ABSTRACT

Promise and Peril: Genetic Technologies; Their Use Today and Potential Consequences Tomorrow

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Knowledge is power. Through tireless research in the lab, new genetic technologies utilized for human treatments are coming to the American marketplace. Of these new technologies, those involved in genetic screening and testing are of particular interest to this thesis because of the subtle tensions that exist within these new tools of medicine. These technologies have great potential in identifying diseases so that they can be properly addressed through medical treatment. They reveal the genetic predispositions and history of individuals found in their very genetic code. However, these screening and testing technologies also present potential challenges to the American healthcare system. Questions concerning the implementation of such technology through traditional healthcare channels and access to these technologies remain unanswered. Such powerful pieces of technology, like those used in genetic screening, may also exacerbate societal divisions among the population. The potential, and unequal, use of these technologies coming to market is a crucial aspect to consider as those with more resources may become the sole, and repetitive, benefactors at the expense of those with less resources. Thus, this thesis serves as a vehicle to consider such key questions and hopefully inspire the necessary deliberation required to use these new technologies in a way beneficial to all.

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PROMISE AND PERIL: GENETIC TECHNOLOGIES; THEIR USE TODAY AND POTENTIAL CONSEQUENCES TOMORROW

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DEDICATION

I would like to dedicate this work to Belinda Shi.

In the storms of adversity, she kept me upright. When I would lose the will to keep going, she kept me onward. And when I felt most alone, her presence reminded me that she was there for me always. Her love and support were what made this work possible and what inspires me to press onward.

INTRODUCTION

Today's actions are the history of tomorrow. We sit upon a precipice in the history of our species. As humanity looks to the stars with hope for a new future, true visionaries recognize that our future is being made today, here, in our everyday decisions. Much like the agricultural revolution was a milestone for our progress in human development, we are now on the cusp of yet another revolutionary event: the age of genetic revolution. No cataclysmic event, nor sudden act of fate, has thrust us into this age, but rather the gradual unrelenting advance of scientific achievement. Although this may seem like a grandiose claim or a prophesying of the future, evidence bears out the claim that we have entered an age of human genetic technologies and engineering.

One of the most recognized human genetic engineering procedures occurred in 1989, and ever since that day we have been enamored by the possibilities that exist within our own genetic code. Unlike previous eras that utilized the practices of selective breeding, this procedure in 1989 was one mediated through mechanisms designed on the lab bench for the expressed goal of changing genetic information within an individual rather than future progeny. The fantastical prospects of the possibility of eradicating previously untreatable diseases, increasing life expectancy, and of cloning ourselves permeated our fiction as the rush of this new field of experimentation came over the public. Many offset such advancements as unachievable and something of the distant

future, but is this really the case? Today we are capable of identifying the genome of a person through a simple sample collection, our ancestral history is revealed from drops of saliva; we can treat infertility, select for genes that allow for disease resistance, and may soon be capable of creating offspring with desired phenotypic traits down to the color of the eyes as previously complex traits are better mapped by scientists today. Advances once thought to be off in the distant future arrive in the 21st century through rapidly advancing understandings of who we are as a species. New developments, drug treatments, and research into once far-flung ideas are now a reality. Although this is an incredible achievement, it could also be the next greatest threat to our global stability. Indeed, when one is sobered from the highs of what is possible, we begin to consider if it *should be* possible. What is our role or authority that allows us to tamper with our own genetic makeup let alone our progeny's? Are we capable of understanding and preparing for the consequences of today's actions that will shape the trajectory of our future? Questions such as these have inspired the creation of this thesis. This work seeks to better understand exactly what we are capable of in terms of utilizing genetic technology. One can observe how genetic technologies have been exiting the polished floors of research centers and have entered our homes. By first understanding the state of this revolutionary science, we are able to ask informed questions of how this technology will be accessed by the masses, which groups stand to benefit, and which are likely to be left behind from our rapid scientific achievement if careful considerations are not made today.

The most learned person is one who realizes they do not know it all, but rather knows enough to ask informed questions. The purpose of this first chapter is to provide the basic knowledge of what genetic technologies exist today, both those in the labs and

those in the marketplace. Within this preliminary chapter, basic biological mechanisms are described in order to better understand the biology behind certain key procedures. This understanding is important for a few reasons. Knowing the intended use of key technologies will become important in understanding the pricing practices and social stigmas surrounding the technology or procedure in question. Specifically, those screening procedures and technologies that impact future generations is what should concern us today the most. Recognizing how the use of such technologies may allow for disease avoidance in the population is important in understanding the future consequences of the choices made today.

Following the first chapter's glimpses into the current state of genetic technologies and medications, chapter two will then consider how access to these technologies would be possible within the setting of our healthcare system. Because we have the medical knowledge to make these technologies and procedures possible, that does not mean people will have equal access to them. It is true that as research often improves efficiencies in production, and as more businesses become involved in this burgeoning branch of medicine, costs of the technologies seem to decrease at least in projected pricing models. Yet, one must remember that oftentimes for a product or service that reaches the consumer, the suggested market price is not the same as what the consumer is charged at the point of purchase. Indeed, markups for medications, services, and technologies occur from the point of production, through hospitals, and through insurance agencies. Healthcare institutions may further restrict access through other practices beyond pricing as well. While too deep a subject to explore fully, chapter two will provide a brief consideration of the healthcare and insurance practices currently at

play that may restrict access to care. Lacking coverage, price discrimination, variable and lacking price transparency, and unaddressed concerns in policy by insurers and government officials all play a part in crowding out many to healthcare services. Certain groups may find even greater obstacles to obtaining these new technologies as a result of lacking and ill-defined policy. Fears of discriminatory practices and lack of privacy are concerns meant to have been addressed through key legislation. However, these legislative acts have not adequately served their purpose, often because of unclear divisions of jurisdiction and questions of who ultimately can mandate policies for such services like *in vitro* fertilization (IVF). Finally, chapter two looks at possible changes to the healthcare model through the actions of large employers. Employers recognize the reality of genetic technologies coming to the healthcare market and have begun taking proactive steps to add such technologies to their insurance plans to both benefit employees and the company. Given that the federal and state policies meant to address the concerns of consumers is often lacking in clarity, employers and their company insurance plans may provide the avenue by which such concerns of coverage and costs are better addressed. New healthcare paradigms like the Consumer Driven Health Plans (CDHPs) may provide a new avenue to addressing concerns of access and affordability.

Chapter three considers the societal implications for the introduction of these new waves of genetic technology and how they perhaps pose risks to society as a whole. Because of the promise of these new technologies, especially those screening technologies, to perhaps allow consumers to avoid diseases, questions of affordability from chapter two are pertinent as affordability often governs access. The wealthy have more access to genetic technology simply by possessing more resources to command.

Without proper management, we may realize a society wherein certain groups will have access to the technologies capable of allowing them to enhance themselves more readily than others and screen for offspring unburdened by certain genetic conditions. Certain theories suggest that health disparities exist between groups of differing socio-economic status, where those with resources use their power to avoid negative health outcomes. Technologies introduced in chapter one indeed demonstrates great potential for avoiding and treating debilitating chronic diseases and editing genes for a wide range of purposes that can serve to better the outcomes of patients. People without the ability to prevent such debilitating and costly diseases would be at a financial disadvantage to others who can avoid such outcomes. In this way, harder economic division between socio-economic groups can become a reality as power and resource potential accumulates in the well-off. These well-off of society, may become frequent users and benefactors compared to others with less ability to access such consequential technologies. In the past, pursuits were undertaken where social elites like this would work with the cooperation of government to concentrate power. We must be keen to recognize the subtle power dynamics that exists in society that favor those with more resources at the expense of those without. In the face of traditional institutions that typically wield the power to control, we must be willing to explore alternative avenues like those CDHPs to perhaps gain more equal levels of access to technologies in order to avoid worsening societal division.

Overall, this structure of the thesis is meant to transition the reader into the conversations being had today. By first understanding the technology in question, its mechanisms and uses, one realizes the potential implications of these technologies entering the field of medicine. The second chapter discusses models of healthcare and

considers specifically how certain practices and concerns that exist may be restricting the access to new technologies for the majority. In the face of new waves of genetic technology, how can we better understand key flaws in our healthcare system that may prevent equal access to these new developments. Finally, the last chapter encourages readers to consider how such consequential technology may pose a risk to our society by making distinctions between socio-economic levels more rigid. Recognizing the power dynamics that exist in society is key to addressing such dynamics. There is a need to form new behaviors informed by first understanding the current behaviors we engage with today.

The great promise of these genetic technologies is not lost upon us today. Hard questions on how to treat devastating conditions and diseases are now finding answers. The continual march of scientific research pushes us further, advancing our species and improving the lives of many people. Yet, we must be diligent and not become lost in this new potential. The importance of addressing questions of equal opportunity to access these technologies, and doing so in well-thought-out ways, is imperative to minimizing ill-effects to our society. Recognizing both the complexities and subtleties before us is crucial in adopting these technologies in a way that maximizes their benefit. It is up to us today to secure a future that successive generations can look back upon in admiration.

CHAPTER ONE

Genetic Technologies and their Market Availability

Introduction

This chapter is concerned with promoting a fundamental understanding of current genetic technologies. Briefly, this chapter will observe and seek to explain a few of these technologies – either those in the market currently, or those expected to be introduced soon. After identifying these technologies, specific consideration and focus will be given to three, namely: Preimplantation Genetic Diagnosis (PGD), Genetic Screening such as Newborn Screening, and Direct-to-Consumer (DTC) technology. For these three in particular, a more detailed explanation is given of how each works, how they are currently utilized in practices, and what they can offer to patients or consumers who seek to use them. By considering each of these details, further chapters in this thesis can expound upon questions of access to these technologies, and the potential of these technologies in furthering social divisions amongst people to an irreconcilable point. As cautioned in the thesis' introduction, we must be informed to how these technologies work to truly maximize their benefits and minimize potential ill-effects to our society. Therefore, this chapter will provide basic scientific understanding of a range of genetic technology with specific consideration on PGD, Newborn Screening, and DTC technologies as these will become the focus of later chapters.

Gene Therapy and Gene Editing

Perhaps one of the most notable examples of a branch of current genetic technologies is that of human gene therapy. The definition of gene therapy itself is warranted for review. According to the FDA, gene therapies are those procedures "used to modify or manipulate the expression of genetic material or to alter the biological properties of living cells."[1] This definition, from 1993, is considered by some to be obsolete, as there has been considerable advances in the field today. Yet, the FDA maintains this definition, expanding on it in 2018 to include "those products that mediate their effects by transcription or translation of transferred genetic material or by specifically altering host (human) genetic sequences."[2] The FDA keeps this definition intentionally vague because it allows the regulatory agency significant oversight in a field with constantly advancing technologies. Critics of the definition hold that, again, it is antiquated and does not recognize certain differentiations thought to exist within the realm of gene therapy. In an article for the *Journal of Law and the Biosciences,* the authors Sherkow, Zettler, and Greely put forth a new definition that seeks to accommodate the needs of regulators, policymakers, scientists, and the public alike. The definition they suggest states that, "gene therapy is an intentional and expected permanent alteration of a specific DNA sequence of the cellular genome that can be further categorized into at least three types: direct, compensatory, and augmenting, depending on the purpose of the therapy."[3] This definition therefore addresses issues of

[1] Jacob S. Sherkow, Patricia J. Zettler, and Henry T. Greely, "Is it 'Gene Therapy'?" *Journal of Law and Biosciences* 5, no. 3 (Dec. 2018): 786-793, doi: 10.1093/jlb/lsy020.

[2] Ibid.

[3] Ibid.

permanency, expanding the term past editing of genes only labeled 'defective' by using the word 'alteration' instead. Additionally, this definition makes clear the intentional aspect of the technology and notes the derivation of cells from the patient as a part of modification. For this paper, these two definitions can be referenced when discussion of gene therapy takes place depending on the context. We note that oftentimes the FDA definition is used by policymakers, insurers, and other healthcare institutions while the Sherkow et al. definition may be more appropriate in the scientific context.

There are two chief ways in which gene therapy can be accomplished either *in vivo* or *ex vivo. In vivo* refers to research or work being done within a living organism. For *in vivo* gene therapy, a healthy copy of a gene is delivered inside the body so it may compensate for a damaged or mutated one. These healthy genes are carried into cells via vectors – which are carriers of desired information or material – administered through either an injection or intravenous (IV) infusion.[4] Typically, the vectors utilized in therapeutic treatments are viral agents. This introduction procedure is relatively well understood, being that it is modeled after our understanding of viruses. For decades, it has been understood that "once a virus infects a cell, it hijacks the cellular processes to produce virally encoded proteins that will replicate the virus's genetic material."[5] Viral infections work to "reproduce in their hosts as viral DNA interacts with the host's machinery for transcribing DNA into mRNA – in some cases it becomes integrated into the host-cell chromosome where it remains quiescent and is replicated as part of the cell's

[4] "Gene Therapy," Cleveland Clinic, last modified August 17, 2019, https://my.clevelandclinic.org/health/treatments/17984-gene-therapy.

[5] Fredric S. Cohen, "How Viruses Invade Cells," *Biophysical Journal* 110, no. 5 (Mar. 2016): 1028-1032, doi: 10.1016/j.bpj.2016.02.006.

DNA from one generation to the next."[6] By modelling this well understood mechanism, the reliability and even safety of the technologies being developed in gene therapy can be better understood. The second type of gene therapy, *ex vivo* gene therapy, uses a similar mechanism to its *in vivo* counterpart, yet is noticeably different in that the location of genetic manipulation is outside the body of the organism rather than within. In *ex vivo* gene therapy, "genetic manipulation of cells is undertaken remotely and more safely outside the body;" this strategy is particularly "well suited to targeting a specific organ rather than treating the whole organism itself."[7] Outside the body, the person's cells are introduced to vectors containing the desired genetic material. Once the modifications take place between the cells and the vectors, the manipulated cells are subsequently transplanted back into patients. This is thought to be safer than *in vivo* therapy because the vector and cell interaction happens outside the patient, rather than within, mitigating the potential for unintended vector effects that may invoke an immune response in the patient, potentially harming them.[8] Both of these methods of gene therapy, *in vivo* and *ex vivo*, are currently in use today.

Although increasing in frequency, full understanding of gene therapy procedures remains somewhat elusive to researchers as sometimes the therapies do not work the way they were intended. This is because there is a chief challenge in developing gene

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[6] Berk A. Lodish, and S.L. Zipursky, *Molecular Cell Biology* (New York: W.H. Freeman, 2000), 6.3 Viruses: Structure, Function, and Uses.

[7] Kevin Gregory-Evans, A. Emran Bashar, and Malcom Tan, "Ex Vivo Gene Therapy and Vision," *Current Gene Therapy* 12, no. 2 (2012): 103-115, doi: 10.2174/156652312800099607.

