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Between Past and Future: An Exercise in Politics and DTCGT

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Between Past and Future: An Exercise in Politics and DTCGT

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Abstract

Between Past and Future: An Exercise in Politics and DTCGT By Aric Edwards

Until recently, the US had a “wild west” scenario regarding Direct to Consumer Genetic Testing quality control and consumer protection: anything goes. Yet the bioethical community has started to help create guidance for various governmental agencies about DTCGT. Right now, consumers can purchase DTCGT, but the FDA has begun to have “private” dialogues with DTCGT’s various manufacturers. This may mean that DTCGT is susceptible to the FDA’s oversight and will result in removing DTCGT from the market with no consumer input.

Hannah Arendt has been praised as a purveyor of political philosophy since her text “Origins of Totalitarianism” was published in 1951. Arendt’s perspective and philosophy can help shed light into new regions for bioethical thought. Within the context of “institutionalized” bioethics, or the field of biomedical ethics, there is a link between what occurs in the political realm and the course of biomedical conversations. Arendt allows us to maneuver fluidly between the two; and, in particular, her work can be applied to the topic of DTCGT.

In this paper, I will show how several key points in Arendt’s system can be used when discussing DTCGT. Experts and their aforementioned “private” dialogues have removed citizens from the DTCGT discussion. Forcing individuals to the masses category hinders them by not allowing access to the polis -- the forum where active citizens convene to discuss the issues. With many individuals being made superfluous, experts make up the majority of those consorting in the polis but non-experts are most affected by DTCGT.

Arendt’s development of an “active citizenry,” would help to facilitate an open dialogue about these tests. Rather than allowing bureaucratic systems control the gates of the access, a group of individuals who bring this discussion to their fellow citizens would be ideal. An active citizenry is needed to determine its own choices and preferences about accessing DTCGT. With an active citizenry, individuals determine their genetic information’s meaning and creating standards and precedents for how to handle the management/regulation of these new tests.

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Chapter 1: Introducing the Complexity of DTCTs

Direct to Consumer Genetic Tests (DTCTs) at a Glance

For several decades, the discussion about personalized medicine has been one of the litmus tests for the medical community's measurement of progress. Home pregnancy tests established the foundation for consumers to obtain their own diagnostic testing within their homes. Medical testing done at home has allowed consumers to bypass the rising costs, inconvenience, and the effort of visiting their doctor's office. Within the last ten years, multiple new forms of "at home" tests have entered the market. A recent example is an HIV test approved by the FDA (2012) and various types of blood-glucose testing for diabetes.

Many of these new, "at home," tests have taken advantage of advances in genetics. These newer tests, known as direct to consumer genetic testing (DTCT), have prompted a variety of responses, mostly speculative, about DTCT's future. The main conversation revolving around DTCTs is whether the testing is to be permissible at all. Some European nations and thirteen U.S. states declared DTCTs be banned and, as a result, have passed nationwide/statewide legislation doing so. (ESHG 2010, Vorhaus 2010) In other European countries, stipulations came into effect mandating that DTCT's users have conversations with healthcare professionals (HCPs) prior to or after its use. The federal government has been pondering whether to create legislation regulating or prohibiting the tests. (GAO Report 2010)

Meanwhile, studies have shown that DTCGT's manufacturers are not being entirely forthcoming with those who buy their products. (GAO Report 2006, 2010) Manipulative tactics, questionable scientific validity, and vague language by DTCGT's manufacturers have resulted in mistrust by governments. It is this surreptitious nature, made evident within several commission reports from the federal government, which likely resulted in some locations banning DTCGT's or the government's desire to regulate them. (GAO Report 2006, 2010)

While there are several layers to this problem, the core issue is *who currently* controls access to our genetic information versus *who should be* controlling our access. The only viable solution lies with consumer choice. Corporations and governments' lack of transparency creates a crisis for individuals since their input is withheld from the dialogue. Superstructures are influencing an individual's ability to access this important information. In this chapter, I will explain both the contemporary issues with DTCGTs and how the current discussions have fallen short of touching the main cruxes of a systemic issue. The following chapter will consist of a philosophical analysis describing the trend of governmental control over DTCGTs. Lastly, I will invoke Hannah Arendt's philosophy to show how DTCGT's solution can come from those who recognize the stakes.

DTCGT's Emergence

Genetic testing allows for a descriptive analysis of an individual's genetic make-up. The testing available before 2003 helped diagnose a variety of ailments and helped

identify at-risk individuals. After the human genome's successful mapping in 2003, more possibilities for genetic testing emerged. (Ridley 1999)

Following the genome's mapping, the world expected cures for diseases, explanations for phenotypic traits, and an overall mastery of genetics. Early estimates placed the number of genes at around 100,000, which then dropped to 30-40,000, and eventually found to be about 20,000 in total. Because the genome proved to be simpler and more daunting than originally anticipated softened the expectations on just how much we could know from mapping the genome. Overestimates of gene numbers proved environmental and epigenetic¹ factors were more important than previously believed, thus, tempering expectations.

Despite setbacks, there remained an intense interest from the biotech industry surrounding genetic testing. These companies still believed profit could come from genomic mapping. Early in the post-genomic mapping period, companies began to patent sets of genetic data. Biotech groups hoped investments into purchasing and patenting genes would extend into profits. Companies were also hoping to capture the public's interest in the exciting post-genomic world by developing a new subset of tests for consumer marketing. Several companies came forward and advertising their tests to the public. DTCGT entered prominently into the public's view in November 2007 when deCODE genetics and 23andMe, funded by Google, became publicly traded. (Genomic Law Report 2010)

¹ Epigenetics accounts for genetic variation caused by non-heritable factors (diet, stress, etc.) .

During its primitive phase, the cost for these tests was exorbitant; it was “\$1,000 to review hundreds of thousands of Single Nucleotide Polymorphisms (SNPs)” (Vorhaus 2010) and about \$350,000 for entire genomic analysis. (Vorhaus 2010) The price has dropped significantly since then and you can buy a complete genomic test for a fraction of its former cost: today, the cost for full genomic translation is about \$10,000.

Variety of DTC Tests

DTCGTs have the potential to provide a great amount of information for individuals who purchase them. DTCGT comes with a variety of purposes and, with each purpose, the test and its results raise various problems. There are three common DTCGT forms: clinical tests, risk assessment tests, and informational tests.

Clinical tests calculate specific genetic illnesses and have clinical relevance. These tests are highly desirable for diagnosing genetic changes that have already disrupted a person’s health. In addition, they can anticipate a person’s reaction to an activity or chemical. A common example of a DTCG clinical test is to establish drug-based interactions. For instance, you can assess whether abacavir, a drug used in HIV treatment, will cause an adverse reaction. Hypersensitivity to abacavir can be fatal and affects the treatment course for an HIV positive individual.

A risk assessment test provides an individual’s chance for a genetic trait’s expression and disease manifestation risk. This category encompasses various subcategories including cancer, pre-reproductive tests and late onset diseases. A large body of DTCGTs falls under these categories. These tests, which provide multi-factorial disease information, are rooted in complex genetic and environmental interactions

(Skirton et al 2012). Due to the complexity of these diseases, the majority of these tests can only determine the statistical chance for the disease's manifestation. The statistical potential for disease manifestation can be, and often is, a very low percentage. The information often shows a 1% risk or a "twofold elevated risk of 2.4 percent" (Spaulding 2011) which, clearly, does not account for certainty. Although one popular test, BRCA1/2^{2,3}, indicates a woman has a five times greater chance of developing breast cancer than the rest of the population, and a ten to four hundred times greater chance of developing ovarian cancer over the general population. (NIH 2012)

Informational tests refer to the testing types providing less disease-oriented information. These tests include earwax type, ancestry, and paternity tests that are not necessarily important for disease status, but may affect self-perception and other psychological or emotional factors.

DTCGT's Harms

DTCGT's harms have evoked concern from HCP's since their incarnation. As a result, professional entities consisting of physicians, nurses, genetic counselors, and other health care personnel have protested access to DTCGT. Many professionals feel access to DTCGTs creates harms to consumers. This concern resulted in numerous organizations calling for regulating DTCGTs or banning them altogether. These groups feel that the harms caused by these tests far outweigh their potential benefits.(Skirton et al 2012) The surface harms are: risks to consumer privacy protection; potential breaches of

² This is a mutation found on Chromosome 17 leads to a heightened risk for breast, ovarian, and colon cancer.

³ This test is provided in clinical care with only one DTCGT version that identifies risks through linkage.

confidentially⁴; overburdening of the health care system; and inaccurate test results.

Another set of concerns exist at the meta-level including: harm to self, harm to others, and the loss of self-determination.

The "direct to consumer" aspect of DTCGT has both a positive and negative impact in relation to privacy. DTCGT allows individuals to bypass the healthcare/research system to obtain their genetic information directly from the companies. One justification for DTCGT use is that they provide a sense of privacy -- the test results would remain hidden from health insurances and HCPs. Your personal health information's (PHI) protection is different when using this method.⁵ Medical records are susceptible to inspection by your medical insurers but not if the test results are never placed within them. Therefore, by removing the opportunity for insurers to have access to that information you can plan for another course of action for your care that may not affect your insurance rates.

The U.S. has interceded and introduced the Genetic Information Non-Discrimination Act to try to prevent a genetic based insurance rate increase for those who obtain genetic testing. While maintaining some protections, it has fallen short in others. This act was to insure that insured individuals were transparent with insurers; as an insurance purchaser, it is your prerogative to protect your costs and plans. Therefore, the

⁴ I contend privacy represents the information one would consider embarrassing while confidentiality represents the loss of PHI from a system of control.

⁵ "*Individually identifiable health information*" is information, including demographic data, that relates to: the individual's past, present or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number). (DHHS 2003)

U.S. law can be seen as an attempt to establish solid legal ground for both sides (insured/insurer).

Despite these effects, concerns regarding privacy remain. Traditional forms of medical information being transmitted have several protection layers to maintain PHI's integrity.⁶ DTCGT's test results are sent through the internet and the test's purchaser is notified when their results are ready. They then log into the system using their username/password combination and receive the testing results. Though the average computer user's network offers little protection for the transmission of PHI but when done carefully, it may provide adequate protection.

The medical infrastructure is not inherently superior to the privacy protections that that DTCGT corporations proffer on site. Maintaining PHI's integrity creates a struggle for any organization. Protecting large data reservoirs with numerous ways for the release of these data into external systems has proven difficult or impossible. Recently, Emory University Hospital lost medical information on over 315,000 patients from its surgical department. Maintaining PHI and its subsequent need for confidentiality is a struggle for all involved.

A genetic predisposition for negative drug interactions, established from DTCGT, could assist individuals in their medical care. However, this is a key problem with at-home testing: since there was no HCP interaction, the medical record would not reflect the information. If an individual comes to the Emergency Department after a car accident or any other incident that may make the individual unable to communicate, there would

⁶ More advanced network/firewall protection

be no knowledge of the patient's negative drug interactions because the information is absent from the medical record for the HCP.

Since the medical community is not involved in the disclosure of this information, there is no process or policy to guide the disclosure of information. The information disclosed in this type of testing can have a profound impact on the psychological or social situation for a family, which makes the lack of guidance problematic.

Misattributed paternity is a concern during any genetic testing form. Providing paternal information can severely disrupt familial relations. Disclosing the information to the mother and not the father is the common HCP practice. Still, there is a constant dialogue about the ethical nature of their current plan but as of now; there is no clear consensus on the medical community's role in disclosure.

The second Government Accountability Organization (GAO) report found that due to DTCGT's misleading information, "DTC advertising can result in an inappropriate increase in demand for testing services" because people who are receiving the information via DTCGT can disclose genetic misinformation within their families. (GAO 2011) This issue is a reflection of DTCGTs, and their manufacturers, not providing ample education during the test results dispensation. Another possible reason is the consumer's misunderstanding of the test results or their implications. This problem is consistent with providing any information to consumers or patients and not solely in DTCGT's purview but any "at home" test.

One belief is that people will have purchased the tests without HCP intervention and be confused about the information. Some studies indicate a large percentage of those

who were to receive these tests indicated they would contact their primary care physician for their result's clarification. (Samuels 2011) With DTCGT, one can go to HCPs, and some do, for translating their test results; so there may be an increase in the use of healthcare resources. However, other studies indicate only a small portion would partake in HCP guidance. (Bloss et al 2011)

Many professionals are wary of consumers obtaining results of tests without consultation because they believe the testing results will harm the consumer's mental or physical state. Professionals argue that the provision of this information should be tempered by their expertise. (Skirton et al 2012) However, there has been little proof that divulging or receiving DTCGT genetic information has a negative impact on individual's well-being. For example, although a woman will have a five times greater chance to develop breast cancer if she has one of the known mutations for which she is tested, this places her risk at 600 out of 1,000. This means that even of those women who HAVE the mutation, 400 women of those thousand will NOT develop breast cancer. Yet it is difficult to ensure that individuals who have not had this test interpreted by a health care provider will understand this difference. For some, regardless of the lack of certainty conferred by a risk assessment test, a positive test result is enough of an indicator to spur them into prophylactic actions based on this information. The various tests for susceptibility to breast and ovarian cancer⁷, some women choose to have mastectomies or oophorectomies to help avoid that cancer type if they have a positive result.

Late onset risk assessment testing is just as daunting for an individual as cancer testing, and may result in serious implications for which, unlike cancer, we currently do

⁷ BRCA 1/2 is not commercially available but 23 and Me offers a test that looks at linking

not have prophylactic capabilities. An example of this testing type is the APOE4 marker. This genetic marker may indicate the future risk for developing Alzheimer's disease. Yet unlike other tests such as those indicating higher risks for diabetes, currently, there are no prophylactic treatments. While a positive test result does not indicate disease certainty, it does indicate an increased chance for mental degeneration.

