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## DESIGNER EUGENICS: GERMLINE'S FUTURE INTERESTS

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### INTRODUCTION

Germline engineering<sup>1</sup> and relevant complementary technologies are at the brink of changing mankind's future, permanently. But, has the United States adequately considered the implications of germline engineering technology, and are the current policies sufficiently qualified to remain viable as germline engineering advances in the future? Conservatives and liberals have weighed in; it is now the duty of the U.S. government to provide clarity to its position and take action accordingly. Germline engineering is ripe for definitive reformation, but Congress' inaction and *laissez-faire* approach to this technology has left the territory amorphous. Currently, the technology and its practitioners are regulated by unstructured agencies; subject to quick regulatory change often at the discretion of an agency administrator; and, burdened by the inability to seek recourse for quick change. It is time for the U.S. to get in the driver's seat and declare a stance, both on moral and policy grounds.

This article submits that, under the current regulations, the U.S. is unprepared and vulnerable to drastic consequences that are inherent in this technology's potential abuse. From a scientific standpoint, the U.S. lacks a fundamental legal basis to support or appropriately limit germline engineering's promulgation; from a policy standpoint, the U.S. apathetically throws out-of-date regulations at an emerging technology;

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<sup>1</sup> For the purposes of this note, "germline engineering" is defined as the process by which the DNA in a young embryo (of age less than 3 to 5 days) is manipulated so that new physical characteristics are inherited by the resultant human, impacting – not only the resultant human – but all future DNA of the resultant human's progeny.

and, from a moral standpoint, the U.S. has remained silent on declaring any principles or standards that address the rationale for its policy. It is, therefore, necessary that the U.S. temporarily restrict all germline engineering technology until clear definitive regulations are in place.

In Part I, this article examines the current state of germline engineering technology and presents the moral positions on the conservative and liberal ends of the spectrum. Part II reviews the legislative and regulatory environments of selected countries (exclusive of the United States) that maintain robust biomedical institutions for research and healthcare, and attempts to place these countries within the moral position spectrum. Part III considers the history of the current legislative and regulatory environment in the United States and makes recommendations where necessary to give clarity to an articulated moral position; and advocates that the U.S. adopt a conservative stance on germline engineering.

By comparing the consequences that are implicit within the conservative and liberal moral positions, this article lays a foundation that strongly submits that the U.S. actively advance a conservative moral position. Additionally, this article will attempt to provide a legal counter-argument to the liberal justification of germline engineering, as the technology is void for policy reasons rooted within the Anglo-American common law Rule Against Perpetuities.

#### I. THE TECHNOLOGY AND ETHICS

The field of eugenics entered its renaissance with the Human Genome Project (HGP). Launched in the mid 1990's and declared complete in 2003, the HGP provided the vehicle whereby international researchers identified and characterized the 3.2 billion nucleotide base pairs that comprise human deoxyribonucleic acid (DNA).<sup>2</sup> Data from HGP was made publically available and free, thus spawning applications in medicine, pharmaceuticals, forensics, anthropology, agriculture,

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<sup>2</sup> NAT'L INST. OF HEALTH, HUMAN GENOME PROJECT (2010), available at [https://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject\(NHGRI\).pdf](https://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject(NHGRI).pdf).

animal husbandry, archeology, biofuels, and a myriad of other disciplines.<sup>3</sup>

*A. State of the Technology*

Some of the earliest applications of the knowledge and information gleaned from the HGP involved genetic testing. Genetic testing techniques, including genome-wide association studies (GWAS) and next-generation sequencing (NGS), were developed to facilitate diagnosis of rare genetic diseases, to select cancer treatments based on the molecular makeup of cancerous tumors, and to track outbreaks of infectious diseases.<sup>4</sup> As such techniques and technology advanced, the uses of genetic testing in medicine moved the diagnosis of a disease to its earliest possible point before clinical manifestation, and moved the testing of individuals to earlier points in their lives: at birth (newborn screening), in utero (prenatal diagnosis), or preconception (carrier testing).<sup>5</sup> As research progressed further, genetic testing spawned genetic manipulation, most often for the prevention of disease.