[8] Brandon K. Sack and Roland W. Herzog, "Evading the Immune Response Upon *In Vivo* Gene Therapy with Viral Vectors," *Current Opinions in Molecular Therapy* 11, no. 5 (Oct. 2009): 493-503, PMID: 19806497.

therapies: choosing a suitable vector.[9] A vector is not suitable if it initiates a severe immune reaction because of the molecular markers of the virus triggering an immune response. With knowledge of the importance of vectors in unlocking successful gene therapy techniques, research seeks to find vectors suitable to a variety of conditions so that genetic integration will be more auspicious. Human gene therapy research has become more commonplace among labs since 2009 where a search of the National Institute of Health (NIH) Genetic Modification Clinical Research Information System (GeMCRIS) revealed 908 total gene therapy clinical trials had been completed since 1990 and were recorded in this database.[10] By expanding the perspective to a global context, and adjusting the timeframe from 2009 to 2015, it was observed through the publicly available database, *Gene Therapy Clinical Trials Worldwide*, that 2,335 gene therapy clinical trials have been completed.[11] These figures indicate a few things: an increasing ability to make successful therapies, a growing global sense of acceptance for these types of procedures, and a market willing to utilize these technologies continually in development. As of 2015, almost 163 trials were in development with 95% of these making it to early stages of testing, and of those 72% are ongoing.[12] These estimates show a sustained effort on the part of drug developers to enter this market of genetic

[9] E.L. Scheller and P.H. Krebsbach, "Gene Therapy," Journal of Dental Research 88, no. 7 (Jul 2009): 585-596, doi: 10.1177/0022034509337480.

[10] Scheller and Krebsbach, "Gene Therapy," 585-596.

[11] Eve Hanna, Cecile Remuzat, Pascal Auquier, and Mondher Toumi, "Gene Therapies Development: Slow Progress and Promising Prospect," *Journal of Market Access & Health Policy* 5, no. 1 (Jan. 2017): 1265293, doi: 10.1080/20016689.2017.1265293.

[12] Hanna, Remuzat, Auquier, and Toumi, "Gene Therapies Development: Slow Progress and Promising Prospect."

technology. With these waves of development reaching the American marketplace, people must be informed about both the benefits and potential risks of these new medical technologies.

Closely related to gene therapy is the field of gene editing. Gene editing is a slightly more aggressive approach for genetic alteration in humans. Gene editing is differentiated from gene therapy, in that, for gene editing the 'machinery' involved in altering genetic material "is directly transferred into host cells to modify the genome within the recipient rather than using vectors to transfer the modified genes and can be used to add, inactivate, or correct a gene with permanent effect.[13] Rather than vectors containing desired gene codes themselves, they contain the machinery needed to facilitate the desired genetic change. Typically, the machinery transferred into recipients are protein nucleases – which are protein enzymes that specifically interact with genetic material comprised of nucleic acids – classified based upon their mechanistic function. There are three main types of nucleases utilized for gene editing technologies currently: zinc finger nucleases (ZFN), transcription activator-like effector nucleases (TALEN), and clustered regularly interspaced short palindromic repeats with associated nucleases (CRISPR).[14] These three types of nuclease categories represent the machinery that creates the changes within recipients themselves. The understanding and exploration of these nucleases represent the crux of gene editing technology, in that, each have been the subject of intense research aimed to better increase efficacy and targeting ability. For

[13] Alison Sinclair, Saadl Islam, and Sarah Jones, "Gene Therapy: An Overview of Approved and Pipeline Technologies," *Canadian Agency for Drugs and Technologies in Health,* (Mar. 2018): PMID: 30855777.

[14] Ibid.

each of these types, there are enzymes, which is a protein, with specific configurations and marker molecules that allows for certain interactions with genetic material. The names of these enzymes give insight into what markers or main method of activation they use in finding the genetic material to which they are matched. Once the nucleases are in conjunction with the material, a specific modification of genetic sequences is made whether it be an addition, an excision, or a replacement of genetic base pairs. Oftentimes, these modifications are a result of specific shape changes that occur. It is this change in structure of the conjunction material that results in certain genetic modification. The most well-known of these gene editing technologies is that termed the 'clustered regularly interspaced short palindromic repeats-associated nuclease' or more commonly known as CRISPR. These CRISPR sequences are often the sites by which enzymes, like the Cas9 enzyme, facilitate a specific interaction similar to the processes described in this paragraph.

CRISPR represents the cutting edge of genetic editing technology, and thus merits special attention. The rising medical tool of CRISPR has been heavily analyzed over the past few years since its development. Yet, for a basic understanding of the technology for the purposes of this paper, the definition that will be utilized comes from a research publication entitled "Defining and Improving the Genome-Wide Specificities of CRISPR-Cas9 Nucleases" by Shengdar Tsai and J. Keith Joung. In this article, CRISPR-Cas9 is defined as RNA-guided nucleases that are transformative technology for biology, genetics, and medicine; they "can be programmed to cleave specific DNA target sites in

living cells and organisms."[15] The specificity of CRISPR is what makes this technology especially noteworthy as scientists never before had the ability to edit very specific genetic material. By utilizing RNA – a molecule that can read genetic information in DNA – potential sites (often in the nucleus) desired for editing are found; guiding RNA shepherds enzymes associated with CRISPR editing, like Cas 9, to the spot where the DNA edit is required. The enzyme utilized has a specific function that, again, may add, delete, or otherwise modify the target genetic sequence creating the desired change in the cells' nucleus that can proliferate.[16] This field of research into CRISPR has been growing rapidly as many see great potential in having the selectivity of altering specific DNA target sites within living organisms. Further, CRISPR genome editing can allow scientists to quickly combat demanding issues, accelerate research into diseases such as cancer, and perhaps provide a new avenue to address mental illness. There is great promise in the mechanism, but like what was warned with gene therapy, it is important not to be lost in the potential to the point we do not recognize possible negative consequences.

One of the main limitations of CRISPR research is the highly regulated nature of its use. CRISPR tools had, for many years, been tested only *in vitro* for human applications and outstanding questions about efficacy and safety are persistent.[17] Often a sticking point for the development of most medical technologies, the transition from *in*

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[15] Shengdar Q. Tsai and J. Keith Joung, "Defining and Improving the Genome-Wide Specificities of CRISPR-Cas9 Nucleases," *Nature Reviews Genetics* 17, no. 5 (May 2016): 300-312, doi: 10.1038/nrg.2016.28.

[16] Tina Hesman Saey, "Explainer: How CRISPR Works," *Science News for Students,* July 31, 2017, https://www.sciencenewsforstudents.org/article/explainer-how-crispr-works.

[17] Matthew P. Hirakawa et. al., "Gene Editing and CRISPR in the Clinic: Current and Future Perspectives," *Bioscience Reports* 40, no. 4 (April 2020): online only, doi: 10.1042/BSR20200127.

vitro to *in vivo* research is a massive step because of the safety and liability concerns. Conducting research on non-human specimens is already heavily regulated and the additional layers of regulation that exist for human test subjects is a barrier to many developers. However, the world was shocked when Chinese researcher "He Jiankui announced to the world that he had successfully created the world's first gene-edited babies."[18] He was subjected to fines, unemployment from his institution, and currently faces criminal sentencing as a result of his actions. Yet, it was perhaps the spark for further CRISPR use in humans worldwide as the Casey Eye Institute at Oregon Health & Science University, Portland announced in 2020 the first CRISPR usage inside a human within the United States.[19] These uses might suggest changing views of safety concerns, however, recent research suggests that CRISPR may be a cause of "significant on-target mutagenesis, such as deletions and even more complex genomic rearrangements at the targeted sites."[20] Furthermore, there has been concerns about CRISPR's role in altering target cells to be "missing key anti-cancer mechanisms increasing the risk of those cells turning into tumors."[21] Even more concerning to most is the fear of germline changes as a result of CRISPR usage, specifically, potential off-target effects. This uncertainty could be dangerous as these off-target effects can happen in genomes not intended to be

[18] David Cyranoski, "What CRISPR-Baby Prison Sentences Mean for Research," *Nature,* January 3, 2020, https://www.nature.com/articles/d41586-020-00001-y.

[19] Jackson Ryan, "CRISPR Gene-Editing Tool Used Inside Humans for the First Time," *CNet,* March 4 2020, https://www.cnet.com/news/crispr-gene-editing-tool-used-inside-humans-for-the-first-time/.

[20] Michael Kosicki, Kart Tomberg and Allan Bradley, "Repair of Double-Strand Breaks Induced by CRISPR-Cas9 Leads to Large Deletions and Complex Rearrangements," *Nature Biotechnology* 36, no. 8 (Aug. 2018): 765, doi: 10.1038/nbt.4192.

[21] Robert J. Ihry et al., "p53 Inhibits CRISPR-Cas9 Engineering in Human Pluripotent Stem Cells," *Nature Medicine* 24, (2018): 939, doi: 10.1038/s41591-018-0050-6.

modified; if essential genes are modified, like those for vital organs, it could be deadly.[22] In the context of germline cells the concern is even greater. If embryos are being altered to prevent genetic disease without knowing the on and off-target effects of CRISPR, the germlines themselves could be at risk creating population level effects. There is still great hope though that CRISPR could be used to treat heritable diseases like cystic fibrosis, hemophilia, and other such diseases. Some researchers suggest that CRISPR has the ability to edit germlines so that, "over generations, germline editing could reduce disease prevalence in the human gene pool eventually eradicating certain heritable diseases from the population."[23] Again, though, the risk of such germline edits via CRISPR is that there may be unintended mutagenesis off-site from these procedures that will affect future generations as the germline itself has been modified. These concerns are clearly major obstacles preventing the introduction of CRISPR to the wider market at the moment, and further serves as a cautionary tale to truly understand newly developing technologies before implementing them. Ironically, the greatest potential aspect of CRISPR technology is also its greatest concern; the alteration of germline cells without understanding on-and off-target effects is still an issue to be addressed in further research.

So, where is gene editing overall as a field? By most measures we see the technologies presented and available in a state of infancy. Many of the technologies are primed and understood to a fair degree, however, large amounts of clinical trial testing remains out of reach for many of these technologies as concerns still exist regarding their

[22] Hirakawa, Krishnakumar, Timlin, Carney, and Butler, "Gene Editing and CRISPR in the Clinic: Current and Future Perspectives," online only.

[23] Kofler, Natalie and Katherine L. Kraschel, "Treatment of Heritable Diseases," *Seminars in Perinatology* 8, no. 42 (2018): 515-521, doi: 10.1053/j.semperi.2018.09.012.

efficacy and safety during *in vivo* applications.[24] It is imperative that before research pushes this technology further into marketplace use, we thoroughly flush out and explore possible side effects of these technologies or else we risk detrimental consequences to both individuals and the population as a whole.

Assisted Reproductive Technologies (ART)

Not all genetic technologies are as direct as the practices utilized in gene therapy and gene editing; rather, there are subtler technologies available in the market that play significant roles in the human reproductive process. Some of these technologies are classified as Assisted Reproductive Technologies (ART) and include things like *In-Vitro* Fertilization (IVF), genetic screening, and Preimplantation Genetic Diagnosis (PGD). Their relative abundance and use in the current healthcare market may surprise those not following this field of medicine. In 2017 alone the CDC, who had been collecting data on ART procedures since 1995, reported that a total of 196,454 ART procedures were performed in the U.S.[25] They, ART, are notably different than the technologies discussed in the previous section because of the pervasiveness, minimal invasiveness, and lower relative costs of the technologies comparatively.

Assisted Reproductive Technologies (ART) is defined by the U.S. national government in the 1992 Fertility Clinic Success Rate and Certification Act as those technologies that include all fertility treatments in which both eggs and embryos are

[24] Hirakawa, Krishnakumar, Timlin, Carney, and Butler, "Gene Editing and CRISPR in the Clinic: Current and Future Perspectives," online only.

[25] Saswati Sunderam et al., "Assisted Reproductive Technology Surveillance- United States, 2012," *Morbidity and Mortality Weekly Report: Surveillance Summaries* 64, no. 6 (Aug. 2015): 1-29.

handled. In general, "ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman."[26] What is missing from this generalization is that frozen embryos too are utilized in ART procedures. This key addition is important as it plays into other procedures like PGD (which is to be discussed in its own section further in this chapter). One can utilize embryos borne out of a PGD procedure in their own treatment for fertility whether it be the same patient whose embryos were cryopreserved, or a receiving patient being given them through donation. Indeed, according to this fundamental definition, we can see ways in which many technological practices involved in genetic engineering and manipulation enter the conversation of assisted reproductive technology.

An issue of the statutory act by the U.S. government, and the definition it employs, is it has become somewhat outdated. Codified on October 24, 1992, this act and attached definition face calls for redefinition in the wake of immense technological progress in the field over the past thirty plus years. Assisted Reproductive Technologies first became available in the 1980's with the first successful U.S. infant conceived with ART born in 1981.[27] With no observable negative effects from this procedure on birth, the technology soon began to spread rapidly across the United States. The most common procedure done under the branch of ART is i*n vitro* Fertilization (IVF); Penn Medicine reports that from the most recent data it is estimated that one-million babies were born

[26] Statute 106 of the 1992 Fertility Clinic Success Rate and Certification Act.

[27] Sunderam et al., "Assisted Reproductive Technology Surveillance- United States, 2012," 1-29.

via IVF between 1987 to 2015.[28] In IVF there are five main steps as described by Penn Medicine, they are: "boost egg production through superovulation, remove the eggs, collect sperm from a partner or a donor, unite sperm and eggs, and then transfer the embryo(s) into the uterus."[29] These seemingly simple steps constitute an entire IVF procedure, and the procedure offers hope to those individuals hoping to start families who otherwise could not. However, there can be intermittent steps within this framework where genetic testing, screening, and alterations can be done. In these intermittent steps lies the potential for unequal advantages accruing to those parents of higher socio-economic standing. It is estimated that screening done at different stages of IVF treatment can "range from $3,000-$7,000 and is paid entirely by the patient."[30] For those who can afford it, this screening can be used to select embryos least likely to carry diseases. Such screened embryos can be chosen for implantation or donation to those individuals seeking ART services. For those who cannot afford such screening, however, costs are quickly incurred and can decrease familial wealth since having a child – who is unscreened and has a costly disease – can lead to further stratification of society through economic means. For those parents who have the money to use screening technologies and avoid a possible fate where familial wealth decreases due to a child's condition, they are at an advantage over those who cannot afford having a chance at this decision. Problematic

[28] "IVF by the Numbers," Penn Medicine, March 14, 2018.

[29] "Step-By-Step Look at the IVF Process," Penn Medicine, April 20, 2020, https://www.pennmedicine.org/updates/blogs/fertility-blog/2020/april/how-does-the-ivf-process-work.

[30] David Adamson, "If IVF, then PGD or PGS? What Genetic Testing Can Tell You About Your Embryo," *Huffpost*, September 21, 2017, https://www.arcfertility.com/ivf-pgd-pgs-genetic-testing-can-tell-embryo/.

issues, such as this, risk going unconsidered as ART procedures continue to make their way to the healthcare market, and this should be troubling for us today.

