead to substantive legislation), members of Congress did convene hearings that involved FDA employees at least staking out their positions on the regulation of cloning (albeit without explanation). Ultimately, citizens’ juries aim to create a more informed public which sometimes leads to jurors changing their views, but they do not always cause jurors to change their views.²³⁹ Citizens’ juries currently do not directly influence the decisionmaking process, but this does not mean that they could not in the future.²⁴⁰ For example, in addition to potentially changing the views of those on the juries, they could help regulators identify biases in their own decisionmaking, and also provide far more detail on potential ethical issues than comment submissions.

237. Raspberry, *A Citizen’s Look*, *supra* note 221.

238. *Id.* The deliberations of the Clinton Health Plan jury lasted over 60 hours. *See AMERICA’S TOUGH CHOICES*, *supra* note 228 at 10–14.

239. *See* Gooberman-Hill, Horwood & Calnan, *supra* note 219, at 278; Stafinski, Menon, & Yasui, *supra* note 228, at 286 (“All but one of the jurors thought their views had not changed since the jury.”).

240. Pickard, *supra* note 189, at 241.

4. *Consensus Development Review: A Historical Method of Obtaining Expert Consensus*

While consensus methods are often associated with foreign countries, consensus is actually not a foreign concept in the American health care regulatory system. Not only was a method of consensus fostered in some areas related to the Clinton Health Plan, but a “public trial,” referred to as “Consensus Development Review,” was commenced before Medicare added liver transplantation to its list of approved treatments thus rendering it no longer “experimental.”²⁴¹ After this Consensus Development Review, there were Congressional hearings which discussed many issues including who would pay for organ transplantation and how to procure donors.²⁴²

The Consensus Development Review that was used as part of the process of adding liver transplantation to Medicare coverage was described as “[i]n essence . . . a trial by jury of new forms of medical treatment.”²⁴³ As conceived by the Surgeon General at the time, C. Everett Koop, it would be a “[public trial in which] all evidence about liver transplantation would be presented by those who advocated its acceptance and by those who opposed it.”²⁴⁴ The “jury” to deliberate over the inclusion of liver transplantation in Medicare’s covered services was to be fifteen people “carefully selected to avoid bias for or against the proposition under discussion. At the end, the jury would retire and render a verdict.”²⁴⁵

Ultimately, the Consensus Development Conference on liver transplantation took place from June twentieth to twenty-third, 1983 in Bethesda, MD.²⁴⁶ Thirteen people (not the initial fifteen that were proposed) comprised the Consensus Development Panel: ten had M.D.’s, two had Ph.D.’s, and the one individual without an M.D. or a Ph.D. had a Master’s of Science.²⁴⁷ Additionally, the “jury” used in the Consensus Development Review differed from the type of jury used in a citizens jury because the jury was composed of a number of medical experts as opposed to members of the

241. See STARZL, *supra* note 138, at 162, 252–54, 269.

242. *Id.* at 252.

243. *Id.*

244. *Id.* at 253; *Biographical Overview, The C. Everett Koop Papers*, NAT’L LIBR. OF MED., <https://profiles.nlm.nih.gov/spotlight/qq/feature/biographical> (last visited Aug. 16, 2022).

245. See STARZL, *supra* note 138, at 252–53.

246. *Id.* at 254.

247. See *NIH Consensus Development Program, Liver Transplantation: National Institutes of Health Consensus Development Conference Statement*, NAT’L INSTS. OF HEALTH (1983), <https://consensus.nih.gov/1983/1983LiverTransplantation036html.htm>.

general public.²⁴⁸ Further, the Consensus statement was published in a specialty journal, *Hepatology*. Nevertheless, this statement was critical to liver transplantation being designated as a therapeutic treatment instead of as “experimental.” The NIH’s Consensus Development Program was formally retired in 2013. In a statement explaining why the program was retired, the NIH noted that their Consensus Development Program “was created during a time when few other organizations were providing evidence reviews. Today, there are many other organizations that conduct such reviews, including other federal agencies, academic institutions, and private organizations” including assorted task forces and the Institute of Medicine.²⁴⁹