In 2014, a new technique, labeled CRISPR/Cas9, became widely adopted as a way to genetically manipulate DNA sequences in cells and organisms. CRISPR/Cas9 was simple, inexpensive, and effective.<sup>6</sup> The technique was used to correct genetic defects in “whole” animals or change DNA sequences in embryonic stem cells so that those stem cells produced specific defect-free tissues that could be transplanted into patients.<sup>7</sup> But, it was also possible to use the CRISPR/Cas9 technology “to carry out genome modification of fertilized animal eggs or embryos ... so ensuring that the changes will be passed on to the organism’s progeny. Humans are no exception – changes to the human germ line could be made using this simple and widely available technology.”<sup>8</sup> The practice is commonly called germline engineering.

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<sup>3</sup> *Id.*

<sup>4</sup> Jeanette J. McCarthy, et al., *Genomic Medicine: A Decade of Successes, Challenges, and Opportunities*, SCIENCE TRANSLATIONAL MEDICINE, June 12, 2013, at 2.

<sup>5</sup> *Id.* at 5.

<sup>6</sup> David Baltimore, et al., *A Prudent Path Forward for Genomic Engineering and Germline Gene Modification*, SCIENCE MAGAZINE, Apr. 3, 2015, at 36.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 37.

In April 2015, Chinese researchers published findings from their efforts using CRISPR/Cas9 in human embryos.<sup>9</sup> Although the embryos used in the effort were abnormal before editing, and the majority of the altered embryos were “mosaic” (containing a mix of repaired and unrepaired genes),<sup>10</sup> the process of germline engineering of human embryos survived its proof of concept. The researchers acknowledged that their work “highlights the pressing need to further improve the fidelity and specificity of the CRISPR/Cas9 platform”;<sup>11</sup> but those same researchers never entertained a moratorium or suspension of the research that would inevitably lead to genetically engineered humans.

The biotechnology research race continued when, in September 2015, a team of researchers within the Francis Crick Institute in London submitted an application to pursue CRISPR/Cas9 genome-editing research in viable human embryos.<sup>12</sup> The application cites that the intent of the research is to gain “fundamental insights into early human development” and look for answers to more basic questions about the human embryo.<sup>13</sup> The wait is now over. As of February 1, 2016, London scientists were granted approval through the UK Human Fertilisation and Embryology Authority (HFEA) to “use genome-editing technique CRISPR/Cas9 in healthy human embryos.”<sup>14</sup> The London research team, led by biologist Kathy Niakan, is “interested in early development”, but plans to “stop experiments after seven days, after which the embryos will be destroyed.”<sup>15</sup> With the UK now holding the flag, developmental biologist, Robin Lovell-Badge at the Crick Institute says, this “decision

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<sup>9</sup> Puping Liang, et al., *CRISPR-Cas9-mediated Gene Editing in Human Trippronuclear Zygotes*, PROTEIN & CELL, May 2015, at 363.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Center for Genetics and Society comments on First Application to Pursue Genome Editing Research in Human Embryos*, CTR. FOR GENETICS & SOC'Y, (Sept. 18, 2015), <http://www.geneticsandsociety.org/article.php?id=8867>.

<sup>13</sup> Daniel Cressey, et al., *UK Scientists Apply for License to Edit Genes in Human Embryos*, NATURE INTERNATIONAL WEEKLY JOURNAL OF SCIENCE (Sept. 18, 2015), available at <http://www.nature.com/news/uk-scientists-apply-for-licence-to-edit-genes-in-human-embryos-1.18394>.

<sup>14</sup> Ewen Callaway, *Embryo Editing Gets Green Light*, NATURE INT'L WEEKLY JOURNAL OF SCIENCE, (Feb. 4, 2016), available at [http://www.nature.com/polopoly\\_fs/1.19270!/menu/main/topColumns/topLeftColumn/pdf/nature.2016.19270.pdf](http://www.nature.com/polopoly_fs/1.19270!/menu/main/topColumns/topLeftColumn/pdf/nature.2016.19270.pdf).

<sup>15</sup> *Id.*

will give scientists confidence to either apply to their national regulatory bodies, *if they have them, or just go ahead anyway.*"<sup>16</sup> (emphasis added).

### *B. Ethics and Moral Positions*

The ethical issues surrounding germline engineering are monumental, and run the gamut of moral and philosophical positions.

