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## CRISPR Parents and Informed Consent

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# CRISPR Parents and Informed Consent

Naomi Cahn\*

Clustered Regularly Interspaced Short Palindromic Repeat Associated System (CRISPR-Cas9) is evolving as a multi-faceted technology that can help in finding cures for rare diseases, as well as creating babies with gene-edited cells. Yet, along with complex ethical questions, it also raises legal issues in numerous areas, from intellectual property<sup>1</sup> to health to family law, and it has been the subject of philosophers, ethicists, scientists, as well as legal scholars.

The author's focus in this article is at the intersection of family law and health law. The argument assumes that CRISPR will be used (black market or otherwise), and focuses on the rights of parents to make decisions about health care for their children and the subsequent consequences for children. It argues for responsible use by parents, which, in turn, requires responsibility from health care providers in obtaining informed consent and an understanding from the parents concerning any procedures used. The two issues at the core of this article are parents' rights to make decisions concerning their potential children, and the need for informed consent to support parental choices.

The mere possibility of using CRISPR-Cas9 may have a profound change on how parents and the medical profession address preconception and prenatal intervention.<sup>2</sup> Might doctors try to override decisions of parents? Can doctors override that type of decision based on the child's best interests? Might parents choose—or not choose—genetic enhancements just because they can, or because of expectations of what constitutes a good parent?<sup>3</sup> Might children sue their parents for *not* having used CRISPR-Cas9?<sup>4</sup>

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1. E.g., Rob Stein, *First U.S. Patients Treated with CRISPR as Human Gene-Editing Trials Get Underway*, NAT'L PUB. RADIO (Apr. 16, 2019), <https://www.npr.org/sections/health-shots/2019/04/16/712402435/first-u-s-patients-treated-with-crispr-as-gene-editing-human-trials-get-underway>.
2. Ruth M. Farrell, *New Technologies, New Challenges: Women and Prenatal Genetic Testing in the 21st Century*, 23 HEALTH MATRIX 1, 12 (2013).
3. Josephine Johnston, "Good Parents" Can Promote Their Own and Their Children's Flourishing, in HUMAN FLOURISHING IN AN AGE OF GENE EDITING (Erik Parens & Josephine Johnston eds., 2019).
4. Grant Hayes Frazier, *Defusing a Ticking Time Bomb: The Complicated Considerations Underlying Compulsory Human Genetic Editing*, 10 HASTINGS SCI. & TECH. L.J. 39, 43 (2019) ("[W]hat liability do parents face if there is a state statute requiring gene editing in [certain] circumstances?").

There has been some attention given to children's rights to sue providers for illnesses relating to medical involvement,<sup>5</sup> but this article suggests that the real issues center on parents for choosing to engage in and risk their children's future health on a newly developing technology,<sup>6</sup> and on health care providers for ensuring adequate understanding of the technology. The fear, now with a strong basis based on actual experiences,<sup>7</sup> is that the technology will be used in practice before it has been well-validated for clinical use, and thus produce unexpected, and adverse, outcomes for any resulting children.<sup>8</sup>

It is yet another example of a technology that has outpaced regulation.<sup>9</sup> As CRISPR—and any other germline editing techniques—move forward, patients' rights to make informed decisions should be accorded significant attention and protection.

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5. See, e.g., Barbara Pfeffer Billauer, *Wrongful Life in the Age of CRISPR-CAS: Using the Legal Fiction of "The Conceptual Being" to Redress Wrongful Gamete Manipulation*, 124 PENN ST. L. REV. 435, 485–86, 488 (2020) [hereinafter Billauer, *Wrongful Life in the Age of CRISPR-CAS*].
  6. See Sara Weinberger et al., *They Chose . . . Poorly: A Novel Cause of Action to Discourage Detrimental Genetic Selection*, 43 AM. J. L. & MED. 107, 127 (2017) (proposing tort against parents of "civil wrongful selection" for certain disabilities for the misuse of preimplantation genetic diagnosis (PGD) to select a "negative" trait for a child).
  7. Tina Hesman Saey, *News of the First Gene-Edited Babies Ignited a Firestorm*, SCI. NEWS (Dec. 17, 2018, 9:34 AM), <https://www.sciencenews.org/article/gene-edited-babies-top-science-stories-2018-yir>.
  8. *Id.*
  9. See Gaia Bernstein, *The Socio-Legal Acceptance of New Technologies: A Close Look at Artificial Insemination*, 77 WASH. L. REV. 1035, 1035 (2002); Gaia Bernstein, *Accommodating Technological Innovation: Identity, Genetic Testing and the Internet*, 57 VAND. L. REV. 963, 967–68 (2004). It is also an example of how regulation cannot necessarily control technology. See, e.g., Sigal Samuel, *Is it Time to Regulate Biohacking? California Thinks So*, VOX (Aug. 13, 2019, 8:00AM), <https://www.vox.com/future-perfect/2019/8/13/20802059/california-crispr-biohacking-illegal-josiah-zayner> (reporting on the first U.S. law to address CRISPR by banning the sale of "a do-it-yourself genetic engineering kit unless it comes with a clear warning stating that 'the kit is not for self-administration'"; note that the kit itself is not yet for sale). For further discussion of gene-editing regulation, see Naomi Cahn & Sonia Suter, *Regulatory Dilemmas of Gene-Editing* (Symposium: Embryonic Injuries and Nascent Remedies in the Age of Crispr-Cas, 96 Chicago-Kent Law Review, forthcoming 2021). For suggestions on how regulators might "shift[ ] their approach," see Julia D. Mahoney & Gil Siegal, *Beyond Nature? Genomic Modification and the Future of Humanity*, 81 L. & CONTEMP. PROB. 195, 213 (2018).

## I. CRISPR AND ITS DEVELOPMENT/USES

CRISPR/Cas-9 is becoming more widely adopted as a gene editing tool in both humans and nonhuman animals.<sup>10</sup> The tool is particularly useful to researchers and clinicians because it is faster, more efficient, and cheaper than prior gene editing techniques, and it has the potential for a wide range of applications.<sup>11</sup> The technology may be helpful in treating various illnesses, such as sickle cell disease, cystic fibrosis, blood disorders, heart disease, HIV/AIDS, and even several forms of cancer<sup>12</sup>—and it may also be useful for food production and biofuels.<sup>13</sup>

The technique allows researchers to create permanent edits to the genome<sup>14</sup> by targeted insertions or deletions of nucleotides on any section of the DNA molecule to modify a specific gene.<sup>15</sup> It thus allows physicians and scientists the option of changing and “fixing” an organism’s DNA by altering genetic material at specific locations in the genome.

10. “CRISPR-Cas9 was adapted from a naturally occurring genome editing system in bacteria. The bacteria capture snippets of DNA from invading viruses and use them to create DNA segments known as CRISPR arrays. . . . The bacteria then use Cas9 or a similar enzyme to cut the DNA apart, which disables the virus.” *What are Genome Editing and CRISPR-Cas9?*, NAT’L INST. HEALTH, <https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting> (last updated May 26, 2020).
11. *Id.*
12. Frazier, *supra* note 4, at 40–41. For example, CRISPR/Cas9 technology somatic clinical trials are permitted, and the number of such trials is proliferating. *See, e.g.*, Saey, *supra* note 7 (discussing trial for individuals with an inherited blindness, in which subjects are initially injected with small amounts of the CRISPR editor to see how their retina responds and to test for safety).
13. *E.g.*, Stephen S. Hall, *Crispr Can Speed Up Nature—And Change How We Grow Food*, WIRED (July 17, 2018, 6:00 AM), <https://www.wired.com/story/crispr-tomato-mutant-future-of-food/> (noting that gene-edited potatoes have already been planted).
14. DNA, of course, is the basic molecule that is “the hereditary material in all living cells,” and consists of double helix strands. *DNA*, GENOME NEWS NETWORK, [http://www.genomenewsnetwork.org/resources/whats\\_a\\_genome/Chp1\\_4\\_1.shtml](http://www.genomenewsnetwork.org/resources/whats_a_genome/Chp1_4_1.shtml) (last visited Aug. 21, 2020). DNA is composed of smaller units—nucleotides—that are “strung together in a row.” *Id.* Genes are composed of varying lengths of DNA that code for one protein; a protein is the building block of muscles and tissues, and they also produce enzymes, which carry out chemical processes in the body. The twenty-three pairs of chromosomes that each human has are composed of tens of thousands of genes. Finally, the genome is an organism’s complete DNA. *See Mapping the Genome*, INTERESTING FACT OF THE DAY BLOG (Aug. 30, 2017), <https://www.theifod.com/mapping-the-genome/>.
15. Hannah R. Kempton & Lei S. Qi, *When Genome Editing Goes Off-Target*, 364 SCI. 234, 234 (2019).