While the NIH believes that “other able parties” now serve the Consensus Development Program’s role of “evidence review,” it may be worth re-constituting the program to commence a societal discourse on techniques involving reproductive genetic innovation—even if that societal discourse begins at the expert level, as opposed to the public level.²⁵⁰ If the Consensus Development Program were re-constituted, then the public could benefit from the involvement of an agency that is less involved in the regulatory process than the FDA, albeit with a clear bias against germline gene editing.²⁵¹

While there have been a number of International Summits devoted to gene editing, there have been none devoted to cytoplasmic or mitochondrial transfer. Therefore, a panel based on the Consensus Development Panel of 1983 could be a forum for involved scientists and physicians to create any consensus (if possible) and more easily communicate that consensus to the public. While those who received Untitled Letters from the FDA appeared at an Advisory Committee Meeting in 2000, that meeting specifically foreclosed issues related to morality, ethics, or society; this meeting would not have to do so.²⁵² The Consensus Development Panel’s Statement was largely technical and answered specific questions related to the future of liver transplantation research in the United

248. See, e.g., *id.* (“After extensive review and consideration of all available data, this panel concludes that liver transplantation is a therapeutic modality for end-stage liver disease that deserves broader application. However, in order for liver transplantation to gain its full therapeutic potential, the indications for and results of the procedure must be the object of comprehensive, coordinated, and ongoing evaluation in the years ahead. This can best be achieved by expansion of this technology to a limited number of centers where performance of liver transplantation can be carried out under optimal conditions.”).

249. *Retirement of the National Institutes of Health Consensus Development Program*, NAT’L INSTS. HEALTH, <https://consensus.nih.gov> (last visited Aug. 16, 2022).

250. *Id.*

251. See Collins, *supra* note 12 (providing the statements of Francis Collins on germline gene editing).

252. MEETING #59 TRANSCRIPT, *supra* note 83, at 13.

States and the establishment of institutional support.²⁵³ Nevertheless, the Panel did conclude that liver transplantation was “a therapeutic modality for endstage liver disease that deserves broader application[,]” thus recommending expansion of liver transplantation innovation.²⁵⁴

Further, the Consensus Development Panel was not the only method of publicly considering the “experimental” nature of liver transplants. Shortly before the Consensus Development Panel, the Surgeon General and the Assistant Secretary of the Department of Health and Human Services testified before Congressman Albert Gore’s Investigations and Oversight Subcommittee, Committee on Science and Technology. Throughout the hearing Gore criticized federally funded health programs for withholding reimbursement for liver transplants.²⁵⁵ He noted: “I don’t think the word ‘experimental’ can be fairly used to describe a procedure that has a 75-80% success rate. The real issue is how quickly the bureaucracy represented at the table can adjust to change of circumstance.”²⁵⁶

One could argue that it is too early for a Consensus Development Conference for certain forms of reproductive genetic innovation like germline gene editing, but it is certainly not too early to do so for mitochondrial and cytoplasmic transfer. Moreover, contemporary discussion of these reproductive genetic innovation techniques is often halted by a statement about long-term effects.²⁵⁷ Yet, these same unknown long-term effects existed—and still do—with many currently approved procedures, techniques, and medical products.²⁵⁸ Similarly, the ethical issues that accompany reproductive genetic innovation center on issues related to (1) reproduction (and assisted reproduction) and (2) genetic

253. See NIH CONSENSUS DEVELOPMENT PANEL, *National Institutes of Health Consensus Development Conference Statement: Liver Transplantation—June 20-23, 1983*, 4 HEPATOLOGY 107S, 107S (1984). The Consensus Development Panel answered five “key” questions: “1. Are there groups of patients for whom transplantation of the liver should be considered appropriate therapy? 2. What is the outcome (current survival rates and complications) in different groups? 3. In a potential candidate for transplantation, what are the principles guiding selection of the appropriate time for surgery? 4. What are the skills, resources, and institutional support needed for liver transplantation? 5. What are the directions for future research?” *Id.*

254. *Id.* at 110S.

255. Gerald E. Markle & Daryl E. Chubin, Consensus Development in Biomedicine: The Liver Transplant Controversy, 65 *The Milbank Q.* 1, 14 (1987).

256. *Id.*

257. See, e.g., Editorial, *Gene Therapy Needs a Long-Term Approach*, 27 *NATURE MED.* 563, 563 (2021); Lander et al., *supra* note 11, at 166 (explaining some of the criticisms and concerns behind germline genome editing, such as the uncertainty behind its long-term effects, which need more study).

