"PLAYING GOD?": AN EXAMINATION OF THE LEGALITY OF CRISPR GERMLINE EDITING TECHNOLOGY UNDER THE CURRENT INTERNATIONAL REGULATORY SCHEME AND THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

Brooke Elizabeth Hrouda[*]

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[*] J.D., University of Georgia School of Law, 2017.

I. INTRODUCTION

> We are human because of the interplay of many biological, historical, cultural determinants, which preserve the feeling of our fundamental unity and nourish the richness of our diversity. The international community, States and governments, scientists, actors of civil society and individuals are called upon to consider the human genome as one of the premises of freedom itself and not simply as raw material to manipulate at leisure. At the same time, considering that scientific advancements in this field are likely to offer unprecedented tools against diseases, it is crucial to acknowledge that these opportunities should never become the privilege of few. What is heritage of humanity entails sharing both of responsibilities and benefits.[1]

In April 2015, Chinese officials announced that, for the first time, a team of Chinese scientists had successfully spliced, edited, and modified the genes of a non-viable human embryo at the germinal level. Through the experiment ultimately failed, the study's conduction confirmed worldwide rumors that germline testing on human test subjects is indeed underway.[2] Since the beginning of the twenty-first century, scientists have continuously discovered new technologies and processes in genomic engineering and gene modification, two segments of the biotechnology field. But despite the immense potential for positive benefits to society, these technologies have led to increasing ethical, political, and legal concerns due to the lack of international and domestic guidelines, especially with regard to the modification of human genes.[3] In 2012, a new technology known as CRISPR (clustered regularly interspaced short palindromic repeats), or

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[1] U.N. Educ., Sci. & Cultural Org., Int'l Bioethics Comm., *Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights*, ¶ 128 (Oct. 2, 2015), http://unesdoc.unesco.org/images/0023/002332/233258E.pdf [hereinafter IBC].

[2] Lauren F. Friedman, *These are the countries where it's 'legal' to edit human embryos (hint: the US is one)*, BUS. INSIDER (Apr. 23, 2015, 2:15 PM), http://www.businessinsider.com/china-edited-human-genome-laws-2015-4. Though the ethics of the process are still up in the air in the eyes of the world, the inventor of the technology stressed that the Chinese scientists broke no laws in their experimentation, *id.*

[3] David Baltimore et al., *A Prudent Path Forward for Genomic Engineering and Germline Gene Modification: A framework for open discourse on the use of CRISPR-Cas9 technology to manipulate the human genome is urgently needed*, 348 SCIENCE 36, 36 (2015) (noting "genome modification technology offers unparalled potential for modifying human and nonhuman genomes").

CRISPR-CAS-9, was discovered.[4] This new modification process will allow for easier and more efficient gene modification than previous technologies, which tend to be time consuming, expensive, and sometimes dangerous.[5] Scientists and medical professionals believe this technology has the potential to cure and prevent a variety of genetic diseases and mutations in both non-human and human genes. However, the process requires changing DNA in the germinal stage of embryotic development in humans, meaning the new traits will be passed to the child at birth and become a permanent genetic trait in the future bloodline.[6] The lack of consistent regulations within the international community continues to prevent scientists from developing proper boundaries for the use of this technology. Consequently, each country has developed its own regulations, which in turn has created great diversity in the legal spectrum.[7] At the same time, nearly all nations, including the United States, are members of international treaties and covenants establishing basic human rights with respect to the human genome. One such treaty is the Universal Declaration on the Human Genome and Human Rights (Declaration).[8] Any signatory country to these treaties is required to develop their domestic regulations dealing with genomic testing to meet the principles embedded within said treaties, and any future international regulations will be required to uphold these same principles in order to conform to international policy, though these treaties do not have the direct force of law.

Technologies such as CRISPR are extremely controversial because of their ability to manipulate genes at a different level than previous gene modification techniques.[9] The process involves modification of the germinal cells of the subject's parents' egg and sperm cells, the germinal stage of

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[4] Andrew Pollack, *Jennifer Doudna, a Pioneer Who Helped Simplify Genome Editing*, N.Y. TIMES, May 11, 2015, https://www.nytimes.com/2015/05/12/science/Jennifer-doudna-crispr-cas9-genetic-engineering.html.

[5] *Id.*

[6] Baltimore et al., *supra* note 3, at 36.

[7] Friedman, *supra* note 2.

[8] General Conference of UNESCO, *Universal Declaration on the Human Genome and Human Rights*, U.N. Doc. AIRES/53/152 (Dec. 9, 1998) [hereinafter Declaration]. The Declaration was unanimously passed by all seventy-seven national delegates in attendance. The Declaration was followed in 2005 by a complementing UNESCO Declaration titled the Universal Declaration on Bioethics and Human Rights which was signed by representatives of 191 countries that further established the ideals embedded within the 1997 Declaration. For an example of another such treaty, see General Conference of UNESCO, *Universal Declaration on Bioethics and Human Rights* (Oct. 19, 2005), http://portal.unesco.org/shs/en/file_download.php/46133e1f4691e4c6e57566763d474a4dBioethic_EN.pdf.