Genetic Screening Technology such as Newborn Screening

Genetic screening practices vary greatly among healthcare providers often according to the purpose of the screening results themselves. Yet, the best way to think of the screening technologies discussed is that they are the mechanism by which potential genetic conditions are revealed to patients. In many ways these screenings and tests represent the first step of beginning most genetic treatments for many individuals if the results indicate abnormalities. Reproductive medicine as a discipline has demonstrated a continual acceptance and expectation of genetic tests being performed in order to deliver quality care. Genetic tests have become guides for reproductive providers in that they serve "three main purposes in reproductive medicine: the identification of infertility causes, identification of genetic diseases transmissible to offspring, and optimization of assisted reproductive technology (ART) [if needed]."[31] The increasing use of technologies such as diagnostic testing, newborn screening, carrier testing, prenatal testing, predictive and pre-symptomatic testing by reproductive medical professionals has begun to normalize the idea of observing and possibly altering the genetic code of future newborns. According to the NIH-run Genetics Home Reference pages of MedlinePlus, "genetic testing can range from under $100 to a little more than $2,000, depending on the

[31] Federica Cariati, Valeria D'Argenio, and Rossella Tomaiuolo, "The Evolving Role of Genetic Tests in Reproductive Medicine," *Journal of Translational Medicine* 17, no. 267 (Aug. 2019): online only, doi: 10.1186/s12967-019-2019-8.

nature and complexity of the test."[32] The range is important to note as it represents a concerning practice of treating some screenings as add-ons where the most quality and detailed reports are reserved to those who can afford them. Knowing this, and exploring it in the paragraphs to follow, the appearance of affordability should be asterisked.

Of all the screenings done in the human reproductive process, the most common is newborn screening. According to the Mayo Clinic, "newborn screening is the most common type of genetic testing. In the United States, all states require that newborns be tested for certain genetic and metabolic abnormalities that cause specific conditions, so that care and treatment can begin right away."[33] These tests are very significant to the field. The fact that the U.S. government mandated a genetic testing procedure across the country is a major development illustrating the reach of political power into a baby's health and well-being. As well intentioned as the screening of newborn infants may be, it does provide an example by which the government has the power and ability to mandate certain medical testing across the population. The simplicity of the procedure is worth noting and is described thoroughly by an organization called Baby's First Test. This organization describes itself as the "nation's resource center for newborn screening information providing educational and family resources about newborn screening at the local, state, and national levels."[34] The information shared on their website is supported by the U.S. Department of Health and Human Services and it states that "shortly after a

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[32] "What is the Cost of Genetic Testing, and How Long Does it Take to Get the Results?" MedlinePlus NIH, September 21, 2020, https://medlineplus.gov/genetics/understanding/testing/costresults/.

[33] Megan A. Allyse et al., "Direct-to-Consumer Testing 2.0: Emerging Models of Direct-to-Consumer Genetic Testing," *Symposium on Precision Medicine Mayo Clinic* 93, no. 1 (Jan. 2018): 113-120, doi: 10.1016/j.mayocp.2017.11.001.

[34] "Screening Procedures," Baby's First Test, accessed April 19, 2021, https://www.babysfirsttest.org/newborn-screening/screening-procedures.

baby is born, a health professional takes a few drops of blood from the baby's heel and the sample is sent to a state laboratory to be analyzed for severe disorders such as phenylketonuria (PKU), tyrosinemia, sickle cell disease, cystic fibrosis, and many others."[35] Amazingly, a few drops of blood can enable an entire array of testing to be analyzed in a matter of days (if not hours) and results can be sent back to providers either giving a normal or abnormal reading with accompanying steps if needed. Worth noting is that these samples are sent to an intermediate state-run laboratory rather than a laboratory of the hospital system in which the baby is being delivered, which is standard medical procedure unless parents sign an exemption request.[36] Because of the nature of this type of testing, accessibility and mode by which the test occurs – being that the government orders it – is a unique exception to the trends observed across other technologies. The screenings and testing done on newborns every year illustrate the potential for government coverage of certain genetic technologies if they deem it worthwhile to society's health. One can also recognize the importance of these screenings in that they serve as the observational eye and guide from which additional procedures and augmentations can result. It is in these subsequent steps where the government plays less of a role and issues of access to these technologies become more salient as discussed later in the thesis.

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[35] Ibid.

[36] Ibid.

Preimplantation Genetic Diagnosis (PGD)

Another technology worthy of consideration is preimplantation genetic diagnosis (PGD) technologies. The term, as defined by author Molina B Dayal, refers specifically to "when one or both genetic parents has a known genetic abnormality and testing is performed on an embryo to determine if it also carries said genetic abnormality."[37] The motivations behind parents seeking out this screening are typically for the use of an embryo in fertility treatment or to select embryos least likely to possess certain genetic abnormalities. Like other genetic screening or testing technologies discussed in the previous subsection, the main purpose of PGD is to determine if there are genetic abnormalities in a given specimen. Yet, unlike the previous screening or testing technologies, it is specifically performed on embryos rather than being run from say a blood or amniotic fluid sample. What is also a point of differentiation is that typically once the screening and diagnosis is done, there is a transfer of only unaffected embryos to the uterus for implantation.[38] Unaffected embryos does not imply that from the PGD there is an adverse effect to some of the embryos as that is not the case. Current studies have actually consistently demonstrated that there are no adverse effects on either embryo implantation or development to term after PGD procedures conclude.[39] Instead, 'unaffected embryos' refers to those in which a possible genetic abnormality of the parents is not present in a certain embryo's genome. Once these unaffected, or normal,

[37] Molina B. Dayal, "Preimplantation Genetic Diagnosis," *Obstetrics & Gynecology,* (Aug. 2018), https://emedicine.medscape.com/article/273415-overview.

[38] Ibid.

[39] Kim Dao Ly, Ashok Agarwal, and Zsolt Peter Nagy, "Preimplantation Genetic Screening: Does it Help or Hinder IVF Treatment and What is the Role of the Embryo?" *Journal of Reproductive Genetics* 28, no. 9 (Sep. 2011): 833-849, doi: 10.1007/s10815-011-9608-7.

embryos are identified, they are moved to the next stage of uterus implantation while the other embryos are excluded. This perhaps is one of the most notable, and contentious, features of the practice as PGD is an active avenue by which certain embryos are chosen to be discarded due to an observed genetic characteristic deemed unfavorable or unworthy of implantation in the uterus. Clearly, the discarding aspect of this practice has been controversial for some conservative political and religious groups.

There are essentially two main steps involved with PGD as described by Dr. Sermon et al. in the medical literature entitled "Preimplantation Genetic Diagnosis." Initially, there is a "biopsy of polar bodies (which are small haploid cells formed at the same time as an egg cell during oogenesis, but generally do not have the ability to be fertilized)" and embryos (as mediated through polar-body biopsy) followed by the analysis of cells obtained from the biopsy where certain genetic characteristics and markers are identified as either present or absent in the created cells.[40] Another way to describe these two steps is that through the first step, the biopsy of polar bodies, a field of embryos is created to choose from. In the second step, the field of created embryos from step one is then analyzed and the most promising embryos from the created field are selected to be utilized in the implantation process. By 'most promising' the analysis seeks those embryos with the correct number of chromosomes to be selected for transfer in order to reduce the risk of failed *in vitro* fertilization (IVF) and possible miscarriage. Some countries consider this screening process to be a treatment add-on to PGD rather than including it in the service initially. The U.K. Human Fertilisation & Embryology

[40] Karen Sermon, Andre Van Steirteghem, and Inge Liebaers, "Preimplantation Genetic Diagnosis," *The Lancet* 363, no. 9421 (May 2004): 1633-1641, doi: 10.1016/S0140-6736(04)16209-0.

Authority (HFEA) notes "PGS, also known as aneuploidy screening, is a treatment add-on not available for the National Health Service (NHS), and it involves the checking of the chromosomes in embryos created by IVF."[41] This is significant as it presents a possible source of inequality in care received. Unless one is able to afford the additional screening, it is not done. If one wishes to get the screening, but cannot afford it, they are explicitly told by the HFEA that the National Health Service will not provide for the additional screening step. This is, unsurprisingly, a source of controversy illustrating that some financial barriers exist in the practice of PGD, preventing possible patients from receiving the highest quality of care from the procedure.

Another potential source of controversy regarding PGD arises after the procedure itself is done and the need to address gathered embryos arises. As described by Dr. Sermon, after PGD few embryos usually remain for cryopreservation. Although "most centers do cryopreserve surplus embryos, the survival rate of these embryos is extremely low."[42] This indicates that the process itself is very costly in terms of embryos lost as there is a sizeable discard of embryos as a result of PGD. Those embryos which are deemed suitable, but are not chosen, are expected to be cryopreserved for potential future use, and the public has the expectation (and impression) that cryopreservation does not involve the loss of many embryos although sadly, that is not the case. These losses are, again, a point of contention against this practice. The discarding of embryonic material is a hard reality many take issue with, but the practice is continued. Often, the chief benefit

[41] "Pre-Implantation Genetic Screening (PGS or PGT-A)," Human Fertilisation & Embryology Authority, August 24, 2021, https://www.hfea.gov.uk/treatments/explore-all-treatments/pre-implantation-genetic-screening-pgs/.

[42] Sermon, "Preimplantation Genetic Diagnosis," 1633-1641.

to those who utilize the procedure is that they can finally have a child. Those using the procedure are at a point where they need to make use of the technology as no other means have worked in creating viable offspring. Even further, many who use the procedure and cryopreserve embryos often intend to use another embryo later on in the hopes of having more than one child. The PGD procedure certainly is a complex topic as in one hand we see unfortunate losses in embryos discarded, yet in the other hand, there is great joy brought to couples who use PGD for they are able to start a family.

Looking through a more economic lens at the PGD procedure, one is rightly concerned with the low survival rate of embryos as it warrants questions about the cost effectiveness of PGD as a strategy for infertility treatment. Because of PGD's relationship to IVF therapy, the two are often thought of in combination financially. Author Kathryn T. Drazba and her co-authors in their study, seek to provide understanding of the specific financial concerns for couples opting to use IVF or PGD. The study determined that "on average, IVF cycles cost approximately $9,226-$12,513 per cycle, while PGD costs an additional $2,500-$6,000 per cycle."[43] Note again the variability in prices and the framing of PGD as an optional service. These costs fall on the patients/consumers primarily, as often insurance rarely covers these procedures, especially the optional add-ons. Thus, the quality of services received still remains a function of how much money one puts into the procedure.

[43] Kathryn T. Drazba, Michele A. Kelley, and Patricia E. Hershberber, "A Qualitative Inquiry of the Financial Concerns of Couples Opting to Use Preimplantation Genetic Diagnosis to Prevent the Transmission of Known Genetic Disorders," *Journal of Genetic Counseling* 23, no. 2 (Aug. 2013): 202-211, doi: 10.1007/s10897-013-9638-7.

It was estimated by the PGD International Society (PGDIS) in 2005, who is an observing body of this technology, that "approximately 100,000 PGD cycles have been performed in the past 23 years."[44] This number is considerable given the time of its estimation 15 years ago. Indeed, the fact that it has been 15 years since the last PGDIS estimate is telling in itself because this organization was established to monitor implementation of this technology due to both ethical and biological concerns raised at the time. Now that there seems to be an apparent disregard toward monitoring the number of PGD procedures performed, it suggests that the practice has become more mainstream and not a salient concern for many. A public perspectives poll was taken in 2015 regarding PGD. From the data gathered, it was found that a majority supported PGD for diseases fatal early in life and for those diseases causing lifelong disability (72.9% and 66.7% respectively). Almost half (48%) supported PGD for diseases that can come later in life as well.[45] Clearly, there is a recognition by the public to the appreciable level of gain that can result from using such technology. Those who can afford high quality PGD procedures can have fatal diseases and disabilities addressed early on in the life of a new family. Oftentimes, there is a balance between the expense and the quality of the procedure as the truly effective and thorough aspects of these procedures remain a luxury of those who can afford the higher add-on cost. For crucial characteristics, this presents an even greater concern. If we reach the point in which embryo genomes can be

[44] Harvey J. Stern, "Preimplantation Genetic Diagnosis: Prenatal Testing for Embryos Finally Achieving its Potential," *Journal of Clinical Medicine* 3, no. 1 (Mar 2014): 280-309, doi: 10.3390/jcm3010280.

[45] William D. Winkelman et al., "Public Perspectives on the use of Preimplantation Genetic Diagnosis," *Journal of Assisted Reproductive Genetics* 32, no. 5 (2015): 665-675, doi: 10.1007/s10815-015-0456-8.

sequenced to predict characteristics like intelligence, as some suggest, will embryos predicted to be the most intelligent children be implanted over others consistently?[46] If so, will the ability to select for such characteristics be considered an add-on like PGS is considered in the U.K. NHS system today? These questions illustrate that not everyone may receive the same quality of procedure.

Direct-to-Consumer (DTC) Testing

Direct-to-Consumer (DTC) testing is both a type of genetic technology as well as a business model. DTC testing, which provides genetic tests to the consumer through a model like other goods in markets, is perhaps best exemplified by the company 23andMe. 23andMe represents a flagship exemplar of a type of firm that utilizes the Direct-to-Consumer (DTC) technologies for commercial consumer use. The services that they offer are aimed at helping people learn about their ancestral identity as well as explore their disease risks. Early framing of the products were more suggestive of DTC testing as a tool to explore ancestral history – something born out of a consumers personal curiosity rather than medical necessity. However, the motivations and services offered began to expand into genetic screening type testing where a person could find genetic predispositions that they were previously unaware of. It is this type of usage of the DTC testing that this paper is most concerned with especially given the model by which the technology is coming to consumers/patients.

The vanguard company of the DTC movement most certainly is the 23andMe group. The birth of the DTC movement began in December 2007 with the launch of an

[46] Clare Wilson, "Exclusive: A New Test Can Predict IVF Embryos' Risk of Having a Low IQ," *NewScientist,* November 15, 2018. https://www.newscientist.com/article/mg24032041-900-exclusive-a-new-test-can-predict-ivf-embryos-risk-of-having-a-low-iq/.

early DTC genetic testing company that celebrated its launch with a Spit Party.[47] As the name suggests, this party was concluded with partygoers providing a saliva sample to be tested and analyzed. Soon, along with the Dotcom boom, companies began springing up offering similar services for a variety of different needs. Yale researcher Pascal Su defines direct-to-consumer (DTC) genetic testing as "those tests sold directly to consumers via the Internet, television, and/or other marketing venues without involving health care professionals, often for three general reasons: identity-seeking, disease risk-testing that complements healthcare, and curiosity driven testing."[48] These categories of reasons to pursue DTC testing can even be seen in the names of companies. Ancestory.com, as the name suggests, is related to identity seeking, deCODE and Navigenics are used for obtaining medical panels, and 23andMe encapsulates all three categories of DTC testing. Currently, there are many people who have used some form of DTC testing as estimates place this number at 100 million people.[49] Regardless of the specific purpose of the DTC company, the overall proliferation of this model demonstrates market sustainability. What is remarkable about this phenomenon is that it largely occurred from the ground up. Advertising on large social media platforms has grown the demand for such types of genetic testing, framing the technology as a means to

[47] Megan A. Allyse et al., "Direct-to-Consumer Testing 2.0: Emerging Models of Direct-to-Consumer Genetic Testing," *Symposium on Precision Medicine Mayo Clinic* 93, no. 1 (Jan. 2018): 113-120, doi: 10.1016/j.mayocp.2017.11.001.

[48] Pascal, Su, "Direct-to-Consumer Genetic Testing: A Comprehensive View," *Yale Journal of Biology and Medicine* 86, no. 3 (Sep. 2013): 359-365.

[49] Jamie Rosenberg, "As DTC Genetic Testing Grows Among Consumers, Insurers Are Beginning to Get on Board," *American Journal of Managed Care,* April 22, 2019, https://www.ajmc.com/view/as-dtc-genetic-testing-grows-among-consumers-insurers-are-beginning-to-get-on-board.

explore their identity, either ancestrally or in a biological sense, out of personal interest rather than for medical necessity.

