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ORIGINAL PAPER

Direct-to-Consumer Genetic Testing and Its Marketing: Emergent Ethical and Public Policy Implications

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Abstract
This paper provides a marketing ethics analysis that addresses the practice of selling genetic tests (GT) directly to the consumer (DTC). It details the complexity of this emergent sector by articulating the panoply of evolving ethical/social questions raised by this development. It advances the conversation about DTC genetic testing by reviewing the business and healthcare literature concerning this topic and by laying out the inherent ethical complications for consumers, marketers, and regulators. It also points to several possible public and company policy adjustments. Because this area is relatively new and incredibly dynamic, its current discussion is necessarily an exercise in the "logic of discovery" rather than the "protocol of validation". The paper serves as a primer for the types of GT being promoted. It also calls for a public discourse in the academic and general community to uncover and define the ethical guidelines and systemic adjustments necessary to create fairness in the various DTC transactions occurring between genetic test sellers and the buyers/clients of their services.

Keywords Genetic testing (GT) · Direct-to-consumer (DTC) · Marketing ethics · Medical marketing ethics · Public policy and regulation

Introduction

As described in our Abstract, this paper is mainly about the ethics of marketing Direct-to-Consumer (DTC) genetic tests (GTs). It is descriptive of the genetic test environment, and identifies the main risks and public policy issues raised by DTC GT. Further, it provides a three-step ethical analysis that allows formulating some preliminary recommendations for managers and public policy decision makers. Importantly, the manuscript tries to spark a public discourse among DTC GT companies' main stakeholders; it also tries to instigate a societal dialogue desperately needed to tackle some of the thorniest ethical challenges raised by this new business practice.

Despite the enormous complexities in accurately inferring practical and/or clinically useful information from a person's genetic code, the accessibility and marketing of genetic tests (GTs) has been exponentially on the rise (Liu and Pearson 2008; Taylor et al. 2006; Phillips et al. 2018; Delbanco 2018). The global DTC genetic testing market is forecast to grow steadily and to be worth over US$1billion by 2020 (Global Market Insights 2019; Friend et al. 2018) and more than $4 billion by 2025 (PR Newswire 2017). One of the main key drivers of this phenomenal growth has been the dramatic cost/price reduction of testing (Eissenberg 2017; Webborn et al. 2015; Regaldo 2018). While it cost $2.7billion to sequence the first whole human genome, completed in 2001, the price-tag now is less than $2000 and continues to fall (Phillips 2016).

Worldwide, at least 250 companies offer customers DNA tests via mail and/or internet promising everything from locating their ancestors, living healthier lives, finding the right diet, lowering their chances of developing cancer, and discovering their true talents (Friend et al. 2018; Krimsky and Johnston 2017). A typical DTC GT business transaction spans across different jurisdictions, where data collection,

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data storage, and data analysis are often located in different countries. In most cases, the consumer orders the tests online, the private testing company ships a sample collection kit (e.g., buccal, swab, or blood), and the consumer sends back the sample. The company performs the analysis and provides a test report, sometimes including the raw data, via Internet or mail (Krimsky and Johnston 2017). However, most of the claims made by DTC GT companies go unquestioned by outside reviewers (Nelson and Robinson 2014), unregulated by governmental institutions, and unchecked by ethical considerations. Therefore, a meaningful societal dialogue about the use and abuse of DTC GT is still in its infancy, even as it is desperately needed.

In order to contribute to this dialogue, the primary objectives of this paper are to (1) provide an overview of state-of-the-art DTC GT by integrating a slice of the business and health/medical literature on the topic, (2) describe the type of tests offered and their potential impact for consumers and society, (3) briefly analyze these issues from an ethical perspective with the overarching goal to stimulate societal dialogue about the benefits and perils of DTC GT, and (4) offer consumer-centric, ethics focused, suggestions to companies and regulators.

Genetic Testing: What Genes Can and Cannot Tell

While the DNA code was thought to contain the secrets of life, currently, almost two decades after the code has been deciphered in a more than three-billion-dollar international collaborative effort known as the Human Genome Project, it becomes clear that the idea of DNA as a blueprint of life is far too simplistic (Carey 2012). Most of the time, health and disease result from the interplay between genes and environmental factors such as exposure to toxins, nutrition, and behavior—i.e., nature and nurture (Radetzki et al 2003; Klug et al. 2019). An individual's observable characteristics and traits the individual's phenotype—are not only determined by her genetic information encoded in DNA—i.e., the individual's genotype—but also by inherited epigenetic factors,[1] and non-inherited environmental factors. Thus, even individuals with the same genotype, such as identical twins, do not have completely identical characteristics and traits (Carey 2012; Curran 2019).

As it is true for other medical tests, genetic test results are only analytically valid if the sensitivity[2]—the ability of the test to correctly identify those patients *with* the genetic marker in question—and specificity[3]—the ability of the test to correctly identify those patients *without* the genetic marker in question—are known (Lalkhen and McCluskey 2008). Beyond analytical validity a genetic test also should be clinically valid. That is, a test result should correspond with an observable trait, disease, or disease susceptibility (McPherson 2006). Finally, *clinical utility* refers to the usefulness of a test. Genetic tests that accurately predict the presence of a genetic infliction are analytically and clinically valid but might be of limited use in cases where there is no prevention and no cure. For example, Walker (2007) showed that most patients at risk of inheriting Huntington's disease—a slowly progressive neurodegenerative movement disorder with cognitive /behavioral impairment for which there is no cure or known prevention—feel there is no point in getting tested (Walker 2007).

As will be discussed below, many, if not most, tests available on the DTC market do not meet high standards for analytical and clinical validity. Nonetheless, many DTC GT companies use the language of science for their marketing (Schaper and Schicktanz 2018). Further, numerous DTC GT companies promote their products in a way that leads consumers to *overestimate* the clinical utility, that is, the usefulness of their tests (Burke 2004). Thus, as will be elaborated below, much of the promise and premise of DTC GT is based on shaky foundations.