However, notwithstanding its increasing utility, the technology may still result in off-target mutations. Mutations can lead the gene either to not function at all or to function improperly,<sup>16</sup> which occurred with earlier gene therapy experiments.<sup>17</sup> With off-target mutations, the edits could occur within the wrong part of the gene (or regulatory components of the gene) or outside of the gene, potentially in other genes. Because such off-target mutations have unintended consequences (for both research and clinical applications), scientists are developing different techniques to evaluate when the technology goes “off-target” and makes a modification other than in the targeted gene.<sup>18</sup> There are other risks as well.<sup>19</sup>

Nonetheless, CRISPR-Cas9 has multiple uses in addition to its role in basic research in disease prevention. It is also useful in two clinical contexts for the prevention or treatment of disease: somatic cells (such as skin, liver, lung, heart cells, and blood), which affect only the individual involved (and are not involved in reproduction)<sup>20</sup> and reproductive, or germ, cells<sup>21</sup> (sperm and eggs in humans), which impact not just the resulting baby, but also may

16. Kendall Lovell, Note, *Crispr/Cas-9 Technologies: A Call for A New Form of Tort*, 19 SAN DIEGO INT’L L.J. 407, 412 (2018).
17. This is where gene therapy went wrong, with some of the trials to treat an immune deficiency issue that resulted in leukemia in some of the children. See Sonia Suter, *The ‘Repugnance’ Lens of Gonzales v. Carhart and Other Theories of Reproducing Rights: Evaluating Advanced Reproductive Technologies*, 76 GEO. WASH. L. REV. 1514, 1538 (2008); see generally D.B. Kohn et al., *Occurrence of Leukaemia Following Gene Therapy of X-Linked SCID*, 3 NATURE REV. CANCER 877 (2003), <https://www.ncbi.nlm.nih.gov/pubmed/12835668>.
18. Kempton & Lei, *supra* note 15; Beeke Wienert et al., *Unbiased Detection of CRISPR Off-Targets In Vivo Using DISCOVER-Seq*, 364 SCI. 286, 286 (2019).
19. Additional harms include: “the inappropriate activation of cancer-causing genes, and the rearrangement of chromosomes. Additionally, there are the risks of on-target changes with unintended consequences, the creation of mosaics of altered and unaltered cells, and the introduction of changes that generate an immune response. In addition to these potential medical harms, there are also potential social harms.” Françoise Baylis, *Counterpoint: The Potential Harms of Human Gene Editing Using CRISPR-Cas9*, 64 CLINICAL CHEMISTRY 489, 489 (2018), <http://clinchem.aaccjnls.org/content/64/3/489>. For further discussion of “off-target effects; see Adam P. Cribbs & Sumeth M.W. Perera, *Science and Bioethics of CRISPR-Cas9 Gene Editing: An Analysis Towards Separating Facts and Fiction*, 90 YALE J. BIOL. MED. 625, 627 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5733851/>; see also Katherine Drabiak, *Untangling the Promises of Human Genome Editing*, 46 J. L. MED. & ETHICS 991, 991 (2018) (noting the technology’s risks and raising questions about its efficiency).
20. Mildred Z. Solomon, *Gene Editing Humans: It’s Not Just About Safety*, SCI. AM. (Aug. 20, 2019), <https://blogs.scientificamerican.com/observations/gene-editing-humans-its-not-just-about-safety/>.

affect that baby's future offspring.<sup>22</sup> The technology is relatively uncontroversial in contexts when it treats disease and affects only the specific individual involved, with the National Academy of Science concluding, in 2017, that "basic research involving both somatic and germline cells is essential to the advancement of science and should continue with existing regulatory structures."<sup>23</sup> Clinical trials in the United States are underway, with CRISPR-Cas9 being used, for example, in somatic cells for cancer treatments.<sup>24</sup>

CRISPR-Cas9 becomes controversial when it is used for *enhancements* of somatic cells (as opposed to remedying or rectifying disease genes), and in the second category, used to affect reproductive material.<sup>25</sup> Scholars and researchers have raised a variety of objections, ranging from the fear of designer babies to concerns about the riskiness of the technology. These

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21. Germ cells then constitute the germ line. *Germ Line*, NAT'L HUMAN GENOME RES. INST., <https://www.genome.gov/genetics-glossary/germ-line> (last visited Aug. 16, 2020).
  22. Solomon, *supra* note 20.
  23. NAT'L ACADS. OF SCIS., ENG'G, & MED., HUMAN GENOME EDITING: SCIENCE, ETHICS, & GOVERNANCE 2 (2017) [hereinafter HUMAN GENOME EDITING]. The Committee did conclude, with respect to the second category, "that somatic genome editing for purposes other than treatment or prevention of disease and disability should not proceed at this time." *Id.* at 3. Yet "perhaps the theoretically sharp distinction between germline modification and somatic cell editing is somewhat idealistic." Alexandra L. Foulkes et al., *Legal and Ethical Implications of CRISPR Applications in Psychiatry*, 97 N.C. L. REV. 1359, 1394 (2019). An alternative means of classifying gene editing is by function, such as whether it is "therapeutic," designed to "treat or prevent diseases[ ] or enhancement and heritability involving somatic or germline cells." Cribbs & Perera, *supra* note 19, at 629.
  24. E.g., Kat Eschner, *CRISPR is Now Being Used on Humans in the U.S.*, POPULAR SCI. (Apr. 17, 2019), <https://www.popsci.com/crispr-cancer-immunotherapy-pennsylvania/>; HUMAN GENOME EDITING, *supra* note 23, at 92–93 (Table 4-1); Lila Thulin, *Four U.S. CRISPR Trials Editing Human DNA to Research New Treatments*, SMITHSONIAN (Sept. 3 2019), <https://www.smithsonianmag.com/science-nature/four-us-crispr-trials-editing-human-dna-for-new-medical-treatments-180973029/#J9AsVZ3E8DEGFDfo.99>. These clinical trials in cancer research suggest gene editing seems safe. Shaoni Bhattacharya, *Genome Editing Seems Safe Suggests First Study in US Patients*, BioNews (Nov. 11, 2019), [https://www.bionews.org.uk/page\\_146147](https://www.bionews.org.uk/page_146147).
  25. See, e.g., KERRY LYNN MACINTOSH, ENHANCED BEINGS: HUMAN GERMLINE MODIFICATION AND THE LAW 1 (2018) (discussing some of the main objections). Internationally, the World Health Organization has stated "'it would be irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing.'" *Statement on Governance and Oversight of Human Genome Editing*, WORLD HEALTH ORG. (July 26, 2019), <https://www.who.int/news-room/detail/26-07-2019-statement-on-governance-and-oversight-of-human-genome-editing>.

objections include: (1) the “hubris” problem, which is based on a belief that using gene editing transgresses ethical boundaries by interfering in life creation<sup>26</sup>; (2) “the manufacture objection,” that gene editing makes reproduction into a design process,<sup>27</sup> which creates babies with specific qualities, such as enhanced intelligence; (3) the stratification objection, that gene editing will result in further economic inequality, with serious concerns about equitable access to any kind of gene editing therapies, somatic or germline<sup>28</sup>; (4) “the apocalypse objection,” through which the offspring of gene editing will bring about socially disastrous outcome<sup>29</sup>; (5) the embryo-risk problem because gene editing is dangerous and may destroy embryos<sup>30</sup>; and (6) the “ignorance” problem because much is unknown about how genes affect disease.<sup>31</sup> Each of these also has strong counterarguments; for example, intelligence does not depend on one single gene but is also related to interaction with the environment.<sup>32</sup>

Yet CRISPR-Cas9 is moving forward, and it is available, regardless of legal regulation or prohibitions in the United States, whether through a black market or through fertility tourism.<sup>33</sup> While it is premature to predict whether

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26. MACINTOSH, *supra* note 25, at 30–38.

27. *Id.* at 39–47. Philosopher Michael Sandel identified the danger of “hyper-agency—a Promethian aspiration to remake nature [ ] to serve our purposes and satisfy our desires,” which includes these first two objections. Michael J. Sandel, *The Case Against Perfection*, ATLANTIC (Apr. 2004), <https://www.theatlantic.com/magazine/archive/2004/04/the-case-against-perfection/302927/>.

28. Clara C. Hildebrandt & Jonathan M. Marron, *Justice in CRISPR/Cas9 Research and Clinical Applications*, 20 AM. MED. ASS’N J. ETHICS 826, 827 (2018) (detailing such barriers, including mistrust of research, underrepresentation in research participation, and unequal access to the benefits of research).

29. MACINTOSH, *supra* note 25, at 42.

30. *Id.* at 4. Although MacIntosh notes that this danger is inherent to any form of embryo manipulation, it is, the author believes, particularly important to CRISPR-Cas9, because the technology still has so many unknown risks.

31. Tanya Lewis, *Scientists Seek Better Guidelines for Editing Genes in Human Embryos*, SCI. AM. (Aug. 15, 2019), <https://www.scientificamerican.com/article/scientists-seek-better-guidelines-for-editing-genes-in-human-embryos/> (“not a single complex disease or trait is completely understood”).

32. E.g., Mahoney & Siegal, *supra* note 9, at 203–10; *see generally* Kerry Lynn MacIntosh, *Heritable Genome Editing and the Downsides of a Global Moratorium*, 2 CRISPR J. 272 (2019), <https://www.liebertpub.com/doi/10.1089/crispr.2019.0016>.

33. The Second International Summit on Human Genome Editing in 2018 recognized the risks in permitting germline editing, but also noted that: “[p]rogress over the last three years and the discussions at the current summit, however, suggest that it is time to define a rigorous, responsible translational pathway toward such trials.” *On Human Genome Editing II: Statement by the Organizing Committee of the Second International Summit on Human Genome Editing*,

it will be of widespread or even any practical utility, much less capable of genetic enhancements,<sup>34</sup> CRISPR and similar germline editing technologies have arrived and are becoming increasingly sophisticated.<sup>35</sup>

For parents, the possible use of CRISPR-Cas9 poses a set of distinct issues. There are ample ethical and moral issues as well as legal pragmatic concerns: how does the law allocate decisionmaking to potential parents about their potential children? Assuming parents can proceed, how can the informed consent process improve their decision? What are the potential consequences for the resulting children, and what rights might those children have against the parents or the physician?