This DTC space remains a fairly deregulated environment often driven by individual interest rather than insurance mandates.[50] Tests are done within the homes of purchasers making it a more accessible type of technology available simply due to the fact it is delivered to the porch of purchasers. Overall, DTC is a fairly straightforward process getting people genetic results in a streamlined manner. Simple saliva samples provide a low barrier to entry for consumers making the perceived difficulty of getting a test done decrease substantially. The structure of DTC companies indeed may prove to be the catalyst needed in making genetic data and technologies more available to the population, and perhaps dispel some fears surrounding these technologies.[51]

Conclusion

In summary, the variety of technologies presented here is a great indicator of the strength and progress of this field in the healthcare industry. The advances in gene therapy present great opportunities to those suffering from genetic diseases. Future research is being dedicated to gene editing technologies such as CRISPR which present much more specific and applicable avenues of genetic alteration. Finally, this chapter considered the pervasiveness of many technologies already in the market like those involved in the human reproductive process and those of Direct-to-Consumer testing.

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[50] Ibid.

[51] Scott Hensley, "Poll: Genealogical Curiosity is a Top Reason for DNA Tests; Privacy A Concern," *NPR Shots,* June 1, 2018, https://www.npr.org/sections/health-shots/2018/06/01/616126056/poll-genealogical-curiosity-is-a-top-reason-for-dna-tests-privacy-a-concern.

It is important to have this basic understanding in the context of future discussions in this thesis. Recognizing how techniques, like those involved in ART like IVF, genetic screening, and PGD, are utilized to address potentially devastating and costly diseases is important to concerns brought up in this paper's introduction regarding societal stratification. Varying price points for each of these technologies represents a range by which stratification can occur as those with greater socio-economic standing are able to purchase higher quality treatments, and thereby avoid costly diseases in their children. In many ways, these technologies represent a potential for those with greater resources to more frequently and recurrently use these technologies, concentrating the benefits to successive generational groups within families that have means to participate in these markets. Because of the significance of this potential, addressing questions of equal opportunity to access these technologies is important. In the following chapter, specific considerations will be given to how the technologies of screening, PGD, and DTC testing themselves are coming to the American marketplace. How are these technologies being accessed today?

CHAPTER TWO

Distribution of Technologies: A Question of Equal Opportunity

Introduction

In the United States, citizens pride themselves on the belief in equal opportunity for all. The idea that everyone should have the chance to 'pull themselves up by their boot straps' is a powerful motif of the culture and has influenced many changes in our nation's history. The Women's Voting Act provided the equal opportunity for women of this country to voice their opinions on the same level as men. Civil defense attorneys are provided to suspects in court who cannot afford a lawyer so they have an equal opportunity to defend themselves. And, numerous affirmative action policies are in place so minorities have the equal opportunity to access labor markets and educational institutions. These are just a few examples of how the desire to provide equal opportunity to all translates into different practices. What we must consider then is have we done, or are we capable of doing, the same for these new genetic technologies entering the healthcare market? How have we addressed healthcare structures, created relevant policy, and worked to alleviate fears consumers may have in entering the market to seek the benefits of genetic technology?

Healthcare in the U.S.: A Complicated Picture

One of the main mechanisms societies have developed to help facilitate the equal opportunity to access medical care are healthcare systems. Healthcare in the United States is a complex animal with its dual structure. A mixed private and public composition, healthcare coverage, costs, and a complicated structure make obtaining services in this industry a challenge for many. Consumers often suffer in this system because an efficient market allocation of healthcare resources is often inhibited by non-ideal market behavior.[52] Deviations from an ideal market come in the forms of inconsistent pricing practices, backroom deals between insurers and providers, and lack of price transparency in the industry that leads to irrational decision-making by consumers. There has been a growing body of studies that analyze the irrational consumer choices made in the healthcare market. Mounting evidence from these studies suggest "that the classic economic model of the 'rational man' fails to explain several well-established consumer behaviors observed across the healthcare industry."[53] Some reasons put forth as to why this is include the proposition that consumers try to minimize the cognitive effort needed to make a decision.[54] Indeed, hospitals and insurers recognize this and set prices often beyond suggested retail values to maximize profits. These institutions set prices in a non-transparent manner as consumers often feel overwhelmed by the technical nature of medical choices and are typically acting from an emotional

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[52] Ari Mwachofi and Assaf F. Al-Assaf, "Health Care Market Deviations for the Ideal Market," *Sultan Qaboos University Medical Journal* 11, no. 3 (Aug. 2011): 328-337, PMID: 22087373.

[53] "Improve Pricing and Revenue Through Irrational Customer Behavior," *Kearney Communications, Media, and Technology,* accessed April 19, 2021, https://www.nl.kearney.com/it/communications-media-technology/article/?/a/improve-pricing-and-revenue-through-irrational-customer-behavior.

[54] Ibid.

state. Cumulatively, these behaviors by both large institutions and consumers drive up prices of services artificially. So, although the prices of some genetic procedures seem to have fallen, by the time they reach the consumer this is no longer the case as the prices consumers end up paying have been adjusted from the expected market value. Most clearly this phenomenon is observed in medicine markups. Analysis of 20 medications across various hospitals revealed that on average these medications cost patients five times what hospitals had paid to acquire them.[55] This practice, thereby, drives up cost-sharing and premiums for patients across the country.[56] Further, profitability can be measured by median gross profit margin of an entity which is the net sales of a good minus the costs of goods sold. A 2020 report of S&P 500 companies showed that those pharmaceutical firms had significantly high margins an estimated 76.5%.[57] These companies are able to achieve great profitability due to increasing margins often by raising prices for services at the consumer point of purchase. Because the consumer often lacks the same technical knowledge as these institutions, and are often acting out of emotion, they have little choice but to take this adjusted price.

As troubling as the practice above is, it does yield a unique advantage for the healthcare system worthy of mentioning. Because these firms are able to pursue profit maximizing pricing practices, they are also able to reinvest their earning into research and

[55] Holly Campbell, "Study Finds Hospitals Continue to Markup Medicines up to 500% of Their Cost," *The Catalyst,* July 9, 2019, https://catalyst.phrma.org/study-finds-hospitals-continue-to-mark-up-medicines-up-to-500-of-their-cost.

[56] Ibid.

[57] Fred D. Ledley, Sarah McCoy, Gregory Vaughan, and Ekaterina Cleary, "Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies," *JAMA Network* 3, no. 9 (Mar. 2020): 834-843, doi: 10.1001/jama.2020.0442.

development (R&D). A recent study examines the extent to which factors like public investment, intellectual-property practices, and drug pricing policies contribute to medical innovation. The study found that the United States places first overall in contribution to global innovation (on a per-GDP basis) through their policies and practices.[58] The *Wall Street Journal* also supports this claim, noting that the U.S.'s "strong intellectual-property laws, coupled with a comparatively free-market pricing system, encourages firms to research new treatments."[59] Ironically, the same healthcare system that presents possible barriers to equal opportunity to access genetic technologies is the same system driving the research that produces these technologies in the first place.

From this introduction, a complicated picture emerges. Although some technologies may be starting to move toward affordability in their pricing structures, some practices in our healthcare system, such as profit maximizing price markups, can be working against such trends. It is worthwhile to identify such practices that may be working counter to growing affordability and, therefore, access. Insurance practices, policy decisions, the inadequate addressing of consumer concerns, and other barriers are important in understanding the full picture. By learning about these practices and possible barriers in this chapter, we are better able to address concerns regarding the equal opportunity for all to access these powerful technologies.

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[58] Patricia Van Arnum, "Biopharmaceutical Innovation: Which Countries Rank the Best?" April 13, 2016, https://www.dcatvci.org/250-biopharmaceutical-innovation-which-countries-rank-the-best.

[59] Peter Pitts, "How Other Countries Freeload on U.S. Drug Research," *Wall Street Journal,* February 21, 2017, https://www.wsj.com/articles/how-other-countries-freeload-on-u-s-drug-research-1487722580.

Concerns Regarding Coverage and Pricing Practices

Many concerns have been raised by private citizens, bioethicists, providers, and researchers alike regarding the issue of human genomics, particularly on the role of coverage and policy in addressing this burgeoning branch of medicine. The National Institute of Health (NIH) has a dedicated subsection, called the National Human Genome Research Institute (NHGRI), that has focused its efforts on understanding ethical, legal, and social aspects of genomics research, including the technologies utilized for genetic engineering and alteration in humans.[60] This branch addresses several key and noteworthy issues of policy that are implicated with the introduction of genetically based technologies. Genetic discrimination in health insurance coverage is also a concern expressed by many. Discriminatory practices may adjust insurance coverage that many rely on to obtain healthcare services, restricting equal opportunity to access these technologies. This issue of potential discrimination has become a chief concern of not only the NHGRI, but also other leading healthcare institutions.

Discrimination is a primary concern in many settings, but none perhaps as daunting as those faced in healthcare. The current condition of the healthcare market does not alleviate these fears either, but rather perpetuates them for most people. So much distrust and dissatisfaction with healthcare institutions regarding costs and secrecy has made Americans wearily suspicious of new technologies or practices and the people offering them. Recent Harris Polls illustrate this distrust by consumers. People were polled to answer the question "do you believe your health is put over profits?" The poll

[60] "Health Insurance in the Age of Genetics." *NIH National Human Genome Research Institute,* April 12, 2011, https://www.genome.gov/10000879/1997-release-health-insurance-in-the-age-of-genetics.

directed respondents to answer this question in the context of specific healthcare institutions where the percentages given indicate the affirmative response that patients are put over profits. The following results to this poll were: "9% of U.S. consumers believe pharmaceutical and biotechnology companies put patients over profits, 16% believe health insurance companies do the same, 36% for health care providers, and 23% for providers in a hospital setting specifically."[61] From these results, we see overall that consumers were strongly pessimistic toward each of these institutions and their intentions. A source of pessimism undoubtedly comes from the lack of price transparency and variable pricing practices in the industry. Medications, doctor visits, procedures, tests – all of these are subjected to a highly variable and non-transparent chargemaster system where insurers negotiate prices with providers to secure profitable deals. These deals are often at the expense of unknowing consumers and ultimately foster the observed distrust suggested in the Harris Poll.[62]

Often a symptom of discriminatory pricing practices, variable costs for the same services between different hospitals create a barrier in access to care. We see many sensational popular media reports highlighting this variability in cost because the discrepancies are often shocking to consumers. In an article from *USA Today,* a notorious case was discovered where "the cash price for a lower-back MRI ranged from $475 at the Castro Valley Open MRI practice to an incredible $6,221 at the University of California,

[61] "Only Nine Percent of U.S. Consumers Believe Pharma and Biotechnology Put Patients over Profits; Only 16 Percent Believe Health Insurers Do," *Harris Poll,* accessed April 21, 2021.

[62] Ibid.

San Francisco at Mt. Zion for the exact same procedure."[63] Large price discrepancies such as this between providers within a confined geographic area –the state of California – demonstrates just how variable costs can be in local regions. Oftentimes, larger price discrepancies for similar procedures appear even more drastic across different regions of the country. A study by the Health Care Cost Institute (HCCI) explored the drastic differences in pricing practices across different regions, finding even more discrepancies. For example, "patients in El Paso, Texas paid 29% above the national average for inpatient services while, in Knoxville, TN, prices were 37.5% less than the national average."[64] Oftentimes, these variable pricing methods across different regions influence the flow of people seeking healthcare. Expanding the scope, people are also willing to travel so far as different countries to receive medical care at cheaper rates, a phenomenon called medical tourism.[65] Overall, this variable pricing is a problem especially in addressing the question of equal opportunity. Although some genetic services may be moving to affordability in one place, that may not be the case for another area due to the regional/local arrangements between individual hospital systems and insurance companies. Further, if you are not capable of traveling to use a service set at a cheaper rate elsewhere due to social constraints, long work hours, or simply insufficient funds, then your opportunity to access these technologies is inhibited.

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[63] Jayne O' Donnell, "Huge Health Care Price Differences Even Within Same Area, by State," *USA Today,* April 29, 2016, https://www.usatoday.com/story/news/politics/2016/04/27/huge-health-care-price-differences-even-within-same-area-state/83340550/.

[64] Maria Castellucci, "Healthcare Costs Vary Widely by Region," *HCCI Modern Healthcare,* April 27, 2017, https://www.modernhealthcare.com/article/20170427/NEWS/170429876/healthcare-costs-vary-widely-by-region.

[65] "Medical Tourism: Travel to Another Country for Medical Care," *CDC,* accessed April 19, 2021, https://wwwnc.cdc.gov/travel/page/medical-tourism.

Variable prices are often a result of pricing practices that encourage profit maximization. As these prices are set to maximize profits, often at much higher levels than what the cost of the actual service or drug might be, people are less capable to access the goods without the help of a third-party. Indeed, the institutional structure of healthcare enables higher profits for the various firms in the industry compared to other industries limiting consumer access to the goods and services. In the face of such practices, many turn to government insurance plans hoping to find respite. In these plans, the government takes some of the price burden by spending on behalf of the consumer.[66] Depending on the policy and coverage, the government pays into the price of the service desired by the consumer. Government policy tries to slow its expenditures for these costs by either raising premiums, sourcing revenue from other government sectors, or changing who and how it insures. Depending on the specific policy, when the government changes who it covers it often means some individuals are entering the private market where they become a part of insurance pools. Once in the private coverage pool, consumers are subjected to the pooling practices described by the American Academy of Actuaries. This body explains risk pooling as a fundamental tool that insurers use to calculate premiums of customers. All the medical costs for a group of individuals in a pool are totaled and used to determine premiums based on the costs.[67] Higher risk patients added to these pools are thought to increase premiums for everyone in the pool.[68] Insurers also have to

[66] Ryan Nunn, Jana Parsons, and Jay Shambaugh, "Brookings Report: A Dozen Facts About the Economics of the US Health-Care System," *Brookings* March 10, 2020, https://www.brookings.edu/research/a-dozen-facts-about-the-economics-of-the-u-s-health-care-system/.

[67] "Risk Pooling: How Health Insurance in the Individual Market Works," accessed April 22, 2021, https://www.actuary.org/content/risk-pooling-how-health-insurance-individual-market-works-0.

[68] Ibid.

renegotiate deals with hospital providers and pharmaceutical companies when their pooling changes, meaning that these other institutions change their pricing behavior accordingly. This process as a whole creates a feedback loop of issues for all parties. Those facing the worst of these issues are the consumers themselves who experience rising prices of the services at the point of purchase in addition to changing premiums and coverage policies from both their insurers and government policy. Ultimately, in the face of these issues, consumers continue to lose confidence and feel underserved in quality for the costs they have to incur. As revealed in a research poll by the Pew Research Center, only 48% of Americans feel the costs of medical treatments today are worthwhile and 51% of those polled say treatments often create as many problems as they solve.[69] With this in mind, genetic technology must be cautiously introduced to the market as its immediate consequences could further worsen this cycle and potentially place additional burdens on consumers.

