When Innovation Exceeds Technological Capacity: A Moral Evaluation of CRISPR/Cas9's Role in Genetic Engineering Research

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The Human Genome Project (HGP) in 2003 showcased the vast influence the field of genetics exerts on biomedical innovation. The National Institutes of Health's (NIH) Human Genome Research Institute called the HGP "one of the greatest feats" and praised it for giving researchers "the ability, for the first time, to read nature's complete genetic blueprint for building a human being" within the public domain ("All About the HGP"). This successful sequencing provided biomedical researchers with a necessary precursor for uncovering the particular genes—and the genetic mutations—that directly correlate with chronic and / or fatal diseases (Venter et al. 2003). In fact, many of the novel methods inspired by the genomic revolution—such as genetic testing—are now essential to the field of medicine. For example, the discovery of breast cancer-related genes and subsequent use of genetic testing kits led to incredible advances in breast cancer diagnosis and prevention (Heemskerk-Gerritsen et al. 668-677). Today, internationally accredited biomedical research scientists and microbiologists explore unprecedented, genomic manipulations of human cells on a continuous basis. Although the ability to alter human genomic DNA offers alluring potential in the biomedical field, researchers know it comes with irreversible changes. Nonetheless, biomedical research has already established an overwhelming pace for real-world applications that is not likely to ease up or scale back anytime soon. Thus, researchers must step back and carefully evaluate the recent discoveries in genetic engineering of the human genome and the implications of innovation without watchful intervention.

Only nine years after the HGP, an explosion of genetic engineering research began immediately after genetic biologists Jennifer Doudna and Emmanuelle Charpentier uncovered the

mechanism of CRISPR/Cas9 system in 2012 (1079). Jennifer Doudna, a biochemist and professor at University of California, Berkeley, and Emmanuelle Charpentier, a French microbiologist, led the research team accredited with the development of the CRISPR/Cas9 system, a gene-editing system derived from the immune response observed in bacteria and similar microorganisms. The system operates by cutting DNA at specific sites and advances the field of genetic engineering because it allows new DNA to be inserted where former DNA has been removed. CRISPR stands for the pattern of DNA functioning as part of the immune defense in the microorganism—clustered regularly interspaced short palindromic repeats—and Cas9 is the term for a type of CRISPR-associated (Cas) protein. Shortly after Doudna and Charpentier's discovery, award-winning science writer Elizabeth Pennisi reported that a group of biochemists and genetics researchers manipulated the bacterial immune defense so that it could modify genes in almost any animal, including humans (834).

Pennisi contends because CRISPR discloses the genetic engineering methods relevant for use in human cells, it led to a "craze" or a massive influx of research, leading to more and more discoveries. This craze was compounded by public and private access to databases worldwide, allowing access to these publications because of their revolutionary implications for the field of synthetic biology, biotechnology, genetics, and medicine (Doudna and Charpentier 1083-1084). The technology originally intended to increase the amount of successful, innovative discoveries within scientific research and biomedicine is now available to anyone interested in purchasing it. Likewise, Dr. Rita Vassena, an internationally recognized expert in regenerative medicine and Scientific Director at the Clínica EUGIN—the leading infertility treatment center and IVF research laboratory in Europe—addresses the sheer power of Doudna and Charpentier's discovery for genetic manipulation. As the Vassena team states, "The development of novel and highly efficient DNA editing tools such as CRISPR/Cas9 systems allows for fast, inexpensive, and precise gene editing" (Vassena et. al 2). This deliberate accessibility benefits the institutions of research

and education. On the other hand, it is also an issue of grave concern because its use is unregulated and coupled with continuously published research.

Since genetic engineering is an enormously controversial practice, any technology that facilitates its practice should require meticulous review and regulation. Blake Wiedenheft, a biochemist at Montana State University admits, "I don't think there is any example of any field moving this fast" (Pennisi 834). The rate at which genetic engineering is developing necessitates thoughtful analysis of its ramifications. Institutions such as Harvard and MIT have hosted discussions during which distinguished scientists and bioethicists examine the ethical concerns associated with the use of the CRISPR/Cas9 system for genetic engineering in human beings and embryos. The prospective biological, social, and political dilemmas based in these ethical concerns are becoming an imminent reality with the rapid advances in research using genome-editing tools like CRISPR/Cas9. Nonetheless, there is currently no official incentive within the research community to slow progress in genetic engineering of human cells, and every incentive for scientists across the globe to accelerate it.