DTC Genetic Testing in the Academic Literature

Business Literature

Despite the tremendous growth rate of the DTC GT market and its uncertain advantages/disadvantages for consumers, there are limited discussions of GT in the academic *business* literature (see "Appendix" section). A search of two popular and comprehensive databases for business journals (ABI Inform and Business Source Elite) using various search terms such as "Direct to Consumer and Genetic Test(ing)" or "Genetic Test(ing) and Consumers" was undertaken. The

[1] Epigenetics refers to genes being switched "on or off" as a response to environmental factors (Rothstein 2013). Those modified gene expressions can be passed on to future generations (Carey 2012; Klug et al. 2019).

[2] To illustrate: A sensitivity of 80% means that the test detected 80% of people with the condition but 20% did not get detected. However, sensitivity does not say anything about how many people had a positive test result but don't have the condition.

[3] To illustrate: A specificity of 80% means that the test detected 80% of people who do not have the condition but (falsely) identified 20% as positive who do not have the condition. However, specificity says nothing about the probability of false positive tests.

search was confined to peer-reviewed journals and search terms appearing in the abstract and/or title and/or key words. After accounting for a considerable overlap between the two databases, the search revealed (only) a total of 39 articles. Of those 39 articles, only three (discussed in "Appendix" section) appeared in core business journals with two of those more than 10 years old. The remaining 36 articles have been published in journals of other disciplines such as Health/Medical, Sociology, Law, and Computer Sciences. In general, this suggests that current academic analysis of GT *in business* is incomplete and additional evaluation of DTC GT is clearly necessary.

The marketing of prescription drugs directly to consumers is in some ways related to the issues of DTC GT (Liu and Pearson 2008). Perhaps unsurprisingly, since this practice has been around since the 1980s (FDA 2020), it has been discussed in much more depth in the business literature than DTC GT. Overall, it is recognized that DTC advertising of pharmaceuticals comes with potential benefits to consumers but it is not without perils and challenges, which often have been addressed through regulation (Liu et al. 2020; Ball 2018; Biegler 2014; Van de Pol and de Bakker 2010; Auton 2004; Calfee 2002). However, this body of literature does not capture many of the issues specific to DTC GT. DTC of medical genetic tests is quite different since consumers can only obtain pharmaceuticals—even when they are advertised with consumers as targets—through a licensed physician. Thus, unlike DTC GT, there is still oversight from a medical professional.

Online diagnosis of medical conditions is another related field which has been discussed—albeit to a much lesser degree—in the business literature. Interestingly, while telemedical diagnosis offers great potential, consumer adoption has been slower than expected (Swan et al. 2019) and according to a study in the U.S., consumers prefer to use telemedicine with their own doctor with whom they have an established relationship (Welch et al. 2017).

Medical/Health Literature

Interestingly, while there is a dearth of academic discussion in business journals, DTC GT is more broadly featured in the *medical/health* literature. Using the same search terms and filters, a query on PubMed—the largest worldwide database for health- and medical-related journals (with more than 29 million references)—yielded 418 articles. Again, see "Appendix" section for additional information.

Eighty-one articles specifically investigated ethical aspects of GT. The need for an ethical analysis is hardly surprising, given the multitude of problematic issues germane to DTC GT (discussed further below). This is in line with Covolo and colleagues (2015) who found in their review of original studies pertaining to the DTC GTs market that negative effects on consumers have yet to be dissected. They observed, *"Online companies offer genetic testing lacking scientific evidence, no proven clinical utility, and misleading marketing claims"* (Covolo et al 2015, p. 2).

While the vast majority of articles appeared in medical journals, the phenomenon of GT, by its very nature, is inherently cross-disciplinary (e.g., Nelson and Robinson 2014).

Types of Direct-to-Consumer Genetic Tests

Before addressing a menu of ethical issues inherent in DTC GT marketing, we provide some basic background about the types of tests being promoted to the public by GT sellers. In general DTC companies provide both medical and non-medical tests. While medical tests, which are usually also available through a physician, aim to provide *medical* information, non-medical tests are supposed to be informatively recreational (Vorhaus 2010). Clearly, as discussed below, the dual availability of medical GTs has been creating many new challenges.

Ancestry

Perhaps the greatest impetus of increased demand for GT stems from growing consumer interest in knowing their heritage via so-called "ancestry tests" (Regaldo 2018). More than one in three DTC genetic tests fall in this category (Phillips 2016). Ancestry tests by companies such as *Ancestry* and *23andMe* use an inexpensive DNA chip to retain around a million measurements of a person's genome, which in turn provides a clue about what (global) region people's ancestors are from and helps to locate family members, including distant cousins (Regaldo 2018). In general, these tests rely on each company's proprietary database of the ancestry markers of people living in different geographic regions. That is, since our ancestors are dead, these tests rely on a comparison of a consumer's genetic information with the DNA of contemporary populations living in those regions (Krimsky and Johnston 2017; Duster 2009).

Relatedness

Relatedness testing can be used to discover or verify familial relationships, especially paternity. The most common "relatedness tests" are performed by companies such as *Who'z the Daddy?, Test Country*, or *Gensys*. While only some of the offered tests are admissible in court, all of them may reveal results with disruptive social effect. This is especially true if the test is performed without the informed consent of the person whose DNA is being analyzed. Some companies specifically offer 'infidelity' tests and encourage customers to send in samples such as hair or fingernails from relatives/

friends without their knowledge. This type of sample collection by individual consumers also poses a substantial risk of sample contamination or misuse (Phillips 2016).