#### 1. The Conservative Position

The conservative position and the moral authority from which it draws, well-articulated by Dr. Dianne N. Irving in her address at the John Carroll Society Rose Mass, are based on Natural Law and Divine Law. By virtue of this theological basis, the conservative position "transcends different cultures, times, ethnic backgrounds, etc. – and is therefore truly applicable to all people at all times."<sup>17</sup> Within the conservative position, a human being is considered a "whole", not the sum of its parts, and "requires to be treated as a whole in society."<sup>18</sup> There is no distinction between "human" and "person". Moreover, when judging whether a particular action is "right", the conservative position requires that three conditions must be held as ethical: [1] the *kind* of action; [2] the *intention* for doing the action, and; [3] the *circumstances* under which the action is done.<sup>19</sup> Such conditions do not preclude the use of human material in medical experimentation as a *kind* of action, "with the *intention* of helping to cure diseases ... as long as certain *circumstances* prevail, e.g., the person has given informed consent and any harm sustained is proportionate to the medical good that can be derived."<sup>20</sup> But the three conditions do preclude people from "volunteer[ing] to mutilate or otherwise seriously harm [them]selves."<sup>21</sup> Similarly, the conservative position draws the line whenever any one of the three conditions cannot be met: an ethical *kind* of medical action does not mean that early embryos may be destroyed to

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<sup>16</sup> *Id.*

<sup>17</sup> Dianne N. Irving, M.A., Ph.D., Which Medical Ethics for the 21<sup>st</sup> Century?, Address at the John Carroll Society Rose Mass (Mar. 14, 1999), in CATHOLICCULTURE.ORG, Mar. 14, 1999.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

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

<sup>21</sup> *Id.*

help others. “It is inherently wrong to intentionally kill an innocent human being – regardless of the *intention* or the *circumstances*”<sup>22</sup> (emphasis added).

While it could be argued that the manipulation of DNA in germline engineering does not “kill an innocent human being”, the conservative position’s holding of the human being as a “whole” suggests the contrary. In manipulating certain characteristics of a human, a “new” person is created and the “former” person is lost. The “new” person will enjoy advantages that the “former” person cannot, and live a better existence (presumably) than the “former” person will ever realize. It is destruction of life.

## 2. The Liberal Position

The liberal position, well-articulated by Nicholas Agar in his book, *Liberal Eugenics: In Defence of Human Enhancement*, seeks to protect and extend reproductive freedom beyond the choices of whether or not to reproduce, with whom, when, how often, and “adds the choice of certain of [the] children’s characteristics to this list of freedoms.”<sup>23</sup> The liberal position sees the practice of genetic selection as an extension of parental decisions made after a child is born, such as decisions regarding schooling, activities, discipline, diet, or religious instruction.<sup>24</sup> The position goes so far as to call not only for parents to be free to make the best decisions for their children including selecting genetic characteristics, but that it is a moral obligation incumbent upon parents to make the best choices.<sup>25</sup>

The liberal position is adamant that the extension of freedoms is not absolute or unconstrained, suggesting prohibitions on “reproductive choices that are morally defective in some significant way”<sup>26</sup>, or prohibiting the introduction of abilities that are not inherent in humans,

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<sup>22</sup> *Id.*

<sup>23</sup> Nicholas Agar, *Liberal Eugenics: In Defence of Human Enhancement* vi (2004).

<sup>24</sup> Bonnie Steinbock, *Designer Babies: Choosing our Children’s Genes*, 372, *THE LANCET*, 1294, (Oct. 11, 2008), available at [http://scholarsarchive.library.albany.edu/cgi/viewcontent.cgi?article=1000&context=cas\\_philosophy\\_scholar](http://scholarsarchive.library.albany.edu/cgi/viewcontent.cgi?article=1000&context=cas_philosophy_scholar).

<sup>25</sup> Julian Savulescu, *Procreative Beneficence: Why We Should Select the Best Children* 425 (2001).

<sup>26</sup> *Id.* at 249

such as detecting ultraviolet light or possessing the olfactory powers of dogs.<sup>27</sup> The liberal position is equally adamant in rejecting *governmental authoritarian* eugenics, that is, “the idea that the state should have sole responsibility for determining what counts as a good human life.”<sup>28</sup> This separates the position of “liberal eugenics” from Nazi practices, the forced sterilization efforts in the United States in the early 20<sup>th</sup> century, and other government-based initiatives.<sup>29</sup> But by rejecting governmental authority, the liberal position vests the authority to the parents by default preserving *parental* “liberty, autonomy, and freedom.”<sup>30</sup> Thus, the liberal position recognizes parents’ rights to choices, as subjective as those choices may be, superior to the rights of their progeny.

