

# WHY GENETICS IS CRISPR THAN IT USED TO BE: HELPING THE NOVICE UNDERSTAND GERM LINE MODIFICATION AND ITS SERIOUS IMPLICATIONS

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## I. INTRODUCTION

This note is intended to give the reader a basic understanding of the Cas9/CRISPR (“CRISPR”) technology and the impact the technology could potentially have on germ line modification in early human embryos, sperm, and eggs. This discussion is not meant to give a well-rounded *scientific* account of the technology itself but rather is meant to explore the *legal* questions that need to be addressed if the technology is to be used for germ line modification purposes in humans. But, in analyzing those legal questions, various interpretive paths will require us to look at some of the political and moral issues surrounding germ line modification. Of course, these issues affect the development of legal doctrine itself, both through political and adjudicative processes. *No prior knowledge* of CRISPR or germ line modification is necessary to understand this piece and to grapple with the issues it presents. Only a general understanding of genetic inheritance is required. This discussion is not, and should not, be limited to scientists.

Below are five sections that outline some features of constitutional analysis relevant to genetic modification. First, I will provide background information about the technology and germ line modification to help a reader with little or no knowledge of CRISPR better grasp the issues. Next, I will discuss whether a constitutional fundamental right or liberty interest is at stake, what the different standards of review are for courts and the government generally, and what government interests might be advanced in

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\* In writing this note I am attempting to explain germ line modification and its newest breakthrough in innovation (CRISPR) to those who are not scientists or experts. My aim is to seek out the novices and open up a broader dialogue for a topic that should be an issue of great salience but has instead largely slipped through the cracks of the public’s attention. When I took up the challenge of writing this piece in October of 2015 I did so for selfish reasons—I wanted to understand what I saw as an incredibly interesting technology. Now I hope to inspire more interested novices to take up the task of not only understanding the implications but to start thinking of real-world solutions. I want to thank Professor Michael H. Shapiro for the incredible guidance and feedback he has given me throughout the process as well as Christopher Kuhlen for giving me the topic idea at the outset. Additionally, I want to thank fellow student Charles Thomas, PhD on matters of molecular biology.

an attempt to regulate CRISPR. Standards of review strongly reflect the constitutional values at stake, and thus, are a critical feature of coherent constitutional analysis. An extended discussion of governmental interests will help us foresee some of the potential harms CRISPR may cause or exacerbate. The final section is an overall conclusion. Each section plays into the next in an attempt to give the reader a general understanding of how CRISPR came to be and where the legal discussions and eventual frameworks may be headed. These issues are difficult and far from solved, however, as with many projects, it is best to see the larger framework of the field if we are going to start sorting out the details.

## II. BACKGROUND INFORMATION

It is important to distinguish germ line modification (the topic of this note) and gene therapy (*not* the topic of this note). Human germ line modification refers to the deliberate altering of genes with the intent or effect of passing them on, in their modified form, to future generations.<sup>1</sup> Although gene therapy—the practice of correcting defective genes to battle diseases in *living* humans—has been seen as a potential scientific breakthrough with great promise for future generations,<sup>2</sup> germ line modification has been looked at much more skeptically.<sup>3</sup> Viewed by many as a dangerous method for the creation of “designer babies,”<sup>4</sup> germ line modification in human embryos is often seen as a horror movie theme as opposed to real-life scientific advancement, given its power to alter multiple generations and cause unforeseen impacts on the human species. With the new CRISPR technology it has become easier than ever to alter the genes of a human embryo and its potential descendants.<sup>5</sup>

The history of genetics has been evolving for well over a century since Gregor Mendel revealed results from a pea breeding experiment he conducted in 1865.<sup>6</sup> To explain the entire history of gene modification would be time consuming, boring for many, and unnecessary for all. Therefore, I will touch only on two major historical antecedents of germ line modification that help define the legal issues and alert the public to its prospects.<sup>7</sup>

<sup>1</sup> Center for Genetics and Society, *About Human Germline Gene Editing*, GENETICS AND SOCIETY, <http://www.geneticsandsociety.org/article.php?id=8711#top>.

<sup>2</sup> *What is Gene Therapy?*, GENETICS HOME REFERENCE (Dec. 7, 2015), <http://ghr.nlm.nih.gov/handbook/therapy/genetherapy>. Gene therapy has developed slowly, *but see* Meg Tirrell, *Spark Therapeutics Gene Therapy Hits Goals in Blindness Study*, CNBC (Oct. 5, 2015, 6:00 AM), <http://www.cnbc.com/2015/10/05/spark-therapeutics-gene-therapy-hits-goals-in-blindness-study.html> (discussing gene therapy break-through aimed at preventing blindness in individuals with rare gene mutations).

<sup>3</sup> Center for Genetics and Society, *supra* note 1.

<sup>4</sup> James Gallagher, *‘Designer Babies’ Debate Should Start, Scientists Say*, BBC NEWS (Jan. 19, 2015), <http://www.bbc.com/news/health-30742774>.

<sup>5</sup> Center for Genetics and Society, *supra* note 1.

<sup>6</sup> *A Brief History of Genetic Modification*, GM EDUCATION (July 2012), <http://www.gmeducation.org/faqs/p149248-20brief%20history%20of%20genetic%20modification.html>.

<sup>7</sup> For those interested in other moments in the development of genetic engineering *see* *A History of Genetic Engineering*, SCIENCE GROUP, <http://www.sciencegroup.org.uk/ifgene/history.htm>.

First, consider the eugenics movement—one of the first attempts to apply the expanding knowledge of human genes in a systematic way.<sup>8</sup> Eugenics, which is seen by many in today's society as discriminatory in nature,<sup>9</sup> was a belief that it was socially beneficial to prevent or inhibit individuals with less desirable or "unfit" genes from reproducing (negative eugenics) while promoting reproduction among those with more desirable traits (positive eugenics).<sup>10</sup> It is worth noting that the eugenicists were correct in their *general* belief that genetics has a significant impact on human characteristics, but their endorsement of its deterministic effects apart from those influences is now seen as simple-minded. The belief that genes could predict one's worth to society was seriously compounded with perverse moral values.<sup>11</sup>

While the eugenics movement has been removed from grace in many circles of society, the obstacles the movement faced overlap, to some extent, with today's discussions about germ line modification. Germ line modification is seen as more precise, and potentially more dangerous than eugenics. Ironically, when perfected, its very precision will also promote safety in some forms. An individual altered through germ line modification is essentially living a different version of who she otherwise would have been if her genes had not been altered. How significant that difference is may be impossible to forecast in advance. This is a procreational event quite different from that of a person born of a match hatched within a eugenics movement that simply arranges mating or brings selected gametes together. There were no preexisting embryos or selected gametes to modify. That person's genes were never "altered." She is simply the product of a mating choice involving a eugenically-based selection of parents, voluntary or otherwise. Germ line modification is thus a manipulation of a specific person-to-be (as genetically "defined" by the early embryo or by gametes), rather than an attempt to arrange a suitable reproductive match, which does not determine the genetic fate of any specific person-in-the-making; the "genetic lottery" still governs.<sup>12</sup> It simply unites preexisting sets of unmodified genes. Eugenics is a more group-oriented set of processes and goals, and is less concerned with the creation of particular persons. Eugenicists' goals may be based on statistics of certain sectors of the population defined by race, disability, etc. They may or may not look to germ line modification as a mechanism.

At a *high level of abstraction*, of course, both eugenics and germ line modification involve deliberately altering the trait composition of future generations. But, germ line modification is more specific and focused. As mentioned, germ line modification tinkers with a preexisting physical

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8 MICHAEL H. SHAPIRO ET AL., *BIOETHICS AND LAW* 807 (Thomson West, 2nd ed. 2003).

9 See generally David Pfeiffer, *Eugenics and Disability Discrimination*, 9 *DISABILITY & SOC'Y* 481 (1994) (discussing the Eugenics movement's impact on contemporary law and the discriminatory effects on people with disabilities).

10 MICHAEL H. SHAPIRO, *supra* note 8.

11 See STEPHEN JAY GOULD, *THE MISMEASURE OF MAN* 107-10 (1981).

12 Michael H. Shapiro, *I Want a Girl (Boy) Just Like the Girl (Boy) That Married Dear Old Dad (Mom): Cloning Lives*, 9 *S. CAL. INTERDIS. L.J.* 1, 38 (1999).

information machine—the genome.<sup>13</sup> Eugenics, or more broadly reproductive genetics, is essentially just an alternate form of mating. While most proponents of germ line modification are not pushing for systematic societal alteration as eugenicists did,<sup>14</sup> the differences are not so evident on the surface. This is where a key differentiation comes into play: disease prevention vs. augmentation.<sup>15</sup> This differentiation can significantly alter our analysis of the issues at hand and will later be touched on in greater detail. It is a matter of both constitutional and moral dimension.