[9] Antonio Regalado, *Engineering the Perfect Baby: Scientists are developing ways to edit the DNA of tomorrow's children. Should they stop before it's too late*?, MIT TECH. REV. (Mar. 5, 2015), http://www.technologyreview.com/featuredstory/535661/engineering-the-perfect-baby/.

development, or in other words, the period immediately preceding fertilization and implantation, where the ovum undergoes the first stages of cell division.[10] This means that changes could eventually extend beyond the therapeutic level to be used for enhancement, ultimately giving parents the ability to select, modify, and create exact genetic traits—a made-to-order "designer baby."[11] This creates not only ethical but also legal concerns and raises several pivotal questions. Should this technology be extended to human gene modification or only be allowed on non-human genes? If we allow the technology's use in human gene modification, how far should the use be extended? At what point does the use of the technology begin to violate the principles imbedded within certain international treaties?[12]

This Note will first look at the general background of biotechnology and genetic modification techniques to explain the differences between therapeutic and enhancement modification. Next, it will examine current regulations and laws in several countries to illustrate the varying degrees of restrictiveness of current regulations. The Note will then analyze the Declaration to determine what problems might arise in the creation of international regulations involving human genome modification, specifically focusing on the issue of therapeutic versus enhancement uses and the potential for "designer babies." Finally, this Note will evaluate how far this technology could extend while still falling within the accepted international values embedded in the Declaration. This Note will not attempt to evaluate the legitimacy of current countries' individual regulations or to debate the ethical aspects of the human genome modification issue.

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[10] Kendra Cherry, *The Germinal Stage* (Apr. 26, 2016), http://psychology.about.com/od/gindex/g/germinal-stage.htm.

[11] Obinna Morton & Phil Bolton, *Biotech Summit Launches Atlanta to the Front in Developing Ethical Norms*, GLOB. ATLANTA (Aug. 4, 2015), http://www.globalatlanta.com/article/27755/biotech-summit-launches-atlanta-to-the-front-in-developing-ethical-norms/ (suggesting that while "designer babies" are not the focus of the new technology, they are still a possibility).

[12] For examples of international treaties involving the human genome, see General Conference of UNESCO, *supra* note 8.

II. BACKGROUND OF THE BIOTECHNOLOGY FIELD AND ITS USE OF GENETIC MODIFICATION

A. Biotechnology and the Implementation of Germline Modification in Society

The word biotechnology was coined by Karl Ereky in Hungary in 1919,[13] but informal applications of the technology date back thousands of years to the nomadic societies selective crop cultivation techniques.[14] "Biotechnology" is a cross between the Greek words bios meaning "everything to do with life" and technikos meaning "involving human knowledge and skills."[15] Biotechnology involves the application of scientific and engineering principles to the processing of materials by biological agents."[16] More simply, it is using living organisms to make useful products,[17] but to describe it in more practical terms, biotechnology "harnesses cellular and biomolecular processes to develop technologies and products that help improve our lives and the health of our planet."[18] Biotechnology is credited with providing products that can be used to "combat debilitating and rare diseases, reduce our environmental footprint, feed the hungry, use less and cleaner energy, and have safer, cleaner, and more efficient industrial manufacturing processes."[19] Biotechnology often uses genetic engineering, a method of creating new life forms and organic material by gene-splicing and other techniques,[20] as one of its main processes. An example of one such process is germline gene modification. In a germline gene transfer, the germinal cells of the subject's parents' egg and sperm cells are targeted prior to implantation and genetically modified with the goal of passing on the changes to the offspring, who will then carry the gene as a portion of its genetic makeup upon birth.[21] This modification can be achieved through a variety of methods, but perhaps the most noteworthy is the newly discovered CRISPR technology that can be used to

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[13] Ashish Swarup Verma et al., *Biotechnology in the Realm of History*, 3 J. PHARM. BIOALLIED SCI. 321, 321 (2001).

[14] *Id.* at 322.

[15] Europabio, *What is Biotechnology?*, http://www.europabio.org/what-biotechnology (last visited Oct. 28, 2016).

[16] *Id.*

[17] *Id.*

[18] Biotechnology Indus. Org., *What is Biotechnology?*, https://www.bio.org/articles/what-biotechnology (last visited Oct. 4, 2015).

[19] This is not an exhaustive list. For more uses of biotechnology, see *id.*

[20] *Genetic Engineering*, BLACK'S LAW DICTIONARY (9th ed. 2009).

[21] National Human Genome Research Institute, *Germline Gene Transfer*, GENOME.GOV (Mar. 2006), http://www.genome.gov/10004764.

modify DNA in the nuclei of reproductive cells. The change is achieved by going in while the cells are still dividing to remove a portion of the DNA sequence and replace it with another, different, pre-selected, and pre-created sequence.[22] Unlike previous techniques, CRISPR allows scientists to carry out modification in fertilized embryos both *in vivo* and *in vitro*, guaranteeing a permanent alteration in the genetic makeup that will be passed on to the parents' progeny and to future generations.[23]

B. Creating the "Designer Baby"

Despite CRISPR's very recent creation, germline modification technologies are not a wholly new concept amongst the scientific community or even the general population. The fear of a genetically modified society has been depicted in both the literary world and pop culture dating back nearly 100 years now and was perhaps most famously portrayed in Aldous Huxley's 1932 novel, *Brave New World*:[24]

> A squat grey building of only thirty-four stories. Over the main entrance the words, CENTRAL LONDON HATCHERY AND CONDITIONING CENTRE, and, in a shield, the World State's motto, COMMUNITY, IDENTITY, STABILITY . . . Wintriness responded to wintriness. The overalls of the workers were white, their hands gloved with a pale corpse-coloured rubber. The light was frozen, dead, a ghost. Only from the yellow barrels of the microscopes did it borrow a certain rich and living substance, lying along the polished tubes like butter, streak after luscious streak in long recession down the work tables. "And this," said the Director opening the door, "is the Fertilizing Room."[25]

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[22] *Id.*

[23] Baltimore et al., *supra* note 3, at 37. *See generally* Motoko Araki & Tetsuya Ishii, *International regulatory landscape and integration of corrective genome editing into in vitro fertilization*, REPRODUCTIVE BIOLOGY AND ENDOCRINOLOGY (Nov. 24, 2014), http://www.rbej.com/content/12/1/108 (explaining the scientific process of specific germline modification techniques).

[24] RONALD M. GREEN, BABIES BY DESIGN: THE ETHICS OF GENETIC CHOICE 107–09 (1997) (briefly summarizing the plot of *Brave New World* and explaining its connection to today's society).