### 3. Other Considerations

Running parallel to the moral positions surrounding physical characteristics are issues involving familial, social, and cultural institutions. In some germline editing techniques, such as CRISPR/Cas9 technology, abnormal (or undesirable) DNA sections could be replaced by normal (or desirable) DNA sections *provided by a donor*.<sup>31</sup> The resulting “person” would, therefore, be a DNA “offspring” of the provider of the egg, the provider of the sperm, and the provider(s) of the donated DNA sections. Complexities in current family law involving parentage, custody, surrogacy, inheritance, and liability for choices made or not made, would become even more complex.<sup>32</sup>

## II. INTERNATIONAL RESPONSE

Although the Human Genome Project was well underway in 1997, the announcement in February that year of the cloning of Dolly, the

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<sup>27</sup> Agar, *supra* note 23, at 17.

<sup>28</sup> *Id.* at 5

<sup>29</sup> See Agar, *supra* note 23.

<sup>30</sup> Girard Kelly, Choosing the Genetics of our Children: Options for Framing Public Policy, 30 SANTA CLARA HIGH TECH. L.J. 303, 323 (2014).

<sup>31</sup> Liang, *supra* note 9.

<sup>32</sup> Susan L. Crockin & Gary A. Debele, *Ethical Issues in Assisted Reproduction: A Primer for Family Law Attorneys*, 27 J. AM. ACAD. MATRIM. LAW. 289, 340, 343-7 (2015).

sheep, awakened the international community to the imminent possibility of human engineering.

#### *A. Europe*

The European Union Convention on Human Rights and Biomedicine was the first major international institution to react. The resulting treaty, known as the Oviedo Convention, completed in 1997, declares the EU's moral position in the opening sections by stating that "the interests and welfare of the human being shall prevail over the sole interest of society and science" and that parties to the Convention "shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."<sup>33</sup> From a practical perspective, the Convention banned any alteration of the human genome that would "introduce any modification in the genome of any descendants."<sup>34</sup> The body further extended its position in 1998 by banning cloning in its statement prohibiting "intervention seeking to create a human being genetically identical [i.e. sharing the same nuclear gene set] to another human being whether living or dead."<sup>35</sup> To date, the Oviedo Convention has been signed by 35 European countries; 29 have ratified it.<sup>36</sup> Through this response, the European Union, and the countries that have signed and/or ratified the Oviedo Convention have demonstrated a predominately conservative moral position in their recognition that a human is a "whole" and not the "sum of its parts." The EU, however, continues to

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<sup>33</sup> Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Apr. 4, 1997, E.T.S No. 164, at 2. [hereinafter Convention on Human Rights and Biomedicine] (Signed by: Italy, Luxembourg, Netherlands, Poland, Sweden, and Ukraine. Ratified by: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Latvia, Lithuania, Moldova, Montenegro, Norway, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Switzerland, The former Yugoslav Republic of Macedonia, and Turkey. The UK and Germany have not signed the convention.).

<sup>34</sup> *Id.* at 4.

<sup>35</sup> Additional Protocol to the Convention for the Protection of Human Rights and Dignity to the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Jan. 12, 1998, E.T.S No. 168, at 1.

<sup>36</sup> Convention on Human Rights and Biomedicine, *supra* note 33.

allow constituents the freedom to conduct research and experiments on embryos that will never develop into “persons.”

### B. Canada

Canada drove a stake into the moral spectrum near the conservative end with its passage in 2004 of the Assisted Human Reproduction Act (AHRA) stating in the opening section that “human individuality and diversity, and the integrity of the human genome, must be preserved and protected.”<sup>37</sup> Moreover, the AHRA reflects a deliberate and careful weighing of competing interests by declaring “the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions.”<sup>38</sup> Yet, the AHRA leaves room for the benefits “for individuals, for families, and for society in general” as long as the technology ensures appropriate measures “for the protection and promotion of human health, safety, dignity, and rights.”<sup>39</sup> Under Section 5, the AHRA prohibits (among many actions) germline engineering procedures that “alter the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants” or “create a human clone by using any technique.”<sup>40</sup> The collective prohibitions in Section 5 leave room for the medical community to assist women with complications from *in vitro* fertilization (IVF)<sup>41</sup> and to conduct academic medical research by allowing the creation of an *in vitro* embryo for the purpose of “creating a human being or improving or providing instruction in assisted reproduction procedures.”<sup>42</sup>

Although Canada is among several countries banning germline engineering and/or human cloning, it is one of the few to articulate

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<sup>37</sup> Assisted Human Reproduction Act (S.C. 2004, c.2), <http://laws-lois.justice.gc.ca/eng/acts/A-13.4/FullText.html> (last updated Apr. 7, 2016).