## II. CAN THEY? PARENTS' CHOICES AND LEGAL RIGHTS

CRISPR is relevant at various distinct time frames for potential (and actual) parents, including decision-making prior to conception, post-conception and prior to birth, and post-birth.<sup>36</sup> As a general matter, parents are le-

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NAT'L ACADS. SCIS., ENG'G, MED. (Nov. 28, 2018), <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11282018b>. To be sure, scientists have repeatedly called for a moratorium, while others advise planning for responsible use. *See, e.g.*, Heidi Ledford, *CRISPR Babies: When Will the World Be Ready?*, NATURE (June 19, 2019), <https://www.nature.com/articles/d41586-019-01906-z>; Eric S. Lander et al., *Adopt a Moratorium on Heritable Genome Editing*, NATURE (Mar. 13, 2019), <https://www.nature.com/articles/d41586-019-00726-5>; Landon J. Getz & Graham Dellaire, *Moratorium on Human Genome Editing: Time to Get it Right*, HASTINGS CTR. (Mar. 29, 2019), <https://www.thehastingscenter.org/moratorium-on-human-genome-editing-time-to-get-it-right/>; *but see* Eli Y. Adashi & Glenn Cohen, *Heritable Genome Editing: Is a Moratorium Needed?*, JAMA FORUM (2019), <https://jamanetwork.com/journals/jama/fullarticle/2737667> (noting “the widely feared prospect of human reproductive cloning which, contrary to predictions, has not materialized in the absence of statutory or regulatory measures intended to prohibit it”). For speculation on the future of the business development of CRISPR, see June Carbone, *CRISPR and the Future of Fertility Innovation*, 23 SMU SCI. & TECH. L. REV. (forthcoming 2020).

34. *See* Hank Greely, *Human Germline Genome Editing: An Assessment*, 2 CRISPR J. 253, 253 (2019).
35. Emma Yasinski, *New “Prime Editing” Method Makes Only Single-Stranded DNA Cuts*, THE SCIENTIST (Oct. 21, 2019), <https://www.the-scientist.com/news-opinion/new-prime-editing-method-makes-only-single-stranded-dna-cuts-66608> (reporting on prime editing).
36. This discussion does not address whether there is a fundamental right to use the technologies. *See* Paul Enriquez, *Editing Humanity: On the Precise Manipulation of DNA in Human Embryos*, 97 N.C. L. REV. 1147, 1162 (2019) (“permanent legislative or administrative bans [ ] cannot withstand constitutional scrutiny and . . . impinge on a cognizable fundamental right that protects select uses of [germline genome editing]. This fundamental right flows from jurisprudence in the areas of procreative, parental, and—to some extent—privacy



gally entitled to deference in their decisions about their children's upbringing and care.<sup>37</sup>

This section discusses the types of decisions parents may need to make, including benefits and risks, and then reviews the legal framework for that decisionmaking.

### A. Parental Decisions

When parents use *in vitro* fertilization (IVF), they already have a full range of choices through pre-implantation genetic testing techniques to implant embryos with certain characteristics.<sup>38</sup> CRISPR can go one step further, and repair genetic mutations in embryos, as scientists reported in 2017, when they were able to use CRISPR-Cas9 to cut out a mutated DNA sequences that causes cardiomyopathy, a disease that leads to heart failure.<sup>39</sup> As a result of the procedure, not just that particular embryo, but also any future generations, would not carry that mutation.<sup>40</sup> Although this was a clinical experiment and the embryos were not then implanted, the technology raises the possibility and hope for parents that gene editing can be used to prevent a variety of hereditary conditions.<sup>41</sup> It could create healthier embryos for *in vitro* fertilization, thereby reducing the number of IVF cycles (because each

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rights"); Tandice Ossareh, Note, *Would You Like Blue Eyes with That? A Fundamental Right to Genetic Modification of Embryos*, 117 COLUM. L. REV. 729, 737 (2017) ("parental and procreative rights . . . serve as the justification for an assertion of a fundamental right to genetic modification").

37. See June Carbone, *Legal Applications of the "Best Interest of the Child" Standard: Judicial Rationalization or a Measure of Institutional Competence?*, 134 PEDIATRICS S111 (2014), [https://pediatrics.aappublications.org/content/pediatrics/134/Supplement\\_2/S111.full.pdf](https://pediatrics.aappublications.org/content/pediatrics/134/Supplement_2/S111.full.pdf).

38. These include dwarfism and deafness. Parents have full range of choices, which can include those we typically think of as being in the best interest of the future child (selection for health) and not as clearly in the best interest (selection for "disease" or disability). See Joseph Stramondo, *Disabled by Design: Justifying and Limiting Parental Authority to Choose Future Children with Pre-Implantation Genetic Diagnosis* 27 KENNEDY INST. ETHICS J. 475, 487, 491 (2017), [https://kiej.georgetown.edu/wordpress/wp-content/uploads/2015/09/03\\_27.4stramondo.pdf](https://kiej.georgetown.edu/wordpress/wp-content/uploads/2015/09/03_27.4stramondo.pdf) (discussing situations in which parents may select an embryo with a certain gene such as achondroplasia, the most common form of dwarfism).

39. Pam Belluck, *In Breakthrough, Scientists Edit a Dangerous Mutation From Genes in Human Embryos*, N.Y. TIMES (Aug. 2, 2017), <https://www.nytimes.com/2017/08/02/science/gene-editing-human-embryos.html>.

40. See *id.*

41. *Id.*

cycle is more likely to result in a live birth), or be useful when screening embryos is not an option.<sup>42</sup>

Then, in 2018, there were reports of the first gene-edited babies.<sup>43</sup> He Jiankui announced the birth of gene-edited twin girls, Lulu and Nana.<sup>44</sup> He had recruited seven couples, in each of which the intended father had HIV, for an experiment involving in vitro fertilization.<sup>45</sup> As part of the research, He Jiankui edited the embryos' genes in order to increase the embryos' resistance to the virus.<sup>46</sup> The 23-page informed consent form given to the parents referred to an "AIDS vaccine development project."<sup>47</sup> It included various provisions relating to the medical procedures as well as trade secrets and publicity for the experiment.<sup>48</sup> As a result of this research, He Jiankui was fired by his university for violating Chinese regulations on using gene-editing in conjunction with reproduction.<sup>49</sup> And, in late 2019, a Russian biologist was reported to be engaging in experiments with human eggs to edit the gene

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42. *Id.*

43. Jon Cohen, *The Untold Story of the 'Circle of Trust' Behind the World's First Gene-Edited Babies*, SCI. MAG. (Aug. 1, 2019), <https://www.sciencemag.org/news/2019/08/untold-story-circle-trust-behind-world-s-first-gene-edited-babies>.

44. *Id.*; see Billauer, *Wrongful Life in the Age of CRISPR-CAS*, *supra* note 5, at 437.

45. Mara Hvistendahl, *China's Bioethics Struggles Enter the Spotlight*, SLATE (Nov. 27, 2018, 2:42 PM), <https://slate.com/technology/2018/11/he-jiankui-crispr-babies-informed-consent-china-science.html>.

46. *Id.*

47. *Informed Consent*, SCI. MAG., [https://www.sciencemag.org/sites/default/files/crispr\\_informed-consent.pdf](https://www.sciencemag.org/sites/default/files/crispr_informed-consent.pdf); Hvistendahl, *supra* note 45.

48. "Regarding the project results, only the project team has the right of final explanation and announcement to the public. The volunteers have no right to explain, publish, or announce project related information without permission." *Informed Consent*, *supra* note 47. "[I]t spends more time on who controls baby pictures than on risks." Arthur Caplan, *He Jiankui's Moral Mess*, PLOS BLOGS (Dec. 3, 2018), <https://blogs.plos.org/biologue/2018/12/03/he-jiankuis-moral-mess/>. As one bioethicist commented, it seemed more like a "business form." See Ed Yong, *The CRISPR Baby Scandal Gets Worse by the Day*, ATLANTIC (Dec. 3, 2018), <https://www.theatlantic.com/science/archive/2018/12/15-worrying-things-about-crispr-babies-scandal/577234/>.

49. David Cyranoski, *CRISPR-Baby Scientist Fired by University*, NATURE (Jan. 22, 2019), <https://www.nature.com/articles/d41586-019-00246-2>.

associated with deafness.<sup>50</sup> Such reports reinforce the potential availability of gene-editing, showing it is not the work of one “lone rogue.”<sup>51</sup>

At this point, the experiments are all privately funded.<sup>52</sup> Congress has not only prohibited the Food and Drug Administration from considering clinical trials that involve germline manipulation, but has also barred the National Institutes of Health from funding any type of gene-editing research in human embryos.<sup>53</sup> Moreover, the technique is still not entirely successful in each of the embryos in which it has been tried.<sup>54</sup> And then there are concerns about long-term consequences to the health of any child born through this technique, consequences that must only be imagined until these children mature and have their own offspring.<sup>55</sup> For example, He Jiankui’s efforts may have resulted in “off-target” changes that appear elsewhere in the girls’ genomes.<sup>56</sup>

As one scientist explains, there is always the possibility that either we miss something or our technology cannot pick up on other changes that have been made that have not been directed by us. And the fear then is that those changes lead to antibiotic resistance or other mutations that go out into the population and would be very difficult to control.<sup>57</sup>

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50. Emily Makowski, *Deafness Gene GJB2 Edited in Human Eggs*, THE SCIENTIST (Oct. 18, 2019), <https://www.the-scientist.com/news-opinion/> (search in search bar for “Deafness gene”; then follow the “Deafness Gene GJB2 Edited in Human Eggs”).
  51. *Act Now on CRISPR Babies*, NATURE (June 11, 2019), <https://www.nature.com/articles/d41586-019-01786-3>; see *id.*
  52. See generally Carbone, *supra* note 33.
  53. Belluck, *supra* note 39; see I. Glenn Cohen & Eli Adashi, *The FDA is Prohibited from Going Germline*, 353 SCI. MAG. 545, 545 (2016), <https://science.sciencemag.org/content/353/6299/545>; I. Glenn Cohen, *How Scott Gottlieb is Wrong on the Gene Edited Baby Debacle*, BILL OF HEALTH (Nov. 29, 2018), <https://blog.petrieflom.law.harvard.edu/2018/11/29/how-scott-gottlieb-is-wrong-on-the-gene-edited-baby-debacle/>; see Myrisha S. Lewis, *Halted Innovation: The Expansion of Federal Jurisdiction over Medicine and the Human Body*, 2018 UTAH L. REV. 1073, 1120 (2018).
  54. Jason Glanzer, Note, *The Human Germline Modification Index: An International Risk Assessment for the Production of Genetically Modified Humans*, 9 CREIGHTON INT’L & COMP. L.J. 68, 71 (2017).
  55. *E.g., id.* at 72 (arguing that even if the first generation of CRISPR-Cas9 children did not have noticeable differences from the general population or any genetic diseases, the long-term consequences are “murky” and likely dangerous because of the aggregate impact).
  56. Jon Cohen, *Did CRISPR Help—Or Harm—The First-Ever Gene Edited Babies?*, SCI. MAG. (Aug. 1, 2019), <https://www.sciencemag.org/news/2019/08/did-crispr-help-or-harm-first-ever-gene-edited-babies>.
  57. Greg Licholai, *Is CRISPR Worth the Risk?*, YALE INSIGHTS (Aug. 21, 2018), <https://insights.som.yale.edu/insights/is-crispr-worth-the-risk>.