258. See Lewis, *Is Germline Gene Editing Exceptional?*, *supra* note 15, at 747–49, 810–13 (noting how ART is permissible in spite of its potential long-term effects).

modification or substitution. The ethical issues that accompany assisted reproduction and genetic innovation have existed for decades.

While this Section focuses on methods of soliciting public consultation through the administrative law process, it is certainly notable that discussion has not been occurring in Congress outside of the limited subcommittee context.²⁵⁹ Moreover, even with the conversations that have occurred amongst experts—in Congressional subcommittees, Federal Advisory Committee Meetings, and public agency meetings—and behind agencies' closed doors, a national convening of the experts with the goal of producing the societal consensus or discourse that scientists have requested has yet to occur.²⁶⁰

5. *Agency and Media Outreach: Emphasizing and Addressing Safety and Effectiveness*

Outside of FDA authorization and approval, emphasizing safety and effectiveness presents an avenue to reduce sensationalism. For example, COVID-19 vaccines have been around for far less time than genetic modification, including reproductive genetic innovation, and with far less long-term or follow-up data than reproductive genetic innovation.²⁶¹ Yet, in addition to urgency, the safety and effectiveness of these vaccines has been emphasized in data, media, and FDA presentations.²⁶² As noted earlier, the

259. *The Science and Ethics of Genetically Engineered Human DNA: Hearing Before the H. Subcomm. on Resch. & Tech. of the H. Comm. on Sci., Space, and Tech.*, 114th Cong. (2015).

260. *See id.*; see also I. Glenn Cohen & Eli Y. Adashi, *The FDA is Prohibited from Going Germline*, 353 SCIENCE 545, 545 (2016) (explaining how conversation on germline genome editing is repeatedly undermined by Congressional action).

261. *See* Damian Garde & Jonathan Saltzman, *The Story of mRNA: How a Once-Dismissed Idea Became a Leading Technology in the COVID Vaccine Race*, STAT NEWS (Nov. 10, 2020), <https://www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/>; *Different Types of COVID-19 Vaccines: How They Work*, MAYO CLINIC (JULY 23, 2022), <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/different-types-of-covid-19-vaccines/art-20506465?p=1>; *Understanding mRNA COVID-19 Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html> (July 15, 2022).

262. *See* Heidi Ledford, *Six Months of COVID Vaccines: What 1.7 Billion Doses Have Taught Scientists*, 594 NATURE 164, 165-67 (June 4, 2021), <https://www.nature.com/articles/d41586-021-01505-x>; *Safety of COVID-19 Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html> (Aug. 15, 2022); Tom Shimabukuro, *COVID-19 Vaccine Safety Updates*, VACCINE SAFETY TEAM, CDC COVID-19 VACCINE TASK FORCE (June 10, 2021), <https://www.fda.gov/media/150054/download>; Holly Yan, *Covid Vaccine Myths Debunked: These Reasons for Not Getting a Shot Don't Hold Up. In Fact, They'll Set the US Back*, CNN (July 19, 2021, 2:38 PM), <https://www.cnn>

recent experience with the rapid rollout and relatively high societal acceptance of the COVID-19 vaccines provides lessons for a discourse related to AARTs and heritable gene editing.²⁶³ In addition to FDA pharmaceutical approvals, animal studies have been a part of the research preceding the clinical use of organ transplantations and AARTs.²⁶⁴

Organ transplantation was developed in a way that involved many animal trials.²⁶⁵ While animal trials are a typical component of pharmaceutical development, they are less common in surgical innovation.²⁶⁶ Before bone marrow transplantation was carried out in humans, experiments were conducted on mice, dogs, and nonhuman primates.²⁶⁷ Kidney, heart, and liver transplantation in humans were preceded by canine trials.²⁶⁸ Interestingly, early organ transplantation efforts involved not only animal trials, but also xenotransplantation, or interspecies transplantation.²⁶⁹

.com/2021/07/19/health/covid-vaccine-myths-debunked/index.html; Michelle Roberts, *How Do We Know COVID Vaccines Are Safe?*, BBC NEWS, <https://www.bbc.com/news/health-55056016> (last visited Aug. 16, 2022).