Nutrigenetic

The general idea of these tests is to provide dietary recommendations based a customer's genetic makeup. Some DTC genetic testing sellers' use (and abuse?) their nutrigenetic tests to "up-sell". That is, the results of nutrigenetic testing are often used to sell other related services such as tailored diet plans for better sports performance, food supplements, as well as meal and training protocols. However, the overwhelming majority of these tests have no scientific basis, which means their validity has to be questioned (Webborn et al. 2015). Some examples of companies are: *My Gene Diet* (Natures Remedies Ltd), *Smart DNA*, *Inherent Health*, *Halo Health*, and *Gene Planet* (Phillips 2016).

Talent and Athletic Ability

These tests promise to uncover one's athletic potential. Often, companies such as Genetic Sports Performance and DNA Fit also offer additional services such as customized training plans. Further, some companies specifically promise to predict a child's talents and character traits. For example, the company *Mapmygene* advertises on its website: "*The purpose of the Inborn Talent Genetic Test is to provide you the knowledge you need to thrive in life. When you are equipped with knowledge detailing your strengths and weaknesses, you know exactly what to work on without going through the painful trial and error"* (Mapmygene.com 2019). However, most of these tests have low or even no clinical validity at all. Further, the results of these tests offer little practical utility (Phillips 2016).

Prenatal Tests

In traditional prenatal testing, which is done during pregnancy, genetic information is used to either screen for or diagnose a birth defect. The goal of traditional prenatal GT is to help physicians to initiate early treatment and/or to provide expectant parents with information to make informed choices and decisions. However, tests are on the horizon that will reveal the entirety of a fetus's genetic code using only a blood sample from the expecting mother and a drop of saliva from the father (Klug et al. 2019). Prenatal "whole-genome" sequencing will provide volumes of information beyond the currently available tests for genetic disorders such as Down's syndrome or Tay-Sachs disease (Scientific American 2013). DTC tests increasingly go way beyond testing for known genetic defects and offer information about likely physical traits such as height and physical strength of the offspring. In these cases, the line between medical and non-medical testing becomes blurry.

Diagnostic Tests

Traditionally, medical GT for adults is used to confirm a diagnosis when a particular condition is suspected based on physical signs and symptoms. These tests identify rare variants in a single gene that causes a disorder such as Huntington's disease. Usually, the result of these tests is deterministic. That is, these tests show (with near certainty) that a person either has or does not have the disorder in question (NHGRI 2019). Importantly, most diseases are not caused by variants in a single gene.

Predictive and pre-symptomatic types of testing are used to detect gene mutations associated with disorders that may appear after birth, often later in life. These tests identify mutations that increase a person's risk of developing disorders with a genetic basis, such as certain types of cancer (NHGRI 2019). Instead of getting tests reactively, (for example) on a doctor's orders, people can use diagnostic data proactively to help make decisions about their own health (Torkamani and Topol 2018).

Typically, a hundred or more changes in genetic letters collectively indicate the risk of common diseases like heart attack, diabetes, or prostate cancer. Tests for these types of changes have recently become possible, and they produce what is known as a "polygenic" risk score. Polygenic risk scores (PRS), in contrast to traditional tests, are on a spectrum of probability from very low risk to very high risk. However, PRSs do not determine that a person will develop the disease. They only can provide a *probability*. The bigger the database, the more predictive power these tests have.

While the results of these tests may be useful in decisions about lifestyle and healthcare, the cost–benefit of such an approach is debatable. And once these data are in the system of GT companies, there are ramifications for their usage in setting health insurance rates for individuals (Nill et al. 2017).

Personalized Medicine

Personalized medicine is the tailoring of medical treatment to a specific subset of patients who are usually identified by genetic markers (Newman and Freitag 2011). The general idea is to use a patient's genetic information to determine which drugs work best for this individual patient. One estimate suggests that about 55 percent of drugs consumed in the United States are not effective (Mintz 2009). While patients still have to deal with the side effects of the ineffective drugs they are taking, there is also a considerable economic cost for such unwarranted or "wasted" care. In the

USA, the cost of ineffective drugs is estimated to be higher than $250 billion annually (Newman and Freitag 2011).

Statin drugs are a good case study in this regard. They are widely used, even though 95% of the people taking them have not had heart disease or stroke and may get no clinical benefit aside from a lower cholesterol reading. One can secure a polygenic risk score (PRS) to reduce unnecessary statin use. If one is in the top 20% of PRS for heart attack, such folks are more than twice as likely to benefit from statins as persons in the bottom 20%, but such "at-risk" parties can also benefit greatly from improving their lifestyle—not smoking, exercising more, eating more vegetables. So, knowing one's PRS might cause people to take statins but also make some needed lifestyle changes (Torkamani and Topol 2018).

Carrier Testing

Carrier testing is used to find people who "carry" a change in a gene that is linked to a specific disease. Carriers may show no signs of the disease; however, they have the ability to pass on the gene change to their children, who then may develop the disease or become carriers themselves (NHGRI 2019). Thus, the main purpose of carrier testing is to assist patients with their [future] reproductive decision-making (Phillips 2016).

Current Regulation of DTC Genetic Testing

As pointed out in the classic writings of Preston and Post (1975) on public policy, comprehensive regulation is the surest path to providing constraints upon negative market outcomes that impact society. However, in complex and emergent market sectors, the path to ample institutionalized oversight is typically slow. Not surprisingly, the pace of advancement in sequencing and genotyping technology has far exceeded the pace of related regulation. Not much has changed since Berg and Fryer-Edwards's (2008) analysis (see "Appendix" section). DTC testing is still poorly regulated with no worldwide agreement (Webborn et al. 2015). In Europe, legislation varies from country to country. For example, while there is no specific regulation in the United Kingdom, Belgium, and Italy, GT is only allowed under medical supervision in France, Germany, Portugal, and Switzerland. The online availability of DTC GTs has the obvious potential to circumvent local oversights.