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**B. Legal Framework: Parents' Rights, Abuse and Neglect**

Conventionally, each member of the family, child, and state triad holds separate, potentially competing rights, or, in the Supreme Court's jurisprudence, this is a dyad, with parent/child v. state.<sup>58</sup> When children are young, their rights have less strength than those of the parents.<sup>59</sup>

Parents are presumed to act in their children's best interest; there is a huge gap between best interests and neglect or abuse, which is the standard for legal interventions at which the parents' basic rights become attenuated.<sup>60</sup> At that point, the state can remove children from their parents, require some form of schooling, or establish a minimum work age for children.<sup>61</sup> Even when it comes to children's rights to receive adequate services to prevent abuse and neglect by family members, courts have generally deferred to and reinforced the state's decision-making process over children's rights to independent claims.<sup>62</sup>

When parents engage in decisionmaking for their children, the law provides great deference, intervening only at the point of abuse or neglect.<sup>63</sup> Thus, children are legally incapacitated, for example, to enter into their own contracts.<sup>64</sup>

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58. See, e.g., *DeShaney v. Winnebago Cty. Dep't of Soc. Servs.*, 489 U.S. 189, 203 (1989); see also Naomi Cahn, *The New Kinship*, 100 GEO. L.J. 367, 397–398 (2012).

59. See Cahn, *supra* note 58, at 397. Note that this framework is predicated on potential conflicts among the different entities, assuming that interests are unitary and unchanging, contrary to the reality of donor families.

60. *Id.* at 396.

61. Naomi Cahn, *State Representation of Children's Interests*, 40 FAM. L.Q. 109, 111–12 (2006).

62. In *DeShaney*, the Court held that “the State had no constitutional duty to protect Joshua [the child plaintiff] against his father's violence.” *DeShaney*, 489 U.S. at 202. *Marshall v. Montgomery Cty. Children Servs. Bd.*, 750 N.E.2d 549, 553 (Ohio 2001) (holding that even if the social services department had failed to investigate a report of the child's potential abuse, sovereign immunity barred the claim). This and similar cases are discussed in DOUGLAS ABRAMS ET AL., *CHILDREN AND THE LAW* 90 (6th ed. 2018).

63. See *Hodgson v. Minnesota*, 497 U.S. 417, 447 (1990) (parents have the right to raise their child “free from undue state interference”). While parents have historically had “broad authority over a child's upbringing, which included the authority to make medical decisions for a child[, t]his authority is not absolute. The state may override a parent's decision when necessary to protect the child from harm.” RESTATEMENT OF CHILDREN AND THE LAW § 2.30 cmt. A (AM. LAW INST., Tentative Draft No. 1, 2018).

64. Natalie Banta & Naomi R. Cahn, *Digital Asset Planning for Minors*, 33 PROB. & PROP. 44, 46 (2019). Under common law, minors generally have a right to enter into contracts but may later disaffirm a contract using the infancy doc-

Constitutional protection for the family began somewhat sideways, with dicta in early twentieth-century cases concerning due process, and in later cases concerning privacy rights between adult partners.<sup>65</sup> The Court first recognized a parent's right to direct their child's upbringing in *Meyer v. Nebraska*<sup>66</sup> and *Pierce v. Society of Sisters*,<sup>67</sup> while the privacy of the marital relationship—and the ability to use contraception—was not recognized until 1965 in *Griswold v. Connecticut*.<sup>68</sup> This line of cases was followed by expansion of the contraceptive right to individuals in *Eisenstadt v. Baird*<sup>69</sup> in 1972, and the recognition of a right to abortion in *Roe v. Wade*<sup>70</sup> the following year.

The Court in *Meyer* held that a state statute that banned the teaching of a foreign language other than English before students reached the eighth grade violated the Due Process Clause of the Fourteenth Amendment.<sup>71</sup> Two years later in *Pierce*, the Court struck down a statute that compelled parents to send their children to public school, as opposed to private school, until age sixteen.<sup>72</sup> It held that “[the] child is not the mere creature of the State; those who nurture him and direct his destiny have the right, coupled with the high duty, to recognize and prepare him for additional obligations.”<sup>73</sup>

In *Wisconsin v. Yoder*, the next major case addressing parental rights, the Court permitted members of the Old Order Amish to withdraw their children from school after eighth grade, notwithstanding a state law requirement that children remain in school, or receive comparable schooling at home, until they turned sixteen.<sup>74</sup> The Court noted: “This primary role of the parents in the upbringing of their children is now established beyond debate as an

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trine. The infancy doctrine aims to protect minors from their own foolishness in entering into an exploitative contract by allowing a minor to void or disaffirm the contract (although it requires a minor to return the benefit of a contract in order to disaffirm it). Natalie Banta, *Minors and Digital Asset Succession*, 104 IOWA L. REV. 1699, 1711 (2019).

65. See cases cited *infra* notes 66–78.

66. See 262 U.S. 390, 399, 402–03 (1923) (right of teacher to instruct child in foreign language, based on liberty protection derived from the Fourteenth Amendment).

67. 268 U.S. 510, 534–35 (1925) (dicta in case involving private school that recognized the parents' rights to choose how to educate their children); see Cahn, *supra* note 58, at 429.

68. 381 U.S. 479, 485 (1965).

69. See 405 U.S. 438, 443 (1972).

70. See 410 U.S. 113 (1973).

71. See *Meyer*, 262 U.S. at 402.

72. See *Pierce*, 268 U.S. at 510.

73. *Id.* at 535.

74. *Wisconsin v. Yoder*, 406 U.S. 205, 234 (1972).

enduring American tradition.”<sup>75</sup> The parents had argued that their children’s attendance at high school was contrary to the Amish religion and way of life, so forcing high school attendance interfered with their parental right to raise their children as they saw fit.<sup>76</sup> In *Troxel v. Granville*, the Supreme Court reiterated that parents have a basic right to raise their children, and that the decisions of fit parents should receive “special weight.”<sup>77</sup> Four years later, in *Elk Grove Unified School District v. Newdow*, involving divorced parents, the Court reiterated the presumption of deference to parents’ decisionmaking.<sup>78</sup>

Throughout these cases, the Court has largely reinforced the notion that children are most appropriately protected by their parents. Indeed, the Court has tended to assume children’s interests are adequately recognized and asserted by their fit parents, and so these doctrines protect children derivatively through the concepts of parental autonomy and familial privacy. As a result, parents are constitutionally entitled to substantial deference as to choices concerning their children’s upbringing, without “undue” intervention by the state.<sup>79</sup> This right is, in turn, reflected in state abuse and neglect statutes.<sup>80</sup>

When it comes to medical decisionmaking, in *Parham v. J.R.*, the Court reiterated a parent’s liberty interests to determine what was best for their child.<sup>81</sup> The Court in *Parham*, which involved a voluntary commitment proceeding, observed that the parents are presumed to act in their child’s best interest, and parents should take a “substantial, if not the dominant, role in the decision, absent a finding of neglect or abuse.”<sup>82</sup> Further, it held that the state cannot override a parent’s decision just because a child disagrees with it

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75. *Id.* at 232.

76. *Id.* at 209.

77. *Troxel v. Granville*, 530 U.S. 57, 70 (2000).

78. The Court deferred to a state’s right to define parental authority: “Animated by a conception of ‘family privacy’ that includes ‘not simply a policy of minimum state intervention but also a presumption of parental autonomy,’ the state cases create a zone of private authority within which each parent, whether custodial or noncustodial, remains free to impart to the child his or her religious perspective.” *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 16 (2004).

79. RESTATEMENT OF CHILDREN AND THE LAW, *supra* note 63, at ch. 3, Introd. Note.

80. “In a civil child-protection proceeding, a court may find a child has been physically abused if (1) a parent, guardian, or custodian inflicts serious physical harm on a child, or creates a substantial risk of serious physical harm to a child, in a manner that substantially deviates from the standard of care exercised by a reasonable parent.” *Id.* § 3.20 (requiring a finding of both “serious” harm and deviation from the standard of care).

81. *Parham v. J.R.*, 442 U.S. 584, 604 (1979).

82. *Id.*

or “it involves risks.”<sup>83</sup> Thus, when it comes to commitment of a child in a mental institution, parents “retain a substantial, if not the dominant, role in the decision, absent a finding of neglect or abuse.”<sup>84</sup>

Indeed, even though parents will ordinarily provide their children with medical care, there is no legal requirement to do so unless it is “necessary to prevent serious harm or a substantial risk of serious harm.”<sup>85</sup> Parental decisionmaking may even be entitled to deference where there is a substantial risk that the child’s health will be seriously harmed by a particular type of care where, for example, a doctor who recommended such treatment could not be subjected to liability for malpractice for that recommendation, or where the treatment itself could seriously impact the child’s health.<sup>86</sup> When parents have refused treatment, states have considered the parameters of deference.<sup>87</sup>

Thus, for health care decisions, assuming that the parents have received appropriate information about their child’s medical situation, possible treatments, and prognosis, the “courts will generally defer to parental discretion in determining what is in the best interest of their child, even if it is not exactly in accord with current medical standards.”<sup>88</sup> On the other hand, when

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83. *Id.* at 603; *see* Enriquez, *supra* note 36, at 1209–10.

84. *Parham*, 442 U.S. at 604.