The second, more recent event on our brief walk through history is the Human Genome Project. This international scientific project sought to map the entire human genome and was successful in doing so. The project was deemed substantially complete in 2003.<sup>16</sup> The purpose of the project was to map the DNA base-pairs of the human genome while making the information widely available to the scientific community and general public.<sup>17</sup> However, the project has not *yet* had as sweeping an effect on the medical practice as some may have expected.<sup>18</sup> The project, as with most other scientific ventures, had its proponents and opponents but the price tag alone (\$3 billion in U.S. currency)<sup>19</sup> showed a commitment to the advancement of genetics. Moreover, for the “first time in the history of scientific and medical research,” three to five percent of a large development budget was set aside solely to help address the legal, ethical, or social issues that were to arise.<sup>20</sup> For years, members of the scientific community have been trying to grapple with the serious issues that accompany gene modification and it is important for the legal community to try to keep pace as effectively as they can.

While the history surrounding gene modification is important, understanding why the CRISPR system is unique helps explain why this area of scientific development is particularly salient today. The discussion should not remain confined within the scientific community but should be recognized by all people who have an eye towards the future. To understand the legal and moral issues, it is necessary only to provide an accurate outline of the technology.

CRISPR is a targeted genome modification system that uses a guide RNA and the Cas9 enzyme to precisely edit a DNA sequence at a

<sup>13</sup> *What's a Genome?*, GENOME NEWS NETWORK, [http://www.genomenetwork.org/resources/whats\\_a\\_genome/Chp1\\_1\\_1.shtml#genome1](http://www.genomenetwork.org/resources/whats_a_genome/Chp1_1_1.shtml#genome1).

<sup>14</sup> See Nick Bostrom, *Transhumanist Values*, 4 REV. OF CONT. PHIL. 3 (2005).

<sup>15</sup> I refer to augmentation throughout this Note when discussing efforts to edit genes to improve a physical or mental trait as opposed to preventing a genetic disorder. I also use the word “enhancement” when discussing augmentation.

<sup>16</sup> *All About the Human Genome Project*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (JUNE 12, 2010), <http://www.genome.gov/10001772>.

<sup>17</sup> *Id.*

<sup>18</sup> Nicholas Wade, *A Decade Later, Genetic Map Yields Few New Cures*, N.Y. TIMES (June 12, 2010), <http://www.nytimes.com/2010/06/13/health/research/13genome.html?pagewanted=all>; see also The Human Genome Project Completion: Frequently Asked Questions at <https://www.genome.gov/11006943>.

<sup>19</sup> MICHAEL H. SHAPIRO, *supra* note 8, at 924.

<sup>20</sup> *Id.*

predetermined location.<sup>21</sup> The phenomenon was originally discovered in prokaryotic bacteria as an immunity mechanism to defend against pathogens.<sup>22</sup> Scientists have co-opted the phenomenon to edit eukaryotic genomes, which has been proven to effectively work in many different organisms.<sup>23</sup> The guide RNA attaches to the Cas9 enzyme and locates the enzyme at the predetermined location.<sup>24</sup> The Cas9 enzyme can cut the DNA at this precise location,<sup>25</sup> enabling the rearrangement and subsequent modification of the DNA sequence.<sup>26</sup>

The CRISPR technology has made it efficient and effective to edit DNA, causing many members of the bioethics community to call for greater debate—although the germ line modification debate has been going on for decades<sup>27</sup>—regarding the future of the technology, including its safety and effectiveness, how studies are to be pursued, and what boundaries for research and genetic modification, if any, should be established.

Of course, the very idea of “boundaries” is sure to be contested. Such boundary debates will vary depending on the context of the discussion, whether it concerns limits on specific traits to be modified, degrees to which they might be modified, rules about parental consent for gene therapy on children’s body (somatic) cells via CRISPR—which would not usually affect the germ line, as defined by sex cells—and experiments on embryos to be discarded. This “boundaries” debate will be heavily concerned with the criteria of safety and effectiveness, addressed below.

In light of the history of genetic control generally and of the prospective benefits and harms of germ line modification, it is no surprise that CRISPR is widely recognized as one of Science Magazine’s “top 10” breakthroughs of 2013.<sup>28</sup> CRISPR is becoming particularly accurate and successful in experiments around the globe, making genetically modified human beings a real possibility.<sup>29</sup> The technology’s simplicity, precision in targeting, and relatively low price makes germ line modification easier and more accessible than ever.<sup>30</sup> Regulations in many countries around the world, as well as widespread moral objections to the modification of human genes, makes germ line modification in human embryos a touchy and difficult process to administer. Many scientists are more concerned about the use of the technology in countries with few regulations.<sup>31</sup> With

21 Jennifer Doudna, *Genome Engineering with CRISPR-Cas9*, UC BERKELEY/HHMI (Mar. 23, 2015), <https://www.youtube.com/watch?v=SuAxDVBt7kQ>.

22 *Id.*

23 *Id.*

24 *Id.*

25 *Id.*

26 *Id.*

27 Richard Hayes, *The Quiet Campaign for Genetically Engineered Humans*, CENTER FOR GENETICS AND SOCIETY (Spring 2001), <http://www.geneticsandsociety.org/article.php?id=259>.

28 Robert Coontz, *Science’s Top 10 Breakthroughs of 2013*, SCIENCE MAGAZINE (Dec. 19, 2013), <http://news.sciencemag.org/2013/12/sciences-top-10-breakthroughs-2013>.

29 *Id.*

30 David Baltimore et al., *A Prudent Path Forward for Genomic Engineering and Germline Gene Modification*, 348 SCIENCE 36, 36 (2015).

31 Nicholas Wade, *Scientists Seek Ban on Method of Editing the Human Genome*, N.Y. TIMES, (March 20, 2015).

little or no oversight, these countries may push forward before the technology's potential problems have been more carefully assessed.<sup>32</sup>

With fears mounting within the scientific community about the impact of germ line modification on the health and safety of the human species—and indeed its very identity as the human species—some scientists, including one of the inventors of the CRISPR technology, Jennifer Doudna, have called for a moratorium on the use of the technology until further research is conducted regarding its safety impact.<sup>33</sup> These range from clear deformities or disorders to cascading effects of changing fairly simple traits, like height and weight—much less complex ones such as memory and intelligence.<sup>34</sup> While some of the immediate effects may be obvious; some may be hidden or subtle.<sup>35</sup> But the long term consequences of any outcome are largely unknown.<sup>36</sup> The concern generated by this relatively easy-to-use technology is illustrated by the fact that this would be only the *second moratorium in history* where scientists across the globe would voluntarily restrict themselves from further experiments with DNA.<sup>37</sup> To be sure, calling a moratorium is not the same as implementing it. Despite the calls for a holding pattern, researchers in China announced in April 2015 that they had unsuccessfully attempted to use the technology on a non-viable human embryo in order to alter a gene connected to a blood disease.<sup>38</sup> Evidently, then, not all scientists agree with the moratorium, nor will they necessarily obey such calls for stoppage.<sup>39</sup> More experiments in countries without regulation, and potentially in countries with regulations that are simply ignored, seem likely in the coming years. Even since the first draft of this paper, China has already tested CRISPR on a human being.<sup>40</sup>

As the technology continues to develop, the scientific and legal communities will need to better understand its implications and to determine how to best incorporate it into society with appropriate regulations or administer a ban on the use of the technology on human embryos outright. Of course, enforcing such a ban would be difficult, expensive, and generate risks of its own.<sup>41</sup> Consider doping, which will be

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32 *Id.*

33 *Id.*

34 *Id.*

35 *Id.*

36 *Id.*

37 Paul Berg, *Meetings that Changed the World: Asilomar 1975: DNA Modification Secured*, 455 NATURE 290, 290-91 (2008) (discussing the first moratorium called by the scientific community, held at Asilomar, California).

38 Center for Genetics and Society, *supra* note 1.

39 *Id.*

40 David Cyranoski, *CRISPR Gene Editing Tested in a Person for the First Time*, NATURE (Nov. 15, 2016) <http://www.nature.com/news/crispr-gene-editing-tested-in-a-person-for-the-first-time-1.20988>.

41 See Benjamin van Rooij, *The People's Regulation: Citizens and Implementation of Law in China*, 25 COLUM. J. ASIAN L. 116, 121-35 (2012) (discussing difficulties in administering and enforcing many Chinese regulations including pollution).

discussed below, and how hard it has been to regulate in professional sports.<sup>42</sup>

### III. IS THERE A FUNDAMENTAL RIGHT OR LIBERTY INTEREST AT STAKE?

Expanding our analysis of CRISPR and germ line modification requires us to ask whether there is an important constitutional interest at stake regarding one's use of the technologies. The Fourteenth Amendment says that no state shall "deprive anyone of life, liberty or property without due process of law."<sup>43</sup> A substantially identical text applies to the federal government as well under the Fifth Amendment.<sup>44</sup> It is important to clarify that when referring to "liberty interests" that they are akin to, but may not be the same as fundamental rights. The specific standards of review to be used in assessing possible future regulations of CRISPR—strict scrutiny, intermediate scrutiny, or rational basis—are discussed later.<sup>45</sup> For now, we only need to remember that a "liberty interest" typically draws intermediate scrutiny while a fundamental right is more likely to receive strict scrutiny.<sup>46</sup>

In our analysis, we should first try and pin down what exactly the right at issue would be. A right to modify generally? A right to medical treatment or "medical prevention" through avoiding specific genetically influenced disorders? A right to enhancement in particular? We will discuss all three in turn beginning with the broadest interest—a right to modify human traits, but with a focus on doing so via germ line editing, as part of the reproductive process.