Since there is no comprehensive federal regulatory framework in the U.S., DTC GT is often regulated by state law. Many states have developed their own regulations, which range from generally prohibiting DTC testing to largely allowing it. This patchwork of different state laws and regulations is cumbersome for companies and, at best, unhelpful for consumers trying to assess the validity and quality of tests being promoted. Below, we briefly review (in a U.S. context) the patchwork of regulatory oversight that might be applied to DTC GT and its marketing.

As is true for all advertisements, GT ads are subject to the U.S. Federal Trade Commission general principles of truthful advertising (FTC 1984). However, while the FTC has the authority to regulate false advertising and misleading claims, it so far has *not* taken any action to regulate the opaque market for DTC GT (Nelson and Robinson 2014).

The Clinical Laboratories Improvement Act (CLIA) of 1988, which requires federal certification of laboratories that offer tests to diagnose, prevent, or treat diseases, only applies to a small percentage of DTC genetic tests. Further, the CLIA only assures *analytical* validity (i.e., how accurately a particular gene sequence has been decoded) and does not address *clinical* validity (i.e., how a particular gene sequence is linked to the disease or trait the test claims to address) (Nelson and Robinson 2014; Solberg 2009; Hudson et al. 2007). Thus, the CLIA is of little help in comprehensively regulating the DTC market.

Relatedly, the U.S. Food and Drug Administration (FDA) has the authority to regulate drugs, medical devices, and laboratory developed tests. Thus, in the USA, DTC genetic tests potentially fall under the general purview of the FDA (Javitt 2007). In 2017, "the U.S. Food and Drug Administration allowed marketing of 23andMe Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions. These are the first direct-to-consumer (DTC) tests authorized by the FDA" (FDA 2017).

Furthermore, in 2018 the FDA exempted Genetic Health Risk Assessment Devices (such as genetic tests) from premarket review. The exemption is limited to a genetic health risk assessment system that has received a first-time FDA marketing authorization (e.g., 510(k) clearance) for the genetic health risk assessment (Florko 2017). Accordingly, once a company gets marketing authorization for their system, the agency would exempt from premarket review all 'in vitro' tests marketed to consumers for detecting genetic risk of developing a disease. As it happened, for better or worse, by entering early into dialogue with the FDA, *23andMe* contributed to shaping the regulatory landscape rather than reacting to it (Friend et al. 2018; Nelson and Robinson 2014). Arguably, the small number of tests offered by *23andMe* that got FDA approval could help to legitimize the company's other tests with consumers. In other words, consumers might be misled to assume that all of the company's tests are valid (clinically/analytically) as well as being reliable. Interestingly, while the FDA requires advertisements of prescription drugs to provide true and balanced information, including the mandatory disclosure of the drugs' harmful effects, there is no such regulation for the marketing of GTs (FDA 2020; Liu and Pearson 2008).

Finally, in the USA, the Genetic Information Non-discrimination Act (GINA) of 2008 provides customers with some level of comfort by disallowing GT results from impacting health insurance policies and employment (Nill et al. 2018). However, the law does not cover life insurance, long-term care insurance, or disability insurance (Friend et al. 2018). Many DNA testing companies such as *Color Genomics*, *Counsyl*, and *InformedDNA* partner with major health plans (Delbanco 2018) and the cross-availability of such information could prove costly (via increased insurance premiums) for some consumers.

The common use of 'wrap contracts' to govern transactions (i.e., the purchase of a genetic test) between consumer and company exemplifies another problem of regulatory oversight. Wrap agreements normally require the consumer to scroll through the document and then signal their agreement with "terms of contract" by clicking a button (typically labeled "I agree"). However, most consumers never understand or even read the conditions of the contract they sign.

Further, many consumers purchasing tests often contractually permit sending their biological samples overseas. Consequently, their genetic information and other personal information are often processed, stored, and shared in other countries. This data flow is borderless and, thus, it may prove naïve to focus only on national level regulation (Phillips 2016). For example, if genetic information is stored and processed by branches of the company (or its service contractors) residing in another country, the initial privacy agreement of the customer may become subject to a different legal jurisdiction, i.e., a different set of laws and regulations (Friend et al. 2018).

The inherent multifaceted nature of genetic tests does not easily allow putting them in preexisting regulatory categories. While some companies keep insisting that their tests are non-medical and recreational, others argue that consumers should have the right to have access to their genetic information free from government constraint (Vorhaus 2010). The confusion over the categorical boundaries of DTC genetic tests, the widespread interest of consumers in unencumbered access to their genetic information, and business distaste for federal regulation has so far prevented federal agencies from coming up with a comprehensive regulatory framework to protect consumers.

A summary conclusion from the above discussion is this: There is minimal regulation over DTC GT sellers. There are also numerous reasons why global regulatory oversight is needed but the obstacles to multifaceted regulations, as hinted above and below, are many, complex and (in the short-term) perhaps overwhelming.

Ethical Analysis of Direct-to-Consumer Genetic Testing

The overarching goal of the following ethical analysis of DTC GT is to provide valuable guidance for regulators and, more importantly, instigate a constructive dialogue in the business community and broader society. Further, without a comprehensive or effective set of public policies in place to temper the DTC GT segment, the *ethical* aptitudes and practices of individual company managers have a greater (and arguably determining) role in assuring fairness to consumers.

Without guidance, what is ethical to one marketer might be unethical to another marketing manager. In an effort to increase the transparency and applicability of our approach, we introduce a nested three-step model. If the GT and its marketing practices in question passes the first step, the analysis moves on the second, and finally to the third:

1 Do benefits exceed potential drawbacks and risks for the majority of consumers?
2 Is it in accordance with current laws and regulations as well as basic industry standards set forth by the American Marketing Association (AMA) (AMA 1984; 1988) and the American Medical Association (2020a)?
3 Are the most vulnerable clients more disadvantaged by how the GT is marketed and conducted?

This first step is clearly based on a classical utilitarian analysis. While a utilitarian calculus is never devoid of subjectivity and measurement problems (Hunt and Vitell 1986), it still might provide suitable insights, which can further the debate about the ethicality and usefulness of DTC GTs.