85. RESTATEMENT OF CHILDREN AND THE LAW, *supra* note 63, § 2.30 cmt. c.

86. *Id.* Correspondingly, “medical neglect” occurs when the parent engages in an “unreasonable failure or refusal” to provide the care “necessary to prevent serious harm or a substantial risk of serious harm to the child’s physical or mental health.” *Id.* § 3.26. The measure of whether the failure is “unreasonable” is its deviation from the standard of care. *Id.* § 3.26(b). The state may seek an order to mandate the treatment of the appointment of a guardian who can make medical decisions on behalf of the child. *Id.*

87. “It is also well settled that the state may order medical treatment for a non-life threatening condition, notwithstanding the objection of the parents on religious grounds, if the treatment will, in all likelihood, temporarily or permanently solve a substantial medical problem. [ ] There are exceptions to the rule. For instance, courts have held that a state cannot order that a child receive medical treatment over religious objections of the parents when the treatment itself is very risky, extremely invasive, toxic with many side effects, and/or offers a low chance of success.” *In re D.R.*, 20 P.3d 166, 169–70 (Okla. Civ. App. 2001); *cf.* *Newmark v. Williams*, 588 A.2d 1108, 1114–15 (Del. 1991) (parents’ refusal of cancer treatment for three-year-old child was upheld when treatment had only a forty-percent chance of cure, was also highly invasive, painful, with temporary and permanent serious side effects).

88. Elana Bengualid, *The Futility of Futility: An Analysis of the Charlie Gard Case Within the Framework of U.S. Law*, 40 CARDOZO L. REV. 463, 469–70 (2018). Parents’ decisions to subject their child to medical treatment that is potentially life-threatening, painful, or debilitating and that might not be successful in prolonging the child’s life is an emotionally complex process. *In re S.H.*, 2013-

it comes to novel or experimental treatments, this formulation is a little more complex, “as the cost-benefit analysis can be unknown due to inadequate testing.”<sup>89</sup> In light of parents’ recognized rights regarding the care of their children, the expectation is that even if “the potential benefits of the treatment are unclear, or are outweighed by substantial possibility of harm,” parents should still retain “the right to determine which course of treatment is in the infant’s best interest.”<sup>90</sup>

Because children are legally incapable of consenting to medical care, the parents are—in most circumstances<sup>91</sup>—responsible for providing the requisite informed consent.<sup>92</sup> It is typically the child’s “legal status as a ‘child’ that overrides all other potentially relevant individualized factors, like the actual age, maturity, or dependency of the particular child.”<sup>93</sup> Yet, a child does have distinct rights on their own, and there are arguments that CRISPR (or other forms of germline editing) might promote a child’s right to health.<sup>94</sup> The parent, however, makes the ultimate determination, subject to charges of civil or medical neglect.

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Ohio-4380, ¶ 6. Any such medical decision “must be made on the basis of individual values, informed by medical realities, yet within a framework governed by the law. The role of the courts is confined to determining the framework, delineating the ways in which the government may and may not participate in such decisions.” *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 303 (1990) (Brennan, J., dissenting).

89. Bengualid, *supra* note 88, at 469.

90. *Id.*

91. Those under the age of 18 do have authority in some circumstances, such as those relating to contraception. An Overview of Consent to Reproductive Health Services by Young People, GUTTMACHER INST., <https://www.guttmacher.org/state-policy/explore/overview-minors-consent-law#> (last updated Aug. 1, 2020).

92. B. Jessie Hill, *Constituting Children’s Bodily Integrity*, 64 DUKE L.J. 1295, 1309 (2015). “The right of children to bodily integrity is only partially constitutionalized. It has been recognized in some contexts, such as abuse by state actors and access to abortion. In other contexts—such as corporal punishment by parents, medical treatment, and nontherapeutic interventions—it has largely been ignored.” *Id.* at 1315.

93. Anne C. Dailey & Laura A. Rosenbury, *The New Law of the Child*, 127 YALE L.J. 1448, 1475 (2018); see RESTATEMENT OF THE LAW, CHILDREN AND THE LAW, ch. 1, § 1.30, at xvii (Preliminary Draft No. 5, Sept. 5, 2018). A child does not need necessarily parental consent for all medical treatment. *E.g.*, Paul Jerome McLaughlin Jr., *Can They Do That?: The Limits of Governmental Power over Medical Treatment*, 37 J. LEGAL MED. 371, 382 (2017) (listing venereal diseases). Abortion is complicated. See *Planned Parenthood of South-eastern Pennsylvania v. Casey*, 505 U.S. 833, 839 (1992).

94. Bartha Maria Knoppers & Erika Kleiderman, *Heritable Genome Editing: Who Speaks for “Future” Children?*, 2 CRISPR J. 285, 285 (2019).



Moreover, parents may feel various pressures to provide the best genetic future they can for their child.<sup>95</sup> Even if the process starts slowly, with just a few parents making a few cautious choices, these decisions are likely to have an impact on other parents, who may then feel obligated to use the new technology to promote their children's health.<sup>96</sup> Relatedly, the line between what is unusual or labelled as enhancement versus what is customary and normal treatment may not be as rigid as the parents would like.<sup>97</sup>

95. See Johnston, *supra* note 3; Jack Wilkinson et al., *Do à la carte Menus Serve Infertility Patients? The Ethics and Regulation of In Vitro Fertility Add-ons*, 112 FERTILITY & STERILITY 973, 973–74, [https://www.fertstert.org/article/S0015-0282\(19\)32454-9/fulltext](https://www.fertstert.org/article/S0015-0282(19)32454-9/fulltext). This raises what MacIntosh labels the stratification objection. See MACINTOSH, *supra* note 25. The perpetuation of economic inequality, with some parents able to choose CRISPR-Cas9 and others unable to do so, has parallels with respect to other resources that parents provide their children. See JUNE CARBONE & NAOMI CAHN, MARRIAGE MARKETS: HOW INEQUALITY IS REMAKING THE AMERICAN FAMILY 9, 158 (2014); see generally DANIEL MARKOVITS, THE MERITOCRACY TRAP: HOW AMERICA'S FOUNDATIONAL MYTH FEEDS INEQUALITY, DISMANTLES THE MIDDLE CLASS, AND DEVOURS THE ELITE (2019).
96. Nicole A. Vincent & Emma Jane, *Parental Responsibility and Gene Editing, in HUMAN FLOURISHING IN AN AGE OF GENE EDITING*, *supra* note 3, at 126, 129. Johnston suggests “opportunities” may become “obligations.” Johnston, *supra* note 3, at 112. Vincent and Jane predict other effects, such as the potential marginalization of children whose parents did not engage in the screening and intervention, and thus they do not excel in competition, or they get sick. Vincent & Jane, *supra*, at 130; see Sonia Suter, *The Routinization of Prenatal Testing*, 28 AM. J.L. & MED. 233, 242 (2002) (discussing such pressure with respect to prenatal testing based on empirical studies and her own experience as a genetic counselor). Vincent and Jane are also skeptical that gene editing, even if it leads to less genetically-based diseases, will result in improved human flourishing. Vincent & Jane, *supra*, at 131, 132. This argument draws on a strong strand in the disability literature about respecting those with disabilities rather than assuming that they live in “an unhappy place.” Elizabeth F. Emens, *Framing Disability*, 2012 U. ILL. L. REV. 1383, 1386 (2012). That is, there is a “disability paradox,” in which the expectations are that people with disabilities have a low quality of life, when that is untrue. Gary L. Albrecht & Patrick J. Devlieger, *The Disability Paradox: High Quality of Life Against All Odds*, 48 SOCIAL SCI. & MED. 977, 977 (1999). By holding out a promise of reducing disability, CRISPR-Cas9 perpetuates a belief that disabilities are to be avoided. See Jon Cohen, *Parents Weigh Promise and Risks of Germline Editing*, SCI. MAG. (Nov. 1, 2019), <https://science.sciencemag.org/content/366/6465/564>.
97. Vincent & Jane, *supra* note 96, at 134. They give the example of therapies in the form of analgesics; in a society where these did not exist, the ability to live without headaches might be viewed as an enhancement, while in a society where they are ubiquitous, they are seen as treatments. *Id.* By contrast, Sonia Suter suggests that this formulation is “a bit problematic,” because, “[i]n this context, what I think people mean by enhancement is trying to improve ‘normal species functioning’ (by increasing things like intelligence or height) as

Different questions concern a parent's right to make decisions with respect to their fetus or gametes. Consider that the tort of wrongful birth provides rights to the parents for the negligence of the medical care provider, such as failure to give the parents adequate information about the risks that their child may be born with severe birth defects, thereby preventing them from making a decision during the pregnancy about whether to proceed.<sup>98</sup> Parents can recover damages for wrongful birth.<sup>99</sup>

Parental decisionmaking post-implantation is perhaps most obviously regulated through abortion restrictions. Although the Supreme Court has moved beyond the *Roe* framework, permitting regulation ever closer to conception, there is still a protected space for abortion decisionmaking.<sup>100</sup> The focus remains on the undue burdens on the potential mother's access to abortion prior to fetal viability.<sup>101</sup>

Yet a potential parent's decisions during the pregnancy (post-implantation) are also important in other contexts, such as controlled substance abuse and prenatal testing. For example, in Texas, a parent's rights can be termi-

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opposed to eliminating disease. The definition described by Vincent and Jane conflates unusual with enhancement and customary with normal. If gene editing to increase height were to become customary, I don't think that would change the fact that it would still be a form of enhancement (as long as it was not used to treat conditions like achondroplasia)." In addition, she notes that the line between disease and normal species functioning is "blurry." E-mail from Sonia Sutter to Naomi Cahn (Dec. 14, 2019).