Oftentimes, medical costs disproportionately burden different segments of the population. Gary Branning and Martha Vater in their research article, *Healthcare Spending: Plenty of Blame to Go Around,* note that "Americans with private health insurance spend $5,380 per person (on average); by comparison, Medicare paid nearly $12,000 per enrollee, and Medicaid programs spent almost $8,000 per member (on average) in 2015."[70] These varying expenditures per enrollee indicate disproportionate

[69] Isadora Milanez and Mark Strauss, "Americans are Closely Divided Over Value of Medical Treatments, but Most Agree Costs are a Big Problem," *Pew Research Center,* July 9, 2018, https://www.pewresearch.org/fact-tank/2018/07/09/americans-are-closely-divided-over-value-of-medical-treatments-but-most-agree-costs-are-a-big-problem/.

[70] Gary Branning and Martha Vater, "Healthcare Spending: Plenty of Blame to Go Around," *American Health and Drug Benefits* 9, no. 8 (Nov. 2016): 445-447, PMID: 28465772.

burdens being placed upon Americans who differ significantly in insurability. These variations among different insurance populations are often cited as clear expressions of discriminatory practices. This claim is even more pertinent for this topic of genetic technologies coming to market, especially for those involved in fertility and reproductive treatment. For hopeful surrogate mothers, for example, Juudith Daar notes that "some health insurance policies explicitly exclude coverage for surrogate pregnancies."[71] Instead of receiving aid from insurance to make access to this technology possible, these patients are expected to pay for such a procedure entirely on their own. Also, because of their status as surrogate patients, the additional rounds of *in vitro* fertilization (IVF), screenings, and other related treatments to this pregnancy would be precluded from coverage as well. Daar goes further to note that many of the insurance policies and terms of coverage for people in the general health care market are not observed for those seeking ART.[72] This signals a possible discriminatory practice where these types of mothers would be unable to get coverage for services related to their surrogate pregnancy. Overall, Daar cites that many socioeconomic markers may prevent access to ART technologies. She cites that many "causes and explanations for stratification of ART along racial and ethnic lines is a complex matrix of historic and contemporary facts."[73] For Daar, and others looking to alleviate these discrepancies, the solution lies in affordability. These varying price practices represent a major obstacle to addressing

[71] Juudith Daar, *The New Eugenics: Selective Breeding in an Era of Reproductive Technologies,* (New Haven & London: Yale University Press, 2017), 63.

[72] Daar, *The New Eugenics: Selective Breeding in an Era of Reproductive Technologies,* 64.

[73] Ibid

possible disparities and thereby restrict access through an economic means which can translate along ethnic and racial lines.

Privacy Concerns

Certainly, the potential discrimination in health insurance coverage based on genetic information has devastating consequences for those discriminated against.[74] Reasons for such discrimination, medically, stem from costs associated with certain genetic conditions. Many research articles and studies have been dedicated to understanding just how large the financial impact of a genetic disease is on the market. In one study, looking specifically at the financial impact of genetic diseases in the pediatric context, it was found that patients with genetic disorders placed a significant financial burden on the healthcare system.[75] These patients represent a source of increasing expenditure due to identifiable genetic characteristics. Abroad, we have seen characteristics from patient information become a tool for price discrimination. In Australia, specialist physicians practice price discrimination based on patient income status.[76] It was found "that patient characteristics such as age, concession card status, and private health insurance status were all used by specialists as proxies for income status."[77] This provides a degree of tangibility to the fear that personal information can become a

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[74] Kathy Hudson et al., "Genetic Discrimination and Health Insurance: An Urgent Need for Reform," *Science* 270, no. 5235 (Oct. 1995): 391+, Gale Academic OneFile.

[75] Katherine E. Miller, "The Financial Impact of Genetic Diseases in a Pediatric Accountable Care Organization," *Frontiers in Public Health* 8, no. 58 (Feb. 2020): online only, doi: 10.3389/fpubh.2020.00058.

[76] Meliyanni Johar, Chunzhou Mu, Kees Van Gool, and Chun Yee Wong, "Bleeding Hearts, Profiteers, or Both: Specialist Physican Fees in an Unregulated Market," *Health Economics Letter* 26, no. 4 (Feb. 2016): 528-535, doi: 10.1002/hec.3317.

[77] Ibid.

source of discrimination, often in the form of variable pricing. For the U.S., which already struggles with variable pricing practices, this is a salient issue. The Affordable Care Act (ACA) is the main piece of legislation that currently combats this practice we see in Australia from occurring in the U.S. Indeed, the act "barred insurers from denying coverage outright to people because of a health condition."[78] However, this decision has consequences. Such consequences, as mentioned earlier in this chapter, may come in the form of changing insurance pooling practices that can lead to increased premiums for all in the pool.[79] Many see this practice as unfair, as they now have to pay larger premiums for conditions and care they do not use. As a result, there have been many calls of striking or restructuring the ACA to provide a countermeasure. If the act is repealed, however, then insurers could once again deny coverage to people with certain health issues easily identifiable through genetic testing.[80] In 2020, President Trump, backed by House Republican partisanship, made such a move to repeal the act. This illustrates the tenuous position the U.S. faces regarding this issue, and it is a source of concern with regards to genetic technologies as well. For those affected by the status of the ACA, they risk losing coverage and their ability to access genetic healthcare services.

Healthcare discrimination may also become relevant in employment practices. This is significant as 55.4% of people with insurance were getting this coverage from an

[78] Sarah Lueck, "Eliminating Federal Protections for People with Health Conditions Would Mean Return to Dysfunctional Pre-ACA Individual Market," *Center on Budget and Policy Priorities,* October 5, 2020, https://www.cbpp.org/research/health/eliminating-federal-protections-for-people-with-health-conditions-would-mean-return.

[79] "Risk Pooling: How Health Insurance in the Individual Market Works," accessed April 22, 2021, https://www.actuary.org/content/risk-pooling-how-health-insurance-individual-market-works-0.

[80] Lueck, "Eliminating Federal Protections for People with Health Conditions Would Mean Return to Dysfunctional Pre-ACA Individual Market."

employer-provided package.[81] The risk of genetic testing information becoming available to employers, and the insurance companies that they are partnered with, may fundamentally alter the relationship between employees and the organizations that employ them. A persisting concern surrounding genetic testing is that employees may be subjected to adjusted salaries if they possess inherent health risks revealed through a leak of their private testing results leading them to be wary of the technology.[82] This fear may be responsible in and of itself for making the observed numbers of those seeking genetic technology lower than those potentially interested, as the fear of an employer taking this data to adjust company sponsored insurance plans for them is worrisome. The National Human Genome Research Institute (NHGRI) states this as a concern: "many Americans are reluctant to take advantage of new breakthroughs in genetic testing for fear that the results will not be used to improve their health, but rather deny them jobs or insurance."[83] This statement came out in 1998 during a period where these concerns were first coming to light in the wake of new technologies being explored. Yet today, the fear persists. In the NPR-Truven Health Analytics Health Poll, it was found that about half of Americans, or 47%, had privacy concerns while 61% said they would be hesitant to share genetic information with employers.[84] Seeing this fear reflected in 2018 legitimizes the claim that

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[81] Katherine Keisler-Starkey and Lisa N. Bunch, "Health Insurance Coverage in the United States: 2019," *U.S. Census Bureau,* (2020): Report No. P60-271.

[82] Scott Hensley, "Poll: Genealogical Curiosity is a Top Reason for DNA Tests; Privacy A Concern," *NPR Shots,* June 1, 2018, https://www.npr.org/sections/health-shots/2018/06/01/616126056/poll-genealogical-curiosity-is-a-top-reason-for-dna-tests-privacy-a-concern.

[83] "Genetic Information and the Workplace," *NIH,* October 25, 2012, https://www.genome.gov/10001732/genetic-information-and-the-workplace-report.

[84] Scott Hensley, "Poll: Genealogical Curiosity is a Top Reason for DNA Tests; Privacy A Concern," *NPR Shots,* June 1, 2018, https://www.npr.org/sections/health-shots/2018/06/01/616126056/poll-genealogical-curiosity-is-a-top-reason-for-dna-tests-privacy-a-concern.

many are indeed reluctant to use genetic technologies or share results over concerns for employment implications. Thus, the sensitivity of the genetic information available from the different technologies and tests that are out in the market becomes very important to the employee and employer relationship. Negative potential consequences are possible for employees if their genetic information is made available outside a direct-to-consumer transaction.

In an attempt to address the privacy concerns raised above, the Genetic Information Nondiscrimination Act (GINA) was passed in 2008, for the intended purpose of "protecting Americans from discrimination based on their genetic information in both health insurance (Title I) and employment (Title II), is a landmark piece of legislation in this new genetic era."[85] Certainly, this act was key in officially defining the status of one's genetic information and health insurance at their place of employment. Yet, this act could not cover everything, and potential workarounds are easily identified. For example, within Title I regarding health insurance, it should be noted that the GINA's health insurance protections do not cover long-term care insurance, life insurance, or disability insurance.[86] These stated exclusions are significant because potential forms of exploitation can occur. Starting with the first exception of long-term insurance, some questions arise. Long-term care refers to the insurance benefits a person is to receive if they have an injury or illness that requires long-term care. Due to the nature of this, and associated costs of long-term care, the GINA does not ensure that genetic information

[85] "Genetic Discrimination," *NIH National Human Genome Research Institute,* online only, last modified September 16, 2020, https://www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination.

[86] Ibid.

will be protected. Genetic information cannot be protected in this context as it is often the case that illnesses requiring long-term care have genetic sources. So, it is necessary for these situations that the severity of illness be known, oftentimes, through the analysis of genetic markers. With this knowledge, the appropriate entities can adjust services accordingly. Additionally, life insurance and disability insurance being omitted is significant as many genetic diseases may lead to shortened life expectancy and severe debilitation of the body. In these cases, again, the GINA does not cover individuals, as the nature of these conditions is often severe and requires extensive costs for care. In such cases where the costs are expected to be heavy, the GINA allows for genetic information to be made available and considered in the creation of health insurance coverage plans. Thus, in both cases, these individuals are exposed to the issues GINA intended to stop (lessened coverage, underwriting, and premium setting) as they are unable to keep their genetic conditions out of the discussion in creating these types of insurance plans.

Title II of the GINA regarding employment also leaves room for workarounds. When reading through the title, one notices that there is an important exception involving the U.S. military. Perhaps unsurprisingly, the rules under which the military operate are somewhat modified. The military is permitted to use genetic information to make employment decisions. Also, importantly, the GINA does not apply to employers with fewer than 15 people.[87] These two exceptions, although specific, are still important in their potential impact. Regarding the military, the U.S. Department of Defense is the

[87] Ibid.

"largest employer in the world with 3.2 million employees on its payroll."[88] This is a significant chunk of employment available in the U.S., and in all these cases the U.S. Military has the right to make decisions based upon the genetic information of an individual, setting forth grounds for discrimination to take place. The second exemption mentioned in this title (Title II), changes focus from a large employer (the U.S. military), to much smaller employers. Businesses that employ fewer than 15 employees may seem like an insignificant aspect of the GINA exception. Yet, one must consider that firms with fewer than 20 workers make up 89% of the 5.6 million employer firms in the United States.[89] These two ranges have significant overlap suggesting that many of these firms fall outside the provisions of GINA and are therefore free to engage in discriminatory practices according to available genetic information of employees. So, although the GINA was foundational in setting a benchmark for the relationship between one's genetics and their employment, it has not accounted for potential exploitation that can lead to the discrimination it was intended to prevent.

The concerns discussed in these previous sections represent integral fears people have about the advancement of genetic technologies that involve private genetic information. The genetic makeup of an individual can become a troublesome obstacle in the attainment of fair health insurance coverage and employment opportunity. With these potential obstacles facing individuals, there could be mounting pressure on people to utilize new genetic technologies to change their own genetic code in a way that would

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[88] Henry Taylor, "Who is the World's Biggest Employer? The Answer Might Not Be What You Expect," *World Economic Forum,* online only, last modified June 17, 2015, https://www.weforum.org/agenda/2015/06/worlds-10-biggest-employers/.

[89] "Facts & Data on Small Business and Entrepreneurship," *SBE Council,* accessed April 21, 2021, https://sbecouncil.org/about-us/facts-and-data/.

make them better candidates for health insurance coverage and employment. If this is to occur, and people look for technologies to address these concerns, will they have access to the necessary genetic practices?

Legislative Contradiction and Other Concerns

Considering that the median household income in the U.S. is $68,703 as of 2019, we can see that without third-party support, a family cannot reasonably afford many genetic services without sacrificing basic family needs.[90] Except for the well-off in America, the possibility of covering genetic tests and services is almost entirely dependent upon the provisions made by the insurance provider (if that family even has insurance coverage to begin with). And so, access to technology is for most ultimately a question of an insurance provider's coverage. Oftentimes, insurance providers receive mandates from the federal or state government on what they need to include in the health insurance plans offered for a certain area. The problem, however, is that often these mandates and legislative acts leave indeterminate the proper levels of government authorized to set requirements. Generally, confusion on whether or not a person is able to receive a certain service, supplemented by insurance, is difficult to conclude presenting barriers to access needed care.

For many, the greatest joy in life comes from the arrival of a child; yet a large number of Americans have infertility complications. In a 2019 CDC study, "about 10% of women (6.1 million) in the U.S. ages 15-44 were reported to have difficulty getting

[90] Semega, Jessica, Melissa Kollar, Emily A Shrider, and John Creamer, "Income and Poverty in the United States: 2019," The United States Census Bureau, September 15, 2020, https://www.census.gov/library/publications/2020/demo/p60-270.html.

pregnant or staying pregnant."[91] This figure represents a substantial segment of the population who, without genetic technologies such as Assisted Reproductive Technologies (ART), would be unable to have children. ART is a potential solution to this issue. The cost of such services, however, still represents a significant financial hurdle for many of these women and their partners. At the beginning of this chapter, it was noted that most high-cost procedures and medical technologies are only affordable through insurance participation. Individuals must look to insurers for access to these technologies as large national health reforms such as the Affordable Care Act (ACA) of 2010 put this responsibility on private insurers; the federal government's insurance plans themselves do not even require infertility treatment to be covered at the national level.[92] The ACA did not identify fertility treatments as part of the ten essential benefits of the act, and thus left to the states the decision on whether or not insurance policies in their state would provide fertility treatment. So, coverage for such fertility services would be accessed through one's private health insurance plan; this plan, and whether it included such services, would be determined by the policies of the state where it is issued.[93] Thus, access to receiving this form of genetic service and care comes down to state policy and private insurers in the current healthcare model of the United States. The differences between the coverage of genetic technologies between different states are often drastic. Judith Daar compares and contrasts Texas to Massachusetts wherein Massachusetts has a

[91] Esther Eisenberg et al., "Infertility," *U.S. Department of Health & Human Services Office on Women's Health,* last modified April 1, 2019, https://www.womenshealth.gov/a-z-topics/infertility.

[92] Louise Norris, "Does the ACA Require Infertility Treatment to be Covered by Health Insurance?" *Health Insurance & Health Reform Authority,* October 26, 2020, https://www.healthinsurance.org/faqs/does-the-aca-require-infertility-treatment-to-be-covered-by-health-insurance/.

[93] Daar, *The New Eugenics: Selective Breeding in an Era of Reproductive Technologies,* 64.

more comprehensive and complete policy that takes pride in mandating that insurance companies must provide infertility services. Texas, on the other hand, remains somewhat hesitant to require genetic and infertility services be made available to its residents keeping the provisions for these services far more restrictive. Thus, access to this type of fertility care is unequal between residents of different states as states are suggested to have the main authority to regulate differing degrees of mandated insurance coverage.