#### A. RIGHT TO MODIFY TRAITS

Whether one has a right to modify means little without context, but it is a good starting point. If you were to ask most individuals whether they think they have a legal right to cut their hair or shave their chest, they may even be taken aback by the question. Of course, these are hardly "modifications" and one has such rights to personal autonomy easily extended to elementary changes in one's appearance. Still, it is not obvious exactly how to describe the right to major modifications, whether via genetic alterations or biological procedures in living beings—and indeed, some may protest that there is no such right. It is not decisive to say that the interests are not mentioned in the Constitution. "Liberty" is a broad term that is intended to cover matters not mentioned; this is a primary function

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42 Shayna M. Sigman, *Doping in Sports: Legal and Ethical Issues: Are We All Dopes?*, 19 MARQ. SPORTS L. REV. 125 (2008).

43 U.S. CONST. amend. XIV.

44 U.S. CONST. amend. V.

45 Section III, herein.

46 *Planned Parenthood v. Casey*, 505 U.S. 833 (1992). Professor Winkler has argued that not all rights we call "fundamental" clearly draw strict scrutiny. Adam Winkler, *Fundamentally Wrong About Fundamental Rights*, 23 CONST. COMMENT 227 (2006). In some respects, Justice Marshall may have been right in saying that the existing tiered system of standards of review is often, in operation, more finely calibrated. *San Antonio Independent School District v. Rodriguez*, 411 U.S. 1, 98-99 (1973) (Marshall, J., dissenting).

of abstractions. The question concerns which forms of liberty (or equality) merit special constitutional protection. Not all claims under the Due Process and Equal Protection Clauses are equal.

If you were to ask the same person whether or not they have a right to modify an embryo in ways that will affect their future child's entire genome and in turn affect their children's children and beyond, you will receive greater pause. Sure, one should possess the liberty to decide how to style one's hair (leave aside group customs, the armed services, and law enforcement) and to arrange one's "look" when they go swimming at the family beach-house over the summer.

But does the interest still attach when the decision no longer impacts one's personal autonomy alone, but extends to future beings?<sup>47</sup> Further, it permanently impacts one's child's personal autonomy by modifying their traits without their assent. Assent is obviously impossible. Some would argue it is immaterial—at least for prevention of lethal or crippling disorders. But the issue at least calls attention to the problem of deliberately and seriously affecting the child's future range of choices, and for our purposes, that is our main focus.<sup>48</sup> Regulating your child's appearance is one thing. Subjecting her to education and training to hone her existing traits is far more important and permitted and demanded by custom. These processes are strong candidates for constitutional status. But altering her genome is sharply different. The modification today will have impacts on a child born two hundred years from now. Why would anyone trust her ancestors to have made the right choice? Then again, why would we think that the genetic lottery, or Nature, is a superior provenance in all cases? Parents of children with early-onset Tay-Sachs might think otherwise.

These ideas are instructive when examining the state's interests, but we should also consider them when discussing whether a liberty interest should attach at all. The Founders had no way of contemplating such new-age technologies as we have today; at most, they were simply aware that traits "run in families" and one's choice of mate, while not determinative, affected the likelihood of what one's children would be like.

So, the question of whether there is a liberty interest *at all* intersects with questions about *justifying intrusions* on a fully acknowledged liberty interest: what state interests are at stake? If they are so strong that they will usually win out even under elevated scrutiny, why recognize a presumptive right in the first place?

#### B. RIGHT OF ACCESS TO MEDICAL TREATMENT WITHOUT GOVERNMENT INTERFERENCE

Discussing a "right to modify" is a necessary starting point for constitutional analysis because it helps us see how far-reaching some of our

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<sup>47</sup> See generally Axel Gosseries, *On Future Generations' Future Rights*, 16 J. POL. PHIL. 446 (2008) (discussing ideas pertaining to future generations and the rights that do or do not attach).

<sup>48</sup> Joel Feinberg, *Freedom and Fulfillment: Philosophical Essays* 76, 77 (1992) (Feinberg refers to "anticipatory autonomy rights").

actions might be. However, if we describe the right at lesser levels of generality we can better sort out where a liberty interest may attach and where it may not. Selecting the soundest description within our constitutional value system is a major step in rights jurisprudence.<sup>49</sup> A key distinction in the proposed use of CRISPR technology involves the use of the technology for disease prevention, augmentation, both, or neither. Recall once again that we are discussing this right as it would attach in the context of persons-to-be (germ line modification) as opposed to those currently living (gene therapy).

A right to receive medical treatment from the government has been recognized in a few limited contexts, but it never has been found to be a blanket right for all persons in all government regulation contexts. The Eighth Amendment gives prisoners the right to basic medical treatment for serious conditions; failure to provide it constitutes cruel and unusual punishment.<sup>50</sup> Additionally, it has been found that one has a right to refuse medical treatment,<sup>51</sup> although that right can be limited in certain instances, such as when one is imprisoned.<sup>52</sup> Further, individuals cannot be involuntarily confined solely because they are mentally incompetent.<sup>53</sup> This is relevant to analyzing genetic modification services to prevent disorders because there is an absence of competent choice in both contexts. The contexts are certainly quite different: incompetent persons can consider choices and their competence may be restored. The comparison can only be pushed so far. The interplay will be discussed further in the next subsection.

All of these rulings (situated within the Eighth Amendment context by the criterion of “evolving standards of decency”)<sup>54</sup> seem to suggest that the Court hasn’t ruled out the possibility of an individual having a right to medical treatment as against the government. However, no court has ever established this right in broad terms despite having several opportunities to do so. Not having a definitive ruling from the Supreme Court, however, hardly establishes the absence of a right to modify the genome of one’s prospective children. Moreover, the greater the beneficial impact, the greater the challenges to prohibition or severe regulation will be. Overregulation will deny a parent the ability to potentially thwart a genetic hardship in their child-to-be.<sup>55</sup> The prospect for great benefit also brings the possibility of serious adverse effects—a tension that is likely to be litigated.

49 See *Michael H. v. Gerald D.*, 491 U.S. 110, 127 n.6 (1989) (based in tradition, “genetic father’s rights within marital union is the correct description,” not “genetic father’s rights generally”; the latter was denied visitation rights to a child born of an adulterous relationship).

50 *Spicer v. Williamson*, 191 N.C. 487, 490 (1926).

51 *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 270-71 (1990) (holding that a person has a liberty interest to refuse medical treatment).

52 *Washington v. Harper*, 494 U.S. 210, 227 (1990) (holding narrowly that a state may treat an inmate with a serious mental illness with antipsychotic drugs against his will).

53 *O’Connor v. Donaldson*, 422 U.S. 563, 575-76 (1975) (“A finding of ‘mental illness’ alone cannot justify a State’s locking a person up against his will and keeping him indefinitely in simple custodial confinement.”).

54 *Trop v. Dulles*, 356 U.S. 86 (1958).

55 See Antonio Regalado, *Engineering the Perfect Baby*, MIT TECH. REV. (Mar. 5, 2015), <https://www.technologyreview.com/s/535661/engineering-the-perfect-baby/>.

So far, CRISPR has been used to prevent muscular dystrophy in mice<sup>56</sup> via germ line modification and has been shown to effectively target multiple genes at once in zebra fish,<sup>57</sup> potentially opening the doors to curing several genetic diseases, such as: Tay Sachs, cystic fibrosis, sickle cell disease, and hemophilia.<sup>58</sup> The importance of these diseases specifically is that each is relatively easy to diagnose probabilistically; this is in contrast to other conditions involving many genes and environmental variables that are much more difficult to predict in the early pre-birth stage where germ line modification is relevant.

Apart from germ line modification, CRISPR technology has also been shown to have the potential to allow for the use of pig organs for transplantation into humans by eliminating or reducing the immune rejection response to foreign tissue and the risk of viral infection from pig DNA.<sup>59</sup> These advancements have individuals both within the scientific community and beyond on high alert. CRISPR could potentially be used by parents who wish to avoid passing on horrible, debilitating genetic disorders to their children, and this has many proponents pushing for further experimentation and use of the technology.<sup>60</sup>

In determining whether there is a liberty interest in modifying one's germ line to avoid disorders, it may be useful to ask if there really is an underlying moral duty to avoid disorders through germ line modification. Certainly, some members of the disabled community would oppose characterizing their condition as a "disorder" and may further object to prenatal or preconception testing because it suggests that their lives, as disabled persons, are not valuable enough to merit reproduction of those like them. Others may not possess such sensitivities and urge, or even demand, that the technologies be used to prevent the existence of affected persons. But "denying life" to such persons may be viewed by others with even more alarm than curing or improving the condition of existing affected persons, because of this risk of devaluing lives.

These adverse views, although not decisive in themselves, serve as clues to traditional attitudes that are relevant in formulating, evaluating, and interpreting any future regulation of CRISPR. But as is true in many conflicted situations, traditional and current attitudes may be fractured. Worrying over the devaluation of life when we pursue genetic screening and germ line modification to prevent serious disorders may be in strong tension with the long-standing tradition of doing what is best for our

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<sup>56</sup> See generally Chengzu Long et al., *Prevention of Muscular Dystrophy in Mice by CRISPR/Cas9—Mediated Editing of Germline DNA*, 345 SCIENCE 1184, 1187 (2014).