All in all, whether the scientists are novices or experts, they have the authority to experiment with CRISPR/Cas9 gene editing techniques. The use of genetic engineering to eliminate disease genes such as those present in individuals with muscular dystrophy, cystic fibrosis or sickle cell anemia is a remarkable feat. Researchers vie for the distinction associated with pioneering determinable methodologies for improving disease states within these individuals. This unofficial research race unconditionally attracts the experimental participation of scientists at all levels of experience.

Incredibly, no one has disputed effective jurisdiction over the experimental use of the CRISPR system. Although officials have enacted countrywide bans in 40 nations, these restrictions are globally insignificant because the most progressive research in the human genetic engineering occurs in countries that lack any official ban—such as the United States and China (König 502-506). At present, valid concerns for genetic engineering

with gene-editing tools such as CRISPR/Cas9 involve its democratization combined with its fallibility. The risks associated with these issues can manifest at any point in the near future, because legal interventions have yet to be made. In addition, the increasing use of CRISPR/Cas9 calls for legal intervention for the sake of impending issues, such as healthcare inequality and inevitably inspired nonmedical applications. The imminent problems contingent on CRISPR/Cas9's popular use are anticipated to be palpable in the near future unless regulations are instituted for their effective prevention. This paper discusses some of the situational issues that the world is bound to deal with moving forward with the global democratization of CRISPR/Cas9.

The democratization of the CRISPR/Cas9 system paired with its fallibility may threaten the safety of society. Researchers Doudna and Charpentier recognize that there are errors associated with CRISPR/Cas9, although many other research scientists have declared that it is the quickest and most efficient of common genome-editing tools such as zinc-finger nucleases (ZFNs) and transcription activator-like effector nucleases (TALENs) (1081). The maximum efficiency for genetic engineering in humans, depending on target genes, is approximately 80%, which is higher than observed with other genome editing tools. However, the efficiency is still not high enough.

Dr. Emily Leproust, an expert in synthetic biology and CEO of Twist Bioscience, states, "Critical to genome editing are precision and 100% guide representation. Precision (brought about by sequence accuracy of the guides) and effective guide representation are possible only through highly uniform synthesis" (34). CRISPR is also cheaper and easier to assemble than other gene editing tools; and its mechanisms are universal to organisms within all three domains of life (Doudna and Charpentier 1078). Some laboratory procedures using CRISPR/Cas9 techniques are reported to cost as little as $30 (Ledford 21). Its unprecedented affordability and ease of use incited what seemed instant discoveries in the field of genetic engineering. Alternatively, the fact that CRISPR/Cas9 is quick, easy, and affordable may also be the reason for serious mistakes because the system

lacks the precision necessary for any real-world applications.

Genetic engineering of human cells and embryos is proven to be possible, but not precise. A group of bioengineering experts from Harvard Medical School and Boston University led by Prashant Mali determined the efficiency of the CRISPR/Cas9 system in multiplex genome engineering—gene editing of multiple gene targets—within human cells in 2013. Their paper was published just a few months after the discovery of multiplex genome engineering in human and mice cells by a group of biological engineers from Harvard and MIT led by Le Cong. The combination of such similar results being released in such a short time within one another just a year after discovery of CRISPR/Cas9 translated into increased potential for use of CRISPR/Cas9 in gene therapy, which is the medical practice of manipulating existing genes of a patient or inserting cells with manipulated genes into a patient for the purpose of eliminating the effects of a genetic disorder within an individual. Cong et al. declares, "Multiple guide sequences can be encoded into a single CRISPR array to enable simultaneous editing of several sites within the mammalian genome, demonstrating easy programmability and wide applicability of the RNA-guided nuclease technology [CRISPR/Cas9]" (819). Mali et al. were able to devise CRISPR methods to target about 90% of human genes with CRISPR/Cas9 (3).

Although the scientists accomplished the genetic engineering of human cells, they warn readers of the possible errors and toxicity that come with using genome-engineering methods (4). Cong et al. concludes, "Several aspects of the CRISPR/Cas system can be further improved to increase its efficiency and versatility" (4). In March 2015, Liang et al. affirmed success in genetic engineering of nonviable embryos accompanied with detrimental off-target effects, which is similar to the challenges of using CRISPR/Cas9 for medical applications in human cells (Liang et al. 366). Both Liang et al. and Mali et al., along with many other well-established experts in academia mentioning the use of CRISPR/Cas9 in their methods, preach that the technology is not yet suitable for formal clinical applications. During a published discussion on CRISPR/Cas9 hosted at Harvard Univer-

sity, Novel Tech Ethics Professor and Canada Research Chair in Bioethics and Philosophy, Françoise Baylis, remarks:

> We must be wary of the potential consequences of off-target effects, lack of specificity in targeting, incomplete targeting, and so on, all of which could have devastating effects on patients. Here it is worth remembering that we have no idea what most of the human genome does. (Vasilou et al. 2)

Once we understand the dynamic of gene networks in action, scientists can apprehend the source of issues with gene editing like off-target mutations and devise new strategies for precision. However, as Baylis has asserted, most of the genome is a mystery to us.