Although officially state legislative acts are the main determinants of the role of insurance when it comes to the access to these infertility technologies, it is important to note that the federal government is not completely uninvolved in the issue and, actually, has the ability to intervene in this ostensibly state-run decision. Juudith Daar again discusses this issue further by bringing to light federal legislative acts like the Employee Retirement Income Security Act of 1974 (ERISA). This act, Daar states, "may allow for a preempt of a state law as ERISA regulates employee benefit plans, including health plans. The importance of ERISA to infertility coverage is that in some cases the federal law preempts state laws that relate to employee benefit plans."[94] This clause, often called the 'preemption clause', is in Section 514 of the code itself. The Supreme Court has interpreted the preemption clause broadly in the past to often carry out congressional objectives when seen fit.[95] These preemptions, and the frequent use of this clause, clearly raise questions as to which level of the government ultimately has the final say on the restriction of infertility treatments in America. The federal government, on one hand,

[94] Daar, *The New Eugenics: Selective Breeding in an Era of Reproductive Technologies,* 65.

[95] Trish Riley and Erin Fuse Brown, "Empowering and Protecting Consumers: ERISA Thwarts State Innovation," *NASHP,* Feb. 28, 2017, https://www.nashp.org/wp-content/uploads/sites/default/files/ERISA_Primer.pdf.

seems to allow for greater state control for such decisions in the ACA; however, uses specific clauses, from much older legislation like ERISA, to intervene in such decisions. These discrepancies leave gaps for workarounds to arise and further complicates the options available to patients seeking access to services such as infertility treatment.

The layered and complex bureaucratic web, coupled with legislative acts and potential workarounds, leaves access to these technologies limited and difficult to achieve. The crux of the issue is the market costs for procedures themselves. For the majority of Americans, it is clear that access to these technologies, without the aid of third-party payers, would be almost impossible to afford without sacrificing financial stability. Yet, when many Americans seeking new genetic care practices and procedures turn to insurance for coverage, they find these legislative contradictions between both the state and federal levels. Within the realm of fertility treatment, it can be seen that a population of potential consumers are in need to access these technologies, but often encounter difficulties when attempting to do so as contradictions in coverage arise.[96]

A final issue regarding legislation is the inherently slow nature in which legislation is introduced. There is a substantial lag between the introduction of policy and the actual changes to coverage that may result. The pace at which research into genetic technologies moves is much faster than the pace at which policy changes, and with this discrepancy, conflict can arise. An example of this can be seen through mitochondrial replacement therapy (MRT). MRT is a nuclear transfer technique that operates like gene

[96] Esther Eisenberg et al., "Infertility," *U.S. Department of Health & Human Services Office on Women's Health,* last modified April 1, 2019, https://www.womenshealth.gov/a-z-topics/infertility.

therapy but is effective for the entire germ line.[97] This treatment is not only controversial because of its use for germ line edits, but also for potential legal issues that can arise surrounding parents. Opponents of MRT treatment, like the FDA who made the practice illegal, claim that "potential legal problems related to perceptions that the offspring would have 'three parents' as MRT would require putting DNA from the mother's egg into a donor egg and then having that be fertilized. Thus, there would be a perceived case where the child has two mothers and one father.[98]Such issues like this represents areas of conflict that can arise due to the fast-changing pace of technological development compared to the slower pace of legislative change.

Why does legislative change often take so long? The answer, most simply, is because of the way legislation is passed. The American governmental system was intentionally designed to be somewhat redundant with many checks and balances to allow for deliberation over issues rather than impulsive mob rule. So, by nature of its design, legislative change often lags behind the progress of science and the society. Yet, there are additional ways in which policy change is slowed, specifically, through lobbyists and political infighting. Consider legislation to be passed that would make access to technology more available, but would cost insurers or hospitals a portion of their profitability. This legislation would be met with resistance by lobbyists or politicians supported by firms that are threatened with a potential loss of profitability. Even if these

[97] Masahito Tachibana, Takashi Kuno, and Nubuo Yaegashi, "Mitochondrial Replacement Therapy and Assisted Reproductive Technology: A Paradigm Shift Toward Treatment of Genetic Diseases in Gametes or in Early Embryos," *Reproductive Medicine and Biology* 17, no. 4 (Oct. 2018): doi: 10.1002/rmb2.12230.

[98] Robert Klitzman, Mark Toynbee, and Mark V. Sauer, "Controversies Concerning Mitochondrial Replacement Therapy," *Fertilization and Sterilization* 103, no. 2 (Feb. 2015): doi: 10.1016/j.fertnstert.2014.10.028.

attempts to stop legislation are unsuccessful, the effect of the action is a stalling of legislative change. These types of situations can quickly accumulate and slow the process of policy change down noticeably.

Overall, as more genetic technologies with an even broader appeal outside the realm of fertility come to market, it will be vital to consider what role legislation at the federal and state levels play into the coverage of new genetic technologies and practices.

Current Trends Addressing Access to Genetic Technologies and Care

A clear need exists in the U.S. to begin addressing the affordability of genetic technologies and practices as they are introduced to the market. In this section, a new paradigm is considered as a way to perhaps introduce genetic technologies and practices in a more affordable manner by incorporating insurance through employer-sponsored plans. As mentioned in the previous sections of this chapter, the mixed insurance provisions of the U.S. between public and private is unique relative to most other nations. In the U.S. nearly half of the insurance for working Americans (approximately 156,199,800 people) is derived from their place of employment, according to the Kaiser Family Foundation (KFF).[99] Recent changes by large companies such as CVS to include gene therapy, for example, in their health insurance plans for their employees mark the potential beginning of a trend. If companies are to incorporate and include genetic technologies without prompting from the government, many issues of access would then

[99] "How Many Americans Get Health Insurance from their Employer," *eHealthInsurance Kaiser Family Foundation,* online only, last modified January 11, 2021, https://www.ehealthinsurance.com/resources/small-business/how-many-americans-get-health-insurance-from-their-employer.

fall upon companies and their CEO's rather than policymakers. And so, this paradigm of promoting access to genetic technologies will be explored.

The first large company to announce that it is in favor of such employer-sponsored insurance plans was CVS. The CVS-sponsored plans were specifically prompted for genetic therapy. It is important to note that this model is in its infancy stage as it was recently announced in January 2020. According to the report, CVS Health plans to make several gene therapies accessible through its employer-sponsored insurance.[100] The company was said to have recognized the benefit of having employees gain access to gene therapy while also noting the costs of such therapies are out of reach for their workers. One must applaud the company for recognizing how the costs for these therapies are not only problematic for its employees, but for employers too. It is important to note that many employers are hesitant to implement genetic care coverage as they are "struggling to find ways to offer coverage without bankrupting their health plans. These costs will hit plans – and the healthcare system – in one massive blow rather than being spread out over time."[101] In the CVS model, they are seeking a tempered solution to this issue where they can provide these new services while also keeping their company afloat, by gradually introducing the changes rather than being pushed to offer coverage all at once. How CVS intends to do this is from a 'value-based contract model' which essentially allows for the flexibility of the costs of therapy as well as a mechanism to

[100] Kayla Webster, "CVS Health to Launch New Insurance Product for Gene Therapy," *Health Insurance,* January 16, 2020, https://www.benefitnews.com/news/cvs-health-to-launch-new-insurance-product-for-gene-therapy.

[101] Ibid.

allow for refunds/rebates if the therapy is unsuccessful in lowering a patient's genetic risks.[102]

CVS' model, again, is still in its infancy and it remains to be seen how well it can stand up to the realities on the ground. However, the theoretical framework itself seems to be popular enough for emulation. A *Wall Street Journal* article noted how Cigna and Anthem announced their intention to add similar plans in which members pay monthly for access to a feature that helps pay for gene therapy.[103] No hard details have been given on what this model would exactly look like for either employees or insured customers. What is observed in the statements made by these companies is that there will be a great deal of flexibility in the payment for treatments as determined on an individual basis. This perhaps is the best model for increasing accessibility to genetic technologies for employees although it may be time-consuming. An individual approach with flexible plans ensures that employees/insured customers have access to services while the employers/insurers do not risk insolvency in their financing of these services.

Conclusion

Given all this information, it is important to return to the question posed in the chapter's introduction. Have we, or are we capable of, creating an opportunity for all to access new genetic technologies in the healthcare market? It is difficult to find this answer in the U.S. healthcare system today. The sentiment felt by many, as described by

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[102] Cori Gray and James T. Kenney, "Outcomes-Based Contracting for Disease-Modifying Therapies in Multiple Sclerosis: Necessary Conditions for Paradigm Adoption," *American Health and Drug Benefits* 12, no. 8 (Dec. 2019): 390-398, PMID: 32030115.

[103] Joseph Walker and Anna Wilde Mathew, "Insurers Pitch New Ways to Pay for Million-Dollar Therapies," *The Wall Street Journal,* September 5, 2019, https://www.wsj.com/articles/insurers-pitch-new-ways-to-pay-for-million-dollar-therapies-11567677600.

Ajay K. Aggarwal, is that the "US Healthcare system costs too much, gives back too little, and often leaves out millions in coverage."[104]Although pessimistic, Aggarwal captures key concerns felt by consumers. The concern of new high-priced procedures coming to market, being subjected to the variable and high pricing practices of firms, and being unavailable to many due to their cost or policy practice is reflected in consumer polls.[105] In addition, fears of potential misuse of genetic information in the workplace still remain a concern throughout many potential consumers.[106] The fears of consumers are often perpetuated by ill-designed models which were intended to facilitate access to genetic technologies while protecting consumer information. Inconsistencies between federal and state policies and oversight does not inspire confidence in potential consumers to seek genetic services until these concerns are addressed. Yet, there is still an observed demand by consumers to use new genetic technologies if accessed through trusted channels like employer-led insurance plans. These plans, as observed, are often highly flexible and capable of addressing recurring concerns consumers have about traditional healthcare institutions.

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[104] Ajay K. Aggarwal, "Some Issues in US Healthcare," *International Management Review* 4, no. 1 (2008): 101-109, https://search.proquest.com/docview/195551714?pq-origsite=gscholar&fromopenview=true.

[105] Isadora Milanez and Mark Strauss, "Americans are Closely Divided Over Value of Medical Treatments, but Most Agree Costs are a Big Problem," *Pew Research Center,* July 9, 2018, https://www.pewresearch.org/fact-tank/2018/07/09/americans-are-closely-divided-over-value-of-medical-treatments-but-most-agree-costs-are-a-big-problem/; "Only Nine Percent of U.S. Consumers Believe Pharma and Biotechnology Put Patients over Profits; Only 16 Percent Believe Health Insurers Do," *Harris Poll,* accessed April 21, 2021, https://theharrispoll.com/only-nine-percent-of-u-s-consumers-believe-pharmaceutical-and-biotechnology-companies-put-patients-over-profits-while-only-16-percent-believe-health-insurance-companies-do-according-to-a-harris-pol/.

[106] Scott Hensley, "Poll: Genealogical Curiosity is a Top Reason for DNA Tests; Privacy A Concern," *NPR Shots,* June 1, 2018, https://www.npr.org/sections/health-shots/2018/06/01/616126056/poll-genealogical-curiosity-is-a-top-reason-for-dna-tests-privacy-a-concern.

The role of the employer is important in the discussion of genetic technologies and the consumers' ability to accessing them. A majority of health insurance coverage in the United States is provided by employers and their plans for employees. It can be expected that, as genetic technologies become more available in the future, employers will play a greater role in setting the conditions of access via their company-provided insurance plans made for employees. While some federal acts can help oversee this provision of coverage by employers and attempt to prevent possible discriminatory practices, the application of this federal oversight remains unclear. Employers, such as CVS, have recognized their need to step up to the coming wave of genetic technologies as leading companies like CVS, Cigna, and Anthem have begun to create flexible value-based contract models with employees.[107] And so, by recognizing the new demand for genetic technology access, insurance plans are beginning to take shape among employers that will help provide employees with the means of attaining access to key genetic technology.

As new policies form and concerns of consumers are addressed, it may be possible to provide better access to genetic technologies for consumers. Given the nature and potential benefits many see in genetic technologies, it is expected that demand, advancement, and normalization of use for these technologies will continue to grow.

[107] Cori Gray and James T. Kenney, "Outcomes-Based Contracting for Disease-Modifying Therapies in Multiple Sclerosis: Necessary Conditions for Paradigm Adoption," *American Health and Drug Benefits* 12, no. 8 (Dec. 2019): 390-398, PMID: 32030115.

CHAPTER THREE

Genetic Technology as a Means for Social Stratification

Introduction

Chief among concerns for societal well-being is social structure. A source of inequality, fragility, and conflict, a nation's success is intimately tied to its social condition. Historically, the advent and implementation of powerful technologies have created and furthered division within humanity. The agricultural revolution replaced the hunter-gathering groups of prehistory with bustling towns and cities. In such settings, small nomadic tribes traded their egalitarian social structures for distinct strata according to one's labor. From barter to currency exchange, the technology of the coin insured the procurement and isolation of wealth in these new urban centers. From the practices of oral tradition, written words provided a means of restricting access to learning and prosperity to those of the upper echelons of society. Indeed, when we look at history, we oftentimes look through the lens of those with social distinction, great wealth, and unprecedented access to these new revolutionary technologies. With these observations in mind, it is necessary to state that by no means is technology a bad thing. Undoubtedly, the long-term benefits of technology outweigh the cons, and it allows for the advancement of our species. Yet, we must be aware of the fact that technology is something to be respected and can be misused, whether through carelessness or malice.

The question this chapter considers, is whether or not the genetic technologies will become another landmark moment in history where technology led to unmistakable social stratification. In our modern era, we must wonder whether we can ignore these divisions? What will future generations say of the introduction of genetic technology to our population? Was it a story of advancement, or a story of division for our society? Will our tendencies to seek group membership, categorize others, and place people into certain molds of society be made even more permanent through technologies of greater consequence? As we advance further into this age of genetics, we must be aware of the key institutions that, as discussed in chapter two, play a part in the introduction of new policies and practices that affect citizens today and their relationship to new genetic technologies. It is imperative to consider the roles of consumers, citizens, and employees while also being aware of the decisions made by often powerful entities like insurers, government, and employers. Who is to gain in these new decisions? What current power dynamics exist between healthcare consumers and large institutions of the industry? And, how can we take this opportunity of introducing genetic technologies responsibly to also perhaps address previous stratification concerns?

Societal Consequences

In 2013, the direct-to-consumer (DTC) company 23andMe found itself at the face of controversy. In an attempt to patent the method of obtaining donors, for which a human baby could be created with certain phenotypic characteristics, the company faced backlash for its treatment of babies as customizable product. Indeed, the most notorious phrase representative of this mentality was 'I prefer a child with…' followed by a series of choices namely "longest expected life span/ least expected life cost of health care/ least

expected cumulative duration of hospitalization;" further on the 'shopping list,' things such as height, eye color, muscle development, and personality characteristics are included.[108] The overall treatment of the issue, coupled with mistrust surrounding the intentions of the company in trying to patent a practice involving people's genetic coding, led to the noted backlash. What the example showed though was that although people speak out against designer babies and treating them as a customizable consumer good, a clear market demand existed for such a process that some are projecting to be worth $3.5 billion.[109] Indeed, the desire to seek specific traits in the reproducing population is nothing new to human history, but it's the treatment of these decisions as material goods now which is most concerning. Unlike the Spartans who used infanticide, eugenicists who used sterilization, or the Nazis who used extermination, this new form of genetic selection can be wrapped neatly within the framework of a market economy that responds to our demand as consumers. Therefore, in many ways, it is much more important to recognize this subtlety when considering the impact on society new technologies may yield.