<sup>57</sup> Woong Y. Hwang et al., *Efficient In Vivo Genome Editing Using RNA-Guided Nucleases*, 31 NATURE BIOTECHNOLOGY 227 (2013).

<sup>58</sup> Meeri Kim, *Scientists are Growing Anxious About Genome-Editing Tools*, WASHINGTON POST (May 18, 2015), [https://www.washingtonpost.com/national/health-science/scientists-are-growing-anxious-about-genome-editing-tools/2015/05/18/0a4db63c-ef4e-11e4-8abc-d6aa3bad79dd\\_story.html](https://www.washingtonpost.com/national/health-science/scientists-are-growing-anxious-about-genome-editing-tools/2015/05/18/0a4db63c-ef4e-11e4-8abc-d6aa3bad79dd_story.html).

<sup>59</sup> Michelle Roberts, *GM Could Make Pig Organs for Humans*, BBC NEWS (Oct. 12, 2015), <http://www.bbc.com/news/health-34506572>.

<sup>60</sup> Rebecca Taylor, *UK Science Advisor Urges Germ-Line Modification of Human Embryos*, MARY MEETS DOLLY (Jan. 22, 2016), <http://www.marymeetsdolly.com/blog/index.php?archives/1456-UK-Science-Adviser-Urges-Germ-line-Modification-of-Human-Embryos.html>.

children through preventive health measures. It is not clear that this should not extend to “procedures on the unborn” via germ line modification. “Liberty” might encompass a constitutional interest in avoiding government interference with our choices, especially in the context of germ line modification to prevent serious disorders.<sup>61</sup>

With this in mind, let us again consider whether one may in fact have a liberty interest in medical treatment that goes beyond those described in our current constitutional decisions. Consider first a comparison to constitutional doctrine involving incarcerated persons, to see if it sheds any light on our problem of regulating access to germ line modification, either to avoid disorder or to augment. When imprisoned, individuals have limited independent opportunities to secure medical treatment. It is arguably inhumane *not* to provide basic medical treatment to prisoners, or even extraordinary medical treatment in unique cases.<sup>62</sup> Should this same argument be extrapolated to give such rights to individuals who have no choice but live a life with a genetically caused disease that could have been avoided by germ line modification? Perhaps this seems far-fetched, but such disorder-caused *genetic imprisonments* are burdens and often full barriers to one’s liberty. True, the case for doing so may be less persuasive when the disorder, however serious, is curable or substantially controllable. But treatment may be costly and incomplete. The Court may well be swayed by such sympathetic “parties”—persons-to-be who would otherwise be severely impaired, and their parents.<sup>63</sup>

### *1. The Brief Argument for a Right to Treatment in the Form of Genomic Prevention of Medical Disorders*

Much of the logic behind providing prisoners a right to medical treatment while incarcerated revolves around the lack of choice or liberty the prisoners have. Since a prisoner is incarcerated, it would be cruel and unusual punishment to not treat him for his medical ailments if the condition was serious.<sup>64</sup>

An embryo may lack choice, but it eventually becomes a person, and then it makes sense for her to say that her parents should have acted earlier as her intelligent agents and either chosen to avoid a serious adverse condition or to augment a major aptitude. When an embryo develops or becomes predisposed to a serious disorder solely due to her parents’ genes, her liberty has been avoidably compromised in the sense that her opportunities have been severely curtailed or utterly destroyed, as with Tay Sachs.

<sup>61</sup> *Wisconsin v. Yoder*, 406 U.S. 205 (1972).

<sup>62</sup> *See Estelle v. Gamble*, 429 U.S. 97 (1976); *cf. Kosilek v. Spencer*, 774 F.3d 63 (1st Cir. 2014).

<sup>63</sup> Here a question arises regarding standing. Do embryos have standing? Prospective parents only? This is a clear issue that needs to be addressed, but it is beyond the scope of this note. *See Sherley v. Sebelius*, 689 F.3d 776 (D.C. Cir. 2012), *cert. denied* 133 S. Ct. 847 (2013).

<sup>64</sup> *Id.* at 104 (“We therefore conclude that deliberate indifference to serious medical needs of prisoners constitutes the “unnecessary and wanton infliction of pain,” *Gregg v. Georgia*... proscribed by the Eighth Amendment. ... This conclusion does not mean, however, that every claim by a prisoner that he has not received adequate medical treatment states a violation of the Eighth Amendment.”).

So, however edgy, we should make the comparison between captives and embryos. Of course, the Eighth Amendment has zero direct application here: it governs only within the domain of criminal punishment—sentencing and some conditions and actions connected with prison life. But there is a shared moral insight about doing what we think is “right” for persons—or entities—who (for entirely different reasons) have no options for risk avoidance. This shared element covers both prisoners and persons-to-be, even though embryos aren’t literally imprisoned.

Some important distinctions need to be stressed here to clarify the arguments being made. I am not advancing a viewpoint in which someone could effectively advocate for the government to be obliged to provide or fund CRISPR access. The point is to allow those who wish to intervene in their own reproductive processes to affect the genome of their offspring to do so, unimpeded by government. The relationship between a prisoner and an innocent embryo are parallel, though hardly perfect matches: prisoners are existing persons who came by their situations via their own choices. As before, “choice” makes no sense as applied to embryos. But the idea of avoiding the impairment of an embryo’s future range of choice as a person makes perfect sense—just as it does for the prisoner requiring treatment to preserve her future autonomy. The comparison simply helps highlight some of the serious questions we need to ask as a society, one of which is: should innocent embryos, who have committed no wrong, be denied access to genetic alterations that would allow them to thrive as persons by preventing their parents’ access to CRISPR technology? The question is more difficult when we are unsure of the potential impact of genetic anomaly.

## *2. The Brief Argument against a Right to Treatment in the Form of Genomic Prevention of Medical Disorders*

In response to the above argument, some would argue that the impact of the “genetic lottery,” yielding an individual’s genome, has little to do with liberty within society, and cannot trigger any constitutional liberty interests. The genetic results of reproduction are governed by natural processes. Whatever they are, these effects should not be considered rectifiable intrusions on our constitutional liberties imposed by an agent subject to our control. Constitutional rights are not defenses against nature. They were established to limit the federal and state governments to protect individual rights.<sup>65</sup> The intent of the Bill of Rights was to protect the citizenry from the government, not from their genetic makeup. Therefore, drawing the parallel between prisoner’s rights to treatment and a future child’s right to treatment is somewhat off base. That’s why the Eighth Amendment argument should be used simply as an analytical aid for other forms of liberty interest arguments based on different constitutional texts; it suggests lines of analysis, but doesn’t directly address the germ line enterprise as a whole, or so one may argue.

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65 *The Bill of Rights: A Brief History*, ACLU, <https://www.aclu.org/bill-rights-brief-history>.

On this view, then, a person's individual rights are not threatened by her genetic framework. One's opportunities, relatively and absolutely, are limited by one's traits, as well as by one's surroundings. Most of us are unlikely to be able to derive calculus independently. Being born with a smaller, larger, or simply different set of opportunities is not a matter of constitutional right; it is not a matter of being unfree. Indeed, it is extremely risky to think otherwise: allowing CRISPR technology to mess with your developing daughter's DNA may only alter her existence for the worse and limit her future liberty interests. We do not know all that lurks in the shadows of the genome—and even if we did, we would not be able to avoid massive risks. This applies to future generations generally. Again, the question is whether liberty should be extended to irreversibly affecting the trait-composition of future beings through germ line modification. Is “genetic liberty” really a “constitutional thing,” and even if so, was it meant to be protected at such an early stage?

### C. RIGHT TO ENHANCEMENT

The last of our potential liberty interests at stake is one's right to genetic enhancement—not just “repair.” A related possible liberty interest is in enhancement post-birth. One can frame this right as one of personal autonomy—and this requires attention both to parental rights to control reproductive and nurturing processes and to the child's prospects. From a living person's viewpoint, enhancement is a matter of bodily and mental integrity and control over one's identity and aspirations to betterment. Either way the right seems weaker in certain contexts than in others, thus illustrating the point that technological change presses us to more finely calibrate our understanding of constitutional rights and their limitations. For example, in some cases, blocking disease prevention (e.g., early onset dementia) may threaten a person's liberty more than limiting their ability to technologically enhance herself—to become smarter, stronger, faster, taller, or more attractive than the average person. On the other hand, failure to prevent, say, myopia seems trivial compared to disallowing a substantial increase in intellectual powers or physical agility.