Pre-reproductive testing allows for the genetic analysis of two parents' genetic material to determine the probability for disease characteristics and their children. This testing form will help determine the likelihood for a future child to express a Mendelian disease type; the future parents may then choose to use Artificial Reproductive Technology (ART) – particularly Pre-implantation Genetic Diagnosis (PGD)⁸ –to prevent diseases like Cystic fibrosis and Tay-Sachs; or the couple may use an egg or sperm donor; or simply forgo biological reproduction. Tests like this have an overwhelming impact on the way that families and communities are established. In some cases, individuals within certain communities who are carriers for certain diseases have had their reproductive choices managed by authoritative groups such as government or religious authorities.⁹

Traditionally, the largest fear for not allowing genetic information's disclosure to individuals is that the information will lead to a crisis in the individual (Dohany et al. 2011). As I mentioned earlier, some women who test positive for BRCA1/2 do get prophylactic care but, overall, there is little evidence that individuals suffer after

⁸ This costly procedure involves fertility technicians who extract eggs from the mother and an in vitro genetic analysis of the embryo occurs.

⁹ The island of Caprice did this to help reduce the occurrence of Beta Thalassemia. And the most famous case comes from Der Yeshorim, a NY based Jewish group, that would assign randomized numbers to individuals then have members call up and ask if the numbers were a genetic match (they were both not recessive trait carriers).

obtaining new genetic information any more than they do from obtaining other clinical information. (Mayo Clinic 2011; Bloss et al. 2011; Caulfield 2011) Out of 2037 subjects in Bloss' research, who received widespread genomic risk analysis, over 90% felt little to no increase in their stress levels. Bloss's work suggests in genomic DTCGT (a more widespread information type) that subjects become comfortable with knowing their test results. More ominous tests, like late onset diseases, did not faze test-takers emotionally, contrary to intuition. (Mayo Clinic 2011, Wilson 2005)

Various groups question what role professionals should have in the distribution of genetic testing: obligatory or optional. Within the context of DTCGT, expertise becomes a requirement because many believe that the "middle" man, or health professional, is necessary for the lay individual to comprehend these test results. Mitigating the possible danger of an individual being distressed over their genetic information is one of the main goals for the genetic counseling profession. By allowing individuals to discuss pre- and post-testing expectations, the belief is that the patient will understand the implications and cope better. This dialogue has proven effective in helping people understand the information's impact and meaning. Yet the question remains whether or not the clinic should be the *only* locale for receiving our genetic information.

Although the genetic counselors assistance has proven worthwhile, it might go against many people's wishes to require genetic counseling. In Bloss et al, only 10.6% of all who took the genomic analysis spoke to a genetic counselor, with 25.6% discussing test results with their physician. (Bloss et al. 2011) Even with genetic counseling offered as part of the test's cost, very few felt obligated to discuss their results with HCPs.

Placing a requirement will constrain the sense of freedom people might hope to find in DTCGTs.

Extreme cases, like HD, show how imperative it is that the genetic information be known so people can adequately prepare their life plan. This includes choosing if or how to reproduce, insurance purchases, and various other decisions that people make throughout their lives. One way to ensure this planning type is by allowing consumers access DTCGT. When gatekeepers (HCPs) control access to genetic information, it hinders our freedom.

An informational test that discloses our genealogy can have an impact on who we believe we are. This information may alter people's personal views and actions more than risk-assessing tests. Although there are also scenarios wherein finding out one's ancestry will influence their medical care; one such case is the Ashkenazi Jewish genetic structure. The implications that follow from discovering that you have Ashkenazi Jewish ancestry are that you may be more likely to carry genetic mutations for some conditions, including BRCA1/2, MSUD, and others. Knowing one's ancestry may increase the knowledge about the likelihood of passing certain disease potential onto one's children. This may mean that the potential parents choose A.R.T., adoption or rely upon chance.

The final risk, self-determination, works in conjunction with "respect for autonomy." In relation to DTCGT, this creates an interesting juxtaposition between what self-determination would require from an autonomous individual. Wilson argues that genetic information will create people who are better informed and healthier. (Wilson 2005). Acquiring the "necessary" genetic information allows one to better prepare or

understand the implications of genetic information. With education and access about acquiring genetic information earlier, individuals may become more open and less fearful.¹⁰ With DTCGT's access being curbed, the problem potentially reverses any chance for the open and free-flowing genetic information.

Conceding these harms becomes imperative to my argument – citizens should have access to these tests despite the chance of harm. As a whole, the harms, and benefits, become an aspect of individual management and is part of an individual's choice and their freedom. These tests will have different meanings to different individuals and, therefore, weighing the harms and benefits becomes subjective. For some, accessing DTCGT can provide them with insight into how they wish to plan their lives. DTCGT can influence other's lives negatively yet their compelling interest allowed them to muster the courage to take the test. People's urgency and importance must be taken into account within our medical system to provide options to the people.

The Responsibility of Business

DTCGT companies have had pressure to self-regulate and establish greater transparency in their activities. One realm that has prompted criticism is DTC companies' advertising methods. These methods include targeting vulnerable groups, and being unclear in their product's accuracy or results. Since the companies are using in-depth expertise and marketing groups, their methods have been planned and purposeful. The contemporary methodology used by "DTC marketing materials can cause confusion,

¹⁰ This paragraph was used in another essay I wrote entitled "Genetic Ignorance, Principlism, and Pragmatism."

manipulate interest, increase anxiety and exaggerate the test's benefits". (Genomics Law Report 2010)

Vulnerable groups include consumers targeted by companies using timing or locales to invoke a desired concern. The most famous case is from a play that focused on a medical doctor who is dying from ovarian cancer. (Hull and Prasad 2001) Those that attended the play were rapt with attention and the play focused upon our mortality. Within the playbill, there was an advertisement for BRCA1/2 testing which would help diagnose susceptibility to ovarian cancer. While the company was within their rights to advertise in such a manner – it causes some concern about their effort's timing and location.

Companies, some of which are newer, have been aware that scrutiny could come from either the FDA or FTC. They could have anticipated many possible risks or concerns since the tests' implications have been explored since their creation (e.g.; Chronic Villus Sampling (CVS), amniocentesis, paternity testing, family histories, etc). Yet it is not clear that they have done so; I will review their general unresponsiveness in the next section.

The Struggle for U.S. Policy Making and DTCGT

Since the origin of DTCGTs, the FDA has imposed no regulatory requirements upon the DTCGT manufacturers. At the outset, DTCGT may have been covered under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).¹¹ DTCGTs might

¹¹ implemented by the Centers for Medicare and Medicaid Services (CMS), requires laboratories to demonstrate the analytical validity of their tests, and covers most genetic tests regardless of whether they are provided directly to consumers or not – Genomics Law Report

have fallen into the category called a laboratory-developed test (LDT) which requires stringent analysis prior to implementation for use in making healthcare decisions.¹² These tests are not to be sold or used outside of the lab, and include widely used tests such as Pap smears and cross blood matching. Even today, the FDA and legal scholars are not quite sure if DTCGTs could retroactively fit within the LDT category, which includes other tests needed to “diagnose or monitor a particular disease or condition.”

(labtestsonline.org)

By 2008, several states began to regulate DTCGT and some even went so far as to ban them. One company withdrew plans to sell to “citizens in at least 10 states at the time of its launch.”(Genomics Law Report 2012) New York and California’s Departments of Health, delivered “cease and desist” letters stating that the DTCGT providers were operating without required licenses. Some companies wavered under the pressure and acquired the licenses, submitting to CLIA categorization. This forced the companies to relinquish their ability to deliver these tests to consumers. (Genomics Law Report 2012)

In 2008, there was also a request from Congress to acquire information about DTCGTs by convening the Government Accountability Office (GAO). The GAO created the Advisory Committee on Genetics, Health, and Society (SACGHS), which subsequently submitted a report entitled: *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services. (NIH 2008)* The report made several recommendations, including statements that the standards for DTCGTs and its marketing were deceptive; however, the report never gave concrete suggestions for or a plan to implement a regulatory structure immediately. Ironically,

¹² <http://labtestsonline.org/understanding/features/ldt/>>

while Congress chatted about the implications of the committee's report, *Time* magazine named 23andMe's DTC test as the "invention of the year." (Genomics Law Report 2012)

While Congress secretly requested another report by the GAO, DTCGT remained unregulated. Other groups like HCPs "stressed the need for meaningful self-regulation" but DTCGT companies took no steps to assuage the SACGHS's concerns. The FDA was required to alter its ruling about LDTs by removing the LDTs sub-categories and monitoring all LDTs. (Genomics Law Report 2012) There was still confusion after this alteration because the FDA had indicated to some companies earlier that their approval was necessary and that others did not require it. Without openly stating the differences between the companies neither side deviated from their way.

The NIH created a genetic testing registry in hopes of creating standardization amongst the DTC companies. The voluntary registry showed the various tests that DTCGTs offered accuracy, the amount ordered and other information. By making this registry voluntary, the hopes for creating an enthusiastic wave of participating companies fell to the wayside as companies continued business as usual.

In 2012, the FDA also sent five "Untitled Letters"¹³ to some of the main DTCGT manufacturers. (Genomics Law Report 2010)¹⁴ The goal of these letters was to forewarn the companies to fall in line with current medical device guidelines. The "untitled letters" that were delivered sent no guidance or plans for action; also, these letters "provided the company an opportunity to meet with the agency and to have time to take appropriate steps to address these concerns," (Genomic Law Report 2011) thus ruining the

¹³ A warning letter from the FDA indicating that there *may* be some sort of oversight or action; but, these letters are often given years prior to any substantial activity. (Genetic Law)

¹⁴ 23andMe, Navigenics, deCODE Genetics, Knome, and Illuminao

transparency that citizens should expect when the issue directly involves their medical/consumer driven motivation. Shortly after the “untitled letters” were sent to DTCGT companies, the FDA followed with Warning Letters. These letters declared that the company is in direct violation of a law or statute. Accompanying these letters comes the expectation of DTCGTs removed from the market.

Forthcoming Regulatory Actions

Experts predict the FDA will respond to the challenges of DTCGT within the next year or so. My concern is that there will be a widespread ban or that the government will enforce mandatory HCP interaction. The U.S. has attempted to regulate DTCGTs in the past, but has fallen short on ameliorating the DTCGTs issues.

One anticipated form of the FDA’s DTCGT regulation would be increasing their oversight of the companies that create assays. Assays are essentially the tests that make up the DTCGT. However, the assay manufacturers are not themselves selling DTCGTs – other companies buy the assays and then sell tests completed via the assays. One example of this is when the FDA “charged Illumina with making available an array approved for ‘Research Use Only’ to 23andMe and deCODE.” (Genomics Law Report 2012) It may be one step for the FDA to avoid direct conflict with DTCGT’s manufacturers. Those involved in the DTCGT’s role in the free market, investors, and technological progress will certainly feel the burden of FDA regulation on a previously uncontrolled industry.

Another anticipated regulatory method is that the test’s provider also supply or require conversations with HCP in order to access a test. This element would satisfy

many who are calling for a controlling factor for DTCGTs. However, I believe that this element would stifle individuals' interest in learning their genetic information because it creates a formalization that people may be trying to avoid.

Other nations' outcries and calls for regulations about genetic technology have not persuaded the U.S. to establish guidance. Regulation has the potential to stymie technological progress in the U.S., and one nation's restrictions may become the spark for another nation's technological advancement. Francis Fukuyama believed the only effective plan for managing the widespread use of genetic technologies would come from an international agency or legislation. (Fukuyama 2003) Given the U.S.'s general opposition to external policies, it seems unlikely the U.S. would be willing to participate in any international group or legislation restricting its own technological movements. Despite the U.S.'s representation while discussing almost all major international treaties, there is, historically, a non-cooperative attitude by the U.S. Great examples of this disinterest, including the Nuremberg Code¹⁵ and the Kyoto Pact,¹⁶ represent scenarios where the U.S. participated in the creation of the treaty, or signed the treaty, but violated the requirements and/or spirit behind the agreements.

When the U.S. government has tried to manage the impact and distribution of genetic information, like in 2008, it left much to be desired. Federal agencies felt that

¹⁵ Established after World War II in response to the experimental atrocities committed during the war -- it was meant to protect experimental patients from being violated or harmed on an international level. Yet, it was made clear after the Tuskegee Syphilis Experiment and the Guatemalan Prison Experiments, that the U.S. had foregone its abeyance.

¹⁶ The Kyoto Pact was an international agreement meant to drop greenhouse gas emissions. The U.S. refused to sign this pact which resulted in other countries foregoing cooperation since it lacked power without the U.S.

genetic information was important enough to pass the Genetic Information Non-Discrimination Act (GINA) in 2008; the government created this law in order to prevent discrimination by health insurers and employers regarding genetic information. GINA is also emblematic of the disjunction between the Federal government and its goal to protect its citizens because of the law's loopholes. GINA does not protect against discrimination by long-term care insurance, life insurance and from employers employing fewer than 15 people. Long-term care is particularly important for those with degenerative diseases (i.e.; HD, Parkinson's, Spinocerebellar Ataxia) and, as a result of GINA's gaps, they are still unprotected.

We need only look at our historical schema for examples of governmental agencies mishandling genetic information. In chapter 2, I will explore the broader philosophical underpinnings for this movement. While it may also be a polemic analysis, I contend that large portions of genetic *misinformation* are proliferated by policies that arise from the U.S. government. It is well documented, particularly during the 24-hour news cycle, that government representatives have misunderstood the implications and essence of biology and, in particular, genetics.¹⁷ This leads to an inquiry about whether the government should attempt to provide solutions to the problems found in DTCGTs.