263. See Roberts, *supra* note 262; Sarah Kreps, Sandip Prasad, John S. Brownstein, Yulin Hswen, Brian T. Garibaldi, Baobao Zhang et al., *Factors Associated With US Adults' Likelihood of Accepting COVID-19 Vaccination*, 3 JAMA NETWORK OPEN e2025594 (2020); Kimberly A. Fisher, Sarah J. Bloomstone, Jeremy Walder, Sybil Crawford, Hassan Fouayzi & Kathleen M. Mazor, *Attitudes Toward a Potential SARS-CoV-2 Vaccine: A Survey of U.S. Adults*, 173 ANNALS INTERNAL MED. 964 (2020); Peter G. Szilagyi, Kyla Thomas, Megha D. Shah, Nathalie Vizueta, Yan Cui, Sitaram Vangala et al., *National Trends in the US Public's Likelihood of Getting a COVID-19 Vaccine—April 1 to December 8, 2020*, 325 J. AM. MED. ASS'N 396 (2021).

264. See *supra* notes 129 & 138 and accompanying text (describing how scientists used animal clinical trials for research and pharmaceutical trials).

265. See *supra* Part IV.D.4.

266. See Jonathan J. Darrow, Jerry Avorn & Aaron S. Kesselheim, *FDA Approval and Regulation of Pharmaceuticals, 1983-2018*, 323 J. AM. MED. ASS'N 164, 166 (2020) (noting the different phases of pharmaceutical research when scientists would use animal tests); David DeGrazia & Tom L. Beauchamp, *Guest Editorial: Reassessing Animal Research Ethics*, 24 CAMBRIDGE Q. HEALTHCARE ETHICS 385, 387 (2015).

267. See THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION 3–5 (Frederick R. Appelbaum et al., eds., 4th ed. 2009); Frederick R. Appelbaum, *Hematopoietic-Cell Transplantation at 50*, 357 NEW ENG. J. MED. 1472, 1473 (2007).

268. See Thomas Starzl, *History of Clinical Transplantation*, 24 WORLD J. SURGERY 759, 759–60 (2000); Norman Shumway, *Thoracic Transplantation*, 24 WORLD J. SURGERY 811, 811–13 (2000); Gina Kolata, *2 American Transplant Pioneers Win Nobel Prize in Medicine*, N.Y. TIMES, Oct. 9, 1990, at C3; STARZL, *supra* note 138, at 99.

269. See, e.g., Starzl, *supra* note 268, at 760; Lawrence K. Altman, *A Transplant Surgeon Who Feels Surgery*, N.Y. TIMES, July 7, 1992, at C1 (noting failed efforts to transplant baboon kidneys into humans); Harold M. Schmeck Jr., *Hope Gaining for Success in Human Liver Transplants, Surgeon Tells Parley*,

Thus, early transplantation included stories of surgeons transplanting additional hearts onto dogs or attempting to transplant chimpanzee hearts into humans.²⁷⁰ In the 1960s, some physicians participated in the unsuccessful xenotransplantation of hearts and kidneys from chimpanzees to humans.²⁷¹ This sort of xenotransplantation does not characterize forms of genetic modification in human reproduction.

Before IVF was achieved in humans, it was achieved in at least nine animal species, although “[i]ronically, IVF . . . proved unusually difficult in nonhuman primates.”²⁷² Cytoplasmic transfer was also tested in mice and primate models, before and after it was used on humans.²⁷³ Mitochondrial transfer has similarly been tested on mice and non-human primates.²⁷⁴ It has also been tested in human eggs and embryos although not in pregnancies in the United States.²⁷⁵ Before the U.K. legalized the use of mitochondrial transfer in humans, the U.K.’s Chief Medical Officer noted: “The only clinical tests you can do are either in rats, mice and monkeys—and those have been done—or in humans and the mothers now want to do this following those three scientific reviews.”²⁷⁶

Similar to AARTs, heritable, specifically CRISPR-Cas9, and non-heritable gene editing, have been tested in mice, nonhuman primates, and

N.Y. TIMES, Oct. 11, 1964, at 41 (noting a then “successful” “chimpanzee-to-human kidney transplant.”). For more on the history of xenotransplantation, see David K.C. Cooper, Burcin Ekser & A. Joseph Tector, *A Brief History of Clinical Xenotransplantation*, 23 INTL. J. SURGERY 205 (2015).