#### *1. Traditional vs. Technological Enhancement*

Most would argue that we have rights to pursue traditional (if not entirely “natural”) forms of enhancement. As a matter of simple moral perception, at least, they attach to our freedom as humans: whether we lift weights, run, seek coaching, or do nothing is up to us. A government ban on “working out” would seem to be an elementary interference with constitutional liberty—physical liberty, at the least, and with respect to bodily integrity and personal security more generally.<sup>66</sup> But, enhancement through technical means such as germ line modification, or perhaps the more widely discussed sport's “doping,” is less obviously such a right, although it certainly is a matter of personal liberty in the simple dictionary

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66 See *Youngberg v. Romeo*, 457 U.S. 307, 322, 324 (1982).

sense.<sup>67</sup> This alone does not establish a moral or constitutional liberty, however. Still, does this distinction between the traditional and technological make sense? Addressing this question is one of the central occupations of various thinkers in the field.<sup>68</sup>

In the context of technical enhancement, some think humanity is moving progressively towards objecthood rather than personhood.<sup>69</sup> Many opponents of CRISPR technology fear this and call for preventing “designer babies” and maintaining our biological existence as it was “meant to be.” This Note cannot pursue in-depth philosophical or religious discussions about human existence, but such arguments against implementing human modification technologies are being made by many well-respected bioethicists and philosophers, such as Leon Kass and Michael Sandel and are being countered by significant scholars on the other side, such as Nick Bostrom.<sup>70</sup>

Distributional issues aside—we will discuss them in the state’s interest section below<sup>71</sup>—why does the distinction between careful reproductive mating and gene editing exist? And, in the related post-birth field, why does the distinction between traditional “perfectionist” methods (training, practice, coaching) and technological enhancement make a moral or legal difference? Do constitutional rights to traditional enhancement just attach because they are traditional? Is technological enhancement to remain constitutionally unprotected because we never did it before? What is the most constitutionally relevant way to describe “it”? Not everyone would call technologically-enhanced performance personal “improvement” and a reflection on one’s character. But this is part of what is at issue here. Isn’t it just a matter of degree, not kind? And even if the latter, so what? Why is the choice to enhance via technology inevitably a reflection of adverse character? What moral or religious criteria should we invoke to show why technical enhancement is different? Assuming the technology is safe and available, do individuals have a right of access?

Sometimes the rejection of a rights framework, either in moral or constitutional analysis, derives from unfamiliarity with new techniques that challenge the boundaries of familiar understandings. When addressing “constitutional unfamiliarity” the courts will look to custom, traditional definitions, and history when doing their analysis. In working with legal texts, however, we regularly have to go beyond such considerations when faced with innovation and must test it in light of constitutional values—

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<sup>67</sup> It is worth noting that this is also an issue in the gene therapy space, but this Note is maintaining its focus more narrowly on germ line modification. Liberty is defined as “the condition of being able to act of function without hindrance or restraint.” OXFORD ENGLISH DICTIONARY (3d ed. 2010).

<sup>68</sup> Philip Brey, *Human Enhancement and Personal Identity*, in *NEW WAVES IN PHILOSOPHY SERIES* 169, 169-85 (2009).

<sup>69</sup> Shapiro, *supra* note 8 at 55.

<sup>70</sup> See generally Leon Kass, *Triumph or Tragedy? The Moral Meaning of Genetic Technology*, 45 *AM. J. JURIS.* 1 (2000) (discussing the moral implications attached to genetic modification); see also MICHAEL J. SANDEL, *THE CASE AGAINST PERFECTION: ETHICS IN THE AGE OF GENETIC ENGINEERING* 85 (2007); NICK BOSTROM, *SUPERINTELLIGENCE: PATHS, DANGERS, STRATEGIES* (2014).

<sup>71</sup> See *infra* Section IV(B).

deliberately formulated in abstract terms—such as “liberty” and “equal protection of the laws.” If certain issues were not considered by the Framers, it is difficult to see how particular instances can be excluded from falling within an abstraction, such as “liberty,” simply by not having been encountered before. If a particular conception of a value had been rejected by the Framers, that might be decisive for an Originalist, and at least relevant for others. But here, it is not as if any Framer had rejected the particular conception of modification via germ line modification as legitimate improvement and thus within our constitutional liberty. We thus have to probe the nature of the value further. Some interpretive paths focus on comparing the case at hand to accepted exemplars. The differences between the natural and traditional standard instances may not be fully persuasive. Do we care if a top-notch air traffic controller is better able to resolve a difficult situation because of enhancement or natural but honed ability? Still, there is some history on technological enhancement, though it is meager compared to the ample history of traditional efforts to “perfect” oneself.<sup>72</sup> This history on the treatment of doping in sports may be used to draw strong analogies as to why technological enhancement is or is not deserving of constitutional liberty protections.<sup>73</sup>

## 2. Procreation/Family Formation

Parents who wish to use the CRISPR technology to modify their offspring will try to invoke a procreational or family formation liberty interest in the use of the technology. Many cases, at all levels of the judiciary, have held that an individual’s rights to procreate and form families are fundamental and may even predate our Constitution,<sup>74</sup> and therefore should be protected from unnecessary government intrusions.<sup>75</sup> Plaintiffs demanding the use of CRISPR to genetically modify their children to have blue eyes, greater intelligence, greater athletic abilities, or just freedom from genetic mutation will all point to the strong language the Court has used over the years in describing one’s procreational and familial rights. How far do they reach?

What rules of constitutional interpretation are called for here, and how do they apply? There are many theories of constitutional interpretation, but we do not formally analyze them here.<sup>76</sup> Even without seeing the exact text of a germ line modification ban, one important factor to consider, within any interpretive theory, is the history of procreational liberty and the history of how the Court has viewed it. The court announced, almost half a century ago, that “if the right to privacy means anything, it is the right of

<sup>72</sup> See *Historical Timeline: History of Performance Enhancing Drugs in Sports*, ProCon.org, <http://sportsanddrugs.procon.org/view.timeline.php?timelineID=000017>.

<sup>73</sup> *Doping in Sport: What is it and How is it Being Tackled?*, BBC News (Aug, 20, 2015), <http://www.bbc.com/sport/athletics/33997246>.

<sup>74</sup> This raises a controversial issue in legal philosophy that we ignore. These rights seem so basic that many claim they are part of natural law and are simply recognized rather than created by the Constitution.

<sup>75</sup> See e.g., *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977).

<sup>76</sup> *Principles of Constitutional Construction*, CONSTITUTION SOCIETY, [http://www.constitution.org/cons/prin\\_cons.htm](http://www.constitution.org/cons/prin_cons.htm).

the individual, married or single, to be free of unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision to bear or beget a child.”<sup>77</sup> So this place for procreational freedom within the penumbra of privacy rights seems strongly entrenched in the Court’s thinking and analysis. That being said, the Court has not recognized procreational freedom as an *absolute* right and the history of human germ line modification is virtually non-existent. In fact, although it does not foreclose recognition of such a right, the *lack* of history surrounding CRISPR seems, in this case, to cut against doing so. The Justices in *Carey v. Population Servs. Int’l*, were not thinking of CRISPR when they made such a strong statement about procreational liberty back in 1977. It is far from the paradigm of a couple seeking to reproduce even when seeking mates on the Internet, specifying rigorous requirements, in order to increase the chances of having smart children.<sup>78</sup>

Individuals have a right to procreate and start a family in the most basic sense—i.e., having a child. However, certain familial relationships and family-formation methods have long been barred or regulated by the state—polygamy, for example.<sup>79</sup> Therefore, the right is certainly not absolute. Germ line modification, like polygamy, invokes many moral objections and does not so clearly merit protection as many other procreational and familial rights. Whatever uncertainties there are in knowing what a natural genome’s future will be, some of the unknowns are vastly expanded by our intervention—even as others may be narrowed in some sense (e.g., the modification is meant to increase the person-to-be’s height).

Of course, these considerations simply establish that there are limits; germ line modification and polygamous arrangements are quite different processes, and constitutional denunciations of the latter do not require similar rejection of the former. We already stated that one popular moral objection to germ line modification is the idea that creating “designer babies” is playing God and distorts the natural order.<sup>80</sup> So what if they are designed? The “natural order” is disrupted when we wear clothes, take antibiotics, draw water from a well, draft constitutions, and form political parties. We alter species with regularity, both deliberately and inadvertently.

#### IV. WHAT IS THE DEGREE OF PRESUMPTIVE PROTECTION CRISPR TECHNOLOGY USE IS TO RECEIVE?

While we certainly have not reached a conclusion that a liberty interest would protect one’s desired use of CRISPR in any of the discussed

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<sup>77</sup> *Carey*, 431 U.S. at 684-85.

<sup>78</sup> See David Plotz *The Myths Of The Nobel Sperm Bank: The Truth About Who Gave Sperm, How They Gave It, And Who Used It*, SLATE (Feb. 23, 2001), [http://www.slate.com/articles/life/seed/2001/02/the\\_myths\\_of\\_the\\_nobel\\_sperm\\_bank.html](http://www.slate.com/articles/life/seed/2001/02/the_myths_of_the_nobel_sperm_bank.html) (12/31/16).

<sup>79</sup> *Reynolds v. United States*, 98 U.S. 145, 166 (1878) (upholding a ban on polygamy).