[25] This quotation illustrates a society that has replaced the vitality of human conception with "cold, mechanical processes," taking the humanity out of procreation. *Id.* at 107 (quoting Aldous Huxley, *Brave New World* 1 (1932)).

Huxley's fear proved to be prophetic, because in the United Kingdom in 1978, a woman named Louise Brown became the first successful "test-tube baby," and the possibilities for scientifically enhanced procreation began.[26] A world that had previously relied on chance, prayer, and luck to achieve successful procreation now had new hope through the possibility of *in vitro* fertilization. In 1997, the same year Dolly the sheep was successfully cloned, the film *Gattaca* was released, and it provided yet another glimpse into the effects of genetic modification.[27] In one of the most famous scenes from the film, when the parents of the main character, Vincent, go to "order" a brother for him, the geneticist tells them:

> You want to give your child the best possible start. Believe me, we have enough imperfection built-in already. Your child doesn't need any additional burdens. And keep in mind, this child is still you, simply the best of you. You could conceive naturally a thousand times and never get such a result.[28]

In this single statement, the movie illustrates the potential problem with the development of successful germline modification techniques: though these techniques have the potential to cure deadly illnesses, it becomes nearly impossible for society to determine the appropriate boundaries when giving parents the ability to "play God." Human germline modification can be separated into two distinct processes, germline treatment, also known as germline transfer, and germline enhancement.[29] Germline treatment or transfer is considered *negative* genetic engineering and aims to prevent or treat disease.[30] On the other side of the spectrum is germline enhancement or *positive* genetic engineering, which aims to enhance a particular capability or trait.[31] Most people tend to accept that technological advances are

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[26] Ferris Jabr, *Are We Too Close to Making Gattaca a Reality?*, SCI. AM. (Oct. 28, 2013), http://blogs.scientificamerican.com/brainwaves/are-we-too-close-to-making-gattaca-a-reality/.

[27] *Id.* The film *Gattaca* tells the story of Vincent Freeman, one of the last of the genetically unmodified naturally conceived children in a new genetically enhanced world, where life expectancy and disease likelihood are ascertained at birth. Myopic and due to die at thirty, he has no chance of a career in a society that now discriminates on the basis of genes, rather than gender, race, or religion. *Gattaca* (Sony Pictures 1997), PHILOSOPHICAL FILMS, http://www.philfilms.utm.edu/1/gattaca.htm (last visited Oct. 5, 2015).

[28] Jabr, *supra* note 26.

[29] See GREEN, *supra* note 24, at 53–70 for a more complete explanation of the categories of genetic modification.

[30] Fritz Allhoff, G*erm-line Genetic Enhancement and Rawlsian Primary Goods*, 18 J. EVOLUTION & TECH. 10 (2008), http://jetpress.org/v18/allhoff.htm.

[31] *Id.*

appropriate in the first category, the treatment side.[32] The process of selecting traits to create and order these "designer babies" falls within the second category, where most of the controversy is found.[33] The question then becomes, "does a couple's procreative liberty protect their freedom to select or shape offspring characteristics . . . . as part of discretion in rearing offspring,"[34] and are there any legal protections behind this choice? The debate has been highly contested, especially considering the current state of guidelines on the matter and the complete lack of direction in this area.[35]

C. The Biotech Boom in the State of Georgia

While debates continue in the international field as to the proper protocol for these new technologies, the implementation of formal regulations could greatly impact the state of Georgia as it "seeks to raise its profile as a center for bioscience research and development."[36] From 2010 to 2015, 2,400 new bioscience jobs were created in the state.[37] Since 2010, Georgia has blossomed in the biotechnology field due to new discoveries and ideas that have emerged from the state's research universities, particularly the Georgia Institute of Technology and Emory University, as well as a large number of startup companies interested in expanding the field.[38] The city of Atlanta, with aspirations of being a future hub of biotechnology, provides a "business-friendly" climate that currently puts few roadblocks in the paths of those who want to start a new venture in the field or to relocate existing ventures to the state. The Atlanta metro area currently supplies ready access to large groups of patients for a number of firms already doing clinical trials on drugs or medical devices.[39] The creation of accepted international

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[32] GREEN, *supra* note 24.

[33] *Id*.

[34] JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES 165 (1994) (discussing the various slippery slope arguments made against allowing nontherapeutic gene interventions).

[35] *See* Jabr, *supra* note 26; *cf.* Robertson, *supra* note 34, at 24 (arguing that while nontherapeutic enhancement is not covered by the doctrine of procreative liberty, it could fall within the discretion that is traditionally granted to parents in making decisions about how to rear their offspring).

[36] Morton & Bolton, *supra* note 11.

[37] *Id*.

[38] See Randy Southerland, *Biotech Boom*, GA. TREND (Oct. 2014), http://www.georgiatrend.com/October-2014/Biotech-Boom/, for a general background in the developments from these higher education institutes.

[39] Atlanta, Georgia is the home of a variety of biotechnology companies and healthcare IT providers ranging from start-up companies—like Axion Biosystems, which was started by a student at Georgia Tech—to world-renowned giants like Baxter International and McKesson. The state's biotech industry now employs more than 120,000 people and has a $30 billion

regulations with clearer guidelines on human testing has the potential to create many new jobs dedicated to research. Furthermore, the regulations have the potential to allow for more money to be funneled into research, which would benefit Georgia's higher learning institutions. This in turn would allow for safer, more efficient techniques to be developed and streamlined into Georgia's biotechnology businesses. However, legal status of such technologies as a result of any future regulations will determine the ultimate potential for growth in the field. A broad legal framework could initiate the above-mentioned expansions, while a narrow framework would severely limit the availability of these new jobs and the amount of money allocated for future research.