¹⁷ Subcommittee on Oversight and Investigations revealed, "Donor 4 had a pacemaker implanted 13 years ago to treat atrial fibrillation. However, [23andme] and [Decode] found that he was at below-average risk for developing atrial fibrillation, and [Pathway] and [Navigenics] claimed that he was at average risk." The implication is that our collective analysis of his genetic risk must be wrong, simply because he has worn a pacemaker for 13 years. The problem with this conclusion is that genetics does not work in a vacuum, and environment and lifestyle pose a large role in the development of a health condition such as atrial fibrillation. <http://blog.pathway.com/genetics-loads-the-gun-and-environment-pulls-the-trigger-dr-francis-collins/>

The Importance of Being Able

Since consumers have the most at stake, in terms of DTCGT regulation, it would seem intuitive that their expectations, concerns, or desires be placed at the forefront. One concern is that consumers are left in the dark when policy is constructed by bureaucratic entities. These entities, the professional world and the government, appear to be attempting to bypass the affected parties and force themselves into the role of genetic informational gatekeepers.

Our cellular structure, and our understanding of it, is on the brink of being managed by two varying superstructures. These superstructures have acquired the right to commodify, patent, and prevent the consumer's access to goods and services.¹⁸ Since the genomic mapping, the cost for whole genome sequencing has been consistently dropping. Due to that, the resources required to obtain testing has become far more manageable. Yet, the impending regulatory actions may stifle society's potential for a free flowing and informed citizenry.

Perhaps the most pressing concern is the ability for bureaucratic entities to dictate one purpose to DTCGTs. Rather than examining the many meanings DTCGTs carry for many different people; there is an immediate determination made by superstructures. What DTCGTs means to one family can be entirely different from what it means to the next family or even to an individual. Pluralism, taking into account a variety of perspectives and meanings, currently has no place in the DTCGT discussion. In the next chapter, I will attempt to show how the superstructures have created a biopolitical field

¹⁸ Superstructure is used to discuss entities that are far larger than a single individual, therefore, they are not moved by an individual's desires.

that has taken over access to one of our most basic elements: our genes. Looking to Hannah Arendt's philosophy to show how the government has become both an establishment and a tool for biopolitics. I also contend that all of the issues would best be resolved with expertise "on tap," and that Arendt's work offers possible solutions to these fields of inquiry.

CHAPTER 2: Arendt's Biopolitics

Arendtian Biopolitics and DTCGT

Hannah Arendt and Michel Foucault focused on describing and scrutinizing the broadening governmental powers regarding “how we are to live.” Each provides insight into the complicated relationship from the 1800’s to modernity between citizens and government. Neither Arendt nor Foucault described an idyllic position prior to government’s modern power, yet Arendt particularly recognizes a despair resulting from the newfound power structure. Using their work, I hope to display the philosophical root for DTCGT’s locale regulation by the government. Modern government’s new-found power brings a great level of control at the cost to the individual’s political freedom.

Arendt’s two most influential texts, “Origins of Totalitarianism”¹⁹ and “The Human Condition”²⁰, comment on politics’ managing of life’s processes (life and death). Arendt locates our political system’s ails in modernity’s prioritization of biological aspects in our political system. OoT focuses on the politics of death and HC examines modernity’s political *ethos*²¹. Governments’ control over life itself damages Arendt’s ideal for our *ethos*, in the traditional sense, *of* being human.

Michel Foucault²² began his career analyzing the mechanisms that produced the medicalization of madness. His body of work was eclectic but revolved around various biomedical and political issues. Using aspects of his work will help to place Arendt’s

¹⁹ Origins of Totalitarianism, hereafter OoT

²⁰ The Human Condition, hereafter HC

²¹ *Ethos* refers to the spirit or character of a group.

²² Whom I consider to be one of the earliest true proponents of bioethics.

concerns in a more defined model. The concerns displayed by Foucault and Arendt provide insight into how the political system is structured in modernity. Both Arendt and Foucault offer genealogical explanations that will provide the foundation for commenting on “the history of the present.” (Foucault 1979: 31) Philosophical genealogies focus on “the constitution of the subject across history which has led us up to the modern concept of the self,” which provides us a worthwhile analytic method. (Foucault 1993: 202)

Arendt’s Vita Activa

This section provides insight into Arendt’s foundational aspect, *vita activa*. The term refers to our human condition or the way we live. Each element contained in *vita activa* is pivotal in Arendt’s definition for what it means to be human and provides meaning to the human existence. In order to clarify Arendt’s critique of modernity, and its historical roots, HC provides explanation of *vita activa*’s three categories: labor, work, and action and how she perceives their inversion’s roots.

The first part, labor, captures our biological pursuits or the things that enable life and its continuation. Arendt does not specifically refer to chemical or molecular activities but rather the actions that an individual pursues; for example, the act of obtaining food versus emulsification, and reproduction versus meiosis. While we are cognitively aware of these actions, compared to chemical and molecular processes, their essential nature never lets us escape their cyclical existence – outside of death. Without labor, there is no life.

Arendt's hierarchy places labor's position in *vita activa* as least important for what it means to be human. She acknowledges labor's importance but places it below the other two categories. She justifies this position by referencing the Athenian political organization and Aristotelian philosophy. Using a historical lens, Arendt looks to Pre-Socratic Athens to define how, when all is working correctly, society would ideally function.

In ancient Greece, the Athenians had slaves to assist in the procuring of food and the upkeep of the citizen's domiciles. During this period, those relegated to slavery and those never allowed to enter the public world were called *animal laborans*. Those in this situation were considered non-human or animalistic because they were unable to exit the private realm of the household and participate in the activities considered "human." Socially held beneath others, they were forced to feed others, upkeep the household, tend to the children, etc. rather than participate in the *agora* (marketplace) or, more importantly, the *polis*.

Polis refers to "the city, citizenship, or the body of citizenship" from which Arendt believes the true power of politics can be practiced. (Arendt 1998) Slave owning citizens were exempt from many concerns that would normally prevent the ability to access the *polis*. This created an asymmetrical relationship between the people who could partake in the *polis* since slave owners constituted the minority. Basing an "ideal" society on one that relies on slaves is, of course, problematic. Regardless, Arendt used Athens as a model, not because of its social inequalities, but because of its focus on using politics to allow others to see our true nature or our "who."

Man was revered as *homo faber* (man the maker) or *zoon politikos* (an animal of politics) in Ancient Greece. Work, created by *homo faber*, describes creations with more stability or permanence than labor. Work, which adds new objects to the human artifice, was a conquering of nature, and due to its ability to outlast natural processes it was placed, for a time, above labor. (Arendt 1988: 88) Man could take from the natural and create items for his own use. The items will either last longer or serving a specific purpose for man raises work's importance in Arendt's system over labor.

Zoon politikos was reserved for those who were not restrained by labor's pursuit and could exit the *agora* to participate in the *polis*. Once the citizen entered the *polis* there was an opportunity for action. Action was the goal for the Athenian citizens. Stepping forth into the *polis* enables action to be witnessed by others.

Action is the highest form of *vita activa* and is what makes us human. In the *polis*, speech and action allow man to distinguish himself. Action, or "to act," originates from the Greek word *archein*, "to begin" and indicates that in the *polis* it is possible to bring new things into the world. Striving to access the *polis* was a grand pursuit. The *polis* consists of a public realm wherein everyone within is an equal, and where we are able to disclose who we are through our action and speech. The new thing that is brought into the world is action's disclosure of "who" we are. Prior to disclosing "who" all in the *polis* are reduced to being equals. They all share the struggle of labor and are similar. Through action, they stand forth from all others. Without the public witnessing action or speech, "who" we are is unknown. Like a mosaic, the more pieces, or witnesses, the more complete of an image will appear.

Arendt's ideal was to create a human-centered world where, through politics, one could step forth and show uniqueness through speech and action. Arendt's notion of action emphasizes the ability to congregate and publically present an image. Disclosure, the result of acting in the *polis*, is the key factor in Arendt's philosophy. By others seeing our actions then we enable a historical self to arise. Piecing together the actions that others have witnessed, "who" we are becomes relevant and worthy of re-telling.

In HC, Arendt makes the claim that the *vita activa*, or the active life, has inappropriately shifted towards a focus on labor. In her hierarchy, labor is castigated as something to be kept below work and action. With this shift in hierarchy, man is no longer able to enter a shared public world because the private realm, and its focus on labor, has overwhelmed the desire for disclosing our "who." The public world's loss is mourned because only in the public world can an individual perform action and disclose their "who."

Philosophy's Dirge

Arendt believes philosophy attempted to unearth society's focus on labor from historical events during the 19th and early 20th century. Some causes for this disruption were economic and mechanical in nature, such as capitalism's rise and the Industrial Revolution. Arendt focuses on the damage that forced philosophers to rethink and establish a relationship to the world. She noted a particular rift, between "thinking" men, humanity, and the "world at large", in the period following the death of Immanuel Kant

(1801). Kant shifted the entire philosophical tradition via his work and, in a way, he “destroyed” man’s unique disposition.

In her essay, “What is Existential Philosophy?” Arendt shows how Existentialism became a necessary pursuit after traditional philosophy “failed” man. Arendt claims that Kant made humanity painfully aware that its mind lacked the ability to reconcile the world of appearance, consciousness, and man’s existence. (Arendt 2005, 169) Arendt proposes that, “Kant robbed man of the ancient security in Being by revealing the antinomy inherent in the structure of reason; and by his analysis of synthetic propositions, he proved that in any proposition that makes a statement about reality, we reach beyond the concept (the essential) of any given thing.” (Arendt 2005, 169) Antinomies are two statements that independently will stand as logical but in conjunction are paradoxical – thesis and antithesis. In Kant’s instance, he declares that the contradiction of reason stems from reason’s desire to trace originations – including reason’s own source. Yet, reason has limitations found in the examination of essence (Being’s source). We cannot ascertain the origins or cause of reason. Therefore, he illuminated the limitation of “knowing” and “understanding” for humankind, using the logical system that permeated the Western world. As a function of this system, some of mankind’s deepest questions fell far outside man’s ability to answer them. This resulted in listlessness because humanity could no longer compose a “meaningful” reason for *this* world or even *any* world. The world’s given status, rather than its creation for us, led to disenchantment with the world, where reason could no longer rely on itself to understand the world, including the origination of Being and the meaning of *this* world.

Historically, in the Western world, religion had justified *this* world's existence, and for our existence within it, with a divine plan for humanity that God created.²³ Using Kant, Arendt states that his rejection of the "ontological proof of God's existence destroyed any rational belief in God based on the proposition that anything accessible to reason had to exist." (Arendt 2005, 169) This rejection had a profound impact on theology as well as philosophy. God became even more unknowable, and religion, which was already moving further from an influential position, had a lesser role in governmental activities.

Arendt claims Kant damaged previous notions about the individual's consciousness being relevant for *any* world but also wounded historical absolutes.²⁴ (Arendt 2005) Showing reason's limits, we could no longer rely on logic to guide us within *this* world because there was always *something* beyond our sensory understanding. Philosophy had created logical proofs to prove and disprove God's existence, but with reason's limitation, our sensory systems and reasoning fell short. Kant claimed humans would never be able to perceive or understand the pure nature of things. Perceivers could only get to the outer shell of reality and attempts to describe it would not be accurate.

She outlined how philosophers had since failed to re-establish man's place in the world and particularly the mind's relationship with reality. The implications for the separation between man and reality were that philosophers felt obligated to "re-establish the unity of thought and being." (Arendt 2005) Arendt declares that it is at this point Existential philosophy came into the world.

²³ Leibniz declared that this world has to be the best of all possible worlds.

²⁴ These absolutes included: our ability to disclose the true nature of the world (realism), our ability to know God, and that man is completely free (free will).

Existential philosophy is a title given to a set of “widely different revolts against traditional philosophy.” (Kaufman 1989, 11) This category creates an emphasis on the individual and his or her attempt to flourish within a hostile world. It is also marked with an attempt to “bring philosophy down to earth again.” (Kaufman 1989, 51) Arendt credits this group for exactly this – their attempt to bring a meaning to an earth that was no longer held in a special place for man.

Since Kant’s revelation, Arendt shows how other philosophers, including Nietzsche, attempted to reconstruct a world for man by providing him purpose. (Arendt 2005) Writing nearly one hundred years after Kant, Friedrich Nietzsche reflects on the result of post-Kantian philosophy -- the absence of God or an objective truth -- in his “Parable of the Madman.”²⁵ Nietzsche, like many others, attempted to comprehend the consequences of this new void. Arendt suggests that with God’s absence, humanity was now open to interpretation. (Arendt, 169, 2005) When the madman says, “Must we ourselves not become gods simply to appear worthy of it?” our new role becomes clear. Nietzsche believed man was to establish himself as the world’s righteous ruler with the “Will to Power.” Nietzsche’s efforts do not lead to a solution to the moral or existential crisis from losing our objective world, but, instead, appeals to another transcendental category. Because of its transcendental qualities, “will to power” is unknowable via reason’s limitation according to Arendt.

²⁵ God is dead. God remains dead. And we have killed him. How shall we comfort ourselves, the murderers of all murderers? What was holiest and mightiest of all that the world has yet owned has bled to death under our knives: who will wipe this blood off us? What water is there for us to clean ourselves? What festivals of atonement, what sacred games shall we have to invent? Is not the greatness of this deed too great for us? Must we ourselves not become gods simply to appear worthy of it?