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> A technique of assisted reproductive technology (ART), under a process where a woman’s egg is removed from her ovaries; the egg is then fertilized (embryo) outside the woman’s body; and, then is implanted in the same or another woman uterus with the intention of establishing a successful pregnancy.

<sup>42</sup> Assisted Human Reproduction Act, *supra* note 37.

criminal penalties for those who do not comply. Individuals who are found guilty of contravening any of the prohibited procedures enumerated under Section 5 of the AHRA are subject to imprisonment for up to 10 years and/or an imposition of a fine up to \$500,000.<sup>43</sup>

### *C. Australia*

Like Canada, Australia has passed legislation that bans germline engineering and human cloning. The Research Involving Human Embryos Act (RIHEA) of 2002, the Prohibition of Human Cloning Act (PHCA) of 2002, and the consolidated and amended Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act of 2006 (hereafter the "2006 Act") specifically prohibit any person from altering "the genome of a human cell in such a way that the alteration is heritable by descendants of a human whose cell was altered"<sup>44</sup> and prohibit "creating or developing a human embryo by fertilization that contains genetic material provided by more than 2 persons."<sup>45</sup> Any violation of these prohibited offences carries a maximum penalty of 15 years imprisonment.<sup>46</sup>

Unlike Canada, however, the Australian acts do not bear a set of "principles" which establish its moral position. The most that the Australian Acts offer is a commitment to investing in high quality research, support in transitioning and commercializing medical discoveries into available healthcare options, and rigorous guidelines framing research worthy of public trust.<sup>47</sup> Additionally, Australia maintains a licensing body authorized to grant licensed variance to some activities that it bans in the 2002 and 2006 Acts. The National Health and Medical Research Council (NHMRC) can issue a license whereby the applicant can (among other activities): create a human embryo other than by a process of fertilization of a human egg by a human sperm; create a human embryo containing genetic material provided by more than 2

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<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> NHMRC's *Mission and Functions*, NAT'L HEALTH & MED. RES. COUNCIL, <https://www.nhmrc.gov.au/about/nhmrcs-mission-and-functions> (last updated Aug. 27, 2015).

persons, or; create a “hybrid embryo.”<sup>48</sup> The awarding of licenses for these activities is dependent on the availability of embryos already conceived and released by the conceiving parents and the likelihood of significant scientific results from the use of such embryos.<sup>49</sup> But, the door is ajar for germline engineering, albeit heavily monitored and regulated, putting distance between the Australian position and the conservative moral position.

### III. DISPOSITION OF GERMLINE ENGINEERING IN THE UNITED STATES

#### *A. Evolution of the regulations*

As with Europe, the cloning of Dolly, the sheep, motivated a response by the United States. In 1997, President Bill Clinton commissioned a report from the National Bioethics Advisory Commission to “review the legal and ethical issues associated with this [cloning] technology” and then issued instructions to his department and agency executives that “no federal funds shall be allocated for the cloning of human beings” until the results of the report were known.<sup>50</sup> Later that year, in defiance of the President’s position, physicist Richard Seed publically announced his intention to clone a human being in a privately funded effort.<sup>51</sup> In the rhetorical disturbance that followed, Carl Feldbaum, President of the Biotechnology Industry Organization (BIO), suggested to the Secretary of Health and Human Services (HHS), Donna Shalala, that cloning could be interpreted as a “biological product” and would, therefore, fall within the regulatory jurisdiction of HHS’s Food and Drug Administration (FDA).<sup>52</sup> Acting FDA Commissioner, Michael Friedman, agreed with BIO’s interpretation of the law, further adding that human cloning is an “investigational technology” and, therefore, “it cannot be attempted unless the researcher has submitted an

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<sup>48</sup> *Research Involving Human Embryos Act 2002* (Cth) div. 4 s. 20 (AuStl.), available at [https://www.comlaw.gov.au/Details/C2014C00605/Html/Text#\\_Toc396124215](https://www.comlaw.gov.au/Details/C2014C00605/Html/Text#_Toc396124215).