III. PROVIDING A LEGAL FRAMEWORK FOR ANALYSIS IN THE REGULATORY AND INTERNATIONAL SCHEME

With a lack of consistency in developing and implementing these technologies, a problem arises in determining which country's domestic regulations or laws meet, or will meet, the international standards, bearing in mind that international standards are nearly nonexistent at present. The lack of guidance in the international field has forced scientists to attempt to reconcile the level of different legal schemes with international covenants and treaties and decide what, if any, processes may be in violation of such schemes. In order to understand the issue, it becomes important to examine the regulations and current state of the law.

Unfortunately, U.S. law on germline modification technologies is relatively non-existent, and what does exist is questionable as to whether CRISPR technology specifically fits underneath its umbrella. Presently in the United States, there is huge diversity in state regulations,[40] and it is not clear whether any federal law or federal regulations directly address the genetic modification, particularly germline enhancements, of embryos.[41] Most likely the uncertainty is because until recently the technology was only

annual economic impact. It is surpassed in this regard by only a few other U.S. biotech hubs like Boston and San Diego. *Id.* The city of Atlanta is also home to the American Cancer Society and the Center for Disease Control. Jerry Grillo, *Georgia's Biotech Future: The industry accounts for 62,000 jobs, $3.6 billion in labor income and $517 million in tax revenues . . . but we're not there yet*, GA. TREND (May 2010), http://www.georgiatrend.com/May-2010/Georgias-Biotech-Future/.

[40] President's Council on Bioethics (U.S.), *Reproduction and Responsibility: The Regulation of New Biotechnologies* (2004), https://bioethicsarchive.georgetown.edu/pcbe/reports/reproductionandresponsibility/chapter4.html.

[41] *Id*.

speculative.[42] However, gene-transfer research falls clearly under federal regulation by the Food and Drug Administration of the United States (FDA).[43] The FDA has been granted authority over gene therapy by both the Federal Food, Drug, and Cosmetic Act and the Public Health Safety Act—which requires gene therapies to be subject to clinical trials for Investigational New Drugs (INDs).[44] However, there are no ethical requirements within these statutes.[45] It is clear that the FDA is required to oversee articles intended to "diagnose, cure, mitigate, treat, or prevent disease," but enhancements do not fit within these categories.[46] Though no consensus has been reached on the matter, the FDA has argued that its authority extends over all products related to diseases or conditions in human beings, and because enhancements involve conditions of human beings, it must have the authority to regulate enhancements.[47] This argument has been unpersuasive to date. Thus, germline modification appears to be unregulated.[48]

The FDA is further supplemented by the United States National Institutes of Health (NIH) that supplies a forum for the consideration of social and ethical issues dealing with germline modifications.[49] But because the NIH is not a regulatory agency, their authority is limited to determining what technological processes deserve funding.[50] The NIH Recombinant DNA Advisory Committee stated explicitly in a portion of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules of 2013 that the United States "will not at present entertain proposals for germline alterations," but it is not statutorily disallowed at this point in time.[51]

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[42] Girard Kelly, *Choosing the Genetics of Our Children: Options for Framing Public Policy*, 30 SANTA CLARA HIGH TECH. L.J. 303, 336 (2013). *See also* Emily Marden & Dorothy Nelkin, *Displaced Agendas: Current Regulatory Strategies for Germline Gene Therapy*, 45 MCGILL L.J. 461, 473 (2000).

[43] Kelly, *supra* note 42, at 336.

[44] Committee on the Independent Review and Assessment of the Activities of the NIH Recombinant DNA Advisory Committee; *Oversight and Review of Clinical Gene Transfer Protocols: Assessing the Role of the Recombinant DNA Advisory Committee* (2014), https://www.ncbi.nlm.nih.gov/books/NBK195894/.

[45] Marden & Nelkin, *supra* note 42, at 474–75.

[46] *Id*.

[47] *Oversight and Review of Clinical Gene Transfer Protocols*, *supra* note 44.

[48] "Enhancements" in this sense refers to both the therapeutic and enhancement function of germline technologies. *Id.*

[49] *Id*.

[50] *Id*. at 477.

[51] Edward Lanphier et al., *Don't edit the human germ line*, NATURE (Mar. 12, 2015), http://www.nature.com/news/don-t-edit-the-human-germ-line-1.17111. To view the complete text of the NIH 2013 Guidelines, see National Institutes of Health, *NIH Guidelines for Research*

Like the United States, many other countries have somewhat ambiguous regulations.[52] In the Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research of Iceland, research, experiments, and procedures on *in vitro* fertilization embryos to enhance the understanding of the causes of congenital diseases and miscarriages may be permitted. However, the Act's position on germline gene modification for reproduction is not explicitly stated.[53] Similarly, China has the Guidelines on Human Assisted Reproductive Technologies of 2003, which specifies that using human egg plasma and nuclear transfer technology for the purpose of reproduction and manipulation of the genes in human gametes, zygotes, or embryos for the purpose of reproduction is prohibited. However, these guidelines do not have the force of law, leaving ambiguity in whether or not the practice is actually banned, especially with their recent ventures in 2015.[54]

Alternatively, while several countries appear to have ambiguities in their accepted practices, many countries have taken strict positions in banning the use of germline modification for enhancement purposes. Canada, and most European countries, completely ban the technology.[55] In 2004, Canada passed the Assisted Human Reproduction Act that states, "altering the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants is prohibited."[56]

The international field is not currently clear on the subject either. However, in April 2015 an international summit was held in Atlanta, Georgia, to discuss and begin drafting potential international regulations for germline modification.[57] The summit was called Biotech and the Ethical Imagination, a Global Summit (BEINGS).[58] BEINGS was brought about

Involving Recombinant or Synthetic Nucleic Acid Molecules (Apr. 2016), http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html.