<sup>80</sup> James Gallagher, ‘Designer Babies’ Debate Should Start, Scientists Say, BBC NEWS (Jan. 19, 2015), <http://www.bbc.com/news/health-30742774>.

contexts—disorder prevention or augmentation—the next step in our analysis is to assume that there is such a liberty interest and then look to what standard of review a court would apply when addressing an infringement on the technology’s use.<sup>81</sup> I will briefly address the standards of review in the order of likelihood that they will apply: rational basis, intermediate scrutiny, and strict scrutiny. Context always matters in constitutional application and we will address context shortly. This section merely explains the different levels of scrutiny generally; the applications to restriction on CRISPR use are deferred to Section IV.<sup>82</sup>

#### A. RATIONAL BASIS

The rational basis test is the default standard of review for all constitutional claims of right. This is a corollary of the basic principle that all government action is presumed constitutional. It is the easiest for government to pass, and higher standards apply only where specially protected interests arise. Formal recognition and explicit discussion of rational basis review has been a factor in legal discussions at least since the late 1800s.<sup>83</sup> As the default standard of review, it is applied in substantive due process cases in which no liberty interest is said to attach, and in most equal protection cases, absent suspect or semi-suspect classifications or classifications that bear on the exercise of fundamental rights or liberty interests. This would be the case for most economic interests.

As mentioned, all government actions are presumptively constitutional. Thus, at the opening instant of litigation, there is no burden on the government: it’s the claimant’s burden to establish a prima facie case—almost always by establishing a strongly protected interest that has been significantly burdened, requiring nontrivial scrutiny. Once a serious liberty interest claim is preliminarily established, however, the government must produce a justification. One could argue that whenever a claimant shows a significant interference with her preferences, even when no specially protected interest is involved, the government, under rational basis review, has at least the “burden” going forward to prove that its action is rationally related to a legitimate government interest. But, at least within substantive due process, the burden is almost nonexistent. Some argue that the rational basis test has no teeth and is not rational at all.<sup>84</sup> Calling its application a

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<sup>81</sup> In theory, *tiered* standard of review systems kick in only when there is a serious enough infringement. See *Whalen v. Roe*, 429 U.S. 589 (1977). With “sliding scales,” any degree of infringement will—in theory—spur *some* inquiry, although, with lesser intrusions, one presumably receives lesser scrutiny, given the definition of a “sliding scale” or “spectrum” of standards. See *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 62-120 (1973) (dissenting opinion).

<sup>82</sup> See *infra* Section IV.

<sup>83</sup> James Bradley Thayer, *The Origin and Scope of the American Doctrine of Constitutional Law*, 7 HARV. L. REV. 129 (1893).

<sup>84</sup> See generally Clark Neily, *No Such Thing: Litigating Under the Rational Basis Test*, 1 NYU J.L. & LIBERTY 897 (2005) (equating the rational basis test to insanity, apparently because that standard cannot distinguish right from wrong); *but see* *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432 (1985); *see also* *Romer v. Evans*, 517 U.S. 620 (1996); *Willowbrook v. Olech*, 528 U.S. 562 (2000), (where the rational basis test failed because of constitutionally illegitimate goals, rather than (solely) inadequate means-end relationships).

“burden” may be giving the test too much credit; it is hardly even a test, let alone a burden.

Within present doctrine, this “test” of minimal scrutiny would likely be the standard of review that the government would have to meet if it did decide to regulate CRISPR. This is because, as discussed above, there is currently no recognized liberty interest at stake—no right to genetic modification of a potential person. This could change, however, as we put forward several (and certainly not an exhaustive list) of arguments to the contrary.

## B. INTERMEDIATE SCRUTINY

The middle ground between rational basis and strict scrutiny is intermediate scrutiny. Its usual canonical (but not its only) form is that government action requires a law to advance an important government interest and be substantially related to achieving such an interest.<sup>85</sup> Intermediate scrutiny has been used in several contexts such as sex-based classifications under the Equal Protection Clause<sup>86</sup> and commercial speech cases.<sup>87</sup> Most recently, the Court has hinted at the possibility of using intermediate scrutiny in certain Second Amendment gun control cases, but it has left the door open for strict scrutiny as well.<sup>88</sup> If a court were to find that a liberty interest attaches to the use of certain germ line modification technologies it would more likely apply this middle-ground of review rather than strict scrutiny review, given that the right would likely not be fundamental or deal with a suspect classification as is required for strict scrutiny review.<sup>89</sup>

## C. STRICT SCRUTINY

The most demanding standard of review the government has to meet is strict scrutiny. Strict scrutiny review applies in cases in which a fundamental right is being infringed upon<sup>90</sup> or a suspect classification is made within the statute or by other open government action.<sup>91</sup> Strict scrutiny is also triggered when classifications are based on one’s choice to exercise a fundamental right (the “fundamental rights” branch of equal protection strict scrutiny).<sup>92</sup> Presumably intermediate scrutiny would be applied in an equal protection context to classifications based on liberty interests.

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85 *United States v. Virginia*, 518 U.S. 515, 570-71 (1996) (Scalia, J. dissenting).

86 *Craig v. Boren*, 429 U.S. 190 (1976).

87 The default rule is that content-based regulation draws strict scrutiny, except for commercial speech and certain other defined spheres (e.g., broadcast media, nonpublic forums, some forms of professional speech); regulation directed at speech but not at content generally draws some form of intermediate scrutiny, as in time, place and manner regulation.

88 *District of Columbia v. Heller*, 554 U.S. 570 (2008) (court does not come to a conclusion on a standard of scrutiny, leaving the door open for both intermediate and strict).

89 Richard H. Fallon Jr., *Strict Judicial Scrutiny*, 54 *UCLA L. REV.* 1267, 1268-69 (2007).

90 Arguably, even some fundamental rights don’t draw strict scrutiny. See Adam Winkler, *Fundamentally Wrong About Fundamental Rights*, 23 *CONST. COMMENT.* 227 (2006).

91 Fallon Jr., *supra* note 84 at 1268-69.

92 *Id.*

As we discussed above, the lack of even a current liberty interest clearly discernible from prior rulings makes this standard of review very unlikely for germ line modification regulations. But, if a fundamental right were held to be at stake, it would probably be the standard of review applied. This is even more unlikely as courts often look to history to establish a fundamental right, and the history of genetic manipulation is not likely to be strong. Most of the low-tech genetic control efforts—widespread sterilizations—have been all but universally condemned, at least by the more vocal members of the public.<sup>93</sup> On the other hand, speculative analysis aside, there cannot be any history before a process is invented and therefore a lack of history does not necessarily foreclose the possibility of establishing a fundamental right. Suppose there is an extended history of doping, but an accompanying history of strong—but far from universal—condemnation, and of serious—but seriously unsuccessful—efforts to suppress it. Criteria other than an actual supportive—or antagonistic—history of the conduct in question is required. If no such conduct was foreseen, an “actual history” of the Framers’ forethought is also impossible.

Under strict scrutiny review the government must prove that it has a compelling interest in implementing its action, that the statute or other government action is narrowly tailored (in this context, the least restrictive means) to achieving the purported interest, and that the interest is in fact substantially advanced by its action. Note that “narrowly tailored” is also used in intermediate scrutiny, but the requirement isn’t as rigorous as “the least restrictive alternative.”<sup>94</sup> The Court is very loose when it talks about “narrowing”: the concept’s application differs as between strict scrutiny and intermediate scrutiny.

## V. THE GOVERNMENT INTERESTS IN REGULATING GERM LINE MODIFICATION

Whether under rational basis, intermediate, or strict scrutiny review, the government will be required to allege an interest in restricting the use of CRISPR. Several interests may be invoked and we will run through some of these in turn. However, the list is in no way exhaustive as many issues swirl around potential germ line modification. After discussing the interest itself, we will further consider how it would hold up against the three relevant standards of review just discussed.

### A. PUBLIC SAFETY (OR PERHAPS UNCERTAINTY?)

The most immediate issue facing germ line modification and CRISPR is its safety. Never before has the scientific community

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<sup>93</sup> Elizabeth S. Scott, *Sterilization Of Mentally Retarded Persons: Reproductive Rights and Family Privacy*, 1986 DUKE L.J. 806 (1986).

<sup>94</sup> *Bd. of Trs. v. Fox*, 492 U.S. 469, 478 (1989) (ruling in a commercial speech case that the least restrictive alternative criterion wasn't required, but a looser "narrowly tailored" one was).

deliberately altered the genes of future human generations through germ line modification. There is limited knowledge about its near and long-term effects, and so uncertainty resonates around how the technology will impact those who use it to alter their gametes or the early embryos of their children, or how future generations will be impacted by the artificial manipulation of the genes they received from their parents. This uncertainty, in and of itself, is cause for concern.

These issues are broad and certainly confusing, given the ambiguity of “safety.” The safety issue is a combined empirical and value issue. For one thing, we do not know what *kinds* of things will happen. For another, even if we did have some idea of what might transpire, we have no data on which to base probability estimates. Still more, it is not clear what even constitutes a harm or danger that would compromise safety. Finally, even with clear knowledge of what is likely to happen, a conceded measure of harm or risk may be justified by the strength of the benefits—a classic balancing test. This is why safety cannot be evaluated independently of effectiveness—and that too is conceptually and empirically uncertain. Some harms are worth bearing in light of anticipated benefits. And some forms of effectiveness may be compromised by a countervailing disadvantage. Is a capacity for “total recall” necessarily a benefit? If being engineered to enjoy total recall comes at the price of bouts of dysfunctional obsessive-compulsive disorder, is the genomically modified person better off?