98. Daniel W. Whitney & Kenneth N. Rosenbaum, *Recovery of Damages for Wrongful Birth*, 32 J. LEGAL MED. 167, 170–71 (2011); see Barbara Pfeffer Billauer, *Re-Birthing Wrongful Birth Claims in the Age of IVF and Abortion Reform*, 50 STETSON L. REV. (forthcoming 2020) [hereinafter Billauer, *Re-Birthing Wrong Birth Claims*]. For a comprehensive overview of reproductive negligence claims, see generally DOV FOX, BIRTH RIGHTS AND WRONGS: HOW MEDICINE AND TECHNOLOGY ARE REMAKING REPRODUCTION AND THE LAW (2019); Dov Fox et al., *Fertility Fraud, Legal Firsts, and Medical Ethics*, 134 OBSTETRICS & GYNECOLOGY 918, 918 (2019).
99. Billauer, *Re-Birthing Wrongful Birth Claims*, *supra* note 98; see also Billauer, *Wrongful Life in the Age of CRISPR-CAS*, *supra* note 5, at 454–55. The child's claim for wrongful life is rarely permitted to proceed. Billauer, *Wrongful Life in the Age of CRISPR-CAS*, *supra* note 5, at 454.
100. See *Gonzales v. Carhart*, 550 U.S. 124, 146 (2007). In this case, the Court broadened the parameters in which the state can act to limit prebirth decisionmaking.
101. *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2299 (2016); *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 878 (1992). Even if the Court overrules *Roe v. Wade*, individual states will continue to recognize a woman's right to choose.

nated in connection with that parent's use of drugs or other controlled substances during the pregnancy.<sup>102</sup>

Moreover, there are federal regulations that apply to many clinical research trials, influenced, in part, by the 1999 death of Jesse Gelsinger after claims of lack of compliance with ethical procedures.<sup>103</sup> Federal regulations of clinical trials require special attention to a pregnant woman's decision to undergo treatment.<sup>104</sup> Pregnant women can be included in studies only after various additional requirements, not applicable to other populations, have been satisfied.<sup>105</sup> Where the research benefits only the fetus, not the pregnant woman herself, then the consent of the "father" must, where practicable, also be obtained.<sup>106</sup> And the informed consent requirements specify that such information must include the "reasonably foreseeable impact of the research on the fetus."<sup>107</sup>

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102. Where a parent has "used a controlled substance, [ ] in a manner that endangered the health or safety of the child, and: (i) failed to complete a court-ordered substance abuse treatment program; or (ii) after completion of a court-ordered substance abuse treatment program, continued to abuse a controlled substance," then a court may order termination of parental rights. TEX. FAM. CODE ANN. § 161.001(b)(1)(P) (2019). Other states also have regulated this area. For example, Maryland presumes a lack of appropriate care in this situation. MD. CODE ANN., CTS. & JUD. PROC. § 3-818 (2019).

103. Significant questions were raised concerning the adequacy of the information provided about the study's risks. Thulin, *supra* note 24.

104. See Barbara A. Noah, *The Inclusion of Pregnant Women in Clinical Research*, 7 ST. LOUIS U.J. HEALTH L. & POL'Y 353, 368, 372 (2014).

105. See *id.*; 45 C.F.R. § 46.204 (2019). Before an institutional review board (IRB) will approve research involving pregnant women, the IRB must determine that the research will "offer the prospect of direct benefit to [the] mother or fetus." Noah, *supra* note 104, at 368. In addition to the requirements established by IRBs, extra clinical research requirements must be met in order to conduct research on pregnant women. *Id.* at 372 (including looking for preclinical studies, ensuring the risk to the fetus is minimal, and obtaining informed consent from the pregnant women (and sometimes the father)). When research would not otherwise be approved, the Department of Health and Human Services can conduct research only after going through the rule-making process and providing notice and opportunity for comment in the Federal Registrar. *Id.* at 373; see also 45 C.F.R. § 46.207 (2019) ("[R]esearch not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates."). For commentary on an earlier set of regulations, in which pregnant women were classified as a "vulnerable population," see Toby Schonfeld, *The Perils of Protection: Vulnerability and Women in Clinical Research*, 34 THEORETICAL MED. & BIOETHICS 189, 189 (2013).

106. 45 C.F.R. § 46.204(e) (2019).

107. *Id.* § 46.204(f).

Embryos in the IVF context, of course, are not even yet at the fetal stage, so police powers of the state may be even more diluted<sup>108</sup> and potential parent autonomy even stronger. He Jiankui's CRISPR-Cas9 manipulation occurred prior to implantation, where the jurisprudential disputes concern whether an embryo is, as in Louisiana, a juridical person, or whether embryos are part of the right "to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."<sup>109</sup> Given that sperm and eggs can be bought and sold, manipulating eggs and sperm through CRISPR<sup>110</sup> may raise questions about whether CRISPR is a medical product or a medical procedure, but the ability to sell gametes suggests the potential existence of a comparable ability to engage in gene-editing.

### III. SHOULD THEY?

In deciding whether—or not<sup>111</sup>—to move forward with CRISPR-Cas9, the potential parents must contend with not only an internal decisionmaking process that implicates their own hopes for a child, plus cultural or religious pressures to engage in gamete editing,<sup>112</sup> but also the state of the technology.

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108. Ossareh, *supra* note 36, at 740. As Ossareh notes:

Where a parent is making decisions regarding an embryo, current jurisprudence in the lower courts is divided over whether that embryo should be considered a full person. While courts have never clearly agreed on a categorization or definition for embryos, they have typically defined them as either "life, property, or an amalgamation of the two." . . . A litany of cases have considered the allocation of frozen embryos in divorce custody disputes, often using contract law to resolve the matter and ignoring the question of personhood.

*Id.* at 739–40. Similarly, in the embryo dispute cases, the focus is on the parents' rights to use—or not use—the embryos; *cf.* Suter, *The 'Repugnance' Lens*, *supra* note 17, at 1514 (noting that *Gonzales* and *Casey* appear to permit regulation from conception).

109. *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *see* June Carbone & Naomi Cahn, *Embryo Fundamentalism*, 18 WM. & MARY BILL RTS. J. 1015, 1017 (2010); *see generally* Naomi Cahn & June Carbone, *Deep Purple: Religious Shades of Family Law*, 110 W. VA. L. REV. 459 (2007).

110. Charlotte Spicer, *Scientists Use CRISPR in Human Sperm Cells*, BIONEWS (July 9, 2018), [https://www.bionews.org.uk/page\\_137024](https://www.bionews.org.uk/page_137024).

111. *See supra* text accompanying note 87 (discussing *Newmark*), for the parameters of deciding not to move forward, with the court focusing on the risks of the treatment itself to justify the parental right to refuse.

112. *See Johnston, supra* note 3. Parents may feel a need to know as much as possible about the genetic composition of their child. *Id.*; J.A. Anderson et al., *Parents Perspectives on Whole Genome Sequencing for their Children: Qualified*

While parents will almost certainly pursue their own research about the risks and benefits, that is not a substitute for engaging with the physician.<sup>113</sup>

Of course, physicians must obtain informed consent before proceeding, and such consent typically includes the following steps: the health care provider's provision of information to the patient on the risks, benefits, and side effects of the procedure; patient comprehension; patients' freely-given consent to treatment; and the provider's document of the patient's decision.<sup>114</sup> Approximately half of states have an informed consent statute,<sup>115</sup> and the failure to obtain informed consent constitutes negligence (or battery).<sup>116</sup> Approximately half of the states have adopted a standard based on what the "reasonable patient" would find material before agreeing to a specific medi-

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*Enthusiasm?*, 43 J. MED. ETHICS 535, 537 (2016) (reporting on parents' self-perceived moral obligation to obtain such information, even if adverse).

113. He Jankui apparently claimed that his CRISPR-Cas9 patients were "very well educated." Yong, *supra* note 48 (article listing 15 of the "most damning details" of Jankui's experiment). There are additional concerns about whether the parents knew that there were other, less invasive, methods for preventing the transmission of HIV through reproduction and then in the household. See Dena Davis, *CRISPR in China: Why Did the Parents Give Consent?*, HASTINGS CTR. (Dec. 7, 2018), <https://www.thehastingscenter.org/crispr-china-parents-give-consent/>.
114. Jody Lyn   Madeira & Barbara Andraka-Christou, *Paper Trails, Trailing Behind: Improving Informed Consent to IVF Through Multimedia Applications*, 3 J.L. & BIOSCIENCES 2 (2016). Note that, if gene-editing is at the clinical research stage (rather than accepted clinical treatment), then most such research is subject to federal requirements. See Foulkes et al., *supra* note 23, at 1391 ("Regulations governing human subject research in the United States—when said research is either funded by or committed to the oversight of any of fifteen federal departments—are detailed in what is known as the Common Rule."). And, depending on how the research is done, it might not actually be "research" under the Common Rule. Clinical innovations often would not fall under the definition as "a systematic investigation . . . designed to contribute to generalizable knowledge." 45 C.F.R. § 46.102(l) (2019).
115. "As of today, at least twenty-three states have a general informed-consent statute, or another type of statute that addresses informed consent in the health-care setting. [In other states], the common law of the state determines the informed-consent law." Christine Coughlin, *E-Consent: Can Informed Consent Be Just A Click Away?*, 50 WAKE FOREST L. REV. 381, 388–89 (2015). A child may be able to sue for injuries caused by the failure of a physician to obtain informed consent from the child's mother during labor. *Miller ex rel. Miller v. Dacus*, 231 S.W.3d 903,906 (Tenn. 2007).
116. INST. OF MED., INFORMED CONSENT AND HEALTH LITERACY: WORKSHOP SUMMARY 3–4 (2015).

cal procures.<sup>117</sup> These statutes typically require that the healthcare provider act in accordance with the standards of practice in the same or similar communities, that a reasonable person would have a general understanding of the procedures and usual and most frequent risks, and that a reasonable person would have undergone such treatment.<sup>118</sup>

### A. Informed Consent Status

As ample empirical evidence shows, “informed consent” is a slippery concept to define; just how much information is adequate and how to present it is difficult to encapsulate in legal doctrine (or medical practice). Furthermore, patients and doctors tend to make different choices depending on the way statistical estimates of potential medical benefit are presented.<sup>119</sup> Indeed, regardless of their level of literacy, most people do not remember information that is provided to them during the process of obtaining informed consents.<sup>120</sup> And the informed consent process may not be adequately focused on patient understanding as opposed to doctor protection, in other words, the focus is on disclosure, not actual patient comprehension.<sup>121</sup> In addition, pa-

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117. Erica S. Spatz et al., *The New Era of Informed Consent: Getting to a Reasonable-Patient Standard Through Shared Decision Making*, 315 J. AM. MED. ASS’N 2063, 2063 (2016).