[52] Friedman, *supra* note 2; *see also* Araki & Ishii, *supra* note 23.

[53] *See* Araki & Ishii, *supra* note 23, at tbl.S1.

[54] *Id*.

[55] Friedman, *supra* note 2.

[56] Araki & Ishii, *supra* note 23, at tbl.S1.

[57] Around one hundred and forty delegates including some of the world's top faculty and researchers in the field attended the BEINGS Summit. Fourteen universities in the state participated, which brought support from organizations including the Coca-Cola Co., the Marcus Foundation, the Metro Atlanta Chamber, the Georgia Research Alliance, Georgia Bio and Southeast Bio. BEINGS 2015 also partnered with Central Atlanta Progress, the Atlanta Downtown Improvement District, the Atlanta Convention and Visitors Bureau and received support from the Consulate General of France and John Parkerson, the honorary consul general of Hungary. Morton & Bolton, *supra* note 11.

[58] *See generally* BEINGS, http://www.beings2015.org (last visited Oct. 5, 2015) (containing more information about the BEINGS Summit held in Atlanta, Ga).

because "there is a kind of regulatory chaos in the world community around biotechnology . . . . [with] some countries hav[ing] very conservative policies and others very liberal." BEINGS was followed up when, in December of 2015, a group of scientists, policy experts, and bio-ethicists met in Washington, D.C. for the International Summit of Human Gene Editing, to discuss the implications of human gene editing and how these technologies would be regulated moving forward.[59] They decided not to universally ban editing on the human genome but left the decision up to each country to individually determine the extent the use of such technologies would be allowed per their respective law. However, many scientists and researchers urged for a moratorium until these technologies can be evaluated further.[60] Despite these two meetings, international regulations are still a thing of the future.[61] Instead, countries and researchers must look to international treaties and covenants on human rights and the human genome to determine what are and are not accepted international practices.

IV. ANALYSIS

With the lack of guidelines, scientists must look to the principles embedded in the abovementioned international treaties and their own countries' domestic laws for guidance on the proper use of these new technologies. "The Declaration sets universal ethical standards on human genetic research and practices which balance the freedom of scientists to pursue their work in the field with the need to safeguard human rights and protect humanity from potential abuses."[62] The Declaration's main articles attempt to establish some limitations on what is appropriate with gene intervention when it concerns "the genetic heritage of humanity and in individuals."[63] As the Declaration explains, "the international community has a moral obligation not to transgress."[64] There are three basic principles

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[59] Sara Reardon, *Global summit reveals divergent views on human gene editing*, NATURE (Dec. 8, 2015), http://www.nature.com/news/global-summit-reveals-divergent-views-on-human-gene-editing-1.18971.

[60] *Id.*

[61] *See* BEINGS, *supra* note 58.

[62] EurekAlert, *UNESCO Adopts Universal Declaration On The Human Genome And Human Rights* (Nov. 11, 1997), http://www.eurekalert.org/pub_releases/1997-11/U-UAUD-111197.php (explaining what brought about the need for the Declaration and a more in depth discussion of its components).

[63] *Id*.

[64] This quotation refers to the inability to transgress the "heritage of humanity" discussed *supra* note 62. Declaration, *supra* note 8. *See also* Prue Taylor, *The Common Heritage of Mankind: A Bold Concept Kept Within Strict Boundaries*, WEALTH OF THE COMMONS,

that go to the heart of the Declaration.[65] The first principle states that "the human genome is part of the heritage of humanity."[66] The heritage of humanity is an ethical concept that asserts that "some localities belong to all humankind" and all resources, both tangible and intangible, should be available for the use and benefit of the general public while taking into account needs of developing countries and future generations.[67] The second principle specifies a requirement of "respect for the dignity and human rights of every individual regardless of his/her genetic characteristics."[68] The final principle is a "rejection of genetic determinism."[69] Genetic determinism is the theory that character and behavioral traits are determined singularly by the genes that make up a person's genotype,[70] by recognizing that the human genome, because it is subject to mutations through evolution, contains "potentialities that are expressed differently according to each individual's natural and social environment."[71] The issue that remains is whether scientists will be able to square technologies like CRISPR with these three main principles of the Declaration.

A. Brief Discussion of the Components of the Declaration

Several articles within the Declaration deserve careful interpretation and could create potential issues in the creation of international regulations. The opening two articles are at the core of the debate, establishing that the human genome is a pivotal aspect of the living world as it "underlies the fundamental unity of all members of the human family," and international regulations must respect the "inherent dignity and diversity" of all human beings.[72] These articles establish that technology cannot overstep boundaries by interfering with the inherent right of human dignity.[73] In other words, according to the Declaration, regardless of the genetic characteristics of a

http://wealthofthecommons.org/essay/common-heritage-mankind-bold-doctrine-kept-within-strict-boundaries (last visited Jan. 9, 2016) (discussing "the heritage of mankind").

[65] EurekAlert, *supra* note 62.

[66] *Id*.

[67] For more information on the "heritage of mankind" see Taylor, *supra* note 64.

[68] EurekAlert, *supra* note 62.

[69] *Id*.

[70] *Genetic Determinism*, REFERENCEMD (June 6, 2012), http://www.reference.md/files/D033/mD033141.html. *But see* David B. Resnik & Daniel B. Vorhaus, *Genetic Modification and Genetic Determinism*, PHILOSOPHIES, ETHICS, AND HUMANITIES IN MEDICINE 1:9 (June 26, 2006), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1524970/pdf/1747-5341-1-9.pdf (suggesting that there may be more to traits than genes alone).

[71] EurekAlert, *supra* note 62.

[72] Declaration, *supra* note 8, art. 1.