The patentability of genetic traits is still a contentious issue. Although 23andMe's attempt brought up in the previous section reached a dead end, it may be only a matter of time until a successful legal argumentation is made. The culture in which such a legal argument makes its way up is also important, as the culture certainly impacts the level of resistance such a legal case would face. Should a point be reached where legal cases are

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[108] Sigrid Sterckx, et al., "'I Prefer a Child with…': Designer Babies, Another Controversial Patent in the Arena of Direct-to-Consumer Genomics," *Genetics in Medicine* 15, (2013): 923-924, doi: 10.1038/gim.2013.164.

[109] Boston College Law Review Staff, "The Price Tag on Designer Babies: Market Share Liability," *Boston College Law Review* 59, no. 1 (Jan. 2018): 328. https://lawdigitalcommons.bc.edu/cgi/viewcontent.cgi?article=3618&context=bclr.

uncontested by a culture of a nation, one must consider the societal implications of allowing practices like patentable traits. Time and time again news reports come out with sensational stories of gaps among people in several different contexts such as gender, race, political orientation, etc. The problems suggested by these reports may now find an answer in genetic technology. Indeed, the case of designer babies for example, and the hesitations surrounding them, become more meritorious when the motivations behind the practice begin to shift. Rather than creating children that are designer, in that it is being done for superficial beauty, perhaps the motivation is more economically oriented addressing concerns of the gaps among people of different socio-economic status.

Is the motivation for such change warranted? Has technology made society more socio-economically unequal today than in the past, as some reports suggest? According to certain studies, the answer is yes; society perhaps has "never been more unequal than at present, in terms of distribution of income and wealth."[110] Within-country income inequality (measured via the Gini coefficient) is "more unequal today than at any point since WWII."[111] Although it is certainly true that the quality of life for the average citizen has improved greatly since WWII, it is also true that wealth and income inequality has become even further distinguishable as elite classes retain wealth within their own small bands. Again, reaffirming the prevalence of in-group/out-group bias in our psyche, it is natural for those in positions of power to seek others in similar positions leading to a concentration of wealth. It is observed that "members of the upper class live in exclusive

[110] Wim Naude and Paula Nagler, "Is Technological Innovation Making Society More Unequal?" *Economic Development United Nations University*, December 12, 2016, https://unu.edu/publications/articles/is-technological-innovation-making-society-more-unequal.html#info.

[111] Ibid.

suburban neighborhoods, expensive downtown co-ops, and large country estates. They attend a system of private schools that extends from pre-school to the university level; adult members of the upper class socialize in expensive country clubs, downtown luncheon clubs, hunting clubs, and garden clubs."[112] The exclusivity and separation of these elites are not lost upon the people excluded. These bands of privilege may also be marked by certain phenotypic traits considered desirable, or signifying of power, as had been the case in the past with the Habsburg Jaw.[113] There may even be further genetic influences on this grouping to those similar to us. Geneticist Abdel Abdellaoui conducted a study "looking at the genomes of people living in former coal-mining areas, he found genetic signatures associated with spending fewer years at school that correlate with lower socio-economic status."[114] This research publication suggests that there may be a link between people's genes and their socio-economic status. The aspect of schooling also brings in another consideration, that is intelligence. Is there a potential to enhance intelligence? The answer, again, is yes. According to some estimates there are between 30,000 and 50,000 genes that feed into human intelligence. Any intervention into them "will require a good understanding, however, once this information is obtained it is not clear that intelligence is the kind of capacity that should be enhanced."[115] Perhaps what is

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[112] G. William Domhoff, "The Class-Domination Theory of Power," *Who Rules America University of California at Santa Cruz,* last modified February 2012, https://whorulesamerica.ucsc.edu/power/class_domination.html.

[113] Lila Thulin, "The Distinctive 'Habsburg Jaw' Was Likely the Result of the Royal Family's Inbreeding," *Smithsonian News,* December 4, 2019, https://www.smithsonianmag.com/smart-news/distinctive-habsburg-jaw-was-likely-result-royal-familys-inbreeding-180973688/.

[114] David Adam, "The Promise and Peril of the New Science of Social Genomics," *Nature* 574, (Oct. 2019): 618-620, doi: 10.1038/d41586-019-03171-6.

[115] Nicholas Agar, "Liberal Eugenics," *Public Affairs Quarterly* 12, no. 2 (Apr. 1998): 137-155, Accessed April 7, 2021. http://www.jstor.org/stable/40441188.

most notable about this quote is the framing. The author suggests that our understanding of how to alter genes that inform intelligence will be eventual – 'once this information is obtained.' This, more than anything, continues to speak to the eventuality that our ability to understand and alter the human genome is no longer a question of if it is possible, but when will it be possible? Once it is possible, what will society decide? If intelligence can be improved within the population, should it be? Two different views of this question are presented by Nicholas Agar. Advocates of general intelligence (or g) propose that there is some domain general cognitive ability that explains performance across a very wide range of tasks; others hold that there is an alternative multiple intelligence "to which a range of distinct intelligence modules each account for performance in a relatively circumscribed area."[116] Studies like this, suggest intelligence is a measurable and manipulatable component of our genome that could be altered for the benefit of society.[117]

Intelligence alterations may present the ultimate avenue that leads to societal division. Intelligence is foundational to job success, social mobility, and familial advancement. All these aspects traditionally hinged upon the cultivation of years of schooling and applying this learning to life. Indeed, the value of education is a key component of our democracy in the United States, but what if there is a shortcut that exists? As Agar points out, there soon will be an eventuality in which our understanding of how intelligence is informed from a genetic foundation allows for adjustments to be made. Those economically advantaged groups, who are able to access the technology that

[116] Ibid.

[117] Ibid.

enhances intelligence, will be strongly motivated and capable of utilizing such a technological tool as it has the potential of further concentrating economic and political power. Indeed, this suggestion is in line with a key principle put forth by Link and Phelan termed the Fundamental Cause Theory. This theory suggests that "socio-economic status is consistently associated with diseases and embodies how resources like knowledge, money, power, and prestige can be used differently, in accordance with changing situations, to avoid risks for disease and death."[118] For such consequential technology, we must consider how social stratification can be made worse through the use of this technology by small groups with greater resources. As groups with greater resources are able to access technologies for their benefit, a worrying trend may develop where genetic technologies may concentrate greater power in those groups who already have more resources, leading to a repetitive cycle of users and benefactors. In such a case, there is a risk that not only will health discrepancies be made more apparent between different strata, but overall societal divisions will become further distinguishable.

The grouping of potential users and benefactors can lead to the concentration of wealth because, as previously cited studies suggest, those of similar socio-economic status tend to associate together in settings such as employment, educational institutions, or even through mate selection. Mate selection studies specifically have been conducted across the world to gain insight into how humans socialize and ultimately choose a candidate for a mate. In one U.S. study, researchers found that in choosing a mate, college-age women "gave higher ratings than men did to variables related to status and

[118] Bruce G. Link, Mary E. Northridge, Jo C. Phelan, and Michael L. Ganz, "Social Epidemiology and the Fundamental Cause Concept: On the Structuring of Effective Cancer Screens by Socioeconomic Status," *Milbank Quarterly* 76, no. 3 (Sep. 1998): 375-402, doi: 10.1111/1468-0009.00096.

resource potential, and men gave higher ratings to good looks."[119] This illustrates that for college-age female students, resource potential was a significant factor in determining a mate. A similar study was carried out 3 years later in Jordan, also examining a pool of college students, to see how they ranked different factors in the importance of choosing a mate. This Jordanian study revealed similar findings that indicated "women's differential preferences for resource and commitment related attributes, and greater preference for mates exhibiting economic ability; male Jordanians showed greater interest in potential mates' good looks and youth."[120] These two studies suggest that possible banding of certain populations together, in terms of mate selection, is a potential reality as socio-economic status functions as a means of grouping.

Additionally, what these mate selection studies reveal, is the potential homogenization of societal groups that can occur. Certain preferences to smell, looks, and other phenotypic expressions regulated by genetic code become key factors for choosing a mate. In the Herz et al. study, researchers found that "women considered a man's smell to be more important than 'looks,' voice,' or 'how skin feels' when selecting a lover."[121] This importance of smell in selection of mates on the part of women is a consistent and corroborated result among studies since the 1980's and across nations.[122]

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[119] Rachel S. Herz and Michael Inzlicht, "Sex Differences in Response to Physical and Social Factors Involved in Human Mate Selection: The Importance of Smell for Women," *Evolution and Human Behavior* 23, no. 5 (Sep. 2002): 359-364, doi: 10.1016/S1090-5138(02)00095-8.

[120] Yacoub Khallad, "Mate Selection in Jordan: Effects of Sex, Socio-Economic Status, and Culture," *Journal of Social and Personal Relationships* 22, no. 2 (2005): 155-168, doi: 10.1177/0265407505050940.

[121] Herz and Inzlicht, "Sex Differences in Response to Physical and Social Factors Involved in Human Mate Selection: The Importance of Smell for Women," 359-364.

[122] Ibid.

Smell may be paramount to all physical factors, but remaining physical factors like height, weight, and looks followed closely behind. These physical preferences reveal a potential motivation for parents to select genetic expressions desirable to a certain band of physical preferences of women. Genetic similarity also plays a major part in human mate choice. In a research article by J. Phillippe Rushton and Ian R. Nicholson, it was found that "epigenetic rules may incline people to detect and prefer genetically similar others as marriage partners."[123] This theory is termed the Genetic Similarity Theory and again highlights a potential motivation for people to seek genetic technologies in order to improve mate selection outcomes.

Overall, these potential societal consequences to the introduction of genetic technologies are important to consider. The grouping practices we engage in have impact to the socio-economic divisions observable in society. As news reports and studies continue to suggest certain groupings have better socio-economic outcomes, motivations may be greater to pursue technologies that can conform to these suggestions. Intelligence is perhaps one of the main avenues of social advancement and improving status. The traditional means of intellectual development through schooling may soon be replaced by technologies that can alter intelligence aptitude. As such technologies become available, we must recognize key theories like that of Link and Phelan which explain how those with greater resources have greater access to new medical technologies leading to increased health gaps among society's hierarchy. Similarly, these higher socio-economic groups with greater access to technologies may demonstrate repetitive behaviors of use

[123] J. Phillippe Rushton and Ian R. Nicholson, "Genetic Similarity Theory, Intelligence, and Human Mate Choice," *Ethology and Sociobiology* 9, no. 1 (1988): 45-58, doi: 10.1016/0162-3095(88)90004-0.

and benefit. This behavior would further the concentrating of resources to a small few at the expense of the masses who are unable to engage this type of technology as readily. In the face of such consequences, looking at current power dynamics in the healthcare system is important to determine the reality of such concerns like the disproportionate access to care based on group membership.

Power Dynamics: Current Environment

The power dynamic relationships that exist between healthcare institutions and society is important to consider as it may be a way in which societal divisions are furthered. In a world with limited resources, and limited access to these resources, it is key to consider how social stratification may lead to the disproportionate allocation of resources based on an individual's membership in certain groups; this disproportionate allocation can further perpetuate divisions among the population. This idea briefly returns us to the Fundamental Cause Theory which again states that "socio-economic status is consistently associated with diseases and embodies how resources like knowledge, money, power, and prestige can be used differently, in accordance with changing situations, to avoid risks for disease and death."[124] There exists a current asymmetry between those powerful few and the masses, specifically as powerful elite find fewer obstacles in their path to achieve benefits from society's institutions and often have increased access to these benefits by nature of having greater resources.[125] An example of

[124] Link and Phelan, "Social Epidemiology and the Fundamental Cause Concept: On the Structuring of Effective Cancer Screens by Socioeconomic Status,"375-402.

[125] Lourdes Munduate and Francisco J. Medina, "How Does Power Affect Those Who Have It and Those Who Don't? Power Inside Organizations," *An Introduction to Work and Organizational Psychology,* (Mar. 2017): 176, doi: 10.1002/9781119168058.ch10.

this idea is manifested in the context of PGD discussed in earlier chapters. Although basic screening as a part of PGD may be moving toward affordability for a larger segment of the population, only those with greater resources can access the extra benefits of such technologies through the purchasing of 'add-ons' in such services.[126] In this way, we see a system wherein higher quality services are easier to attain for the elite groups of society which can afford them. Further, in those institutions such as insurance, there are less barriers to the wealthy as well; the Fundamental Cause Theory reveals that health discrepancies exist between the small elite groups and the general public often in the form of better health among the elite members of society. For a practice like risk pooling, which is based upon costs for a group of people, those in small wealthy pools are afforded better coverage due to better health; this allows such groups access to more services through coverage compared to those in pools with greater health costs.[127] In this way, we observe an environment that exists where practices by insurance companies create further division.

In the actual healthcare provider setting, socio-economic status becomes an issue in the relationship between provider and patient. Information asymmetry is a key component of inefficient market allocation, and is most observable in the provider-patient relationship. This asymmetry is characterized by the fact that patients "may be able to describe their symptoms, but they have inadequate information to either relate their

[126] "What is the Cost of Genetic Testing, and How Long Does it Take to Get the Results?" MedlinePlus NIH, September 21, 2020, https://medlineplus.gov/genetics/understanding/testing/costresults/; "Pre-Implantation Genetic Screening (PGS or PGT-A)," Human Fertilisation & Embryology Authority, August 24, 2021, https://www.hfea.gov.uk/treatments/explore-all-treatments/pre-implantation-genetic-screening-pgs/.

[127] "Risk Pooling: How Health Insurance in the Individual Market Works," accessed April 22, 2021, https://www.actuary.org/content/risk-pooling-how-health-insurance-individual-market-works-0.

condition to a particular type" or understand the appropriate course of action; thus, information asymmetry creates an "unequal power relationship between experts and clients which the former may exploit at their own interest."[128] This power dynamic is often a result of lower socio-economic individuals lacking education on the subject at hand. For those of higher socio-economic status, this dynamic is less apparent due to educational advantages mediated through income. Gross and net differences in health across the categories of age, education, and income are both absolutely, and relatively, greater than those differences in health across race, sex, or marital-status.[129] Thus, the best health outcomes are most often a result of age, education, and income. For those who are wealthy, and are able to afford better education often in the form of private schools, engaging in conversations about their health with providers is more achievable.[130] In the provider-patient relationship, the aforementioned greater education can lead to informed understanding and better explaining of symptoms allowing patients to be more apt at anticipating a course of action. With this advantage, higher socio-economic groups are able to address the issues of information asymmetry more successfully than those of lower socio-economic status. This difference in agency between the two groups can lead to greater social division as those individuals of higher socio-economic status are less effected by the issues of information asymmetry.

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[128] Gerald Bloom, Hilary Standing, and Robert Lloyd, "Markets, Information Asymmetry and Health Care: Toeards New Social Contracts," *Social Science and Medicine* 66, no. 10 (May 2008): 2076-2087, doi: 10.1016/j.socscimed.2008.01.034.