270. D.K.C. Cooper, *Experimental Development of Cardiac Transplantation*, 4 BRITISH MED. J. 174, 180 (1968).

271. *Id.*; see also Robert M. Langer & Barry D. Kahan, *100 Years Ago: Ullmann’s Pioneering Operation—Autotransplantation of the Kidney*, 34 TRANSPLANT. PROC. 429, 429 (2002) (describing a successful transplantation of a dog kidney into a goat).

272. See HENRY T. GREELY, *THE END OF SEX AND THE FUTURE OF HUMAN REPROD.* 51 (Harvard Univ. Press 2016); see also Barry D. Bavister, *Early History of In Vitro Fertilization*, 124 REPROD. 181, 181 (2002).

273. See Henry E. Malter & Jacques Cohen, *Ooplasmic Transfer: Animal Models Assist Human Studies*, 5 REPROD. BIOMED. ONLINE 26, 28 (2002), [https://www.rbmojournal.com/article/S1472-6483\(10\)61593-3/pdf](https://www.rbmojournal.com/article/S1472-6483(10)61593-3/pdf).

274. HERITABLE HUMAN GENOME EDITING, *supra* note 8, at 49, 117.

275. See *id.* at 49–50; U.S. FOOD & DRUG ADMIN., *ADVISORY ON LEGAL RESTRICTIONS ON THE USE OF MITOCHONDRIAL REPLACEMENT TECHNIQUES TO INTRODUCE DONOR MITOCHONDRIA INTO REPRODUCTIVE CELLS INTENDED FOR TRANSFER INTO A HUMAN RECIPIENT* (2018), <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/advisory-legal-restrictions-use-mitochondrial-replacement-techniques-introduce-donor-mitochondria>.

276. Steve Connor, *Chief Medical Officer Urges Lords to Legalise ‘Three-Parent’ IVF*, INDEPENDENT (Feb. 24, 2015, 1:05 AM), <https://www.independent.co.uk/news/science/chief-medical-officer-urges-lords-to-legalise-three-parent-ivf-10065833.html>.

human embryos.²⁷⁷ The technique was allegedly used in human births, although that use has been the subject of widespread condemnation and also some uncertainty as to whether it was actually used in humans as the public has not been able to verify the births.²⁷⁸

Thus, reproductive genetic innovation would be different than natural reproduction yet the child would still be a part of the “common natural human species genotype” although not necessarily “equally” kin to each parent.²⁷⁹ This information should be emphasized at any public gathering, in order to combat sensationalism and dystopian fears that often enter into the conversation related to reproductive genetic innovation.

* * *

Public participation, especially through models like the U.K. model and citizens’ juries, can make up for gaps in scientific understanding that might contribute to sensational views based on a misunderstanding of certain scientific processes.²⁸⁰ This Article focuses on federal administrative law because the current site for the regulation of reproductive genetic innovation appears to be the federal government, not states. Yet, states have often fostered methods of considering controversial topics, as evidenced through their convening of expert bodies like the Task Force on Life and Law in New

277. See SCIENCE, ETHICS, AND GOVERNANCE., *supra* note 8 at 55, 236; HERITABLE HUMAN GENOME EDITING, *supra* note 8 at 89; Baltimore et al., *supra* note 11, at 36; Jon Cohen, *China’s CRISPR Push in Animals Promises Better Meat, Novel Therapies, and Pig Organs for People*, SCIENCE, (July 31, 2019, 8:00 AM), <https://www.sciencemag.org/news/2019/07/china-s-crispr-push-animals-promises-better-meat-novel-therapies-and-pig-organs-people>; Helen Shen, *First Monkeys with Customized Mutations Born*, NATURE (Jan. 30, 2014), <https://www.nature.com/news/first-monkeys-with-customized-mutations-born-1.14611>; Rob Stein, *New U.S. Experiments Aim to Create Gene-Edited Human Embryos*, NPR (Feb. 1, 2019, 5:00 AM), <https://www.npr.org/sections/health-s-hots/2019/02/01/689623550/new-u-s-experiments-aim-to-create-gene-edited-human-embryos>.

278. See, e.g., Greely, *supra* note 44, at 113, 116. The truthfulness of the reports of the “CRISPR’d babies” in China is unconfirmed. *Id.* at 116.