[73] *Id*.

person, there is nothing that can override his right to respect for his dignity and diversity, and no man-made law can diminish such rights. To further exemplify this principle, Article Ten states that "[n]o research or research application concerning the human genome . . . should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or . . . groups of people."[74] Scholars, jurists, and philosophers have long argued over the definition of "human dignity."[75] The European Court of Human Rights has stated that dignity is "a particularly vague concept, and one subject to random interpretation,"[76] therefore making it difficult to determine precisely what dignity means outside of a factual setting. However, the basis of dignity is said to lie in autonomy of self that is "reflected in every human being's right to individual self-determination,"[77] thus establishing that such a universal right cannot be infringed upon by law because it adheres to individual personhood that is created merely by being a part of humanity.[78] To state it more clearly, human dignity is a respect derived automatically from one's status as a human being, that prevails over all other values,[79] and because this basic ideal is so generally recognized, it appears that there is a general agreement as to what human dignity means at its core: the right to respect of one's individual personhood and uniqueness. The Declaration specifies that practices that go against human dignity shall not be permitted.[80] One explicitly stated practice against human dignity is human cloning, though no others are specifically mentioned.[81] It is important to note that at the time the Declaration was drafted, scientists had

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[74] *Id*. art. 10.

[75] Rex D. Glensy, *The Right to Dignity*, 43 COLUM. HUM. RTS. L. REV. 65, 66 (2011).

[76] In the case of *Siliadin v. France*, the European Court of Human Rights considered trafficking in human beings for the first time. The applicant, a minor female Togolese national who lived in Paris, had served as an unpaid servant for several years. Relying on Article Four of the European Convention (prohibition of slavery and forced labor), the child argued that French criminal law did not provide her sufficient protection against the "servitude" or the "forced and compulsory" labor, which in practice had made her a domestic slave. The court considered that the applicant had, at the least, been subjected to forced labor and held in servitude within the meaning of Article Four of the Convention, which was against human dignity. However, the Court held that it could not be considered that the applicant had been held in slavery in the traditional sense of that concept. Siliadin v. France, 43 Eur. Ct. H.R. 16, 317 (2005).

[77] Glensy, *supra* note 75, at 67.

[78] Matthais Mahlmann, *The Basic Law at 60—Human Dignity and the Culture of Republicanism*, 11 GERMAN L.J. (SPECIAL ISSUE) 9 (2010).

[79] Mette Lebech, *What is Human Dignity?* (2004), http://eprints.maynoothuniversity.ie/392/1/Human_Dignity.pdf (giving a complete historical background of the origin of the phrase human dignity).

[80] *Id*.

[81] Declaration, *supra* note 8, art. 1.

heightened levels of sensitivity to cloning because of the successful completion of the cloning process in Dolly the sheep. The threat to human dignity apparent during the initial forms of genetic modification was at the forefront in the reasoning for such a specific inclusion and has continued to be hotly contested.[82]

A second category of requirements for genetic modification that has the potential to shape the direction of international regulations involves informed consent. The Declaration specifies that free and informed consent must be obtained before any "research, treatment or diagnosis affecting an individual's genome" can be performed.[83] It continues in the same article to state that "[i]f according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law."[84] The Declaration clarifies that if research does not have an expected health benefit, it can only be continued through an exception to the general rule and must be done with the "utmost restraint." Any such research is allowed only if it exposes the person to a "minimal risk and minimal burden."[85] The Declaration does specify that there is an exception to consent for those who are unable to consent, in this case embryos, that allows third parties to make that choice and consent for them if it is in their best interest, but this exception still requires that there be a medical benefit.[86]

B. Can CRISPR Be Squared with the Declaration?

So exactly how far can these technologies extend without contravening international principles and ethics? One form of biotechnology already mentioned, CRISPR, can be split into three major categories: non-human genome modification, human genome modification with regards to genetic diseases and their treatment, and human genome modification with regards to physical traits and enhancement.[87] The Declaration makes clear that it is concerned with human genomes in particular, therefore the economic

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[82] Noëlle Lenoire, Comment, *Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level*, 30 COLUM. HUM. RTS. L. REV. 537, 555 (1999). Representatives from Germany suggested an amendment be added to also preclude germline modification in this Article, but it was rejected by other state representatives. *Id*. at 555–56.

[83] Declaration, *supra* note 8, art. 5(a)-(b).

[84] *Id*. art. 5(e).

[85] *Id*.

[86] *Id*.

[87] Baltimore et al., *supra* note 3.

benefits and relative lack of moral and social implications suggest non-human modification practices will need little regulation and will always be allowed unless the specific technique is found to interfere with public health.[88]

The second and third categories of modification, genetic treatment and genetic enhancement respectively,[89] require more examination to reconcile them with the Declaration, but the analysis for both is ultimately the same. As noted above, the first major concern is that the technology must not violate the "human dignity."[90] Human dignity is a flexible term that is ultimately self-defining, creating an inherent problem due to the fact that every person will have a different definition of what his or her personal "human dignity" involves. Scholars and jurists alike have accepted that the definition of the term "human dignity" changes through time with the development of new technology and changing social norms.[91] Because the phrase is self-defining, the definition will ultimately change as people's beliefs change, which tend to be further influenced by technological expansion. Prior to the development of this technology, the possibility of germline modification was a mere fiction, a futuristic possibility that, while people tended to have opinions about, did not require them to actually decide whether the process was right or wrong under their belief system. Now, with germline modification being at the forefront of the biotechnology field, people's viewpoints on the matter are expanding and changing.[92] As a result, people's definitions of their personal human dignity must also change to allow them to adapt to the feasibility of such technology. The result of constantly expanding viewpoints on the definition of human dignity suggests that such technology, regardless of whether it is therapeutic or enhancement based, can never be violative of human dignity because of the inherent flexibility of the term.[93] However, at the same time, human dignity clearly

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[88] *Id*.

[89] See Alhoff, *supra* note 30, for a review of the differences on treatment versus enhancement modification.