<sup>49</sup> *Id.*

<sup>50</sup> Cloning Human Beings, Report and Recommendations of the Nat’l Bioethics Advisory Comm’n (1997).

<sup>51</sup> Elizabeth C. Price, *Does the FDA have Authority to Regulate Cloning?*, 11 HARV. J. L. & TECH. 619, 624 (1998).

<sup>52</sup> *Id.*

investigational new drug (IND) application.”<sup>53</sup> By requiring the IND application, the FDA asserted its jurisdiction and thwarted Dr. Seed’s effort, adding that the FDA would reject every IND application associated with human cloning, in effect banning all reproductive human cloning in the United States.<sup>54</sup>

In spite of President’s Clinton’s repeated calls for legislative action, the U.S. Congress has remained silent on its position on human cloning and its successor technologies in germline engineering, thus avoiding any political entanglement. The absence of legislation has essentially left the Department of Human Health and Services as the controlling authority.<sup>55</sup> Of the eleven agencies potentially involved,<sup>56</sup> two have policies in place regulating gene therapy and germline engineering: National Institute of Health (NIH), and the aforementioned Food and Drug Administration (FDA).<sup>57</sup>

The NIH oversees “gene-transfer”, a broadly defined term that includes germline engineering for regulatory purposes<sup>58</sup>, and the funding of applications associated with gene-transfer. The NIH’s Recombinant DNA Advisory Committee (RAC) is “responsible for ethical review of all NIH-funded research proposals that involve putting genes into human beings” and makes a stand that it is, “as a matter of policy, not reviewing any proposals that seek to modify gametes or embryos.”<sup>59</sup> The FDA, which is chartered specifically for (among other actions), regulating the introduction of “genetic material into the body to replace faulty or missing genetic material ... for the treatment or cure of a disease”<sup>60</sup> considers its authority to extend to *any* gene-therapy product that contains “genetic materials administered to modify or manipulate the expression of genetic material or to alter the biological properties of living

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<sup>53</sup> Pratheep Sevanthinathan, *Heavy Regulation of Human Cloning as an Alternative to a Complete Ban*, 10 QUINNIPIAC HEALTH L.J. 219, 246-47 (2007).

<sup>54</sup> *Id.*

<sup>55</sup> Susannah Baruch, et. al., *Human Germline Genetic Modification: Issues and Options for Policymakers*, 39 (Genetics and Public Policy Center 2005).

<sup>56</sup> Pete Shanks, *Extreme Genetic Engineering and the Human Future* 37 (Center for Genetics and Society 2015).

<sup>57</sup> Baruch, *supra* note 55.

<sup>58</sup> Kelly, *supra* note 30, at 336-7.

<sup>59</sup> *Id.* at 337-8.

<sup>60</sup> *Id.*

cells”<sup>61</sup> regardless of the end purpose. But, the FDA’s authority may be limited because it can only regulate safety and effectiveness and only on human subjects; an embryo does not receive human subject protection until it is implanted through IVF.<sup>62</sup>

Although the regulatory policies of the NIH and FDA manifest a ban on germline engineering, the “ban” is merely an administrative policy, subject to licensing exemptions and indeterminate oversight. The moral position, therefore, is purely an administrative position, and not a firm stand along the moral spectrum. The only authoritarian moral position offered by the U.S. government was the conservative position within President George W. Bush’s Executive Order 13435, issued in 2007, which stated that “human embryos and fetuses, as living members of the human species, are not raw materials to be exploited or commodities to be bought and sold.”<sup>63</sup> Executive Order 13435 prohibited federal funding for any research conducted on embryos created or fertilized after the date of the order. President Obama removed the prohibition, and the associated conservative moral position, in his Executive Order 13505, issued in 2009.<sup>64</sup>

#### *B. Critique of the position or lack of position*

In understanding an absolute moral truth, Gilbert Keith Chesterton said, “Morality is always dreadfully complicated to a man who has lost all his principles.” Once principles are established, decisions become just. Where are the U.S. principles? Europe’s Oviedo Convention and Canada’s AHRA clearly articulate principles that defend the conservative moral position. The conservative position is that germline engineering techniques which alter human cells, such as embryos, may only be certified for medical advancements and research; provided that no human being is created as a result of such a technique. The conservative approach draws on an objective truth that germline modification is wrong; forbidding, unequivocally, any creation of genetically modified humans. At the same time, however, the

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<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 338-9.