[129] James S. House, Ronald C. Kessler, A. Regula Herzog, "Age, Socioeconomic Status, and Health," *The Milbank Quarterly* 68, no. 3 (1990): 393, https://www.jstor.org/stable/3350111?seq=1#metadata_info_tab_contents.

[130] Wesley Whistle, "Wealth Inequality and Higher Education: How Billionaires Could Make a Difference," *Forbes,* December 31, 2019, https://www.forbes.com/sites/wesleywhistle/2020/12/31/wealth-inequality-and-higher-education-how-billionaires-could-make-a-difference/?sh=57e84bdd39db.

From these considerations, we observe a difference in the power dynamics and agency between those of higher socio-economic status to those of lower socio-economic status. These differences in available quality, relationships to insurers, and relationships to providers creates an environment in which power rests with a smaller group who, through more resources, are capable of benefitting from healthcare systems that facilitate this type of environmental power dynamic. However, we must ask ourselves is this a changing phenomenon? Can advances in technology, education, and consumer choice address current systems of disparity?

Power Dynamics: A Potential Locus Change with Consumers as Drivers?

In this age of technology, are we as consumers able to address some of the differences in power and play a larger role in the healthcare space? In past eras, such as the Eugenics movement of the 1920's, genetic selection in the population was orchestrated from small elite groups in society and aided by government intervention. Today, however, we perhaps have the means to become more powerful agents in the conversation about society's direction and what acceptable goods can enter the market. There are two primary examples demonstrating how market desire prompted research and development of technologies by companies who sought to fill the demand in IVF treatment and DTC testing. Assisted Reproductive Technology (ART) – of which IVF is a constituent – has increased 40-fold across reporting countries in usage from 11,323 in 1989 to 404,364 in 2010.[131] This massive increase is representative of a demand by

[131] Bart C. J. M. Fauser, et al., "Beliefs, Attitudes and Funding of Assisted Reproductive Technology: Public Perception of Over 6,000 Respondents from 6 European Countries," *PLoS One* 14, no. 1 (Jan. 2019): online only, doi: 10.1371/journal.pone.0211150.

consumers to have access to new treatments to old problems. The increased frequency of IVF procedures further illustrates the changing attitudes surrounding certain genetic technologies. In a study conducted by the National Institute of Health (NIH), researchers found that there was "a positive attitude among respondents in an online panel toward IVF, gamete donation, and support for public funding for fertility treatment as a whole."[132] This is a marked change from attitudes in years past – especially when the first IVF baby was born in 1978 – that saw such a practice as an overstepping of science. Indeed, much credit to this change of attitude is attributable to the demystifying of the practices used, an advancing education of the topic, and an overall familiarity to the concept culturally, making it far less of a foreign procedure. The Direct-to-Consumer (DTC) genetic testing market is another prime example illustrating the potential locus change of interest in genetic technologies. According to market research done by BIS Research, the value of the DTC genetic testing market was estimated at "$684.7 million in 2017, and is projected to reach $6.36 billion by 2028", resulting in an expected annual growth rate of 22.84% between 2017-2028.[133] This is certainly an optimistic projection, yet it is revealing of just how much development is expected in this market as time progresses. Thus, these examples illustrate a potentially changing field of control, from small elite bands mediating change with the help of traditional power institutions, to the masses using the market as a tool to have access to technologies they perceive to be beneficial to them. As discussed in chapter two, the availability of these technologies to

[132] Ibid.

[133] Bhavya Banga, "Global Direct-to-Consumer Genetic Testing Market to Reach $6.36 Billion by 2028," last modified May 21, 2019, https://www.prnewswire.com/news-releases/global-direct-to-consumer-genetic-testing-market-to-reach-6-36-billion-by-2028--300853946.html.

people of lower socio-economic status still remains a question of affordability, coverage, and changing roles of insurers and employers. Yet, the market response to common demand illustrates a means by which the broad public can influence the healthcare space.

Another aspect to consider as a potential means to change power dynamics is the role of the provider-patient relationship. As discussed in the previous section, information asymmetry is a problem in the healthcare industry. This asymmetry tends to keep power in the hands of the government, insurers, and providers. However, with the power of smart phone technology and the Internet, for example, the parent-child dynamic of information discrepancy that traditionally characterized the provider-patient relationship may be experiencing change. Solid data, and the ability to access resources at the touch of a button, has given consumers confidence and guidance in the medical space through the use of online databases like WebMD that provides information regarding illnesses, symptoms, and treatments.[134] General consumers are able to be more judicious and aware of quality information when seeking healthcare services, empowering them to become larger agents in the healthcare space. By empowering consumers to exercise greater control in the healthcare industry, through encouraging them to be informed buyers, the general public can become agents of change in this way and reduce issues like information asymmetry.[135]

Perhaps of all the encouraging changes taking place in the healthcare market, those changes that encourage greater consumer participation in their healthcare plans are

[134] Martin J. D'Cruz and Ranjan B. Kini, "The Effect of Information Asymmetry on Consumer Driven Health Plans," *Integration and Innovation Orient to E-Society* 1, no. 1 (2007): 359, doi: 10.1007/978-0-387-75466-6_40.

[135] Ibid.

most important. The growth of "consumerism," or the focus of consumers as agents of change to manage costs of healthcare and drive quality, has been a lauded trend by economists.[136] This growth puts greater emphasis on consumer agency and power in the healthcare space and is observed chiefly through new formatting practices like consumer-directed health plans (CDHP). CDHP "combines high-deductible plans with a tax advantaged health savings account (HSA), and offers Americans a way to save money and invest for future health costs, while maintain funds for current expenses, including cost-sharing."[137] Many policy analysts believe that through the use of such plans by consumers, healthcare procedures and services will become more price sensitive and enhance clinical outcomes.[138] These expectations are certainly encouraging as it represents a means to address power imbalances that exist in the market currently. The key for the success of these plans is to have educated consumers that are willing to put in the effort required to become informed buyers. Unfortunately, the appetite for CDHPs appears limited, as only 4% of American workers were enrolled in a CDHP in 2006. Yet, employers are still promoting these plans as it represents a means of cost-savings for their company and has the added benefit of encouraging greater consumer agency in the space.

[136] Sheldon M. Retchin, "Overcoming Information Asymmetry in Consumer-Directed Health Plans," *American Journal of Managed Care* 13, no. 4 (2007): 173, PMID: 17408336.

[137] "State of the Market Report on Consumer-Directed Health Plans," *America's Health Insurance Plans AHIP,* March 20, 2020, https://www.ahip.org/state-of-the-market-report-on-consumer-directed-health-plans/.

[138] Serena Barello and Guendalina Graffigna, "Patient Engagement in Healthcare: Pathways for Effective Medical Decision Making," *Neuropsychological Trends* 17*,* (Apr. 2015): 54, doi: 10.7358/neur-2015-017-bare.

Conclusion

The role of technology in societies is significant. As new genetic technologies come into the market, they may become significant drivers of societal change leading to further stratification among people, thereby making societal divisions more apparent. In the introduction of genetic technology to our society, we must be cognizant of the power dynamics that exist in the societal environment. Differing socio-economic levels have left divisions among the citizens of this country where a small few have greater resources and, consequently, greater access to more quality services than the general public. In the case of genetic technologies, there is a concern that those with more resource potential may be able to utilize new consequential technologies to further their advantage and societal distinction over others. The concentration of power into small bands of elites can be an issue for genetic technology as these bands may become chief users and benefactors, thereby concentrating power. Further, those of higher socio-economic status often hold power in their dealings with healthcare institutions such as insurers and providers. As suggested by the Fundamental Cause Theory, health disparities can exist between classes where those with greater resources are less burdened by diseases as they are able to avoid illnesses better through the greater market power they command. In this age of new technologies that allow for one to be better educated and informed, there is potential for those traditionally out of power to gain agency in the healthcare space. Through "consumerism" frameworks, issues in the healthcare system can be addressed by both fostering an environment of informed buyers, who utilize the market as a tool, and introducing specially designed insurance plans to the system.

CONCLUSION

What was once theory and lab experimentation becomes reality. The gradual advance of scientific achievement has continued onward, unlocking new genetic technologies. There has been no iconic event signaling our transition into a world with these powerful technologies. No, instead the subtlety of the market infuses these technologies into our society without the chance to fully consider the implications. The introduction of such technologies, through gradual changes, begins to affect our morality and social bonds even now.

The first chapter considered a diverse range of genetic technologies existing across equally diverse levels of development. Some have begun to enter the healthcare market, others right at the cusp of introduction, and even more are lined up in successive waves seeking approval. With lucrative gains to be had in the market, many companies are eager to enter this space as consumer attitudes toward these genetic technologies' warms, especially for those in treatment of infertility and disease among babies.[139] Years of lab bench experimentation turned into clinical trials, and these trials turned into marketplace goods reaching the 'shelves' for consumers to buy. Of the branch of these

[139] Bart C. J. M. Fauser, et al., "Beliefs, Attitudes and Funding of Assisted Reproductive Technology: Public Perception of Over 6,000 Respondents from 6 European Countries," *PLoS One* 14, no. 1 (Jan. 2019): online only, doi: 10.1371/journal.pone.0211150; Cary Funk, and Meg Hefferson, "Public Views of Gene Editing for Babies Depend on How it Would Be Used," *Pew Research Center,* July 26, 2018, https://www.pewresearch.org/science/2018/07/26/public-views-of-gene-editing-for-babies-depend-on-how-it-would-be-used/.

new technologies, gene therapy began the push into the healthcare industry several decades ago. The advances that came with gene therapy treated rare genetic deficiencies using well understood techniques. With new therapeutic mechanisms gaining approval both abroad and in the U.S., the successes of gene therapy spurred further areas of research. Gene editing, through a few key mechanisms, most famously the CRISPR mechanism, saw an increased dedication of research. The possibilities promised in this branch include the restructuring of our genetic coding itself by targeting any specific sites that we desire. Soon, it will be possible to simply set the correct guiding parameters for mechanisms like CRISPR and yield targeted results. This type of technology still resides primarily in the clinical trial stages, but that is beginning to change as we already seen its use in places like China much to the shock of the global community.[140] Commonly entering the market, however, are the new screening and assistive reproductive technologies. Preimplantation diagnosis, panel screening, *in vitro* fertilization (IVF), and other similar technologies have entered the intimate spaces in our reproductive behavior. Now we can better and more commonly identify genetic conditions and diseases through simple tests run from a single drop of blood. Fertility issues now are better addressed through *in vivo* and *ex vivo* procedures. IVF services have observed less stigma surrounding the practice than ever before.[141] The great variety of these technologies illustrates the progress of the field. However, the implications of these technologies must be properly considered. Observing varying price ranges for technologies discussed in the

[140] Dennis Normile, "Shock Greets Claim of CRISPR-Edited Babies," *Science* 362, no. 6418 (Nov. 2018): 978-979, doi: 10.1126/science.362.6418.978.

[141] Bart C. J. M. Fauser, et al., "Beliefs, Attitudes and Funding of Assisted Reproductive Technology: Public Perception of Over 6,000 Respondents from 6 European Countries," *PLoS One* 14, no. 1 (Jan. 2019): online only, doi: 10.1371/journal.pone.0211150.

chapter hinted at possible issues to come. Societal stratification is a concern as those with greater resources are able to purchase the higher end of technologies and procedures leading to more favorable outcomes. Indeed, the ability to more frequently get screening tests, done in more detail, allows those of higher socio-economic standing to avoid costly diseases for themselves, or their children, more readily than other groups may. Chapter one discussed the potential uses of powerful genetic technologies. Chapter one discussed the potential uses of powerful genetic technologies. Chapter three argued that these uses would lead to greater societal stratification in at least two ways. One, those of higher-socioeconomic status would be the primary beneficiaries, and two there would be greater cumulative benefit for following generations of elites who had access to such technology.

For such consequential technology, the ability for people to access these services is crucial. Without proper healthcare policies and planning in place, access to these procedures may still be problematic for many. In an industry plagued by lacking price transparency, inadequate policies, mixed insurance practices, and variable pricing, access to the best of healthcare remains a concern. Insurance coverage becomes one of the chief aspects of the healthcare industry that many look to wearily. Current insurance practices often lack transparency, engage in behaviors that drive up prices consumers pay, and create questionable coverage pools. Indeed, concerns about possible discrimination practices by insurance companies also remains a concern for many people.[142] Furthermore, many are concerned about potential information misuse by insurers or employers who provide the majority of Americans' insurance through work-sponsored

[142] Scott Hensley, "Poll: Genealogical Curiosity is a Top Reason for DNA Tests; Privacy A Concern," *NPR Shots,* June 1, 2018, https://www.npr.org/sections/health-shots/2018/06/01/616126056/poll-genealogical-curiosity-is-a-top-reason-for-dna-tests-privacy-a-concern.

plans.[143] We observe legislation in place meant to address these fears like the Genetic Information Nondiscrimination Act (GINA). Yet, oftentimes policies like this are outdated in the context of the rapidly advancing field leading to potential loopholes typically in the gaps between federal and state government jurisdiction. Further, the GINA notes key exemptions in that protection of genetic information is not guaranteed for those in the military or those employed by small businesses, both of which represent huge chunks of the American population. As more technologies come to market, we as a society must do a better job addressing these concerns and inconsistencies in policy if we are to truly benefit from adding these new technologies to the healthcare industry. Creating greater access should be a chief concern for us going forward, especially as it can address possible social stratification. Current dynamics allow for those with greater resources to more readily receive access to technology and procedures. This reality further exacerbates stratification in society. To address this issue, looking at institutions and their policies for ways to increase access is worthwhile as new technologies continue entering the marketplace.

With new technologies of greater consequence becoming available to the healthcare industry we must be wary of the great potential that exists for increasing the permanency of societal stratification. As technology advances and allows for greater control over the future genetics of successive generations, those with more resource potential and greater access to technology can avoid costly diseases in their children. With children engineered to have better health outcomes, those who cannot afford or access similar changes will be left at a disadvantage especially in an economic sense. The

[143] Ibid; Katherine Keisler-Starkey and Lisa N. Bunch, "Health Insurance Coverage in the United States: 2019," *U.S. Census Bureau,* (2020): Report No. P60-271.

concentration of privilege and power as a result of recurrent use of genetic technologies within small bands represents a real potential for lasting stratification to occur. Current power dynamics favor highly educated individuals with great resource potential. Insurance practices like risk pooling, and mitigated effects of information asymmetry between providers and these small elite bands, allows for those with higher socio-economic status to prosper while others are left behind. Solutions to these concerns may be found in the market and through employers. Access to technologies and information also reduce information asymmetries allowing consumers to be better informed and knowledgeable about their healthcare choices. Taking a more active role through the market or in your own healthcare decisions through consumer driven health plans (CDHP) represents ways one can combat trends that may lead to further societal division.

And so, as new waves of powerful technologies come to market, we must take the time and effort to stay informed about them. The potential these technologies hold for addressing difficult medical conditions and providing avenues for radical change is exciting. However, we must be cautious not to overlook important conversations in our ambitious fervor. The subtle nature of genetic technologies being introduced through the market should make us pause and consider key questions. Do we truly understand the capabilities of these technologies and possible ill-effects? Can the institutions and systems in place facilitate an environment where everyone has equal opportunity to access such a consequential technology? And are we capable of bringing these technologies to our society without having them become tools of division? These are the questions that we must address and answer so future generations may reap the full rewards.

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