The second step draws on the values expressed by American Marketing Association's Statement on Ethics (AMA 1984; 1988): Honesty; Transparency; Trust (foster trust in the marketing system); Respect (Do no harm and acknowledge the basic human dignity of all stakeholders) and existing governmental regulations (as discussed in the previous section). However, our analysis is also grounded in bioethics, since many of the issues raised by DTC GT—specifically GTs providing medical information—relate to this field. The National Institute of Health NIH defines bioethics as "the study of ethical, social, and legal issues that arise in biomedicine and biomedical research" (NIH 2020). Bioethical problems have been dissected utilizing "standard" moral philosophy with the addition of particular examples applying to medicine or biology (Mappes and DeGrazia 2006; Pence 2007). Accordingly, our analysis is partly based on the values propagated by the American

Medical Association (2020). Specifically, this Statement calls for *Non-maleficence*—the duty to provide information and to help patients understand their medical condition and options for treatment; enable patients to participate meaningfully in decisions about health care. Further, our analysis is also informed by the American Medical Association's commentary on Direct-to-Consumer Advertisement of Prescription Drugs (AMA 2020b).

The third step (i.e., special consideration for the vulnerable) is based on John Rawls' *difference principle* (1971). Social and economic inequalities are to be arranged so that they are both (a) to the greatest benefit of the least advantaged, consistent with the savings principle, and (b) attached to offices and positions open to all under conditions of fair equality of opportunity".

In the following section, we analyze the emergent ethical problems in DTC Genetic Tests and their marketing, illuminating the specific issues and consequences that may arise from its various manifestations. The issues are loosely grouped from "least concerning and overall beneficial" to "most concerning and overall detrimental".

Issue 1: DTC GT to Empower Consumers

It is often emphasized by DTC companies that their tests might lead to empowerment of their customers. Few primary care physicians are comfortable prescribing genetic tests and giving genetic counseling, an area they are usually not trained in (Berg and Fryer-Edwards 2008; Liu and Pearson 2008). By selling genetic tests directly to the public, the accessibility of these tests is increased. DTC GT eliminates the hassle of scheduling a doctor's appointment and spending time in the doctor's office. The customer gets direct control over her own genetic information (Nordgren 2014). Therefore, DTC testing reflects a power shift in the consumer–doctor relationship. That is, DTC tests might lead to consumer empowerment understood as the ability of individuals or groups to take control of their circumstances and exercise power (Schaper and Schicktanz 2018). Clearly, from the standpoint of utilitarian ethics, consumer empowerment is a positive benefit of GT and its marketing. Thus, this practice passes our first ethical test. Further, it is in line with the values propagated by the American Marketing Association and the American Medical Association (our second ethical test), and does not violate John Rawls' difference principle (our third ethical test). However, true empowerment requires customers to be able understand the basic advantages and disadvantages of GT. As discussed below, exaggerating and misinterpreting these elements in DTC information provided to the public in an effort to sell more tests does create moral pitfalls.

Issue 2: DTC GT to Improve Health and Encourage Early Treatment

This is a primary argument often brought forward by proponents of [currently] unregulated DTC testing. But the benefit of improved health and early treatment applies only to medical testing and its variants. As discussed, genetic information can provide a polygenetic risk score (PRS) indicating the probability of developing certain diseases. This information can be used to make positive lifestyle changes that lower the risks revealed by the polygenetic risk score. For example, if a person finds out she/he has a higher chance of cardiovascular disease, she/he might start eating healthier and exercising more. Gordon et al. (2011) and Green and Farahany (2014) found in their studies that participants who have a reasonable understanding of genomic risk information are inclined to initiate behavioral changes. However, other studies show that most people might not significantly change their behavior as a consequence of having genetic risk information (Eissenberg 2017; Carere et al. 2015; Boelt et al. 2014; Marteau et al. 2010; Schaper and Schicktanz 2018).

It is well known that the chances of curing many diseases such as cancers improve with early detection. The benefit of early detection potentially extends to relatives of a DTC GT customer who might become alerted to an important genetic condition and seek early intervention for themselves (Eissenberg 2017). Also, the *marketing* activities of DTC GT companies raise the public awareness of genetic tests and inflictions. Since the predictive power of genetic tests increases with the size of the data it is based on, if more people get tested, the size of genetic databases increases. In turn, there will be more scientific progress from using the information of gene technology, which is beneficial to everybody including prospective patients.

Such advantages (regardless if consumers take advantage of them or not) do *not* evoke obvious ethical concerns. Indeed, improving health and medically beneficial scientific progress are certainly in line with the utilitarian mantra of the greatest happiness of the greatest number, the AMA, and the American Medical Association. However, the poorest members of society may not able to take advantage of this opportunity since they cannot afford DTC genetic tests. This is likely true despite the dramatic price decrease in the last decade. Therefore, arguably, a policy supporting unregulated medical GT might not pass our third ethical test (John Rawls' second principle to arrange economic inequalities to the greatest benefit of the least advantaged) and (at minimum) raise questions of distributive justice.

Issue 3: GT to Define Personal Identity

DTC testing might help customers to better define their personal identity (Nordgren 2014, 2008). This is specifically

relevant for ancestry testing. The customer learns about her ethnic background and origin, which potentially leads to a feeling of belongingness and identity. On the surface, there does not seem to be much of an ethical problem with providing people with this kind of information. However, as discussed below, even the largest DTC databases are generally not very representative of indigenous population groups or minorities in general (Eveleth 2015). As a consequence, these groups—while paying the same price for the tests as everybody else—get less useful information in return. Arguably, this outcome, which provides the least benefits to some of the historically least advantaged groups is neither in line with the AMA's propagated value of trust nor with Rawls' second principle.