Furthermore, unintended effects of genetic engineering in sperm cells, egg cells, and embryos will be inherited by following generations. Errors in the genome can be catastrophic because they are essentially irreversible. These factors, coupled with the unparalleled accessibility of CRISPR/Cas9, present the world with a major issue. A group of prominent research biologists led by CRISPR originator Dr. Jennifer Doudna recently called for a worldwide moratorium on the issue, contending they will officially discuss whether the world should continue to attempt to enhance the human genome via genetic engineering (Wade A1). Until then, the group announces, "'Scientists should avoid even attempting, in lax jurisdictions, germline genome modification for clinical application in humans' until the full implications 'are discussed among scientific and governmental organizations'" (Wade A1). Although the moratorium cannot possibly be legally enforced nor may it be successful in encouraging the rest of the world to adhere to the principles it establishes, it is the most effective measure the scientists could take in absence of a legal component.

Nevertheless, because genetic engineering of humans has a place in the biotech industry, the influence of leading scientists must still vie with the influence of business. Companies built on the very foundation of genome editing tools are being funded

by wealthy investors and intrinsically propelled by eager scientists who wish to expand the horizons of genetic engineering. In April 2015, the market for biotechnology companies utilizing the CRISPR/Cas9 system within the human health sector was estimated to be $46 billion (van Erp et al. 88). The main interests of these markets include "gene-therapy, cell-therapy, immunotherapy, fast and efficient development of transgenic research animals, drug discovery, as well as target validation and screening" (88). At least 14 different companies have been identified in furthering these interests—not including the accessory companies like Twist Bioscience that actually synthesize DNA sequences for CRISPR/Cas9 targeting. Many of these companies have predicted the advancements of genetic engineering in human cells and have been accruing capital since before human applications of CRISPR/Cas9 have even been published. Similar to how business has dominated the pharmaceutical industry, its influence is closing in on the newly established market of genetic engineering.

The looming threat of business's influence on genetic engineering industries presents further complexity for the establishment regulation. Since the biotech industry is in its infancy, critically relevant healthcare and business policies have not yet been set. For example, in terms of novel drug discovery, the pharmaceutical industry requires rigorous conditions to be met before drug approval (Eisenberg 477-491). Furthermore, high demands for new therapies have resulted in noncompliance to existing standards. In his book, *Corporate Crime in the Pharmaceutical Industry*, John Braithwaite—an expert on business regulation and a distinguished professor at Australian National University—writes about issues such as these. Braithwaite states, "The pharmaceutical industry has a worse record of international bribery and corruption than any other industry, a history of fraud in the safety testing of drugs, and a disturbing record of criminal negligence in the unsafe manufacture of drugs" (5-6). Criminal behavior in an industry responsible for the health of human beings is reprehensible. The pharmaceutical industry parallels genetic engineering of human beings in how they both affect human health. Since health concerns can-

not deter criminal behavior in the pharmaceutical industry, it is possible a similar trend will be observed in the human health sector of the biotech industry.

Moreover, infringement of business may not always be illegal even if it is inherently wrong. Recall when Mylan, the manufacturer of the EpiPen—a treatment necessary to save lives—risked many lives in raising the price of the emergency treatment to $600 in order to maximize profit during a lag in FDA approval for alternative, generic forms ("O'Toole Calls on FDA to Approve Generic EpiPens to Combat Mylan's Monopoly on Market"). Dr. James Baker, the CEO and chief medical officer of the advocacy group Food Allergy and Research Education, reluctantly reports, "Is Mylan doing anything illegal? No, it's taking advantage of all these things to take the market and basically push it to an extreme" (qtd. in Lupkin). Problems like these mirror future expectations for the market of genetic engineering. Once businesses have leverage in a particular market, it is their goal to maximize profit, even if it is at the expense of others' lives. An economist from Indiana University and Ameritech Chair of Economic Development, David B. Audretsch, suggests:

> To generate a successful regional cluster, the existence of world class scientific talent is a necessary condition. However, it is not a sufficient condition. The ancillary or complementary factors must also be available to translate this knowledge into a commercialized product. The complementary factors include the presence of venture capital and other forms of finance, the existence of an entrepreneurial culture, and transparent and minimal regulations fostering the start-up and growth processes. (3)

Since science sparked the market of genetic engineering, businesses now have the capacity to continue without the impediment of harsh, legal restrictions. Also, since gene-editing technology is democratizing the practice of genetic engineering, it will only require a degree of training for basic procedures to be accomplished. In conclusion, the open market or "laissez faire"

approach to business in America conflicts with any progress made to reduce democratization of CRISPR.

The commercialization of genetic engineering opposes any formal, attempted evaluation of the social impact its routine use will have. Regarding some of her first thoughts on how the creation of CRISPR/Cas9 may inadvertently cause societal issues, expert Jennifer Doudna reflects, "It was clear that governments, regulators and others were unaware of the breakneck pace of genome-editing research. Who besides the scientists using the technique would be able to lead an open conversation about its repercussions" (Doudna 470). A dilemma exists in intertwining the law, business, and science in a laissez fare, capitalist country, all while attempting to maintain health and welfare of its citizens and to preserve its future. She also recognizes that scientists can "shape the direction of the global scientific enterprise to some extent through self-censorship" (Doudna 471); however, there is clearly more of an incentive to do the opposite when scientists involved in genetic engineering research are being paid by non-scientist entrepreneurs.

In addition to inspiring business endeavors, the democratization of CRISPR/Cas9 has spawned a biohacker movement. Jeff Wheelwright, experienced freelance journalist and former science editor of *Life Magazine*, enthusiastically remarks on the ventures of biohacking. The movement is comprised of "non-scientists, quasi-scientists and a substantial number of moonlighting professional scientists who are taking molecular biology into their own hands with big and little 'why not?' projects" (Wheelwright). A single individual versed in CRISPR/Cas9 techniques is able to educate unqualified members of the movement so that they can independently use the system. The benefit of this movement is related to the benefit of democratizing genome editing for scientists alone. Supporters of democratizing gene editing with CRISPR/Cas9 argue that increasing the amount of people able to use the technology increases the amount of contributions to advancing the success of genetic engineering for applications in medicine.

Contrary to Wheelwright's observations, the complications involved with this mentality seem to supersede any benefit. As

previously mentioned, genetic engineering in human cells is not flawless and democratization of CRISPR/Cas9 allows people ignorant of its consequences to experiment with it. In theory, when businesses dominate the practice of genetic engineering, all they will need is a single experienced individual to educate others in gene editing for the business to prosper. The complications embedded in the principle of regulating genetic engineering in human beings are enough to warrant its termination altogether. Being that the termination of genetic engineering in humans as a whole is unrealistic, society must depend on stringent regulation. Regulation can improve safety as well as satisfy ethical concerns for the role of genetic engineering of human embryos and germ line (sperm and egg) cells.

The concept of genetic engineering of embryos and germ line cells for elimination of disease is widely praised, but the utilization of the technique to produce desirable physical traits is controversial. The genetic engineering of an embryo before implantation is called in vitro eugenics and the resulting baby is sometimes referred to as a "designer baby." According to Dr. Robert Sparrow, a philosopher from Australia, there are three valuable applications that in vitro eugenics may have, "to research the heredity of genetic disorders, as a means by which to produce cell lines with particular genotypes for research and therapeutic purposes; and as a method to bring into existence children with a desired genotype" (728). The first application involves "fusing gametes [sperm and egg cells] of stem cells derived from stem cells derived from embryos" (Sparrow 728). Following this process, scientists can determine how genes work together to bring about certain genetic disorders and how a genetic disorder is transmitted through generations. The second application describes the use of genetic engineering in gene therapy and for the testing of drug therapies on cells engineered to possess disease genes of focus. The third application embodies the genetic engineering of embryos so that they are endowed with desirable traits. These traits can be desirable in that they are rid of a defect gene that causes disease or that they are indicative of physical or mental superiority. Examples of physical or mental superiority are subjective and include eye

color, intelligence level, athletic ability, and so on. Prior to any formal introduction, these three applications require deep exploration by way of heavily surmised predictions for their respective impacts on society.