<sup>63</sup> Exec. Order No. 13435, 72 Fed. Reg. 34,591 (June 22, 2007).

<sup>64</sup> *Id.*

importance and value of the technology is not discounted, as the purpose of the technology is to further the discovery of medical advancements and preventative care treatment, limiting any risk of any future harm.

On the other hand, the liberal position calls for much more than germline engineering's exploitation of research and medical advancements, giving way for the introduction of genetically created human beings, i.e., "designer babies." The liberal justification for its position is less concerned with the social, moral, and legal issues, but rather places more emphasis on parental rights and freedoms to make choices on behalf of their progeny. The liberal position rejects the conservative moral *objective* principles, instead supplanting them with the "harm principle."<sup>65</sup> This harm principle, serving as the liberal validating principle, implies that the use of the technology is limitless except in a case where it could "directly harm offspring, families, women, society, or others."<sup>66</sup> This theory is highly *subjective*.

The subjectivity of the liberal approach is well-illustrated by the example of Sharon Duchesneau and Candace McCullough. Sharon and Candace, wanting a child of their own, sought out deaf sperm donors with the intention of conceiving a deaf child.<sup>67</sup> Both deaf, Sharon and Candace did not perceive congenital deafness as undesirable because "they believed that they would make better parents to a deaf child, because they would be better able to guide them."<sup>68</sup> In this case, the harm principle is imperfect and is swallowed by the nature of the subjectivity of parental right of authority. The liberal stance in essence is unbridled and the risks are unlimited; the U.S. should not adopt this hazardous position.

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<sup>65</sup> RONALD HAMOWY, THE ENCYCLOPEDIA OF LIBERTARIANISM xxi (SAGE Publications, Inc. 2008) ("It is a basic principle of libertarian politics that no one should be forcibly prevented from acting in any way he chooses provided his acts are not invasive of the free acts of others.").

<sup>66</sup> Kelly, *supra* note 30, at 323.

<sup>67</sup> Couple 'Choose' to have Deaf Baby, BBC NEWS, April 8, 2002, <http://news.bbc.co.uk/2/hi/health/1916462.stm>; See also Agar, *supra* note 23, at xxx.

<sup>68</sup> BBC NEWS, *supra* note 67.

### C. Public Policy Considerations

The legal argument surrounding germline engineering, in any form that would produce viable progeny, starts with the legal status of the embryo. The legal status of the embryo, as the starting point of life, has sparked much debate among bioethicists, theologians, scientists, and legal scholars, and remains within the purview of the States, varying per jurisdiction.<sup>69</sup> Courts have categorically labeled a frozen embryo's legal status as "property, property deserving of special respect, [or] human life."<sup>70</sup> Courts that hold the legal status of the embryo as property or property deserving special respect, apply contract and property law principles.<sup>71</sup> Loosely aligning with the liberal position, courts "consider the decision to beget children as being a significant and intensely personal choice to be made by the progenitors",<sup>72</sup> similar to that of parental liberty, autonomy, and freedom.

From a morally conservative standpoint, advanced by this article, if the legal status of the embryo is "human", germline engineering or modification is forbidden because germline modification is the destruction of life. However, even if one were to concede the point at which the embryo obtains human legal status, germline engineering cannot stand, because in applying simple Anglo-American property law principles, the technology is void under the Rule Against Perpetuities.<sup>73</sup> The common law language of the Rule states, "an interest in property is void unless it will necessarily vest, if at all, within a life in being and twenty-one years."<sup>74</sup> While the language itself is not directly applicable to germline engineering, the underlying rationale behind the Rule provides

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<sup>69</sup> Angela K. Upchurch, *A Postmodern Deconstruction of Frozen Embryo Disputes*, 39 CONN. L. REV. 2107, 2019-20 (2007).

<sup>70</sup> *Id.* at 2120.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 2135.