Sometimes a person may find out unexpected information about her origins, which may have a significant impact on how she defines her personal identity (Phillips 2016). For some people, this information is unwelcome and might cause stress. For example, many indigenous tribes in the U.S. have their own cultural histories that explain their origins. Having a scientist come in from the outside telling them where they are "really from" might be perceived as threatening (Eveleth 2015).

Issue 4: Reliability and Clinical Validity of GT Data

Many of the currently available tests on the market (internet or elsewhere) are not very reliable (Korthals and Komduur 2010). The U.S. Government Accountability Office (GAO) found that samples of DNA from the same people, which were sent under different names and to different laboratories, yielded different genetic results for the same individual (GAO 2010). The GAO concluded "*the fact that different companies, using the same samples, predict different directions of risk is telling and is important"* (GAO 2010, p. 2). For another example, Tandy-Connor and colleagues found in their study that, *"40% of variants in a variety of genes reported in DTC raw data were false positives"* (Tandy-Connor et al. 2018). A false positive can instill severe fear in consumers (for example if it indicates a high chance of developing breast cancer) and may lead to expensive and unpleasant but unnecessary follow-up tests.

Clearly, companies do not only have a legal obligation—CLIA regulation in the U.S—, but also an *ethical duty* to ensure the analytical validity and reliability of their tests. Specifically, for medical tests, which—as pointed out in the example above—pose a significant risk of causing harm, the ethical principle of non-maleficence applies—"First, do no harm". However, a lack of reliability also negatively affects non-medical tests such as ancestry or relatedness. For example, if a customer is wrongly identified as someone she is not, this presents a significant ethical issue.

There are no generally accepted guidelines for DTC companies concerning the *clinical validity* of genetic test data (i.e., how a particular gene sequence is linked to disease or specific personal traits). The offered tests are too often ineffective at measuring exactly what they purport to measure (Webborn et al. 2015). A report from the U.S. Government Accountability Office (GAO) found that many test results were misleading and did not measure what they claimed they would (GAO 2010).

Clinical validity or the lack of thereof becomes a major ethical issue if companies mislead consumers by making false promises. In this case, the benefits of misleading customers clearly do not outweigh its cost. Thus, this practice is in violation of our first ethical test. Further, deception is undoubtedly not in accordance with the AMA's values of honesty and transparency, our second ethical test. Finally, if such exaggerated promotional claims are egregious, they certainly could reach the legal threshold for "false and misleading advertising" (FTC 1984).

Issue 5: The Problem of Equal Access to GT

The majority of genetic studies have been performed in populations of European ancestry (Torkamani and Topol 2018). For example, out of more than 160,000 genomes, only 3 percent of *23andMe* customers who authorized their data for the study were black, compared with the approximately 14 percent of the United States population who identifies as such (Eveleth 2015). Polygenetic predictions might not apply to people with different ethnic backgrounds other than European. That is, "many effects, tested on European populations, may not be generalized to other populations" (Korthals and Komduur 2010, p. 439). For example, Kido and colleagues found in their study using DNA samples of Japanese consumers that some of the disease risk prediction offered by DTC companies was not accurate (Kido et al. 2013).

Taking a global perspective and realizing that "the greatest number of people" are not of European ancestry, such database usage may not be in accordance with a utilitarian perspective. Building an ethnically skewed database is likely neither in line with the AMA's value respect nor the Rawlsian fairness principles. Thus, as suggested by Kido and colleges (2013), the development of a universal core database for non-Caucasian samples will be important for achieving better medical outcomes for people of non-European decent and, by doing so, for avoiding ethical concerns.

Issue 6: The Specter of Discrimination via GT

Documented cases of genetic discrimination are relatively rare and gene technology did not lead to the emergence of a social underclass of carriers of bad genes (Zwart 2015; Hall

and Rich 2000). However, this might be more due to laws and regulations prohibiting the use of genetic information in health insurance and employment than due to people's antipathy towards discrimination. Indeed, as humanity has a long and unfortunate history of overemphasizing racial differences and using these real or imagined differences to discriminate against people of other ethnic origins, DTC GT focusing on ethnic origins might propel further racial divisions (Phillips 2016; Popovsky 2010). Genetic tests have been (ab)used to explain a difference in behavior or intelligence between races. For example, Nobel prizewinning geneticist James Watson publicly (and controversially) argued that "there's a difference on the average between blacks and whites on I.Q. tests. I would say the difference is… genetic" (Harmon 2019, p. 4).

From an ethical perspective, it is not the genetic information per se that is of concern but its racially motivated misinterpretation. Instead of denying genetic differences among people of different ethnic decent—which, as discussed above, could severely backfire as in building ethnically skewed databases—companies and regulators could focus more on providing clear and easily understandable information about the danger of race-related extrapolations based on GT. In this era of heightened "identity politics" along with the social movement to secure tolerance for all, *possibly* racially bias GT information is problematic. Unqualified use of GT information no doubt is not in line with the AMA's value of acknowledging the basic human dignity of all stakeholders.

Issue 7: Parental Reactions to Genetic Tests

Parents might guide their children academically and/or push them in a specific athletic direction based on talent tests. Since, at present, these tests cannot provide any useful information that goes beyond mild entertainment (Phillips 2016), doing so is likely to cause more harm than benefits and is not in line with the AMA value of respect.

Another potentially even more worrisome issue arises from prenatal tests. *Should parental response to pregnancy be based on genetic information about the offspring?* This debate is not new (and has supporters on both sides). Parents have been using genetic information to potentially end a pregnancy after they find out that their child will almost with certainty suffer from a terrible disease such as Down's syndrome. What is new is that DTC genetic tests potentially provide information—unrelated to devastating diseases—about many aspects of a child's future physical conditions such as height and strength. This new information about the unborn child available to parents adds a whole new ethical dimension to this discussion.