The use of genetic engineering of unborn children can prevent harmful, latent effects linked to certain genes. However, it can also cause society to overstep moral boundaries and therefore legal guidelines should be established to prevent future chaos. Genetic modification of genes can improve the length and quality of life for an unborn individual. Germ-line cells (egg or sperm cells) contributing to the creation of a human being can be genetically edited before fertilization as well as the embryos themselves. Editing genes within embryos or germline cells that possess mutations known to cause disease can inhibit the expression of disease outside of the womb. Gene editing can answer prayers for couples who have a history of genetic disease as well as those who obtain unfavorable genetic test results during pregnancy. Expecting couples' excitement can turn to panic after genetic testing of a fetus via amniocentesis or chorionic villus sampling (CVS).

These two methods of genetic sampling can only be done after a woman has been pregnant for months. If genetic tests reveal results that indicate eventual onset of devastating genetic disease in their child, a couple can proceed in two different ways. The parents must decide between terminating the pregnancy, or giving birth to a child whose life will be spent in and out of a hospital and in many cases, awaiting premature death. Abortion late in a pregnancy is a troubling issue for some people, establishing a daunting conflict. Regardless of which choice is made, the decision made could haunt those involved for the rest of their lives. Alan H. Handyside, an expert in developmental biology and molecular genetics from the University of Cambridge, was motivated by this conflict. With the help of his colleagues, he performed the first pre-implantation diagnosis (PGD) of cystic fibrosis for a couple with a known history of the disorder (905-909). The research conducted by Handyside et al. suggests preimplantation genetic diagnosis (PGD) following in-vitro fertilization (IVF) as a cure for couple who "re-

peatedly terminate pregnancies in an attempt to have a normal child" (905), because they "could be certain before pregnancy that their offspring would be free of a certain defect" (905). This is true for a couple of prospective parents who are both carriers for a genetic disease and have a high chance of giving birth to a child with a disease. The idea of PGD is amplification of an embryo's genome using common lab techniques to detect whether the embryo possesses mutated genes. When PGD of an embryo shows that a child will not express a genetic disease, it is implanted into the woman's uterus. The results of the studies by Handyside et al. were a revolutionary breakthrough for couples carrying monogenic disease genes, specifically those with a history of cystic fibrosis. However, couples with more complex conceptive issues do not benefit as greatly, if at all, from in vitro fertilization (IVF) and PGD.

These complex conceptive issues include deadly diseases in which the in vitro selection of unaffected embryos is much harder, or even impossible. The method of genome selection is relatively simple for a monogenic disease in which both parents need to contribute the recessive allele (homozygous recessive) because probability predicts that only 25% of the embryos produced through IVF would possess the disease if both parents were carriers, which is normally the case. Alternatively, three of every four embryos produced via IVF would be desirable for implantation. In cases where the probability of disease being expressed is higher, PGD and IVF become less efficient and typically more expensive for a couple. For instance, inevitable, painful side effects of egg retrieval are enough to discourage a couple from further IVF trials, if they haven't been driven away from the procedure to begin with. Pascal-Henri Vuilleumier, an established expert in anesthesiology and pain therapy research, elaborates on the difficulty of egg retrieval in a study conducted with several colleagues in his department. Successive IVF treatments are not ideal since more eggs are needed, which can be both challenging and painful to obtain from a female (313). Genetic engineering can provide a more efficient solution for couples that carry diseases more genetically complex than monogenic, homozygous recessive disease. For instance, genet-

ic engineering is ideal if one parent possesses a unique form of infertility, if the disease is deadly and autosomal homozygous dominant, if the disease is expressed with the contribution of only one allele, or if it is polygenic—involving more than one gene (Vassena et al. 5). However, Dr. Rita Vassena and her colleagues suggest that PGD should continue as the prevailing use for simple, monogenic diseases since genetic engineering is not always precise.