These issues all play into the safety concerns the government will argue for when advancing its interests. However, we cannot be confined to “safety” as one might perceive “safety” in its usual meanings, both everyday and legal. For example, certain alterations may seem unsafe to some (improving physical strength in a human being to unheard levels, leading to injury to self and others) while beneficial to others (Barry Bonds, perhaps).<sup>95</sup> And the safety calculus involves both the probability of specific adversities of various degrees combined with their gravity (expected disutility—as in the Hand Formula)<sup>96</sup> and *whether this prospect is outweighed by the gains*. Is this to be judged entirely through the lens of the person who may be affected (Barry Bonds) or does society have a say? Given our traditions of ordered liberty we would expect both society and its constituent individuals to share decisional power.<sup>97</sup>

A major aspect of CRISPR’s dangers is this uncertainty, both as to *what* will happen and *how* it is evaluated. Indeed, some will think that a harm is a benefit, and vice versa. Being the tallest, strongest, or best looking person in the room can be both. Many safety concerns the government is likely to raise will deal with the unknowns, not merely what is known. And these unknowns will not only involve the harms/benefits of the immediate individual but the greater impact to society as a whole and

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<sup>95</sup> AP Feed, *Lawyer: Bonds Admits Using Steroids*, FOX SPORTS (May 21, 2011), <http://www.foxsports.com/mlb/story/Barry-Bonds-perjury-trial-begins-032111>.

<sup>96</sup> *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947)

<sup>97</sup> O. John Rogge, *Concept of Ordered Liberty: A New Case*, 47 CAL. L. REV. 238 (1959).

how these overlapping concerns will interact with one another. Safety concerns regarding the technology could range from mutated embryos, birth defects, death, and more—but we don't know what this "more" will entail just yet. We may never know, fully. We are easily paralyzed by uncertainty, and although this is sometimes beneficial, such indecision is not something we strive for. Complete knowledge is not always required for rational conduct.

CRISPR, being a newly discovered technique, has not been sufficiently researched and understood to reasonably assure even uncontroversial safety, much less effectiveness, however these are defined. Moreover, there are serious moral and legal issues in even getting to know more about the technology's safety and effectiveness in human use—both in the modified embryo and in future beings. Results from experiments with mice cannot tell the whole tale. While technological progress in this area is far more rapid than ever before, this progress is causing many researchers, including Dr. Doudna herself, to worry about premature uses of the technology in soon-to-be humans.<sup>98</sup>

Germ line modification not only alters the genes of the immediate child but also influences the genetic makeup of their offspring and so on and so forth.<sup>99</sup> This is because all cells of the modified person are altered, including the germ cells.<sup>100</sup> Therefore, due to the very speculative and remote nature of the risks, they are difficult, if not impossible to assess in any compressed timeframe. It would likely take decades or even centuries to be able to properly analyze exactly how the use of CRISPR will impact the human species.

That being said, some results could be visible quickly, such as the elimination in specific individuals of problematic genes that may cause debilitating disorders. Excitement over these immediate benefits could lead the populace to call for greater use, but we—the novices—must understand that germ line modification should not be pursued with obliqueness to our uncertain future. Scientists would not only be changing the eye color of this baby or curing a disease in that baby, but rather would be altering the genetic makeup of a series of offspring—all to unknown effect. We could in theory start to see a "butterfly effect"; and what may seem like a small alteration to a person's IQ could compound into a large, unforeseen result to him—and when aggregated to others, to society as a whole.<sup>101</sup>

What may be seen by some as benefits, such as increased intelligence, athletic ability, or liberty could be seen as detrimental or unethical to others.<sup>102</sup> With these implications in mind, society must begin to balance whether the safety risks are worth the potential benefits the technology

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98 Wade, *supra* note 17.

99 Center for Genetics & Society, *supra* note 1.

100 *Id.*

101 See generally POUL ANDERSON, *BRAIN WAVE* (1954) (hypothesizing potential results to society and the world based on a wide-ranging butterfly effect caused by an increase in the average IQ after the solar system passed out of an intelligence-dampening force field).

102 *Id.*

offers.<sup>103</sup> Many scientists clearly believe the answer to that is: not yet.<sup>104</sup> But they are not solely in charge, and their value analyses are not necessarily sounder than anyone else's. Also, given that many moral disputes about whether certain events and conditions are good or bad are never-ending: some say the answers will never come, and righteous risk aversion should result in a flat ban. This is an outcome of some "precautionary principles," although that concept is difficult to define.<sup>105</sup> Scientists, although having better knowledge of the technology and the facts, are not the only individuals who can make judgments about the use and values of the technology. Democracy and equality require that opinions be secured from all segments of society.

Assume that we apply the standards of review identified earlier to this governmental interest in keeping persons safe from injury and in mitigating uncertainties deriving from use of CRISPR.<sup>106</sup> It appears the government would have a plausible case for serious regulation. If we are in rational basis territory, the government clearly has a legitimate interest in protecting us against serious physical harms. The law would only need to be rationally connected to such an interest, and it is hard to imagine a failure showing this. Further, I would go on to suggest that this interest—looking ahead to more rigorous scrutiny—is both important and compelling. Protecting the human species from a technology that has the power, over time, to significantly alter the species would seem to be a compelling interest. Suppose, however, the species change would be beneficial. In that light, why is species integrity so compelling? It may make a critical difference whether we characterize the interest as "species harm" or "species integrity." With the latter, any nontrivial change is viewed as a harm to avoid. More problems in interest and rights characterization arise in the following sections.<sup>107</sup>

The government's toughest obstacle would likely be narrowly tailoring their law to be the least restrictive means of achieving their goal under a strict scrutiny standard.<sup>108</sup> Because of the novelty of the situation, the Court may, perhaps without admitting it, be more lenient with the government in such a circumstance. We have seen the Court make questionable decisions in situations involving great uncertainty and fear, if not actual danger.<sup>109</sup> The Supreme Court is unlikely to prevent the government from regulating a technology if the government can effectively portray the serious dangers germ line modification may pose.

<sup>103</sup> John Timmer, *How to Weigh Enormous Promise, Potential Danger of CRISPR/Cas9 Technology*, GENETIC LITERACY PROJECT (Mar. 25, 2015), <https://www.geneticliteracyproject.org/2015/03/25/how-to-weigh-enormous-promise-potential-danger-of-crisprcas9-technology/>.

<sup>104</sup> Nicholas Wade, *supra* note 17.

<sup>105</sup> CASS R. SUNSTEIN, *THE LAWS OF FEAR* (2005).

<sup>106</sup> *See supra* section III.

<sup>107</sup> *See Note, Legislative Purpose, Rationality, And Equal Protection*, 82 *Yale L. J.* 123, 127 (1972); *Note, Less Drastic Means and the First Amendment*, 78 *Yale L.J.* 464, 466 (1969)

<sup>108</sup> An argument could be made that the toughest challenge for the government would be proving that wildly speculative harms constitute a compelling interest.

<sup>109</sup> Eugene V. Rostow, *The Japanese American Cases—A Disaster*, 54 *YALE L.J.* 489, 491 (1945).

## B. DISTRIBUTIONAL PROBLEMS

The government may also argue that regulation of CRISPR would be justified by the prevention of any distributional issues that may arise if the technology was made legally available to the general public—for a price. Here, we examine the nature of this interest and how it is to be advanced. A key distinction in pursuing this analysis is that of preventing disease as opposed to augmenting persons.

### *1. Economic Distributional Problems as they Relate to Disease Prevention*

The potential health benefits of CRISPR technology were discussed in the previous sections,<sup>110</sup> but these benefits must be compared to the problems of access. If the government is advancing the goal of preventing distributional problems regarding access to the technology in the context of disease prevention, their interest is likely to be *weak*. Certain cancer treatments are very expensive, for example. Restricting treatments in development make many people angry.<sup>111</sup>

In this section, we assume that access to genetic modification services is not forbidden and has been cleared for marketing by the FDA or other relevant government agencies. If the services are highly restricted to catastrophic genetic disorders, bans on their use likely would cause much outrage.

Distributional problems arise whenever a desired commodity is scarce, for whatever reason—production problems, distributional blockades, regulatory laws, etc.—anything that makes it not a free good. All economic problems are matters of scarcity—not having what you want when you want it, because it hasn't been produced or distributed or legalized—for whatever reason. These issues are serious and should not be ignored. That being said, this section is concerned with issues related to economic problems of access.

We further assume that CRISPR has reached a point where it is viewed as effective and safe in the prevention of certain debilitating genetic diseases. The argument we consider is that avoiding catastrophic disorder is so desirable that, if everyone can't have it, no one can. The distributional injustice is too great to tolerate.

Assuming some serious constitutional protection, the right of access almost certainly could not be constrained with such a meager interest. Preventing individuals from curing their offspring of disease for the reason that others could not afford it would likely not be upheld in court under an intermediate or strict scrutiny standard. Although the governmental interest of preventing distributional issues may be important in and of itself (i.e. without context), or even compelling in certain circumstances, the ban must be looked at not only for the interest it advances but the detriments it causes. The interest is not important nor compelling in the face of the

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<sup>110</sup> See *infra* sections I & II.