Further, the company *23andMe* has been awarded a patent for a computational method that allows prediction of likely traits of their offspring using the parent's DNA (before conception). The method can be used for screening sperm and ova for Invitro Fertilization (Klug et al. 2019). Thus, such technology can potentially be (ab)used to create "designer babies".

The information provided by these new and emergent tests could undoubtedly be used in an unethical way. This begs the question whether the information obtained is the issue *or* the purpose it has been obtained for is the issue. In other words, if the information were not available to begin with, people could not abuse it. At the same time, if people acted ethically and responsibly, the information would be harmless. An ethical dialogue seems desperately needed to inform regulators, businesses, and consumers about these new ethical challenges brought on by DTC prenatal testing. At the very least, companies and regulators could further this dialogue by informing the public of these new technological possibilities and their ramifications. From the standpoint of transactional justice (i.e., Rawlsian "justice as fairness"), consumers are owed *all* relevant information by sellers that affects the exchange.

Issue 8: Unpredictable Psychological Impact of GT on Consumers

Learning about one's own genetic impairments can be highly distressing since, given the current state of technology, a person's genes can only be altered in a handful of conditions (Friend et al. 2018; Sobel and Cowan 2003). Thus, genetic risk information is likely to make some people feel anxious or fatalistic or might give others a false sense of security (Torkamani and Topol 2018; Hudson et al. 2007; Burke et al. 2002). For example, Dohany et al. (2012) showed in line with older research (Bredart et al. 2001) that consumers who bought genetic tests online without the involvement of a doctor experienced anxiety and distress if they tested positive for BRCA (a genetic marker for breast cancer). Further, DTC marketing campaigns may increase anxiety by exploiting consumers' emotional concerns (Miron-Shatz et al. 2014; Gollust et al. 2002).

The danger of causing psychological distress has often been used by the proponents for banning DTC GT (Lippi et al. 2011; Liu and Pearson 2008). However, overall, the current literature suggests there is little evidence for lasting psychological harm caused by DTC genetic tests (Eissenberg 2017; Schaper and Schicktanz 2018; Green and Farahany 2014; Nordgren 2014; Bloss et al. 2011). Further, some companies work collaboratively with genetic counseling services to counteract potentially detrimental psychological impact of their tests. For example, *23andMe* advises its customers to seek counseling with the service *InformedDNA* (Friend et al. 2018). Certainly, such services would add considerable cost to the full evaluation process of GT results.

Since causing emotional distress constitutes a violation of the American Medical Association's ethical duty of non-maleficence and the AMA's value of respect (Do no harm and acknowledge the basic human dignity of all stakeholders), companies should proactively help consumers in this respect. Beyond the advice to seek genetic counseling, this might also entail informing consumers about the potential psychological dangers before a test is ordered. One way to do this would be to have customers sign (even electronically) an informed consent form. Whether such a solution would be treated dismissively by consumers, like most privacy agreements on websites, is an issue worthy of empirical investigation.

Issue 9: Uninformative, Misleading, and Deceptive Ads for GT

It is not surprising to find some cases of outright deception and fraud among consumer companies. The DTC GT industry is no exception. While deceptive and fraudulent marketing is certainly unethical, it is not new or unique to the DTC GT industry.

A potentially new form of deceptive advertising is employed by some DTC GT companies that take advantage of consumers' trust in the medical community. That is, consumers might easily get confused when DTC companies create the allusion of engaging in a medical communication when, in reality, they use the same persuasive methods to sell their tests that are common in consumer marketing. For example, while most consumers are aware that companies use "puffery" to sell their products, they are less aware of such persuasions when nudged into believing that a DTC company provides unambiguous scientific information (Schaper and Schicktanz 2018). In other words, the information provided by DTC sometimes creates the allusion of medical legitimacy. This is a clear violation of the norm of Trust that all Marketers are expected to foster as part of their professional code of conduct (AMA 2004/2008).

Many DTC GT companies employ traditional strategies of persuasion like those used for commercial products (Covolo et al. 2015; Wen 2015). Liu and Pearson (2008) found in their analysis of 46 DTC GT websites, far from providing objective information, assorted subjective appeals (e.g., social inclusion, assurance; as well as negative emotions such as fear) were used to influence customers. They conclude that, "…companies deliberately employ emotional appeals and present themselves as compassionate agents when communicating with consumers" (Liu and Pearson 2008, p. 142). Further, most advertisements have a tendency to highlight potential benefits and minimize any possible shortcomings (Berg and Fryer-Edwards 2008; McCabe and McCabe 2004).

As pointed out by Schaper and Schicktanz (2018), the use of persuasive appeals designed to convince consumers to undergo a genetic test would not be ethically acceptable in the medical community. While deceptive communication is certainly not in line with the AMA values honesty and transparency, it is interesting to point out that the same type of communication that might be perceived as acceptable and non-deceiving in most commercial contexts might be deceptive when used in the context of perceived medical communication. In other words, if DTC GT companies engage in communication that is perceived by its customers as medical, this communication should adhere to the values propagated by the American Medical Association (for example: provide information and help patients understand their medical condition and options for treatment; enable patients to participate meaningfully in decisions about health care).

Issue 10: The Problem of Sufficient Customer Discernment

While misinterpretation of test results poses a potential problem for all genetic tests, it is most severe for medical tests. Interpreting genetic tests is highly complex since almost all inferences from test results are probabilistic. That is, with the exception of very few genetic inflictions such as Huntington's disease, aberrations in a person's genetic sequence only provide a *probability* of developing a specific disease or trait. Unsurprisingly, most consumers are not in a position to meaningfully interpret their test results (Leighton et al. 2012; Lippi et al. 2011). Nonetheless, many consumers are overconfident in their abilities to do just that. For example, Miron-Shatz' et al. (2014) showed that patients' subjective confidence in their ability to interpret test results was a more important driver of their decision than more objective factors such as their actual ability to numerically assess their test results. As has been shown in a different context, overconfident consumers are likely to make bad search and purchase decisions (Liu and Pearson 2008; Alba and Hutchinson 2000).