—Nietzsche, *The Gay Science*, Section 125, tr. Walter Kaufmann

Phenomenology is an attempt to reconcile human senses with what is perceived and what is “actual.” This became a popular field of philosophy during the late 19th and early 20th century, with its progenitor being Edmund Husserl. The overarching purpose, according to Arendt, for Husserl’s efforts were to “re-establish the ancient tie between Being and thought that had guaranteed man his home in the world.” (Arendt 2005) Many philosophical fields became self-sufficient during the 19th century that were originally rooted in philosophy,²⁶ and philosophy itself was having a crisis of identity as a result. Husserl’s work was an attempt to create a positivist philosophy to “save” philosophy from the gap between man and the world by making it unique and personal. Creating a more scientifically-based philosophical form, Husserl sought the legitimization of traditional philosophy through the same avenues that other fields, particularly psychology, were beginning to traverse²⁷. Ironically, his effort to legitimize and reconcile the world coincided with the beginnings of quantum physics, which, in its own way, sabotaged his project by furthering the gap found in man’s ability to comprehend the world around him while also using the more universally appealing mathematical systems.

Phenomenological studies conceded the gap between receiving the sensory input and the “pure” world -- that world that exists without interpretations. Its attempt to provide the “life of the mind” some form of grounding bears importance. The foundation that emerged allowed the individual to become master of a unique and personal world. The result Husserl wished to attain with phenomenology, reality itself, “would no longer appear to man as a world given, but as one created by him.” (Arendt 2005)

²⁶ Sociology, psychology, physics are just several. I believe this specialization occurred due to the rise of the collegiate world.

²⁷ This does not take into account logic, which has been found within the borders of philosophy and mathematics since its incarnation.

Husserl's efforts sought to recover a meaning for any world via a newfound subjectivity, and hoped this world would take on new meaning. However, Arendt believed Husserl's efforts were inadequate to recover *this* world. Husserl's work resulted in subjective worlds and failed to discuss our relationship to people in the worlds. Arendt turned to politics to provide this meaning, and used a phenomenological perspective to reconcile people's worldviews in a shared world; thus, taking phenomenology's efforts and refocusing them into her solution.

Science as Destroyer

According to Arendt, the groundlessness quickened with the telescope's invention. Throughout several of her works, Arendt postulates the impact of the telescope as creating "smallness" and cynicism within humanity. (Arendt 1958, 1963) When Arendt assessed the world's smallness after the telescope, she understood why some felt the "free gift from nowhere" was problematic. (Arendt 1958, 3) Witnessing immense planetary bodies let us know that earth is not truly "special" and makes it clear we did not and could not exert influence upon existence's entirety. This world, and other people, were there before our individual existence and the world shall continue without our existence.

The telescope's ability to enhance our sense of sight beyond its capability made people wary about sense-based knowledge. The telescope solidified Galileo's hypothesis that the earth revolved around the sun and "destroys not only our faith in the 'eyes of the body,' but also our faith in the 'eyes of the mind.'" (Biser 2009) Mistrust seeps into

almost every avenue of the material world for humans and doubt extends into our metaphysical existence. (Biser 2009, 54)

Cynicism resulted from the loss of “common sense.” Arendt’s definition of “common sense” derives from Thomas Aquinas’ *sensus communis*. (Arendt 1975, 50) Its role is to gather the five senses and create a certainty about reality. Through “common sense”, we obtain certainty that what I am speaking about is the same as another’s conversational object. It collapses our sensory input into a shared reality. We then communicate our perceptual differences via “*doxa*” or opinions that proclaim, “it seems to me.”²⁸ With a collection of *doxa*, it becomes possible to discuss and create a shared world of experiences and facts.

Arendt believed with science’s rise, nature’s framework begins including man; man, now studied within the framework as other fields of study, becomes an object for study. Arendt claims fields such as psychology, sociology, and anthropology result in sameness, or a lack of unique properties, and, as a result, the downplaying of human innovation and action. (Biser 2009, 75) Knowing all humans share biological similarities and needs, Arendt placed biology in *vita activa*’s lowest level; however, it is at this period where we see an equating of behavior and personality with a biological sameness projected as the defining features of man.

World Alienation and the Rise of Nation States

²⁸ Common sense and *doxa* are extremely important for the recovery of the polis. I will substantially address this as a turning point for how we are to access DTCGT’s future.

Embedded within science's systemization, a new emphasis on work and labor appear. The telescope's destruction of "common sense" invariably led to man's trust going elsewhere. World alienation was a result of recognizing our mental limitations and our inability to rely on sense experience. Arendt described world alienation as people's disinterest in participating within the common world. Since our senses could no longer be trusted (as scientific inquiry demonstrated) and our rationality was limited, the mistrust in our "world" proved too much. According to Arendt, the consequence for these revelations was mass exodus from the common world. World alienation took many forms; some chose to spend time within the mind's expanse rather than the world-at-large through *vita contemplativa*.²⁹ This group consisted of philosophers, theologians and other theorists who participated in the world, at times, in a different manner than those involved in action.

Another group chose to turn away from a common world and focus on creating new worlds. World creation, a new form of work, was to bridge the gap between man and all that was lost. It provided a new grounding and introduced a new way for man to conquer his limitations. Within these worlds, everything was able to be interpreted – history, science, and even man – in a manner that suited its creator(s).

World creation allows fictional ideas to become facts. Facts can occur only in a shared world where interpretation is not possible. With a disbelief in our senses, distrust permeates into facts' existence. With "common sense," it becomes possible to discuss what two people believe to be facts and come to a mutual agreement. In world creation, this did not occur because like all work it occurs in isolation. Arendt's concern was that a

²⁹ *Vita contemplativa* consists of the three mental faculties: thinking, willing judging and are focused on in Arendt's "The Life of the Mind."

non-pluralistic world's fact-making ability would further embed alienated people. With the ability to create our own narratives, a great confidence or mastery will prevent people from wanting to recommit to a shared world.

Another problem with such activities is that these subjective worlds are not pluralistic. Each world contains, unlike our shared world, inclusive and exclusive criteria. This stifles natality or the ability for anything new or poignant to arise. Natality is an event solely found in the *polis* where an individual creates a new activity. Limiting who can enter these worlds, there is little chance that new events or ideas will come into existence.

Arendt showed how many found comfort of political states and shirked the common world goal. The nation states were exclusive/inclusive as worlds and only allowed "citizens" into its folds. Nation states provided comfort because they existed solely due to man's creative ability to escape dealing with a common world. Those who entered felt a sense of unity despite all that was lost. Joining these worlds, labor became a political aspect and no longer were people striving to participate in politics. Instead, politics surrounded every avenue of their life.

Origins of Totalitarianism

Arendt's text, "Origins of Totalitarianism," created a historical and philosophical interpretation of how Europe became the fertile soil for the atrocities committed before and during WWII. Weaving her way through the 18th and 19th centuries, she sets the stage for the rise of the totalitarian regimes in Germany and the U.S.S.R. The insights from this text are legion, in that they reflect and analyze the structures that arose in the 20th century

and their implications upon individuals and history. These points of concern transcend the contemporaneous topic of her text (totalitarianism) and provide critical warnings for merging labor and politics. In *OoT*, she discusses the implications for a politics revolving around labor.

Totalitarianism arrived from a period of existential distrust of man qua man, she claims. Humanity could no longer trust itself as a superior being from the rest of the natural world. Worst of all, humanity could no longer trust its own world's comprehensibility. New worlds were created that could be comprehended and pacify man's mourning. The nation state's arrival came at a perfect time to save many from this crisis. A new world type would provide a foundation and comfort. Identifying with a nation state gave a new identity and a purpose for those who had felt purposeless.

At the summation of *OoT*, Arendt encapsulates the historical trends that provided some fuel for empowering totalitarian governments and reducing the individual's power with bureaucracy, imperialism and the creation of the superfluous. Bureaucratic power allowed people to remove themselves from the responsibility for individual behavior. Arendt credits bureaucratic methods with the power to shroud people from the "common world." They could escape from this world and retreat into a small and isolated world where their one goal was to accomplish "X." We can best describe this by using the example of an assembly line. Worker Y is to place a transistor into the same place on one thousand like items; Worker Z is to place a cord onto another part of one thousand like items. Neither worker has a stake in the product itself. Instead, they fixate upon the specific procedure they were assigned. With their job's accomplishment, a sense of safety

washes over the workers. This safety emanates from the fact that if something goes awry in the final product, odds are, it was neither their fault nor their responsibility. This argument, used to discount the sense of guilt, can be aptly entitled the “cog in the machine.” By being one small part of a large body, it was difficult to ascertain the blame’s actual location.

Although Arendt explores this idea heavily in *OoT*, the bureaucratic problem comes into focus in her text, “Eichmann in Jerusalem: The Banality of Evil.” Arendt witnessed the Israeli trial for Adolf Eichmann, the Nazi in charge of transporting people to the concentration camps, in the early 1960’s. Her analysis of Eichmann’s character indicated traditional “evil” did not move him towards becoming a harbinger of death and suffering. She saw that being a bureaucratic worker forced him into an alternate “uncommon world” where he saw himself as innocent. He specifically used language like “cog in the machine” to show his innocence despite his knowledge about the death camps. Ultimately, Arendt believed that he was guilty, not for the crimes charged by the Israeli state, but for finding safety in the bureaucratic assembly. It allowed him to forgo acknowledging responsibility for how his actions would affect the “real world.”

Totalitarianism’s rise resulted in two unique forms of purposelessness. Initially, it was salvation for some, and leads to devastation for others. Science’s ability to destroy the common-sense appearance of the world led humanity to scatter. Man no longer had an assurance that this world was, in fact, the real world. Coupled with rising capitalist mechanization, many felt purposeless. Not satisfied with being bureaucratic assembly line workers, some struck out to foreign lands: in particular, Arendt refers to the Boers

and to New World immigrants. The difference between the Boers and the New World immigrants was what world they joined. For instance, when the New World immigrants joined the U.S. they had a foundation or world from which to function. Whereas, those who went to Africa were met with a world that was, in a sense, foundationless to them. There was no tradition for them to rely upon, so the Boers created a new world where they created a mythos. (Arendt 1966) Their purpose was lost in Europe with no transcendental meaning in their lives, so when they arrived in Africa they created a purpose. According to Arendt, the world they found in Africa was tribal and reflected an absence of traditional authoritarian influences. Since Rome, authority and tradition had been a staple of European nations and without the established rules of Europe, the Boers felt that man was able to interpret himself. (Arendt 1968) The result was twofold: the Boers knew they had no authority to watch over them and they interpreted themselves as authority figures via a racially motivated ideology. As a result, we witness atrocities and a world creation's ability to harness the power to oppress.

I will call this positive superfluosity because this creates an empowerment for a group and establishes a specific-world for humanity. Its consequence, of course, is unsettling. It was this "finding" of new worlds which perpetuated many nation states' atrocities. The Boers found themselves in a position to oppress and forge an exclusive world. Civility, and opportunities for citizenship, existed with a group's exclusion from created worlds. Those on the outside were not welcomed and were not able to enter into positive relationships with those in the created worlds.

Superfluosity allowed some to find or create new worlds but for others it forced people out of the hegemonic worlds. Negative superfluosity refers to the position for the marginalized. In *OoT*, Arendt details negative superfluosity's genealogy as a warning for exclusion and believes the European Jewish people suffered from this fringe categorization the most. Excluding a group of people outside of a world is a common quality for totalitarian regimes. Consequentially, this exclusion removes access to the *polis* and political rights. Arendt's key example stems from the Jewish people's treatment during WWII. *OoT* moves the reader through the historical events which prompted the superfluous category that, in Europe, the Jewish people encountered. Social movements and laws stimulated the "reality" that left no place for the Jewish people.

Once Germany removed the rights of the Jewish people (property, individuality, and legal status), it, as a falsified "world", abdicated itself from responsible action towards that population. This action created a stateless and rightless group of people who were unable to access the world that was steadily consuming Europe. After the war, the newly founded United Nations disseminated the Human Rights doctrine to insure that this did not happen again. Its inability to protect those who became superfluous after this period has also become clear with the continuance of human rights violations.

The Power of Statehood

Michel Foucault proposed that the government's intervention into the body, or the medicalization of the body, culminates into a concept called biopower. Biopower can be

defined as a method for exerting control on the ways we perceive our body and what actions we are capable of enacting upon our bodies. (Rose 2007) When we exert this control via political systems, what results is the creation of the biopolitics. Biopolitics came to be “defined as a ‘power over life’, as the domination over life achieved through the control of the life process itself.” (Vetter 2005, 144) Foucault believed this controlling system began during the 17th century, when governments found that power over death was limited since death’s power could not be stored. (Foucault 1995)

Labor, on the other hand, could be collected and stored within the fixed industrialized complex. Knowing labor’s importance in nation-states, rulers “in alliance with many others, took on the task of the management of life in the name of the well-being of the population as a vital order and of each of its living subjects.” (Rose 2007, 52) Rulers chose to harness the overflow of mechanized labor created during this period through the industrial revolution. Therefore, new methods of control came into the government’s purview, including the prison system, the welfare system and most importantly for our discussion, the clinic.

I believe that, outside of Foucault’s proposed reasoning for biopower manifesting into governmental faculties, or biopolitical, there was another incentive for participation in these governments. The government ebbed into the vacuum left by the loss of place created by the Kantian and scientific rifts, and created a new identity for man as members of “the state.” Adhering to “the state” enabled the comfort of bureaucracy *and* provided new meaning for *this* world – state membership. Labor shifted to the forefront for its member’s lives, and with that paradigm shift, came a greater level of control. With labor’s new position, governments literally gained control over life and death.

Labor, which is properly located at the base of *ethos*, became forefront in politics and day-to-day living. By making labor political end goal, man's relegation to *animal laborans* and not a political being became the norm. Following the historical trends of this period, we begin to see how each totalitarian regime appears to have colluded with the new labor focused existence.