118. See, e.g., ME. REV. STAT. tit. 24, § 2905 (2019).

119. Dena S. Davis, *Opportunistic Testing: The Death of Informed Consent?*, 23 HEALTH MATRIX J. L. MED. 35, 40 (2013).

120. Linda Aldoory et al., *Best Practices. and New Models of Health Literacy for Informed Consent: Review of the Impact of Informed Consent Regulations on Health Literate Communications*, in INFORMED CONSENT AND HEALTH LITERACY: WORKSHOP SUMMARY, *supra* note 116 at 120.

121. See Naomi Cahn & Jennifer Collins, *Fully Informed Consent for Prospective Egg Donors*, 16 AM. MED. ASS’N J. ETHICS 49, 50–51 (2014); Pamela Laufer-Ukeles, *Reproductive Choices and Informed Consent: Fetal Interests, Women’s Identity, and Relational Autonomy*, 37 AM. J.L. & MED. 567, 573 (2011); Jody Lyneé Madeira, *Woman Scorned?: Resurrecting Infertile Women’s Decision-Making Autonomy*, 71 MD. L. REV. 339, 393 (2012); Seema Mohapatra, *Using Egg Freezing to Extend the Biological Clock: Fertility Insurance or False Hope?*, 8 HARV. L. & POL’Y REV. 381, 411 (2014); Sonia M. Suter, *Genomic Medicine—New Norms Regarding Genetic Information*, 15 HOUS. J. HEALTH L. & POL’Y 83, 94 (2015) (discussing how *Canterbury v. Spence* makes clear the focus is on *disclosure* rather than actual patient *comprehension*). The question is often phrased as “whether a ‘reasonable patient’ would find the information ‘material’ to her decision, without regard to the professional community’s prevailing practices or views.” Carl H. Coleman, *Regulating Physician Speech*, 97 N.C. L. REV. 843, 890 (2019).

tients consenting to a medical procedure are influenced by numerous factors, “both individualistic and relational, and are even at times irrational.”<sup>122</sup>

In the somewhat analogous reproductive technology context of pre-implantation genetic testing,<sup>123</sup> researchers have hypothesized various stages of decision-making, as well as various levels of psychological stress that accompany those stages.<sup>124</sup> There is: (1) the “Identify” stage, in which couples realize they may want to consider repro-genetic testing; (2) a “Contemplate” stage, in which couples make the decision of whether to become parents and their various options for doing so; and (3) the “Resolve” stage phase, during which couples decide to test, not to test, or remain committed to keeping their options open; with those who move forward entering (4) the “Engage” phase.<sup>125</sup> The psychological stress takes numerous forms, including feeling pressure to use all available technologies.<sup>126</sup>

Psychological issues, in turn, appear in analyzing how the individual (or couple) approaches the gene-editing process.<sup>127</sup> These may include “intra-individual factors,” such as how the individual interprets health information—is more or less better?—and ethical/moral attitudes.<sup>128</sup> Interpersonal

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122. Jody Lyneé Madeira, *The ART of Informed Consent: Assessing Patient Perceptions, Behaviors, and Lived Experience of IVF and Embryo Disposition Informed Consent Processes*, 49 FAM. L.Q. 7, 8 (2015) (suggesting that the informed consent is of low utility to either physicians or patients).

123. See Santiago Munné, *Status of Preimplantation Genetic Testing and Embryo Selection*, 37 REPROD. BIOMED. ONLINE 393, 393–96 (2018). Through this process, embryos can be tested for genetic disorders before they are implanted into the woman’s uterus, thereby allowing parents to make pre-implantation decisions about the health and viability of the embryos. Gene-editing can be performed to improve viability. See *id.* at 393.

124. L.M. Pastore et al., *Patients’ Preimplantation Genetic Testing Decision-Making Experience: An Opinion on Related Psychological Frameworks*, 4 HUM. REPROD. OPEN 1, 2 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6777985/>.

125. *Id.*; Patricia E. Hershberger et al., *The Decision-Making Process of Genetically at-Risk Couples Considering Preimplantation Genetic Diagnosis: Initial Findings From a Grounded Theory Study*, 74 SOC. SCI. & MED. 1536, 1538 (2012).

126. M.C. Genoff Garzon et al., *Review of Patient Decision-Making Factors and Attitudes Regarding Preimplantation Genetic Diagnosis*, 94 WILEY CLINICAL GENETICS 22, 39 (2018), <https://onlinelibrary.wiley.com/doi/pdf/10.1111/cge.13174>. Five themes emerged from a meta-review, including that: “(1) patients [are] motivated by prospects of a healthy, genetic-variant-free child; (2) PGD requires a commitment of time, money, energy and emotions; (3) patients concerned about logistics and ethics of discarding embryos; (4) some patients feel a sense of responsibility to use available technologies; and (5) PGD decisions are complex for individuals and couples.” *Id.* at 22.

127. See Pastore et al., *supra* note 124, at 2.

128. *Id.* at 3.

factors include the health of the couple's relationship as well as their support system, and finally, situational factors, such as the cost of the testing.<sup>129</sup> And then there is the impact of knowing that reproductive decisionmaking affects the future child.<sup>130</sup>

In considering the particular circumstances of potential parents who may be interested in pursuing CRISPR-Cas9, there are few studies of informed consent in the reproductive technology context. One of the only studies found that the majority of patients who had been given IVF and embryo disposition informed-consent forms read and understood them.<sup>131</sup> Moreover, almost three-fourths believed that the forms were part of a longer process of providing information to them.<sup>132</sup> In another study of the use of a multimedia platform—EngagedMD—to aid in informed consent, a majority (fifty-five percent) of approximately 3,000 participants still believed that physician consultations were their most effective source of information, but nineteen percent of the participants judged the platform as most valuable.<sup>133</sup> Almost all of the participants agreed that the platform helped make them better prepared to sign the informed consent form and improved how satisfied they were with their care.<sup>134</sup>

This study should, however, be contrasted with studies of other types of informed consent, albeit outside of the medical context. In one such study, researchers created a fictitious social networking site, NameDrop, with a privacy policy and terms of service, comprised of approximately 8000 and 4000 words respectively, and modeled it on existing documents for another social network (LinkedIn).<sup>135</sup>

The fake site's policies included a few "gotcha" clauses: one concerned data sharing, and specified that the site could share the signer's information with the NSA "and other security agencies in the United States and abroad," while the other required that participants sign over their firstborn child: "In

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129. *Id.* at 4.

130. See Cribbs & Perera, *supra* note 19, at 630 (suggesting that the unforeseeable risks of CRISPR-Cas9 for the child and subsequent generations may make it "impossible to derive an informed consent on behalf of the offspring").

131. Madeira, *supra* note 122, at 9. She observes: "As surprising as these conclusions may seem, past studies have also documented high patient self-reports of consent form reading and comprehension." *Id.* at 15.

132. *Id.* at 14–15.

133. Jody Lyneé Madeira et al., *Using the EngagedMD Multimedia Platform to Improve Informed Consent for Ovulation Induction, Intrauterine Insemination, and In Vitro Fertilization*, 110 FERTILITY & STERILITY 1338, 1343 (2018).

134. See *id.*

135. Jonathan A. Obar & Anne Oeldorf-Hirsch, *The Biggest Lie on the Internet: Ignoring the Privacy Policies and Terms of Service Policies of Social Networking Services*, 23 INFO., COMM. & SOC'Y 1, 11 (2018), <https://www.tandfonline.com/doi/full/10.1080/1369118X.2018.1486870>.



addition to any monetary payment . . . all users of this site agree to immediately assign their first-born child” to the site, and even “[i]f the user does not yet have children, this agreement will be enforceable until the year 2050.”<sup>136</sup>

The researchers recruited students from a large public university, and 543 participants signed up.<sup>137</sup> Of those, 399 participants skipped reading the fine print and just clicked through to sign up for the site.<sup>138</sup> For the other 144 participants, the average time spent reviewing the privacy policy was seventy-three seconds, while it was fifty-one seconds for the terms of service.<sup>139</sup> When asked if they had any concerns about the agreement, only nine participants mentioned the “Rumpelstiltskin” clause (concerning the first-born child), and eleven participants noticed the data sharing provision.<sup>140</sup> Other studies have reported similar findings concerning the acceptance of unconscionable terms in such agreements.<sup>141</sup> These findings suggest that people may sign terms of service or informed consent forms without necessarily having full comprehension and recall (even if they believe they do at the time).<sup>142</sup>

In the other somewhat analogous context of donor conception, patients may sign agreements that involve somewhat questionable terms.<sup>143</sup> For example, in its customer agreement for donor sperm, Northwest Cryobank precludes the buyer from attempting to obtain any information (other than through the Cryobank) about the anonymous donor whose sperm has been purchased.<sup>144</sup> When Danielle Teuscher used a DNA test for her donor-con-

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136. *Id.* at 11–12.

137. *Id.* at 9.

138. *Id.* at 14.

139. *Id.* at 16.

140. *Id.* at 16–17. A few other participants mentioned additional concerns, such as the length of the policies. *Id.* at 17.