If genetic engineering of human embryos ameliorates the presence of hereditary illness in society, its introduction for this purpose will create new and more complex issues requiring control. For instance, the accepted use of modern eugenics will augment socioeconomic inequality in ways that may be irreversible. Genetic engineering itself is inexpensive; however, the IVF procedure associated is cost prohibitive for a good number of the population. IVF is a stressful, expensive, and inefficient process. Barton H. Hamilton—a distinguished economist and professor from Olin Business School, Washington University in St. Louis who conducts research in healthcare economics—along with his colleagues, report that out-of-pocket costs for IVF are around $10,000 to $15,000 per cycle (3). The distinguished physician Dr. David Meldrum, clinical professor at UCLA and UCSD, and founder of his own fertility clinic in San Diego, supplements these findings in a study conducted by himself and his research group. Meldrum et al. reports there is only about a 30% chance that a successful pregnancy will result each cycle, with the success rate decreasing significantly after around the fourth cycle (1005). As time passes between cycles, the increasing age of the mother can have a profound effect on success rates as well. Although ten states have mandated insurance coverage for IVF, the procedure is still thousands of dollars per cycle. The possibility of producing multiple children is another expense IVF couples are subject to. Higher order births are common in IVF pregnancies and can be problematic for the mother, physically and financially—twin births cost approximately $115,238 and triplet births cost $434,668 (Hamilton et al. 7). Gestation periods are shortened in higher-order pregnancies and the early

births that follow require neonatal intensive care, which can double the price of birth cost alone. At birth and throughout their lifetime, the costs of medical care are higher for children resulting from early births. Looking at these statistics, it is rational to conclude that genetic engineering involved in producing human offspring will only benefit the wealthy. There is hope that insurance will eventually cover modification in genes expressing deadly mutations; however, for all other gene-related health issues, genetic engineering will only be available to the rich. Advancements in genetic engineering in the United States will cause health disparities across the nation. If advancements are profound in the United States, they will extend to other countries and cause health disparities worldwide.

Genetic modification of embryos for medical purposes can also add to the complexity of genetic engineering issues by its potential abuse for unnecessary, unethical benefits. Giving couples the ability to modify disease genes will also open the door to genetic modification for aesthetic purposes. The market for these procedures would indubitably be of interest; however, the interest must be suppressed in order to preserve ethics within genetic engineering. Because insurance will not cover all uses of genetic engineering, its benefit is also only accessible by the rich. If socioeconomic inequality can create health inequality with the allowance of genetically engineered (GE) embryos, it could also cause other inequalities. The richer people in the nation could also eventually become the more attractive, more intelligent, more athletic people in the nation. Arthur Caplan, the director at the Center for Bioethics at the University of Pennsylvania, along with assistant professors Glenn McGee and David Magnus, admit

> Allowing parental choice about the genetic makeup of their children may lead to the creation of a genetic "overclass" with unfair advantages over those who parents did not or could not afford to endow them with the right biological dispositions and traits. Or it may lead to homogenisation in society where diversity and difference

> disappear in a rush to produce only perfect people, leaving anyone with the slightest disability or deficiency at a distinct disadvantage. (2)

The idea of gene manipulation extending onto physical fitness and attractiveness is alarming. Michael J. Sandel, an American political philosopher and a professor at Harvard University, articulates, "The fundamental question is not how to assure equal access to enhancement but whether we should aspire to it" (16). The complications involved with equal access can be avoided if we do not allow non-medical, genetic enhancement in the first place. Sandel continues with this question, "Should we devote our biotechnological ingenuity to curing disease and restoring the injured to health or should we also seek to improve our lot by reengineering our bodies and minds" (16). The technologies involved in bettering the health of individuals via genetic engineering are not infallible, and require incalculable amounts of research ahead. If health improvement and elimination of deadly disease are the main cases for moral permissibility of genetic modification, research efforts should be concentrated in these areas. Physical and mental enhancement via genetic engineering should be legally prohibited because of the negative ramifications its allowance will generate.

Genetic engineering is a remarkable advance for science; however, it may be a threat to the rest of society. Genetic engineering is not yet fit for medical applications. Even so, its democratization through availability of CRISPR/Cas9 technology does not prohibit the genetic engineering of humans. Research in genome editing of human cells and embryos is published on a regular basis and there are no formal regulations imposed that inhibit its practice. In addition to these concerns, the biohacker movement and influence of business puts authority in the hands of non-scientists who are not well versed in genetic engineering techniques. Although genetic engineering will improve quality of life for unborn individuals who possess disease genes, ethical concerns such as inequality and use in nonmedical applications will emerge with the routine use of genetic engineering of hu-

man cells and human embryos. The termination of genetic engineering in humans is unlikely; therefore, the best solution for all of its complications is stringent regulation and well-formulated policies. Until we can bridge the gaps of human-gene networks, clinical trials should be suspended. Instead, researchers can engage in experiments analyzing the cellular effects observed in various applications of CRISPR/Cas9 in vitro. Therefore, experts in biomedicine should promote efforts to fund only in vitro research until regulatory organizations can keep pace with scientific innovation.

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