At the beginning of this period, around the 1850's, there is a shift in the Western world. Many individuals appeared to have lost their desire or power to access the Arendtian *polis* due to world alienation. Instead, their new goals, in collusion with the state's goals, included the following: increasing the number of state members; reducing the variation or difference between its members; and reducing the state non-member's rights or eliminating them.

To increase the number of state members, conquest became a priority. With imperialistic mechanisms, the largest nation-states gathered natural resources. During the mid-18th century to the 1930's, we witness an exceedingly large number of land battles. The Sino-Japanese War and conflicts in Manchuria, Alsace-Lorraine, and Czechoslovakia all resulted in the acquisition of land for one group or another. The natural resources acquired served to bolster the rate of proliferation, not only of those who would follow the conquering state's agenda, through conquest, but also fueled the propagation for members of the state. In 1900, the most aggressive states including Russia, Germany, and Japan³⁰ had enormous swells of population numbers; conquests and increase of agricultural capabilities account for the influx of citizens. The government succeeded in incorporating their agendas into conflicts that satisfied their

³⁰ Tacitus Historical Atlas: Each country represented from 1850, 1900, and 1939 respectively. Russia: (62,000,000 to 132,000,000 to 170,000,000) Germany: (35,300,000 to 56 million to 79.8), Japan: (28,000,000 to 42 million to 70 million)

consumptive natures and by convincing its citizens that it was the state's destiny to conquer others. Coupled with various biopolitical and public health appeals focused on population growth, these numbers drastically increased the state's members.

The second method used by the states to procure a large increase in members was unification efforts. Done by appealing to its members' historical sense, biological superiority, and nostalgia via myth making, nations created facts. With no "common world", there exist no points of contention. The greatest example is in Germany after WWI, when it slowly began to reclaim the Sudentland. Justifying its activities to glorify the Germanic people as Aryan overlords, it declared its "natural" claim over the conquered lands. The reinterpretations of the past pervaded Germany's philosophy, conflicts, and even its race relations in this mythical world.

Another result of participating in the state membership system is the state's denizens sought to remove differences. This, perhaps more than all other actions taken in the rise of the nation state, created an undesirable goal in any type of "standing –forth" or difference³¹ creating. The members³² of the state became subservient to the state rather than participants in it; thus, threatening the homogeneity resulted in placement outside of political activities.³³ Those attempting to operate within the historical ideas of politics (protest) were called "dissidents" and was used as a derogatory term for those standing in opposition to the state. Those who historically stand against the movement of any

³¹ Masses term refers to people who are inactive in the eventful discussions about the issues and who are content to be a part of the bureaucratic system. Difference creates a new type of person and allows one to be distinguished from the Masses.

³² Members although it doesn't quite capture the powerlessness of those living in the states. I will use citizen later in a far more positive manner.

³³ "Politics arises *between men*, and so quite outside of *man*. There is therefore no political substance. Politics arises in what lies *between men* and is established as relationships" (Arendt, 2005; 95)

government evoked a powerful feature found in the new nation-states: the creation of stateless individuals.

Arendt believes the inability to participate in the *polis* helped encourage the denigration or “beastialization” of man.³⁴ Once removed from the ability to be political, it becomes possible to treat him or her as sub-human. Consequently, this methodology was accomplished with negative superfluosity in the totalitarian systems. The marginalized were depicted as beasts or animals; this strengthened their exclusion from membership and allowed for their complete dissolution.

Thanopolitical Traits

Thanatopolitics resulted from man’s reduction to *animal laborans*.³⁵ Humans were no longer individuals but only as species members or, in the case of nation states, state members; all others were considered superfluous or hostile. Thanatopolitics, the politics of death, came into existence with the nation-states’ rise.³⁶ This includes the period from the early 18th century to the mid-20th century and includes World War I, World War II, and many other conflicts. The reasoning behind such an ominous title stems from its inordinate emphasis on managing the biological towards immateriality. Freud defined the phrase “Thanatos or death-drive” to refer to an individual’s movement

³⁴ Arendt concludes that totalitarianism became possible once political action was made to serve the *animal laborans*, rather than vice versa. (Biser 2006, 146) In addition, propaganda throughout history shows races depicted as inhuman. For instance, black people were depicted as apes.

³⁵ According to Foucault, totalitarianism is one potential outcome of the modern redirecting of politics towards species life. This is because the other side of a power over life is the power to let die; totalitarianism is one manifestation of the politics of death which is an always immanent potential of biopolitics. (Foucault, 1990, 138-139 (Vatter 2006, 144)

³⁶ Giorgio Agamben popularized thanatopolitics, the phrase, in his text, “Homo Sacer.” I encountered the phrase in my reading of Nikolas Rose.

towards death or inorganic status. (Freud 2004) In thanatopolitics, the power of the sovereign (government) “gained control over a specific territory” and power was “linked to the living bodies of its subjects.” (Rose 2007, 54) Because power was gained from its subjects, any who were not its subjects became expendable. As such, rather than allowing non-subjects to affect their government the non-subjects were reduced/eliminated via death. Elements of thanatopolitics still exist today in the activities of regimes in Africa, the Middle East and Eastern Europe. Yet, in the Western world, it has steadily disappeared.

Much like totalitarianism, this political system was a movement to a return to an earlier time that resulted in an ideal’s attempt to overtake a life’s value. In the case of thanatopolitics, a government that manages life and, it eventually moves towards the opposite of life. It merged rather cohesively into both the U.S.S.R. and Nazi Germany’s nationalistic eruptions and via propaganda, concentration camps, and gulags we recognize the move towards death.

The eugenics movement is a clear cause for thanatopolitical’s rise. By appealing to controlling the “health” of the population, members of the nation state could justify their government’s violent and fatal actions. As mentioned earlier, nation states were composed of membership that rejected difference and this difference removal was demanded. Along with the political leaders, the medical community was complicit in establishing the differences that warranted “cleansing.” People labeled as suffering from specific mental illnesses, varying race, or non-heterosexual proclivities were enemies of the state. Many nations followed the eugenic cleansing trend, including the U.S.A. As a

result, a large amount of distrust occurred, and still exists, between these “non-normative” individuals and the medical community

Only after the fact, when the world questioned what had actually occurred under these regimes, did thanatopolitics begin to fade away. The created world, introduced to the public world during the 18th and 19th century, was rejected because of its immoral position. Thanatopolitics was also untenable due to its rapid movement. When these nations ran out of categories to marginalize, there was no longer an enemy to target within its territory. As a result, a new biopolitical aspect arose. Without the harms and fears introduced by thanatopolitics, considered a form of biopolitics, our modern system would lack the knowledge for the consequences that follow thanatopolitics. (Rose 2006)

Zoepolitics and Modernity

The Nuremberg Trials and the assembly line-like mechanisms at thanatopolitics core showed some reasons why thanatopolitics could not establish itself permanently. Thanatopolitics and totalitarianism caused disorientation and death in their wake and, as a result, could not harness labor’s resources. The Nuremberg Trials attempted to reclaim individual accountability for behavior of the Masses in bureaucratic systems to no avail.³⁷ The consequences from World War II’s fallout, are heavily felt in many categories of our existence. One powerful impact was the death of thanatopolitics. Consequently, some elements remained.

³⁷ Masses term refers to people who are inactive in the eventful discussions about the issues and who are content to be a part of the bureaucratic system.

The untenable structure of thanatopolitics led to another form of politics: zoepolitics. The term stems from “*zoe*,” “the biological life shared by all living species” being coupled with various characteristics of totalitarianism or labor focused governing. (Vatter; 146) Zoepolitic’s distinction resides in its scope. Previously, government was limited in controlling the individual and the population. A shift towards the new form of biopolitics occurred when life began to be managed at the smallest level, or molecular, by political entities. Microbiology, genetics and pharmaceuticals began to permeate into political dialogue. Zoepolitics seeks to promote or enhance the human species through DNA, individual’s behavior, and even managing entire populations.

Thanatopolitic’s roots established so rapidly it consumed resources (people) far too fast for establishing any stability. Allowing itself to adapt, zoepolitics follows an economic approach and, consequently, flourishes. Zoepolitics leaves room for politics – certainly more than thanatopolitics -- due to its desire to inculcate rather than remove. Removing all political elements creates far too much unrest from the citizenry; however, the zoepolitical calculation leaves just enough to stymie the citizen’s sense of oppression.

Zoepolitics contains characteristics found in totalitarianism: imperialism, bureaucracy, and a superfluous population. Its imperialistic traits spread amongst bodies and ideas versus totalitarianism’s actual territorial and war-like struggles. Within the globalized world, there is little mobility for established nations to pursue other nation’s natural resources. Western world borders are arguably more definite now than ever before. Instead, there exists an ideological pressure to obtain consumers or physical

bodies for subjugation. Profit margins, the insured, and patients are some examples of zoepolitic's imperialistic successes.

Zoepolitic's superfluous capability creates the largest gap between it and thanatopolitics. Precisely, zoepolitics forces people into a homogenized group versus thanatopolitic's population removal from the world. Movement like this eliminates individuality by normalizing their existence and reducing them into a category sans a narrative ("whats"). Focusing on the biological makeup and attempting to increase its denizen's health instead their individuality conscripts the individual to zoepolitics.

Public health initiatives have an underlying focus on viewing people in a reductive method as statistics and demographics. The efforts for raising its citizen's health are akin to the eugenic movements in thanatopolitics. So, each individual can be broken down to demographics and statistics providing narrative without a real word from an individual. Stories, reduced to checked boxes and numbers, are irrelevant in zoepolitical activities because the system deciphers important information and categories without them.

With these tools (statistics, public health, etc.), zoepolitics enforces ideals and regulations on its citizen's bodies. (Thacker 2005) These sciences of the state allow for creating a mold for an ideal and healthy citizen. Rather than removing the unhealthy, like in thanatopolitics, zoepolitics attempts to lift them up. Zoepolitics, rather than eliminating difference through violence, does so through normalization. Using biological categorization, zoepolitics has a greater ability to include and then mute differences. We can witness this methodology be examining the steady inclusion of various groups (black,

Hispanic, LBGT) that has been occurring post-WWII. The public health field places an emphasis on the historically marginalized and makes an effort to raise their overall health status. Watching trends in public health provides indication in its focus on the various groups. For instance, post-1960's a focus was placed on African-American health and today with the focus on LBGT health an olive branch is extended to these populations. Zoepolitics accomplishes this effect through dialectical methods, that slowly diffuse marginalization and implements various categories of inclusion.

Bureaucratic entities dominate zoepolitical systems. Each group (HCPs, ethicists, federal agencies, medical insurers, and biotech groups) offers the diffusion of responsibilities for another group. This permits unmitigated killing in thanatopolitics but in zoepolitics provides shielding for "letting die." Differing from thanatopolitics, zoepolitics uses the shield of resource limitations to indicate its non-fault. Actively killing would consume far too many resources for any stability. Whereas, letting die enables the slow declination of the unhealthy.

Zoepolitical powers include lawmakers, and governmental agencies (FDA, NIH, or DHHS), biomedical companies, and the various experts that dominate the discussion of life itself. Moving autonomously is solely an appearance in bureaucracy. Each power participates in the cumulative system while perceiving an abstract position. These groups profit from the bureaucratic procedures that progressively encompassed Arendt's labor. This profiting allows various groups to represent and flow effortlessly from one bureaucratic entity to the other. We see this by examining the resumes of many higher-ranking experts who move from government agencies to biotech companies or vice-versa.

Data, Biology, and Doxa

Zoepolitic's inclusionary process can lead to an overall increase in personal and population based health assessments but, in the process, its efforts reduce personal meaning. Each year, zoepolitics gains momentum and defines more and more labor based activities including what food we have access to (for health reasons).³⁸ In the past two decades, our genetic information has fallen under its purview. The consequence that results from DTCGT's control by zoepolitical forces is twofold. (1) Confusion between the actual biological meanings for DTCGT's, or how they describe genes, and the informational meaning; (2) neither approach assists citizens who find personal meaning in their genetic makeup.

Eugene Thacker provides insight into how zoepolitics has interpreted the advent of genome-based testing. In his book, "The Global Genome," Thacker adds analysis about how the globalized system has convoluted genetic information as both a code – dry – and biological – wet. This categorization has affected the biological and medical perspectives held by many. (Thacker 2005)

Confined to the globalized zoepolitical perspective, genetic information is "disembedded", or removed from social relations and personal relations (Thacker 2005, 6) Once the interpretation is removed from a personal position, it becomes entrenched in a system that places its meaning upon the citizen. It becomes either data or something that is shared across biological multitudes and nothing else.

³⁸ Removing of trans fats and limiting the size of soft drinks are well-publicized examples.

Zoepolitics has thrived in handling genetic information by choosing which title suits genetic information at the appropriate time. When mapping the genome, scientists justified new computer based programs by saying “only computers can break the code.” This allowed the U.S. government, and biotech groups, to advance the software for genetic *de-coding* and hire programmers to create new systems for reducing the human genome into A,C,T, and G in the same way binary is used (1’s and 0’s).

On the other hand, placing genetic information as biologically meaningful has enabled zoepolitics to make it further impersonal. Rather than using experiential information, behavior becomes solely defined in biological terms – genes. This provides some continuation for the genetic determination fallacy as well. Genetic information becomes viewed as matter of fact. Our fate, and who we are, becomes susceptible to the biological condition of genetic makeup. Contrary to the extremely complex environmental-genetic interactions, the biological approach provided gives only meaning to labor based decisions – life, resources, and death. Zoepolitics’ deflection of personal meaning is an example of a historical conflict between the individual and the superstructure.

Laying the groundwork for explaining zoepolitics rise allows us to examine exactly how we can work from within such a system. Similar to individuals changing the legal system, an effort must be made to salvage the desirable and correct a wrong from within the system. In the next chapter, I hope to insert Arendt’s analysis and solutions into bioethics and how the citizenry can reclaim the “meaning” of genetic information.