<sup>73</sup> "The traditional common law Rule Against Perpetuities limiting the time period within which contingent remainders interest must vest is currently in effect either by statute or by judicial adoption in only a few states." *The Law Of Trusts And Trustees* § 214 (2015). "The unmodified Uniform Statutory Rule Against Perpetuities (USRAP) is currently the law in roughly one-third of the states." Lynn Foster, *Fifty-one Flowers: Post-Perpetuities War Law and Arkansas's Adoption of USRAP*, 29 U. ARK. LITTLE ROCK L. REV. 411 (2007).

<sup>74</sup> George L. Haskins, *Extending the Grasp of the Dead Hand: Reflections on the Origins of the Rule Against Perpetuities*, 126 U. PA. L. REV. 19 (1977).

guidance. The rationale behind the Rule Against Perpetuities involves an understanding of the “dead hand”, *i.e.*, the ability under which a grantor may control future ownership of property, specifically land, for a measurable length of time after a conveyance. Simply put, if the interest in land was tied up for too long, whatever measurable length that is, then the interest would amount to perpetuity and would thus be void. The policy, historically, intended to “remove the threat to the public welfare from family dynasties built on great landed estates or on great capital wealth.”<sup>75</sup> Analogously, in editing or modifying the germline, the progenitors are effectively controlling the germline of their progeny that by its nature will remain in perpetuity. As such, from a policy standpoint, germline editing should be held void. *A fortiori*, in applying this doctrine, each individual’s germline is his own fee simple estate, his transferable germline, to “hold to him and his heirs forever; generally, absolutely, and simply ...over which the [progenitor] has unlimited power of disposition in perpetuity without condition or limitation.”<sup>76</sup> Germline engineering cannot even stand when examined under long-standing property principles, if the liberal position insists on such.

## CONCLUSION

Germline engineering is at the doorstep. Failure to address and implement clear regulations leaves the U.S. unprepared to proceed with this technology. There have been many arguments on both sides of the germline engineering debate regarding social, economic, cultural, anthropological, and environmental impacts of a future containing genetically engineered humans. But, suppose the technology was 100% successful; suppose it was available to all; suppose that genetically engineered humans were social equals to non-genetically engineered humans; and suppose all of the peripheral issues surrounding germline engineering were rendered moot. The fundamental question still remains: Is it *right*?

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<sup>75</sup> W. Barton Leach, *Perpetuities in Perspective: Ending the Rule’s Reign of Terror*, 65 HARV. L. REV. 721 (1952).

<sup>76</sup> 31 C.J.S. Estates § 12.

Many countries believe not and have driven legislative or regulatory stakes into the ground to mark their moral positions. The United States has not; ambiguous regulatory authority and executive orders that sway depending on the political ideology of the executive are not viable substitutes for an articulated moral position – *any* moral position.

#### *A. Solution*

As a world leader, it is now incumbent on the United States to take action and to compel other countries to follow a morally conservative path, calling for an international ban on all germline editing techniques that result in the creation of a human being. In the 2015 Center for Genetics and Society's report, *Extreme Genetic Engineering and the Human Future*, key researchers called for "explicit and expansive public engagement ... including considerations of not just safety thresholds, but also social and ethical concerns..." with an "ongoing, transparent, democratic process" holding "scientists and entrepreneurs accountable to responsible regulations."<sup>77</sup> Ultimately, it is critical that the Congress' legislation center on how to minimize potential environmental, health and social risks, while maximizing the use of this technology for the preventing and curing of diseases.

At a minimum, until a suitable resolution has come to pass in the United States, a moratorium should be issued on germline engineering techniques. A moratorium is clearly needed because the current regulatory framework fails to: [1] adequately articulate moral principles that would inform a governmental position; [2] hermetically regulate the technology; and [3] define and organize accountability at all levels through top-down regulation, including the imposition of criminal, civil, and monetary damages for violations within the private and public sectors.

For now, it makes sense to pause: The U.S. should enact a *clear* prohibition of germline engineering for the purpose of creating a human. How it chooses to do so and how it chooses to sanction noncompliance should be the focus of the immediate debate. All of the other issues,

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<sup>77</sup> Shanks, *supra* note 56, at 6.

including moral positions and/or the protection or extension of parental choices, can be debated subsequently. It is far easier to prohibit and later allow than it is to allow and later deny. And, during germline engineering's abeyance, the integrity of the human germline is preserved for the subsequent generations whose views on the choices could differ. In this case, too, a moratorium on germline engineering would be erring on the side of natural human biology.