[90] Declaration, *supra* note 8.

[91] *See generally* Glensy, *supra* note 75; Lebech, *supra* note 79.

[92] Mairi Levitt, *Would you edit your unborn child's genes so they were successful?*, CENTER FOR GENETICS AND SOCIETY (Nov. 3, 2015), http://www.geneticsandsociety.org/article.php?id=8966 (suggesting that parents must choose between seeking the best life for their child based on the genetic possibilities at the time, while keeping in mind that we live in a rapidly changing world and the success of genetic technologies is never guaranteed, and letting their child develop naturally).

[93] Glensy, *supra* note 75, at 98, *quoting* Bundesverfassungsgericht [BVerfGE] [Federal Constitutional Court] June 21, 1977, 45 BVerfGE 187 (Ger.), *reprinted in* DONALD KOMMERS, THE CONSTITUTIONAL JURISPRUDENCE OF THE FEDERAL REPUBLIC OF GERMANY 306, 307 (2d ed. 1997) (stating "this absoluteness is not frozen in time; rather, '[n]ew insights can influence

embraces the idea that "the differences among human beings, regardless of the measure of their endowment, are exactly what the recognition of their equality presupposes and therefore protects."[94] This suggests that changes in the germline that have the potential to create a means of discrimination or eliminate differences would always be against human dignity.

As discussed earlier, cloning is specifically mentioned as being against human dignity.[95] Therefore, it stands to reason that processes that are procedurally similar should, by default, go against human dignity. Because cloning involves an entirely different process than CRISPR, it does not fit entirely into either the treatment or enhancement category but instead includes portions of both. This means that the above statement from the Declaration alone cannot declare either category as a whole as going against human dignity. Like cloning, both the treatment and enhancement categories involve the artificial selection and implantation of traits that are passed on through birth,[96] naturally creating a means of discrimination and eliminating differences because the traits are scientifically generated and are uniform regardless of the host. However, despite the technological similarities and discriminatory function, it may be possible to distinguish these processes and make the latter conform to the principles within the Declaration.[97] The argument is that there is an inherent economic and social benefit in the prevention of genetic ailments versus in an artificial creation of life,[98] so while cloning is cited in the Declaration as against human dignity, the prevention of medical ailments is distinguishable because it involves more than just artificial creation due to its preventative function. In other words, the treatment category merely replaces damaged or harmful traits rather than creating new traits. This must be contrasted to trait modification that lacks a therapeutic or medical function and falls solely within an enhancement function. Opponents of artificial modification of human traits characterize practices lacking therapeutic value, such as specific trait selection, as another form of artificial creation of life that places little to no economic value in the ability to hand select traits because it lacks any preventative value.[99] Furthermore, critics believe it is unlikely that a technology carrying a risk of

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and even change the evaluation' of claims made under the right to dignity because the 'understanding of the content, function, and effect' of this right can, and does, deepen").

[94] IBC, *supra* note 1, ¶ 111.

[95] Declaration, *supra* note 8, art. 11.

[96] Araki & Ishii, *supra* note 23.

[97] Zoë Corbyn, *CRISPR: Is It a Good Idea to Upgrade Our DNA?*, THE GUARDIAN (May 10, 2015, 2:30 AM), http://www.theguardian.com/science/2015/may/10/crispr-genome-editing-dna-upgrade-technology-genetic-disease.

[98] *Id.*

[99] Regalado, *supra* note 9.

creating new forms of discrimination and stigmatization for those who cannot afford such enhancement or who do not want to use such technologies could ever be said to uphold human dignity.[100] For the international community, this most likely means that technologies such as CRISPR will be limited in their scope if they intend to follow the principles embedded in the Declaration.[101] In other words, the technology can be used in germline modification up to the extent that it begins to interfere with the natural creation of life before it goes against human dignity. This means that uses having some preventative function would not be seen as an unnatural creation of life, whereas specific trait selection would. Perhaps a better distinction is illustrated by thinking about the modification of traits being acceptable and the mere changing or switching of traits being unacceptable.

The authors of the Declaration recognized that the ideals embedded in the document were not absolute and would require reexamination over time.[102] Article 24 of the Declaration specifies that the International Bioethics Community of UNESCO is required to further examine the issues raised by the application of such technology and the potential for evolution.[103] It is further required to give advice "concerning the follow-up of th[e] Declaration, in particular regarding the identification of practices that could be contrary to human dignity, such as germ-line interventions."[104] Opponents to germline modification argue that this clause of the Declaration views any form of technology that promotes modification at the germinal level as inherently against human dignity.[105] Based on the specific mention of germline technology in the Declaration, it is apparent that the authors contemplated the effects such a technological feat would have on human dignity, but proponents for allowing the technology argue that their use of the word "could" instead of "would" combined with the necessity to further examine the issues derived from the application of such a technology signify an intent to delve deeper into the technology before determining that the technology as a whole automatically defies human dignity.[106]

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[100] *Id*.

[101] Nathaniel Comfort, *Better Babies*, AEON (Nov. 17, 2015), https://aeon.com/essays/the-dream-of-designing-humans-has-a-long-and-peculiar-history.

[102] Declaration, *supra* note 8, art. 24.

[103] *Id*.

[104] *Id*.

[105] *See, e.g.*, *Stop Genetic Modification of Human Embryos and the Creation of 3-Parent Children*, CITIZEN GO (Feb. 18, 2015), http://www.citizengo.org/en/17728-please-keep-uk-allowing-germline-genetic-modification-human-embryos-and-creation-3-parent.

[106] ANDERS NORDGREN, RESPONSIBLE GENETICS: THE MORAL RESPONSIBILITY OF GENETICISTS FOR THE CONSEQUENCES OF HUMAN GENETICS RESEARCH 183 (2001).