Chapter 3: Exploring the New Human Condition

Introduction to Zoepolitics and DTCGT's Relationship

The DTCGT dialogue revolves around banning or funneling DTCGT access through zoepolitical powers. In this chapter, I will argue that removing citizens' capability to access these tests impedes people's freedom. Detailing the route towards zoepolitic's rise and Arendt's skepticism for biopolitical systems provides prospective for how DTCGT's regulation fits into modernity's infrastructures. Zoepolitic's hegemonic presence defines DTCGT's meaning and, therefore, overwhelms personal interpretation or *doxa*. Zoepolitic's expertise-based criteria prevent an individual from standing forth or accessing the political realm for promoting his/her own *doxa* in DTCGTs.

Zoepolitic's influence has allowed for progress in various arenas and has improved people's well-being in Western Civilization. These positive effects range from improved sanitation, advances in medicine, and many strides in public health. This progress provides enough justification to embrace its existence. There are innumerable other critiques against zoepolitics and its various mechanisms but my focus remains on providing access to DTCGT. I believe time for action is waning and has not accelerated beyond our control since legislation is still pending. Discussing continued access to DTCGTs is in hopes of salvaging this matter before it becomes a negative facet.

This project's end goal is the reconsideration of DTCGT as a tool for citizens. The utility of DTCGT for citizens trumps/outweighs the impetus within zoepolitics to ban or strictly regulate these technologies. Within zoepolitics, DTC genetic tests are a novel and emergent issue. DTC genetic tests lack the historical precedents compared to other

issues (e.g.; abortion, right to die, etc.), so they provide an opportunity for creating a novel and proactive ethical response. Therefore, seizing potential solutions now, with proper effort, can preserve zoepolitics' positive effects while empowering its citizenry.

In chapter 1, I explored the current DTCGT crisis by discussing the contemporary approach and where regulation appears to be headed. The three arguments from chapter 1 were that the government should not have a prohibitive role in DTCGTs; DTCGTs may provide a free-flowing and open structure for genetic information; and government interference reduces DTCGT's meaning to one that suits its own regulatory needs.³⁹

Chapter 2 traces the historical shift towards biopolitics and zoepolitics, or the politicization of every facet of life, ascension. This produces clarity for the modern regulatory system's creation. Arendt and Foucault's explanation would have fallen short without zoepolitics firmly establishing itself as reality. Using Arendt and Foucault was essential because they each provide insight into my focus – politics and the biomedical field. As a result, they each contain philosophical and historical descriptions for zoepolitic's arrival.

By placing it in the following contexts, we can begin to exculpate how Arendt's philosophy can provide a reasoning and solution to zoepolitics' methodological approach to DTCGTs. The following shifts are required to safeguard DTCGT access for the public. Further discussion in bioethics to empower individuals and allow their *doxa*, or the "it seems to me," to shape DTCGT's political meaning. From this emerges a new citizen type that uses Arendtian ideals to create a political role for citizens in zoepolitics. Lastly,

³⁹ Eugene Thacker's description of genetic information as data and biology applies here. Where genetic information can mean many things to many people, it is relegated to the aforementioned categories by the political world.

bioethicists and citizens are charged with managing the new political demands, safeguarding the public realm, and purposefully including other groups within zoepolitics.

Addressing Regulatory Issues

Arendt's concern about labor's governance or political focus stems from her belief that politics did/should not revolve around labor or our biological activities. With a focus on labor, a reduction in political activities occurs. Labor, which is consuming, leaves nothing behind; instead, labor consumes and exudes in a biological rhythm. Removing oneself from labor and participating in politics provides the chance to create something permanent⁴⁰ or memorable. Once political entities control labor-based items, the focus is no longer on creating stable or new objects. Instead, politics distributes labor based needs.

Arendt's text, "On Revolution" provides a powerful justification for the belief that labor and politics should not mix. (Arendt 1978) When discussing why the French Revolution was comparatively unsuccessful to the American Revolution, she notes the French Revolution's goals were labor-based. Americans focused on a political terminus, separation from the British Empire; however, the French infrastructure collapsed and France's citizens became concerned about provisions such as food and shelter. As a result, the French were happy to reward authority to one who could provide solutions for labor problems (Napoleon). In America, the result was a purposeful removal from an

⁴⁰ Arendt uses this term but the temporal value is more akin longer than one's lifespan.

authority and tyranny – evoking political terms such as liberty and freedom. However, in France, the new authority removed potential powers from the citizens.

Ultimately, Arendt hoped to show the consequences of labor being the focal point or that once politics is taken away citizens become true subjects of the state rather than vice-versa. DTCGTs removal from public access creates a barrier preventing the citizen from entering larger politics. Instead, the time and effort is funneled through zoepolitical elements.

Zoepolitics creates criteria (expertise, licenses, and degrees) for who can decide the test's importance and funnels informational access through Health Care Professionals (HCPs). These groups often proliferate that genetic information is solely data or biological underpinnings. (Thacker 2005) The FDA and others who restrict or ban DTCGT forces citizens to spend more time on the labor process and reduces citizen's subjective interpretation of genetic information to data/biology. The general populace's inability to obtain DTCGT access will likely result in these smaller problems: clinician visits, anxiety about unknown information, and a lack of educational resources as was described in Chapter 1. Without the citizen's input about DTCGT's meaning, the zoepolitical purpose for genetic tests remains the same – data and biology. As such, it becomes a bureaucratic or paternalistic determination that this can be regulated to manage or protect the citizens.

My protest against removing the citizenry from the DTCGT discussion is grounded in Arendt's *The Human Condition*. In this text, Arendt warns about embedding labor within politics and distinguishes man's condition as *zoon politikos*, or the political

animal. The Greeks, and Arendt, believed man was made to live in societies or amongst others. The term *zoon politikos* concedes man's status as animal and designates the "political" title as an essential aspect of being human. The result allows for a balance of politics while emphasizing our biological imperatives. Man, being unable to shirk his animal title, must seek to balance labor and his political presence.

The Role of Bioethics in DTCGT

Arendt, like many other philosophers, placed an emphasis on intermediaries between two systems.⁴¹ She believed citizens would remove themselves from the mundane world of labor and seek to become immortal through their actions in the *polis*, or the public sphere/political world. These empowered individuals enter the *polis* and, ideally, bring the *doxa* from two or more worlds. In my discussion, the two relevant worlds are policymaking and the citizenry, and one discipline is capable of representing the citizenry in policymaking in the *polis*: bioethics.

Bioethics combines issues of medicine with those of policy or regulation. Since DTCGTs emergence, bioethicists have often taken a stance against DTCGTs because of their potential harms and, as a result, neglected the possible importance to citizens. (Skirton et al 2012) Bioethics, succinctly defined, is "a discourse in which many people discuss, argue, and attempt to resolve perplexities into decisions and policies." (Jonsen 2001) As I have shown, the determination for who actually gets to participate in the

⁴¹ One common theme in philosophy is an adoration or exaltation for those who could access two worlds at once. Arendt specifically cites historical "exceptionals." (Disraeli and Rahel Vargannon) For instance, Deleuze speaks of sorcerers, Antonio Gramsci speaks of "the intellectual," and there are countless others. Each seems to represent an ideal form that balances analogues such as mind/body, man/woman, and intellectual/layman.

discussion is where the problem lies. It is imperative, when discussing DTCGTs, to include the bioethics field for its influence and capabilities.

Bioethicists could take two approaches to solve the DTCGT dilemma: (1) they can mold a permanent place for citizens in zoepolitical dialogue and (2) forcing *doxa* into the political discussion in DTCGT's regulation. These adjustments may allow bioethics to be useful for all and still function independently between two different worlds (zoepolitics and the citizenry).

Explaining briefly the origin of bioethics will clarify my suggestions for how bioethics can function as a finely honed mediator between zoepolitics and the citizenry. In the scramble during the post-modern period (particularly the 1970's and 1980's) medicine hit a new wall.⁴² Questions about how the newer medical technology should be used arose. Medical technology permitted new categories of people access to the biomedical world (engineers, device manufacturers, technicians). Contributing to the crisis of traditional medical questions, these new technologies enabled the medical world to alter life, extend life, or end life at unparalleled levels. The ability to redefine life extended into citizen's lives and created an ethical conundrum.⁴³ During this period, discussions resounded throughout academia, hospital hallways, and Congressional forums about biomedical issues. Those who felt they could provide insights into the medical world's difficulties were the forerunners of the professionalized bioethicists. Formerly working in applied ethics or in other disciplines (medicine, nursing, law, etc.),

⁴² I am referring to this period in this manner because in philosophical academia a shift was occurring that places an emphasis on the individual rebelling against pre-inscribed norms. Various schools of thought emerged that involved systems critiques that essentially stated the systems were inherently flawed and the individual held no alliance to them. (Deleuzian, Feminist, Marxist)

⁴³ Famous cases such as the Quinlan case and the limited resources found in dialysis machines are some examples of citizens being brought into the bioethical fray.

these specialists chose to focus on the biomedical issues; thus, turning bioethics into applied ethics of biomedical inquiries and not so much the “ethics of life” as its etymological roots imply. This category, bioethicist, grants an authority or expertise upon those in the field. Such a power allowed ethics and its purveyors to enter the biomedical world, political world, and the economic world with great confidence. As such, bioethicists have continually moved towards becoming a professionalized entity, which results in a reliance on expertise and zoepolitics for emerging policies. With more and more accreditations and professionalized groups coming to the forefront, the individuals who are present during policy-making can become elite.

How can bioethics assist in handling DTCGTs? This is an extremely difficult problem to analyze since bioethics exists, derives power, and resides in zoepolitics’ framework. When approaching the individual, via principles and other theories, actions are guided through individualistic approach in clinical ethics. Patients are provided adequate information and then choose of their own accord. Remaining silent or even when discussing DTCGTs, many bioethicists are allowing a paternalistic process to take control. The result is the individual approach is lost. The freedom to choose a course for immediate and clinically relevant actions is present. However, finding difficulty in acquiring your genetic information without a HCP shows a strange asymmetry; something that has a clear bearing on your health status, the clinical choice, provides more freedom than accessing genetic information.

Introducing Arendt’s term, representative thinking, we find an ideal middle ground between the citizen and zoepolitical trends. An effort to use this approach solidifies bioethics’ two ideal roles assisting the citizenship and influencing policy.

Representative thinking is an effort to “visit” the perspectives of others. (Biser 2002) Similar to empathy or placing the “Self in the Other,” Arendt describes its importance as making other’s *doxa* relevant. Never capable of displacing our entire existence and supplanting another’s existence, it allows impartiality to take place and *represent* other’s *doxa* despite our own private interests. (Biser 2010) Bioethics must use representative thinking to move towards an intermediary position when thinking through the DTCGT problem. Rather than relying on the pre-set meanings of genetics (data/biology), bioethicists should allow the variation found in citizen’s minds for genetics.

Brandishing expertise in various fields has allowed bioethicists to wield influence in the public. Perhaps the most famous bioethicist in the media, Art Caplan, has acquired a job working for MSNBC where his role is to notify the public of various bioethical conversations. While the discussions are generally cursory overviews, they often provoke dialogue that may inform the citizens’ *doxa*. The public bioethicists have a forum to influence the culture, politics, and individuals in their opinions and concerns. DTCGT discussion, and its possible prohibition, has taken place mostly outside of the public light. I charge that bioethicists should be concerned about the lack of public involvement in the DTCGT dialogue. Bioethics can create a position to connect citizens to zoepolitics by providing them gateways and educating them about zoepolitical concerns.

Pluralism versus Multiplicity

While some could perceive my opposition to DTCGT’s regulation as giving credence to the free-market system, in actuality, the business practices contain a part of the zoepolitical assemblage. The DTCGT business element also uses the pre-determined

and narrow meaning, data/biologic, found in zoepolitics. The other issues found in DTCGT's business market (accuracy, costs, etc.) are certainly problematic, and the similarity between the zoepolitical and business approach results in alike positions when approaching DTCGT's meaning.

When managing DTCGTs, both zoepolitics and business models entail the use of multiplicity. Henri Bergson described multiplicity in two ways: qualitative and quantitative (Bergson 1910). My focus will be on his description of quantitative multiplicity, since I contend that the quantitative is the method of approach for zoepolitics and businesses. Multiplicity creates an invocation of mathematics and reduces individual values/meanings. A well-described example involves Bergson's description of sheep:

When we look at a flock of sheep, what we notice is that they all look alike. Thus a quantitative multiplicity is always homogeneous. But also, we notice that we can enumerate the sheep, despite their homogeneity. We are able to enumerate them because each sheep is spatially separated from or juxtaposed to the others; in other words, each occupies a discernible spatial location. Therefore, quantitative multiplicities are homogeneous and spatial. Moreover, because a quantitative multiplicity is homogeneous, we can represent it with a symbol, for instance, a sum: "25." -- S.E.P. 2012

In short, quantitative multiplicity eliminates the idea of an actual individual and places no emphasis on the individual's action outside of an end number. While this reductive method can provide a strong foundation in criminal laws and statistics when discussing DTCGTs, it is overly reductive.

On the other hand, in a plurality, each individual's presence is meaningful and individually weighed. Plurality acknowledges individual distinction, allows for the individual's representation, and uses that representation to help guide actions. Arendt applauded this method of perception because pluralism is counter-reductive and gives a

locale for politics by being based on the *doxa* of many individuals. Existing in a common world, pluralism exists because the world is filled with people who share the common world.⁴⁴ With citizens providing *doxa*, absent in the DTCGT discussion, many items and experiences acquire unique meanings for people. In the vein of the DTCGT problem, the meaning reveals many forms of difference such as providing ease to a citizen who has a family history of cancer, or simply satiating another's curiosity about his/her genetic makeup.