279. See Kass, *supra* note 57, at 21. While Kass’ article focused on making a case against cloning, which is not a part of this Article’s analysis as the Author does not consider cloning to be reproduction, Kass’ article is a part of a larger scholarship focusing on limiting human interventions in reproduction.

280. See, e.g., Marchant & Askland, *supra* note 183, at 106–07 (“... on most science-laden policy issues, the majority of the public is woefully ignorant of the subject, whether measured by their own self-assessments or by more objective evaluations employing questionnaires or survey” and “the ‘major finding’ of the National Science Foundation’s (NSF’s) most recent survey of public understanding of science and technology is that ‘Americans are highly supportive of science and technology (S&T), but lack knowledge of them.’”).

York and the California Advisory Committee on Human Cloning.²⁸¹ The current structure is one in which the regulatory system seems to be at an impasse. Instead of facilitating research that would explore these concerns, progress is halted in the United States, driven abroad, or driven underground.²⁸² Questions and clarifications related to the underlying science of these procedures, safety and efficacy, and whether certain moral, social, or political concerns should influence regulation could be explored in a public consultation. Earlier sections have provided potential questions and issues to consider in this consultation, which does not have to take place all at once—an iterative approach may be warranted and more practical.²⁸³

CONCLUSION

This Article has introduced some potential means of increasing participation in scientific decisionmaking, both in an effort to increase transparency in administrative agency decisionmaking and in response to scientists' calls for a societal discourse.

Scientists continue to call for public and societal discourse related to the topic of germline gene editing. When scientists and the public finally do engage in conversation, it is worth reminding the public how similar reproductive genetic innovation is to many other initially controversial medical techniques and approved medical products, including organ transplantation and somatic gene therapy.

This Article has also examined commonly accepted medical procedures that are often accompanied with genetic changes, including whole organ and bone marrow transplantation and gene therapy, that were initially treated as controversial but are now viewed as commonplace.²⁸⁴ In addition to genetic transfers, the Article has considered changes to the human immune system, such as those that accompany vaccination.²⁸⁵ Emphasizing the similarities between reproductive genetic innovation and other societally accepted techniques such as organ transplantation, vaccination and IVF, could move

281. See New York State, *Task Force on Life and the Law*, https://www.health.ny.gov/regulations/task_force/ (last updated Dec. 2017); Henry T. Greely, *Cloning Californians – Report of the California Advisory Committee on Human Cloning*, 53 HASTINGS L.J. 1143–1203 (2002).

282. See Lewis, *Subterranean Regulation*, *supra* note 10, at 1259–62.

283. See Myrisha S. Lewis, *Segmented Innovation in the Legalization of Mitochondrial Transfer: Lessons from the U.S. Common Law Neighbors in Australia and the United Kingdom*, 22 HOUS. J. HEALTH L. & POL'Y (forthcoming 2022) (describing a potential incremental approach for the U.S. regulation of mitochondrial transfer based on the experiences of the United Kingdom and Australia).

284. See, e.g., Carl Zimmer, *DNA Double Take*, N.Y. TIMES (Sept. 16, 2013), <https://www.nytimes.com/2013/09/17/science/dna-double-take.html>.

285. See *supra* Part III.B.

both the societal discourse and the regulatory framework forward by situating gene-modifying techniques in larger context of medical practice.

While techniques involving reproductive genetic innovation are controversial now, they share many commonalities previous practices, namely organ transplantation and medical products, like gene therapy. Broadly, AARTs and germline gene editing are part of the larger medical field which involves counteracting natural processes to increase lifespan, prevent disease, treat disease, or improve quality of life.

Normalizing reproductive genetic innovation means legalizing reproductive genetic innovation. One step towards that normalization lies in medicalizing those techniques within the discourse. The practice of medicine involves human interventions that interrupt the “natural” process of evolution.²⁸⁶ This Article has juxtaposed a number of long-standing medical procedures, including some that are societally accepted as evidenced through extensive insurance coverage, as well as others that remain controversial and often unsubsidized through insurance coverage despite being legal, such as IVF and egg freezing. While reproductive genetic innovation does not currently seem to enjoy societal acceptance, if the societal discourse and regulation of reproductive genetic innovation followed the trajectory of previously controversial techniques that are now well-understood, it could at the very least enjoy a societal acceptance that leads to increased research, innovation, and use by interested individuals.

286. Suter, *supra* note 15, at 960.