The International Bioethics Committee (IBC) recently issued a memorandum that helps to clarify their viewpoint on the issue. In the memo, which addressed the ethical challenges and practical implications of advancements in human genetics and biotechnology, the IBC created a distinction between germline technologies for the medical purposes of prevention, diagnostics, or therapy, from those with the goal of enhancing human genes; the first being acceptable and the latter as going against human dignity by creating unnecessary similarities in the recipients of the technology.[107] This viewpoint supports the theory that the authors of the Declaration recognized that changes in technology would impact the definition of human dignity, and new technologies would need to be continually evaluated over time. Upon their most recent examination the IBC seemed to emphasize the importance of regulations drawing a line for the acceptable use of the technology by placing restrictions on uses for non-medical benefits. The alternative would "jeopardize the inherent and therefore equal dignity of all human beings and renew eugenics, disguised as the fulfillment of the wish for a better, improved life."[108]

Even if the technology is established as being compatible with human dignity there are further requirements. As discussed earlier, the Declaration also lists strict guidelines for when informed consent can be waived when dealing with processes affecting the human genome.[109] It is apparent that an embryo is unable to give informed consent; therefore, the research, treatment, or diagnosis of the human genome must fall under one of the exceptions. While proponents argue that the parents are the ones who are required to give informed consent and not the embryo, making this exception unnecessary,[110] perhaps there is another way to reconcile the two differing viewpoints. Genetic modification curing genetic abnormalities and diseases appears to fall under the "direct health benefit" that requires no consent. However, it is not clear whether mere modification of traits would ever have a health benefit and would therefore require an exception in order to be performed.[111] Since the Declaration specifies that exceptions must be taken with the "utmost restraint," it seems unlikely that international regulations

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[107] IBC, *supra* note 1, ¶ 107.

[108] *Id*.

[109] Declaration, *supra* note 8, art. 5.

[110] John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439, 477–78 (2004) (discussing whether parent's procreative liberties are enough to allow them to edit their child's genome before birth).

[111] Tina Hesman Saey, *Editing Human Germline Cells Sparks Ethics Debate*, SCIENCENEWS (May 6, 2015, 4:17 PM), https://www.sciencenews.org/article/editing-human-germline-cells-sparks-ethics-debate.

would allow full-scale trait modification.[112] Furthermore, the second part of the consent test is that it must have minimal risk and minimal burden to be undertaken.[113] Based on the current scientific data of CRISPR use, there are inherent medical risks with the technology that must be thoroughly evaluated to make sure the risks do not outweigh the benefits.[114] Because the process requires precision cuts of very specific gene sequences, the risk of accidentally splicing the gene in incorrect places is extremely high and could cause unintended mutations. Oftentimes, even if the gene is spliced in the correct location, the newly inserted sequence may still bind to different locations upon insertion.[115] This indicates that until CRISPR is thoroughly investigated and developed, it can never meet the standard of an allowable exception under the Declaration because there is too much of a health risk to the subject. This is not an absolute ban, however. The IBC addressed this issue in its recent memo, stating that the international community of scientific researchers must be thorough and constantly update the consequences of these technologies.[116] This suggests that the Declaration did not mean to completely eliminate the use of all such technologies, despite risks. The IBC does caution the international community on the implications of "medical tourism," the concept that because of the lack of international guidelines once an application of a technology is legal in one country it is legal everywhere.[117] Therefore, the "race to the first should be avoided."[118] Taking the inherent medical risks and informed consent arguments into consideration, it seems highly unlikely that presently the international community can justify non-medical uses of CRISPR technology due to its complete lack of necessity, further supporting a line-drawing in its implementation of regulations.

V. CONCLUSION

Ultimately, it seems that while some uses of CRISPR can be justified and reconciled with the Declaration, international regulations must be careful to distinguish between the "correction" of human genes and the "swapping" of

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[112] Declaration, *supra* note 8, art. 5(2).
[113] *Id.*
[114] Tia Ghose, *Human Embryo Editing Is Incredibly Risky, Experts Say*, LIVESCIENCE (Apr. 23, 2015), http://www.livescience.com/50596-what-are-genome-editing-risks.html. *See also* Britt Erickson, *Editing Of Human Embryo Genes Raises Ethics Questions*, CENTER FOR GENETICS AND SOCIETY (June 29, 2015), http://www.geneticsandsociety.org/article.php?id=8689.
[115] Ghose, *supra* note 114.
[116] IBC, *supra* note 1, ¶ 110.
[117] *Id.* ¶ 112.
[118] *Id*.

them. It is clear from the current legal scheme that the level of acceptance of any practice involving the human genome varies amongst countries; therefore, international regulations can be established on a clean slate. International regulations will probably allow technology to advance as far as medical benefits and correcting abnormalities in the genome are concerned but draw a line with respect to changing traits just to change traits, because it is seen as too much of an unnatural creation of life. This means that regulations should distinguish between processes involving therapeutic values and those involving enhancement values. The creation of new forms of discrimination and the elimination of differences through specific gene selection is likely to be found to go against human dignity—which values individual personhood above all else—and therefore this practice may be an invalid use of the technology. Furthermore, it seems unlikely at this time that scientists have a valid argument for voiding consent, regardless of whether parents should be allowed to make this choice for their progeny even when it comes to enhancements, because they fail to have a direct health benefit. It seems more likely that the prevention of diseases could be seen as directly beneficial to one's health and may be an acceptable practice. At present, it seems that scientists should be strongly discouraged, even in those countries with lax regulations where it might be permitted. The inherent health risks currently seem to outweigh the benefits, and it appears unlikely that waiving informed consent is a valid option. This will enable pathways to responsible uses of this technology to be identified and will allow time for the ethical issues to be examined in light of the international ideals embedded within the cultures of the world and portrayed in international covenants, ultimately leading to international regulations to guide the scientific community in this ever changing field of genetic modification.