Separating multiplicity from pluralism is imperative in discussing the difference between citizens and consumers/zoepolitics. Consumer and zoepolitical based perspectives of an individual entails multiplicity. Meanwhile citizenry, ideally, contains a pluralistic account. Economic analysis stems from the consumer's final action – purchasing or not purchasing the good -- that comes with its own problems and burdens. Currently when discussing an individual's right to access DTCGTs in the zoepolitical climate, only two meanings for genetic information is applied to its constituents – data/biology – but I contend it can have as many meanings as there are people. For some, DTCGT results can create a conflict in their racial identity, others may feel heightened pressure to monitor their health for their children. These points certainly matter more than the data or biology interpretations found in zoepolitics; and this negates the potential introduction of *doxa* to the DTCGT discussion and creates a reduction of the individual's meaning.

Zoepolitic's reduction of all citizens into "whats," necessarily goes against Arendtian politics and the staple of objective bioethics. Individuals' attempts to access

⁴⁴ "the fact that men, not Man, live and on earth and inhabit the world." (fn 138 HC)

DTCGT helps highlight the “who” as actors, while the test’s results simply describes the “what” they are. With stories and meaning providing motivation for acting, we can begin to see what moves others and gives individual’s *doxa* the accountability when discussing politics. The stories and meanings, when kept silent and stifled, are never introduced in the public world and, therefore, a reduction into “what” one is occurs.

Natality, Freedom and Bioethics

In THC, action is the most important element of *vita activa*. Action is panacea once an individual has entered the political realm. Arendt attributes action as the ultimate element of being human. Attempting to describe action as both an event and an activity, Arendt establishes the Grecian framework in THC to show how action was the culminating result of those who briefly “escaped” labor’s grasp.⁴⁵ Action occurs when one enters the public realm - *polis* - and distinguishes themselves from others. One does this through speech and acting in front of, and in concert, with others.

Arendt claims action was discarded by philosophers and political thinkers due to its unpredictability and that “it sets in motion processes that in their automatism look very much like natural processes, and action also makes the start of something, begins something new, seizes the initiative, or, in Kantian terms, forges its own chain.” (Arendt 1976, 115) Action creates momentum propelling itself forward with no guidance. Action ebbs through the world and elicits a domino effect carrying endless possibilities and

⁴⁵ Escape from labor was only temporary since all biological beings require labor, but political beings find reprieve from the ceaseless pursuit of labor. Arendt used the Athenian example of a man who was free to enter the polis where “freedom was understood to be the free man's status, which enabled him to move, to get away from home, to go out into the world and meet other people in deed and word.” (Arendt 1958, 148)

influence.⁴⁶ Unfortunately, action can also have a negative effect on people and the world.⁴⁷ For this reason, action was removed from humanity's tools by newer political forms and the philosophical tradition.⁴⁸

Freedom suffers with the rising importance of expertise and government agencies restricting the opportunities for action. Freedom to act is of great importance to Hannah Arendt's philosophy. Proof of freedom's declination comes from the DTCGT climate being so far along without citizen's input. Exemplifying Arendt's notion of freedom from her essay, "What is Freedom," (WF) we find a base for freedom and a new citizenry type. I must clarify, her freedom differs from classical ideas. She distinguishes between the two oft-referenced ideas of freedom, access to one's mind and unrestrained physical mobility, to her own meaning.⁴⁹

Arendt focuses on political freedom, which necessarily entails the ability to access the *polis*, being political and participating in "the miracle of freedom is inherent in its ability to make a beginning." (Arendt 1976, 115) She believed that there had been a purposeful shift in freedom's definition by philosophers, scientists and even politicians. Her claim is that freedom became an inward process for our thinking life rather than an event in the world. Forgoing freedom's usurped purpose, she harkens back to its original definition in order to be free politically.

⁴⁶ "Since action acts upon beings who are capable of their own actions, reaction, apart from being a response, is always a new action that strikes out on its own and affects others," (Arendt 1958, 190)

⁴⁷ Benedict Arnold is an example of someone who acted in a political way but was demonized. His action did not cause his derision and death but the politics involved with it did.

⁴⁸ Specifically, the post-Socratics gave an emphasis on controlling the political system.

⁴⁹ Every attempt to derive the concept of freedom from experiences in the political realm sounds strange and startling because all our theories in these matters are dominated by the notion that freedom is an attribute of will and thought much rather than of action. (Arendt 1978, 155)

Freedom, as a worldly pursuit, must occur to protect the potential for autonomous and “human” life. This can be applied to the issue of DCTGT. For example, without the ability to rewrite our life’s plans via readily accessing our genetic information, concerns about our bodily existence could dominate individuals’ minds. Relying on the HCP’s knowledge base, individuals have no choice but to use them for self-preservation and guidance. Furthermore, with DTCGT’s restriction, there is more reliance on HCPs for obtaining genetic information. The freedom lost reduces our ability to begin something new and places further burdens upon the citizen to participate in zoepolitics.

Zoepolitics burdens citizens by reducing them to somatic individuals (composed by their physical/biological existence) and placing the burden of “self-care” upon them. (Rose 2006) Health, perceived as a personal burden, is dictated as knowing, and acting, upon your medical knowledge. This imposes an ethical responsibility to enter the biomedical world upon citizens, forcing zoepolitics’ experts to overpower their freedoms. Rather than discussing or commenting on the political facets, the citizen follows the guidance found in zoepolitics – an established system – and does not participate in politics.

Left with an attempt to restructure the current biopolitical mode, we must try to salvage zoepolitics into a system that allows for natality. Natality will come from the ability for the populace to have individual voices heard. Natality, or the ability to begin something new, is a characteristic that humans acquire at birth. “Beginning.....is the supreme capacity of man; politically, it is identical with man's freedom. Initium ut esset homo creatus est -- 'that a beginning be made man was created' said Augustine. The beginning is guaranteed by each new birth; it is indeed every man." (Arendt 1976, 478-9)

Events were in motion before our births and shall continue after. The world is not a gift for the “I” but a gift from nowhere to “us.” Acknowledging worldliness’s vicissitudes, or its being not made for one, can come from embracing the limits of our biology. While our genetic code is inarguably unique at the molecular level⁵⁰ and creates a “newness” of the biological kind, it is not sufficient for telling our tale or disclosing “who” we are. Only in the *polis* can this disclosure happen.

Though the potential for natality erupts with each new birth, action and freedom’s existence need to be in place. Natality results from action, and without freedom there would be no action. Natality, ultimately, would be what Arendt would describe as “human-ness.” A trait found in all of us, “it is the freedom of life, and because it is the condition for the selfhood on the human being and the history of its self-initiated actions”. (Biser 2010, 146) By creating the “new,” we exist in the public realm and disclose our “who.” The difficulty and danger of natality lies in its reliance on action’s unpredictability.⁵¹ One can inspire many people through displaying one’s self in politics and, hopefully, with authenticity that provides a “new” way of seeing the world. Coupled with representative thinking, political decisions in Arendt’s system are made with an emphasis on novelty and “care” for a common world.

DTCGT provides the opportunity for citizens to embrace natality for several reasons. Primarily, our genetic information begins to provide the boundaries for “what” we are. We compare ourselves to others by our facticity, which refers to the given status of our existence or emergence in the shared world, includes our physical makeup, social

⁵⁰ Outside of monozygotic twins.

⁵¹ "Since action acts upon beings who are capable of their own actions, reaction, apart from being a response, is always a new action that strikes out on its own and affects others," (Arendt 1958, 190)

status, parents, etc. All of these traits come with simply being born. Establishing “what” we are enters us into various categories that, while relevant, do not encapsulate our existence. It is these elements that we *cannot* escape because they create the understanding that this world, in which we are born anew, came before and will continue past our existence.

Our genetic information is unique, though not that different from some of our closest primate ancestors, and exists only in us. Despite this fact, we must require a shift from perceiving our genetic code so narrowly. Our genes tell a unique story and it should be our right to read from the story’s text. With DTCGT, the elements of our existence, the “what,” can better be fleshed out and can prepare us for how we can step beyond the “what” and provide a “who.” Knowing risks can alter what battles one chooses to participate in and gives credence to the personal meaning behind our genes. For example, with knowledge about cancer risk, individuals can step beyond general screening and become an advocate for funding more cancer research. Those who have access to genetic clinical testing can obtain this information far more readily; those who do not have clinical testing access are left with DTCGT as their only option. Though the genetic information provides a “what,” in terms of what risks threaten one’s biological life, this information transgresses to a political life. It, as it always has, takes an effort to be political and to stand forth from the “what” and in modernity it is no different.

Freedom as a worldly pursuit must occur to protect the potential for autonomy and a political life. Without the ability to rewrite our life’s plans via accessing certain health information, we may abandon the common world and focus only on a personal world. Withdrawing to the confines of the mind (*vita contemplative*) or creating new

worlds for comfort can have dire consequences for the common world as discussed in Chapter 2.

Zoepolitics differs from previous forms of labor-focused politics because politics *can* still happen.⁵² Preferring expertise, and not relying on creating superfluous categories, like thanatopolitics, permits non-denizens to create many public spaces for political activities. Zoepolitics, in differing itself from thanatopolitics, ostracizes in a far less lethal matter by forcing an expertise criterion before anyone can access the world of zoepolitics. Without the power of expertise, the weight of one's *doxa* is reduced or not allowed into the zoepolitical realm. The internet and other tools allow for public forums from which politics can catalyze. New lines of flight from zoepolitic's biological reduction arise in the public spaces that distinguish people from being solely biological beings.

The Burden of Accessing the Polis

When discussing DTCGT, it becomes clear that the various groups that have genetic diseases, biosocieties, or those who are fearful of specific genetic ailments, have no real access to the *polis* for DTCGT. Without this opportunity, their *doxa* remains uninvolved in the *polis*. Public discussions are dominated by expertise, studies, and data with not enough citizenry or bioethicists coming forth to demand an assessment via other means.

⁵² "Political action, in so far as it intensifies the condition of natality, is to be understood exclusively in terms of the freeing of life, and in opposition to the totalitarian attempt to dominate biological life by dehumanizing it, that is, by eliminating its singularity." (Biser 2010, 157)

Using a dialectical approach, zoepolitics slowly brings other categories of people, or “whats”, into its fold.⁵³ Using a Hegelian dialectical helps provide insight into how a system can attain a “cyclical” method of acceptance. For instance, since the HIV crisis in the 1980’s public health initiatives including homosexual men have taken place. These practices help attain new information and allow some form of representation in zoepolitics. AIDS Coalition to Unleash Power (ACT UP) shows a key example in how representation can be gained. During the late 1980’s, with public protests, ACT UP “forced” themselves into the zoepolitical discussion. At the outset, the homosexual populace was marginalized and perceived as outside of normative health care issues, their health needs were neglected. With ACT UP’s activism, zoepolitics began to acknowledge this population. As a result, zoepolitics could find no justification for the population’s marginalization and the process of inclusion begins. I contend that the homosexual community is becoming closer to being “accepted” into zoepolitics completely.

What potentially comes from the dialectical discussion is “what” one is versus “who.” The one-size fits all approach certainly has its merits for allocating public health resources. In fact, bioethicists can assist in the demarginalization process. Once recognized as not having access to the *polis*, a liaison (active citizen or bioethicist) must come forward to provide a prototype for the demarginalized in the *polis*. Once this “exceptional” has stepped forth, then the accumulation of Arendtian power, “the ability for humans to act in concert,” can reduce the time needed for demarginalization. (Arendt

⁵³“At each stage, then, consciousness recovers the alien, incorporates it into itself, understands that it is not actually alien at all, but an expression of its own nature. Because only the subject can supply meaning to the object, there is *no object without a subject*. Wherever consciousness looks, it sees nothing but *itself*. Absolute knowledge is the stage in which nothing is any longer alien to the subject, where there is no more discrepancy between the knower and the known. (Melchart 2009, 362)

1976, 143) With a single individual cultivating his/her own courage, an imprint is made where a single person moves from a “what” to a “who.” This shift, to the “who,” forces a reassessment of others who previously were held to be “what”-only. The risk of courage comes with the risk of failure. At times, the system disregards those exceptional individuals and they, and many others, are left in the “what” category; this is the consequence of Arendt’s action and the misfortune it can provide as well.

The expectation that individuals can procure rapid and forward moving change within zoepolitics is difficult to imagine. Occasionally, large paradigm shifts do occur yet for the sake of preserving much of the good that zoepolitics has wrought, my emphasis lies on opening and maintaining the *polis*.⁵⁴ In preserving the *polis*, the dialectical mechanism needs to become a tool for active citizenry and bioethicists. The *polis* is established as a locale where *all* are equals upon entering it. It then becomes an ethical imperative for bioethics, in particular, to bring the non-represented into the *polis* for equality.

An example of this slow inclusion at work can be found in the American legal system. Its steady shifts commonly occur from within its own system by those who are “at home” within the system. For instance, when two laws contradict each other, the court must take context into account. Was one law created to target a specific population? Is the law constitutionally sound or antiquated? These questions are then used, potentially, to alter the legal system. Until someone takes the burden of adjusting/destroying the law within the system, the law remains.

⁵⁴ One such shift was in the transition from thanatopolitics to zoepolitics.

While not all systems are plastic, there necessarily remain rule sets within most systems that promote inner change. In the vein of Arendt's work, she notes a stellar example in Norway during World War II. (Arendt 1963)After the Nazis had created negative superfluosness⁵⁵ in the German-Jewish population, many fled to Norway for asylum. When the German bureaucratic mechanism arrived to reclaim the German Jews and bring them to extermination camps, they met with a strange resistance from the Norwegian people. Unlike many of the other countries conquered by the Nazis, the Norwegian government used the bureaucratic system against the Nazis by questioning their claim to the Jewish refugees. The principles used to deprive many rights from the refugees shielded them from being exported to the concentration camps. Citizenry, and its bureaucratic importance, was used to counter the violence of the Nazi regime by forming a group of Norwegian citizens with one unified cause: rebellion.