<sup>111</sup> *Abigail Alliance v. Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied* 552 U.S. 1159 (2008).

potential benefits in the prevention of disease in young offspring. It is hard to imagine, in a liberal regime infused with market-economic ideas, that incomplete distribution even of the most critical resources would sustain a government ban on something for which (we assume) individuals have a non-interference right.

The rational basis test would probably pose no problem. The government will be able to meet that standard because the tailoring of the statute must only be rationally related to the government's legitimate interest. But, if that interest is in avoiding the social demoralization and outrage of having incomplete access, then banning distribution is obviously rationally related to that goal. Whether the goal is itself constitutionally legitimate is another question. As a policy matter, one can well understand why blocking a "fountain of youth" technology would make sense if only some received it. But it might well be worse if everyone received it. In any case, uneven distribution through ordinary market mechanisms may not be a matter of constitutional dimension.

## 2. *Distributional Problems as they Relate to Augmentation*

More controversial and less appealing to the electorate is the idea of editing the genes of one's offspring to make them more attractive, intelligent, or athletic. The use of germ line modification in an individual's offspring can create two related issues: (1) questions regarding equality of access generally; and (2) competition for selecting the most appropriate genes to give one's offspring a competitive advantage. Some parents will select genes largely to promote their children's personal opportunities and satisfaction.

Allowing parents to choose the genes of their children to make them more athletic, attractive, or intelligent could create a "genetic arms race."<sup>112</sup> Many parents are likely going to want their children to have the latest and greatest gene sequences that will allow them to thrive within an increasingly competitive society. With this competition between parents, the distributional problems may well exacerbate inequalities. While CRISPR is relatively cheap in comparison to other genetic manipulation technologies, it is inevitable that the ability to edit genes will be more accessible to some—the more well-off—than others.<sup>113</sup> Moreover, altering complex polygenic and multifactorial traits will not be cheap. Nor will retaining the services of the best and often most expensive physicians and genomic engineers, in the hope of securing better outcomes. Making a future person more intelligent or memorious than she otherwise would be is not the same as preventing her from developing sickle cell anemia.

Are these distributional problems significant enough to torpedo the potential for such enhancements? Similar, perhaps less extreme, examples

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112 Girard Kelly, Book Note, *Choosing the Genetics of our Children: Options for Framing Public Policy*, 30 SANTA CLARA HIGH TECH. L.J. 303, 324 (2013).

113 Robert Sanders, *Simple Technology Makes CRISPR/Cas9 Gene Editing Cheaper*, BERKELEY NEWS (July 23, 2015), <http://news.berkeley.edu/2015/07/23/simple-technology-makes-crispr-gene-editing-cheaper/>.

exist, like the relative availability and expense of elite coaching and nutritional supplements. Other examples, arguably more extreme, include the use of human growth hormone and steroids. There are certainly arguments to be made that the distributional issues that enhancement technologies are likely to cause could be outweighed by the potential benefits of overall societal enhancement—but again, “*benefits*” to some may be “*detriments*” to others. It is not yet known to which interests the court will give greater weight.

Overall, the government’s interest in preventing distributional problems for either disease prevention or enhancement overlap. But, the tailoring of the government’s means for ameliorating distributional conflicts may be easier when addressing augmentation. For starters, judges and the electorate are likely to be less sympathetic to an individual who wishes to have his kid jump the highest than they would be for a mother who just wants her child to live a normal life by preventing a genetic predisposition to disorder. Further, the idea of allowing access for enhancement purposes will not only benefit the child at the moment the technology is used, but it theoretically would allow her to succeed in certain realms of society at a higher level. This compounding effect would mean that the problem of future worsening of inequality would be more effectively halted in this context with an effective government regulation.

### C. MAINTAINING SOCIETAL NORMS

A final potential governmental interest that could be advanced when regulating or banning CRISPR technology could be to preserve our normative system of evaluating any individual person’s abilities and efforts. The distinction between traditional and technological enhancement plays a pivotal role here.

In climbing the societal ladder through grade school, high school, college, and graduate school, students build up their human capital to make them more marketable. However, how would an employer judge an individual who has lesser credentials but better genes?<sup>114</sup> You see it in sports all the time, where an athlete is described as “raw,” but his athleticism, or “god-given” talent makes him valuable enough to be given a spot on the roster.<sup>115</sup> It is unclear how society would deal with such a conundrum if it was extended to things such as the practice of medicine or law. Would we still value self-improvement and reward individuals who worked hard and earned their place in society, or would employers look at their medical records and assess their genes? What would happen to the very idea of merit? It seems likely that weight would be given to each

114 If they were born with better genes, they are likelier to have better credentials; that’s one of the reasons parents want germ line enhancement for their children. However the result would not be universal. See also Rachel Feintzeig, *The Boss Doesn’t Want Your Resume*, WALL STREET JOURNAL (Jan. 5, 2016), [http://www.wsj.com/articles/the-boss-doesnt-want-your-resume-1452025908?mod=trending\\_now\\_3](http://www.wsj.com/articles/the-boss-doesnt-want-your-resume-1452025908?mod=trending_now_3) (many employers prefer not to rely on resumes).

115 Cian Fahey, *Why Barkevious Mingo Will Become a Household Name in 2014*, BLEACHER REPORT (July 5, 2014), <http://bleacherreport.com/articles/2113874-why-barkevious-mingo-will-become-a-household-name-in-2014>.

credential, but confusion would likely result as we adjusted to our changing assessments. Universities may have to change their way of thinking and perhaps market themselves differently. Other sectors would be similarly impacted.

Further, non-enhanced individuals who put in the same amount of effort would likely see lesser results. People who decided not to use the technology or had no access to the technology at birth would put in the long hours in the library or the gym, only to find out that their efforts will not reap the same fruits because artificially enhanced individuals whose parents (or someone) used CRISPR to edit their genes can achieve the same ends through less difficult means. Confusion and unfairness would surely result and our entire system for evaluating talent and merit would be thrown into flux. Avoiding this would be the governmental interest—more specifically, maintaining the integrity, and our confidence in, the system of social norms.

So, it appears the government may have an interest to advance, but how do we value this interest? How do we even describe it? Arguments could certainly be made that characterizing this as a “problem”—never mind a compelling interest—is incorrect. Those who believe this interest is weak would argue that this “problem” is not a problem at all but a benefit of having great technological advancement. Using these advancements would allow parents to improve the intelligence and attractiveness of future generations by using the technology on their children. Holding that there is a compelling interest in preventing parents from doing this would seem far-fetched to some.

Additionally, the government could potentially look to less restrictive means of maintaining these societal norms through regulation or strict rules—however, this is a very difficult thing to administer nation by nation as it is a world-wide dilemma.

### *1. The Risk of Objectification*

The “risk of objectification” that many “designer baby” critics like to point to is a more specific risk that has been mentioned in several earlier sections above, but it now should be elaborated. This risk is the fear that developing an ethic of permitting or encouraging mere use of persons reduces them to objects.<sup>116</sup> Even if the reduction is incomplete, it would seem to be a grave harm. The displacement of chance in forming our human traits by specific planning forms the core of this risk.<sup>117</sup> Knowing that individuals have been engineered and objectified will likely have cultural impacts on the way children are raised and how people view and treat each other.<sup>118</sup> Again, arguments that oppose this viewpoint would be raised and the speculative nature of these harms only adds to the problems of establishing that these interests are, though legitimate, weighty enough to overcome rights of access.

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116 Shapiro, *supra* note 8, at 5-11.

117 ALLEN BUCHANAN, ET AL., FROM CHANCE TO CHOICE (2001).

118 *Id.*

But, *partial* objectification and its accompanying risks might be considered an acceptable price to pay for the benefits of enhancement. Complete objectification might be a decisive argument, but a regime of total enslavement of the many to the few seems unlikely, however familiar this literary theme. One cannot properly segment the enhancement picture by addressing only the risks and painting over the benefits—or vice versa.

Overall, preserving social norms probably would not meet the standard of “compelling,” but it might get past the important interest standard and would almost certainly be viewed as legitimate. The tailoring of regulations or bans would probably not be as problematic in this context because the technology is what would cause the confusion in the first place.

## VI. CONCLUSION

We haven’t answered, or even posed, all the questions facing CRISPR technology and its effects on both the United States and the world overall. We have broached the CRISPR topic and, one hopes, presented it in a crisp, understandable fashion.

A liberty interest has not been recognized by the Court that would protect society’s use of the CRISPR technology outright, but arguments can still be brought pointing to a liberty interest in a right to modify, receive preventive medical treatment, and enhance one’s offspring, whether at or before the time of germ line formation or afterwards. Of these interests, a right to preventive medical treatment appears to be the most legitimate claim to a higher standard of review from the courts, but the Court has not recognized such a broad right to medical treatment in the past and it is unclear whether they will ever do so. Additionally, the government has many interests to advance for regulating or eliminating the use of CRISPR on humans in any capacity. These include safety, distributional, and normative considerations, and they are to be judged within possibly differing standards of review the court may apply.

Additionally, research could be done on how a regulatory framework would be implemented and whether the technology should be limited or banned.