141. “A similar experiment in the UK in 2014 found the same results, with users unwittingly signing away their firstborn in exchange for access to a free WiFi hotspot. A UK-based retailer found the same in 2010 when their customers happily, and unwittingly, signed over their immortal souls.” Kate Cox, *Study: 98% of Us Will Sign Away Our Firstborn Because We Don’t Read the Terms of Service*, CONSUMERIST (July 13, 2016, 10:36 AM), <https://consumerist.com/2016/07/13/study-98-of-us-will-sign-away-our-firstborn-because-we-dont-read-the-terms-of-service/>.

142. *See id.*

143. *See* Ellen Trachman, *Beware of the Home DNA Kit! You May Find Yourself Being Sued by a Sperm Bank*, ABOVE THE LAW (Feb. 6, 2019, 1:17 PM), <https://abovethelaw.com/2019/02/beware-of-the-home-dna-kit-you-may-find-yourself-being-sued-by-a-sperm-bank/>.

144. *See id.*; Declaration of Danielle Teuscher in Support of a Motion for Preliminary Injunction at 4, *Teuscher v. CCB-NWB* (No. 19-CV-00204), 2019 WL 53995404 at \*1. The agreement also required her to agree “never” to contact or

ceived daughter, she found a close relative to her daughter who was “open to contact.”<sup>145</sup> After reaching out to that person, she received the following in reply, “I don’t understand.” Danielle did not pursue further contact.<sup>146</sup> Northwest Cryobank, the sperm bank which had sold her the sperm used to conceive her daughter, then sent her a letter, demanding that she cease and desist from attempting to contact the donor or any of the donor’s relatives, threatening to seek liquidated damages of \$20,000, and informing her that they were denying her permission to use the remaining four vials of the donor’s sperm that Teuscher had already purchased.<sup>147</sup> She was shocked at the reaction and responded by suing the Cryobank for a preliminary injunction. She did not remember reading the “fine print.”<sup>148</sup>

Turning to how informed consent plays out in court, in lawsuits to determine whether the physicians have provided sufficient disclosure, courts seek to protect both patient autonomy and physician discretion.<sup>149</sup> Moreover, while physicians must disclose material information, they are not required to assess a patient’s understanding of that information.<sup>150</sup> Plus, “the scope of disclosure is defined either by what a reasonable physician would disclose or by what a reasonable patient would find material, but not by what this particular patient would find material.”<sup>151</sup> Of course, determining the needs and comprehension level of each individual patient would be onerous and require a different informed consent process.<sup>152</sup> But perhaps that is what is needed: ongoing attention to just how informed consent is procured and the development of new techniques that attend to the potentially irrational decisionmaking process of potential parents.<sup>153</sup> Looking ahead, medical students may need to receive new types of education necessary to provide adequate disclo-

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try to contact the donor. This was not an informed consent form, but is instead an example of the types of terms in a reproductive technology agreement.

145. Trachman, *supra* note 143.

146. *Id.*

147. *Id.*; Jacqueline Mroz, *A Mother Learns the Identity of Her Child’s Grandmother. A Sperm Bank Threatens to Sue*, N.Y. TIMES (Feb. 16, 2019), <https://www.nytimes.com/2019/02/16/health/sperm-donation-dna-testing.html?auth=login-google&login=google>.

148. Mroz, *supra* note 147. Or, consider what happens in another reproductive technology context, the disclosure on fertility clinic websites of the potential tax consequences for egg donors. One study found that only twelve percent of clinics provide such disclosure. Bridget J. Crawford, *Tax Talk and Reproductive Technology*, 99 B.U. L. REV. 1757, 1783–84 (2019).

149. See Suter, *Genomic Medicine*, *supra* note 121, at 83–84.

150. *Id.* at 94.

151. *Id.*

152. See *id.* at 95.

153. See *id.* at 96.

sure and counseling to patients on highly experimental techniques.<sup>154</sup> And one of the reasons for permitting germline gene editing in the United States is to ensure domestic establishment and control of informed consent standards.<sup>155</sup>

## B. Improved Consent

So what might this new informed consent process look like? The author suggests it would not resemble the 23-page form used by He Jiankui, the only reported CRISPR gene-editing experiment to date.<sup>156</sup> The approach must attend to both the substance of what is disclosed, as well as to the process of obtaining the consent. It will certainly build on existing disclosure obligations and norms, particularly with respect to pre-implantation genetic testing. That process, however, differs because it does not involve actual genetic manipulation, but is rather a screening process.

The substance of the consent must adequately detail the risks of the procedure, focusing on the limits of the procedure itself in accomplishing its intended goals, as well as the possibility of long-term repercussions for any resulting child.<sup>157</sup> It also seems appropriate that there should be disclosures about alternatives, such as prenatal testing/preimplantation genetic diagnosis (PGD) and any medical treatment that might exist for a child's condition.<sup>158</sup>

People respond better when the information matches their "informational coping style,"<sup>159</sup> although that means that crafting a one-style-fits-all approach is difficult. Using multiple approaches during the consent process might serve as a better response than only written or online content, or even only physician counseling.

Current American Society for Reproductive Medicine guidelines appropriately recommend comprehensive counseling and information disclosure.<sup>160</sup>

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154. Lisa Ward, *The Ethical Dilemmas AI Poses for Health Care*, WALL ST. J. (Oct. 14, 2019), [https://www.wsj.com/articles/the-ethical-dilemmas-ai-poses-for-health-care-11571018400?fbclid=IWAR3AdXoYsufHsbON\\_\\_DyvXse\\_iN-CyCMbL4giS7GcysIb0fWxirB\\_noiauWA](https://www.wsj.com/articles/the-ethical-dilemmas-ai-poses-for-health-care-11571018400?fbclid=IWAR3AdXoYsufHsbON__DyvXse_iN-CyCMbL4giS7GcysIb0fWxirB_noiauWA) (raising similar fear in the context of AI medicine).

155. See, e.g., Glenn Cohen, *Circumvention Medical Tourism and Cutting Edge Medicine: The Case of Mitochondrial Replacement Therapy*, 25 IND. J. GLOBAL LEGAL STUD. 439, 462 (2018).

156. See Caplan, *supra* note 48.

157. See, e.g., *id.* (speculating that He Jiankui's gene-editing might not prevent the babies from contracting AIDS or might weaken their immunity to other diseases).

158. See *id.*

159. Pastore et al., *supra* note 124, at 3.

160. PRAC. COMM. AM. SOC'Y REPROD. MED., *Revised Minimum Standards for Practices Offering Assisted Reproductive Technologies: A Committee Opinion*, 102 FERTILITY & STERILITY 682, 685 (2014). Informed consent includes pro-

New forms of “patient decision aids” involve not only written consent forms but also multimedia approaches, including computer and video, and they serve to supplement physician patient counseling.<sup>161</sup> Shared decisionmaking, which involves a “collaborative communication process between clinicians and patients that integrates” medical information with the patients’ values has shown promising results in not just ensuring that patients have more information but also tempering their expectations about the procedures.<sup>162</sup>

Models exist. For example, Washington State has established decision-making aids specifically for genetic screening in an effort to improve patient care coordination.<sup>163</sup> Ensuring that patients are involved in developing these decision aids can help in satisfying a reasonable patient standard and ensuring that the informed consents are protective not just of physicians but of the patients and their potential child.<sup>164</sup>

Focusing on informed consent is not a means of eliding ethical responsibilities for the technology itself.<sup>165</sup> Instead, it serves to acknowledge that technological developments will have no utility to humans unless they are actually operationalized, and that responsible use of those developments depend on fully informing patients.<sup>166</sup> The goal is openness and transparency.<sup>167</sup>

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viding patients “with full information concerning risks, benefits, and alternative procedures available to circumvent their specific infertility problem” and requiring documentation of the communication process. *Id.*

161. See, e.g., Nanette Elster, *Enhancing Shared Decision Making in Assisted Reproductive Technologies Through the Use of Multimedia Platforms for Informed Consent*, 110 FERTILITY & STERILITY 1267, 1267 (2018); See Madeira et al., *supra* note 122, at 28.

162. Spatz et al., *supra* note 117 (citing to a 2012 meta-study).

163. *Id.* at 2064.

164. See *id.* at 2063–64.

165. J. Benjamin Hurlbut & Jason Scott Robert, *CRISPR Babies Raise an Uncomfortable Reality—Abiding by Scientific Standards Doesn’t Guarantee Ethical Research*, CONVERSATION (Dec. 3, 2018, 6:33 AM), <http://theconversation.com/crispr-babies-raise-an-uncomfortable-reality-abiding-by-scientific-standards-doesnt-guarantee-ethical-research-108008> (questions about informed consent seemed “to be groping for a smoking gun—some clear violation of existing standards—in order to declare what people already felt: that the research was unethical”).

166. See *id.*

167. See, e.g., Mahoney & Siegal, *supra* note 9, at 213 (suggesting that an appropriate regulatory response is “one that places more emphasis on encouraging the disclosure of information about developments in heritable genome editing and other innovative technologies”).

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#### IV. CONCLUSION: MOVING FORWARD

Notwithstanding all of the unknowns about CRISPR, its very existence makes clear the need to address ethical and legal issues surrounding reproductive technology. Each new advance in gene-editing techniques raises complex questions about parents' roles, responsibilities, and decisions, the medical profession's obligations to patients, and the appropriate regulatory response.

Given all of the unknowns about CRISPR and future gene editing techniques, it is certainly possible that a child will develop as anticipated, and that child's future offspring will experience no adverse impacts because of CRISPR. The problem is that this ideal may not happen, given the state of the technology. First, it may not be as precise as intended, with potential off-target results and adverse consequences. Second, even if the technology is on-target, the impact on the child and future generations is unpredictable and may be adverse. While the existence of malpractice raises conventional tort and health law issues, the question is what happens when CRISPR-Cas9 is performed as intended (without malpractice) as a state-of-the-art intervention. In that situation, informed consent becomes the critical question; did the intending parents receive appropriate disclosure of the risks and potential benefits of the technology?<sup>168</sup> If so, then the fault may lie with the parents.

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168. Informed consent issues do raise malpractice concerns, of course, but those differ from liability for the actual performance of the gene-editing technology.