Arendt specifically warns about retreating from the world by "world-creation" or the mind's expanse. The consequences have been displayed with her analysis on totalitarianism. Her other main concern resides in the consequences of the loss of a common world: the destruction of the *polis*. Zoepolitics has removed the shared world experience by reducing "the common worlds" meaning by focusing on labor's elements. The result is others decide an item's importance, like DTCGT. According to Arendt's system, the citizen, and not zoepolitics, should determine who gets DTCGT access and importance. Yet, the citizen still exists within zoepolitical confines. We can "think without banisters" as Arendt suggests but we cannot move without the common world's barriers.

⁵⁵ This negative superfluosness' was described in chapter 2 as a tool for marginalization.

It takes immense courage to enter the polis for a citizen. Sparked by finding an intense meaning, the active citizen earns that title by entering the *polis*. The “who” results from our activities in the *polis* and is out of the actor’s control even despite their greatest effort.⁵⁶ Historians, storytellers, or any other witnesses who describe the acts of the active citizenry subsume it and attempt to guide it.

Courage, being the virtue exemplar, has always existed – even in the darkest eras of humanity. Removing the *poli* has not stymied the capability to speak or historian’s interests. What does occur, and substantially separates zoepolitics from thanatopolitics, is the value of life. Life could be de-marginalized within thanatopolitics that death could easily be a result. In zoepolitics, life, in particular, the active life holds great value. Thus, courage can thrive and active citizenry can act.

Courage alone allows anyone to use DTCGTs. Courage allows the individual to explore the future found, or only possibly found, in one’s genetic information. Abound with potential burdens, DTCGT can give insight for what struggles may lay ahead. It also forces the somatic responsibility to be accepted as consequence. Some may do nothing with their genetic data, while others find enough meaning to become active citizens. The active citizenry’s courage assures the continuation of the *polis*. It requires courage even to leave the protective security of our four walls and enter the public realm, not because of particular dangers, which may lie in wait for us but because we have arrived in a system that concerns itself with our bare lives or our “whats.” (Arendt 1976, 156)

⁵⁶ Courage, which we still believe to be indispensable for political action, and which Churchill once called “the first of human qualities, because it is the quality which guarantees all others,” does not gratify our individual sense of vitality but is demanded of us by the very nature of the public realm. (Arendt 1976, 156)

The federal government has debated banning DTCGTs for some time. With no assurances, or public dialogue, regarding their banning, will there be enough time for active citizenry and bioethics to gather? If a plan to ban or require a HCP's intervention comes into effect, would it be reversible? What will action's unpredictability yield if DTCGT's are continually accessible? Will the momentum needed to stop the government intervention lead to an increased quality and accuracy of test? Politics is many things – including a gamble. The promise DTCGTs provides, access to our genetic code, warrants an effort on all fronts to allow access to them.

Active Citizenry

In order to counter zoepolitic's momentum and influence, a new type of citizen must emerge. Active citizenry is appropriate because citizenship is something that we can be "given" through our birth within the borders of a country. To be active entails an attempt to proceed past the pre-determined "what." In activity, there comes the opportunity for action. Motivation for the citizen to become active, due to the need to represent *doxa* relevant to them, can often result in political activity.

Although citizens cannot interject themselves easily into zoepolitics, they can insert their *doxa* when they acquire a certain level of expertise and/or amass power by working with others. This expertise is one powerful quality of active citizenry because their expertise has direct meaning to them. Active citizenry exudes a responsibility and knowledge "about the disease and applying it to him or herself, with the aim of optimizing health and improving quality of life." (Rose 2006, 128) The disparity,

between the inert expertise of zoepolitics and those who have anecdotal/lived experience, may provide a personal expertise and a deeper meaning in political decisions.

Anecdotal meaning carries similar problems as action in its unpredictability. An example is the *post hoc* arguments found correlating autism or other disorders to vaccines. After receiving a vaccination, some families found their child had manifested autistic behavior. Using the argument that “before the vaccine their child was fine” does not give credence to vaccines causing autism.

Parents who have a child affected by a disease can be great representatives for minors in the zoepolitical schema. Taking the role of active citizens despite not having the disease, they form entities that may disrupt the status quo by joining other parents or those stricken like their children. These groups, called biosocialities, create new “*poli*” where politics can happen. This term is used by Paul Rabinow to “characterize forms of collectivization organized around the commonality of a shared somatic or genetic status”. (Rose 2006, 134) Exchanging *doxa* within the biosocial confines encourages those whose lives are affected by diseases to share “who” they are outside of their disease status or their biological identity. In addition, working within these groups there can be purposeful direction for their activities. Moving together, an effort can be made to support access to DTCGTs because of citizen’s desire to create life plans and the desire to have a say in political decisions. Maintaining DTCGT access allows other battles that the citizen wishes to fight.⁵⁷ Allowing for an exchange of freedom, the creation of a new life plan

⁵⁷ Political institutions, no matter how well or how badly designed depend for continued existence upon acting men; their conservation is achieved by the same means that brought them into being. (Arendt 1976, 153)

and accessing their biological information is an imperative for the bioethicists to insure completion of their role.

Creation of a common world using DTCGT and active citizenry will occur via acknowledging the flaws or difference found in *everyone's* genetic information. Once accepted, the struggles of others may make significantly more sense. Active citizenry needs a consistent engagement with other elements of the biomedical community since politics does not simply cease. Gaining assistance of other political beings creates a system of compromise that is necessary when sharing a world and assists in handling other new problems that may arise.

Active citizenry must move purposely when approaching zoepolitical topics. In the case of DTCGT, placing pressure on the manufacturers to raise their standards may release some of the tension between the companies and the Federal government. Alone, not purchasing a company's products will result in the multiplicity judgment (x amount of people versus supplying an individual's reasoning). The activity of openly protesting one's issues with this company's DTCGT because of its inaccuracy, cost, advertising, etc., will provide a story and put pluralism into consideration. It also displays a responsibility in the citizenry towards determining its own fate and access to DTCGT.

DTCGT Revolution

Exploring Arendt's work culminates into what I would describe her "call-to-arms" involving political crises. Purposely applying her thoughts helps in describing not only how we have arrived at our current positions but also the importance of recognizing pivotal moments. Her poignant analysis tracks historical instances, theorizes the

instances' origins, and provides warnings e.g.; totalitarianism and zoepolitics. The present crisis, the impending legislation regarding DTCGTs, plagues the bioethical world since "a bioethical problem is a problem that must be resolved at a certain time and place." (Jonsen 2001) Waiting is not an option. Using Arendt's ideas described prior (representative thinking, action, and freedom), we come to what I would describe as a harmonization moment.

I believe harmonization is the true spirit of bioethics. An interdisciplinary field that allows in clinicians, academics, and many others to enter into bioethical discussions in hopes that viable solutions will be found. With one goal being to fuse the two worlds, citizens and zoepolitics, its power depends on timing and bringing these worlds together. This final element (harmonization) can result in bringing forth the "new", individual's *doxa*, and creating something stable, the *polis*. It is precisely this activity, creating new and stable items in the world, which explains Arendt's glorification of the American Revolution.

As mentioned earlier, the juxtaposition between the French and the American revolutions fell between labor and political activity. With the French Revolution, labor allowed for a great loss in freedom (Napoleon), whereas, excluding the following white landowning privileges, Arendt saw the success of the American Revolution in its political focus. My contestation is if citizens lose the right to DTCGT, which appears to be the impending action, then it becomes a labor-based struggle. The right to access would have to be reconquered and then honed to be more finely tuned (regulating the quality, safety, etc.). By placing the rights permanently in the hands of the citizens, we allow for rights and, as a result, DTCGT to be managed on the proper end. Similar to the American

Revolution, which placed Arendt's freedom into the colonists hands, shows that there has been a deliberate act towards a founding freedom. (Arendt 1976, 216) Ultimately, I am calling for the zoepolitical interpretation of genetic information to change in hopes of capturing the diverse meaning behind genetic information.

Finally, can bioethics manage the responsibility of being the "council" while not overreaching and impeding the citizen's rights? It has to. The bioethical problem, and a manageable solution, depends on the ability for those in the middle ground to practice representative thinking while introducing citizens to the *polis*.

Addressing Gaps and Concerns

Handling plurality is the greatest struggle that arises in true democratic societies. In true democracies, complications arise from so many people being represented. This can create a standstill in political movement. Many people pulling in different directions burdens political progress. My argument, that each individual's *doxa* carries relevance when discussing DTCGTs, can certainly problematize the political machine. A form of political dissonance may occur when too many people exist in the *polis*.

The world has limited resources and, as such, too many people demanding from the political system will be met with the oppressive weight of "public relations men." Arendt claims that during the 1960's the advertisers, or lobbyists, were harmless and that Senate was to guard "against the transient moods and trends of society at large." (Arendt 1972) Yet, the lobbyist's influence undeniably increased while society's influence has remained the same. Biomedical agencies hire and lobby for their own cause in the political world at the expense of the citizenry's power.

The concern becomes, again, how can the individual “stand forth” in our current political structure? “Grass roots” movements or a small local group, at first, who share some concerns or *doxa* and, in time, create a network on a larger scale to address the problems they have chosen to represent. In the modern age, the internet facilitates our interactions. Various groups have acquired influence through internet groups for health care concerns or support groups for parents of children who are ill.

In more concrete regulatory mechanisms, we find that there remains a difficulty in altering these agencies. Currently, there are calls for “open commentary” where accumulated opinions are examined by the regulatory bodies. The problem with this mechanism is twofold: there is no way to measure the actual impact that the opinions hold in these commentaries and behind closed doors the final decisions are made.

The tests themselves are a large part of the problem in the regulatory system’s purview. This issue may need to be parsed out before the regulatory net will be loosened. One possible way for the test quality to improve, outside of economic pressures, is for a powerful call by various active citizens. Removing the title of consumers, the citizenry can openly denounce the product and bring the problems into the *polis*. With enough boisterous demands, the odds a business will respond becomes far more likely. At times, the forceful citizen can create a powerful enough case to prompt government action. The perfect example is Ralph Nader’s demands on the auto industry that put seatbelt laws into effect in the 1960’s. His book, “Unsafe at Any Speed,” along with his political pressure resulted in the beginning of the safety movement that forced automobile manufacturers to have safety requirements.

Another key problem of using Arendt's work stems from its reliance upon the Grecian structure. There are numerous ways to critique her use of the Greek structure but the problems that most relate to using the ancient Greeks is how exclusive the system was and the discussion of an escape from labor. By only allowing the wealthy elite to enter their politics, it is difficult to reconcile this system in modernity. With the rise of capitalism and introducing a true simulation of the Greek system, we would be forced to co-opt a plutocracy.

Arendt specifically chose to focus on narrow historical movements and certain traits for her points. The Greek example from THC and the American forefathers in "On Revolution," provide little attention to the slavery problem, or that both populations thrived off conquered individual's domination for their aristocracies/freedom's existence. Accounting for *every* individual is important in my theory but Arendt's efforts focused on political philosophy and not ethics.⁵⁸

Defining exactly who will be able to remove themselves from labor enough to participate in the DTCGT discussion is another Greek element that demands attention. The Greeks had to exploit populations in order to focus on having a political life. Purposely degrading labor, the Greek citizens established their entire system towards a focus on politics. While accessing politics was ideal in the Greek system, in modernity labor is so intertwined with politics that I contend we all already are able to access politics or that the system forces us to focus on labor. Zoepolitics enforces a specific merging of political life and life itself; this differentiates the life of the ancient Grecian

⁵⁸ Arendt was in the process of creating a text on her ethical viewpoint before her death. The notes and drafts are found in "The Life of the Mind."

and that of modern man. While the ancient's political system refused to focus on labor, ours forces a focus on labor.

Arendt's contempt for a labor-focused politics relied on using the Greek system and for human nature to be unshifting. Arendt purposely avoids describing human nature and yet her focus on the "human condition" entails qualifiers for what it is to be human. Her focus on modes of human existence (how we are to live and how we should not live) results in a definition of what it means to be "human." Using the Greeks as a template results in a temporal pause for human nature and describes it as a static entity.

Ultimately, the current DTCGT arguments by zoepolitical agents demand non-traditional approaches. The common ethical language of rights, principles, and calculi are inadequate solutions to handle DTCGTs. Allowing for other's *doxa* to enter the political realm, promulgates a freedom and spurs citizens into action. Arendt provides new insight for possible solutions and addresses justification for permitting DTCGT's use.

Conclusion

The government's efforts are en route to extinguishing pathways for citizens to acquire their own genetic information. Its legislative attempts would not appear so heavy-handed if the discussion was brought to the citizenry. Arendt's work strives to introduce ways to reclaim the political world for its denizens. Her work also provides insight into why the decision to prohibit DTCGT came about (zoepolitics) and how best to counter it. Bioethicists and HCPs have the ability to bring the discussion to the people and begin empowering citizens. Once the citizenry is involved, solutions that are far more palatable appear.

We will hear the Supreme Court's decision about companies' right to patent genetic markers this summer. This conflict arose because these patents prevent other businesses from profiting or even researching these markers. A shared thread is that public discussion about the use of genetic information remains sorely absent from the impending decision. The issue becomes particularly problematized by the fact that the government and businesses, foregoing citizens' input, to resolve each issue. Hopefully, unlike the fight for patenting genes, DTCGT access is settled by the "people" rather than in the Justice's chambers.

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