Even if consumers seek the advice of health care professionals in interpreting the results of their genetic test, it does not ensure the avoidance of wrong conclusions. As revealed in surveys conducted across the US, Australia, and New Zealand, 80%-95% of primary care practitioners did not feel confident to comment on genetic test results (Friend et al. 2018; Powell et al. 2012). Indeed, most primary care physicians are ill-equipped to provide genetic counseling (Liu and Pearson 2008; Taylor et al. 2006). For example, a study of consumers who had been genetically tested for their risk of colon cancer showed that physicians misinterpreted the test results in more than 30% of cases (Marchant 2014). Most consumers who do not understand the probabilistic nature of results and the significance of false positives (and

false negatives) might make decisions that are endangering their long-term well-being physically and mentally (Lee and Brennan 2002). In line with the American Medical Association's deontological duty of non-maleficence and the AMA value of respect, companies should provide information that can more easily be understood by laymen and point out the importance of getting help from qualified genetic counselors. The danger of GT misinterpretation should be obvious and the "greatest good" (for the many) ought to underscore the need for better information for consumers.

To be clear: Misinformed consumers might seek unnecessary and expensive follow-up tests to look for problems that are not there or—in the case of a false negative—avoid further tests out of a false sense of security (Winslow 2007). From a social welfare (and utilitarian) perspective, undergoing unnecessary testing or avoiding early useful interventions lead to a misallocation of resources that contributes to the overburdening of the health care system. Therefore, further following a utilitarian ethical perspective, the misunderstanding of genetic information by consumers poses a significant ethical problem.

Issue 11: Data Security

While certainly not unique to DTC GT, cyber-security breaches—i.e., database, password, server hacking, storage device theft, human error or failed oversight by data custodians—represent a grievous privacy threat. It is a severe issue that affects all types of GTs. Unauthorized theft or sharing of genetic data can negatively impact not only the consumers (whose DNA data have been stolen) but also their family members, who typically have not given any consent. Negative outcomes could range across a variety of areas including employment prospects, jeopardized personal relationships and higher insurance premiums (Friend et al. 2018). As is true for other sensitive consumer data, GT companies have an ethical obligation to take reasonable precautions to avoid cyber-security breaches—another specific ethical obligation represented in the code of conduct for all professional marketers (AMA 2008).

Issue 12: Privacy Concerns

In principle, DTC GT could lower consumers' privacy concerns because the likelihood of the test results appearing in the patient's medical records is reduced (Liu and Pearson 2008). That is, it has been argued that "DTC testing offers greater privacy than testing offered through a physician's office" (Berg and Fryer-Edwards 2008, p. 19). However, this assessment underestimates the lure of taking advantage of the vast financial opportunities GT databases provide for companies selling them as well as for a host of other commercial users. Thus, the promotional claim by sellers that commercial GTs are more "private" than having those tests conducted by one's doctor (thus becoming part of the patient's medical record) may be dubious.

Many DTC testing companies share their database with law enforcement agencies. For example, *23andMe* revealed that law enforcement has been retaining genetic data from the company's database of DTC genetic test customers looking to find out about their ancestors (Phillips 2016). The unintended side effect of these "familial searches" is that innocent family members of a potential criminal could be put under unwarranted police surveillance (Nelson and Robinson 2014).

Genetic information revealed by commercially available tests provides clues about some of the most intimate details of a person's identity. Still, as the case of two co-workers at the newsletter *New Scientist* exemplifies, it is relatively easy to "hack" another person's genetic code. In this case, one coworker—without the knowledge of his colleague—took samples from a water glass from which his colleague drank and sent those in to a DTC GT company. He had no problems receiving the test results revealing many intimate details about his colleague (Aldhous and Reilly 2009). Similarly, the GAO reports that some companies told a GAO fictitious consumer (i.e., secret shopper) that she could secretly test her fiancé's DNA to "surprise" him with test results (GAO 2010, p. 2).

Genetic information by its very nature is family connected. It reveals facts about persons beyond those who have consented to the tests (Klug et al. 2019; Webborn et al. 2015). Parents ordering a genetic test for themselves and/or their children might receive genetic information that not everybody involved wanted to know. For example, one spouse might learn that the other has progeny of which they are not aware. Children might learn that they have (up-until-now) unknown half-brothers or sisters. Once the DNA sample is processed by the DTC vendor, the genetic data can forever serve as a unique identifier for the individual tested and (as noted) can also be used to identify related individuals. Further, in many cases, anonymized or aggregated data supposed to protect the identity of individual customers can be reversed. That is, knowledgeable data analysts can identify individual customers in an anonymized data set (Gymrek et al. 2013) since the data seller's record likely includes demographic and lifestyle factors that (with effort) could be linked to a specific individual. Consider the now infamous case of a 15-year-old boy who was able to track down his anonymous sperm-donor father using a DTC test along with public information on the Internet (Motluk 2005).

Arguably, genetic information, the building blocks of life, potentially reveals the core of a person's physical makeup and mental identity. Forcing a person to know her 'genetic destiny', one might contend, restricts her personal freedom and can be seen as a violation of her basic right to

self-determination (Nill et al. 2018). This criticism is in line with Hans Jonas' (1985) ethical postulate of the "right to not know". Interestingly, 34% of individuals who were willing to buy a DTC genetic test evoked concern about discovering something about their genetic profile they would rather not know (Friend et al. 2018).

It is difficult to see how the benefits of disregarding consumers' privacy concerns could exceed its cost and risks for the majority. Further, it can be argued that having control over one's own most intimate data constitutes a basic personal right (Nill et al 2018). Violating this right is neither in line with the AMA's value of respect nor with the American Medical Association's ethics code (2020d).[4] Accordingly, consumers should be in control of with whom they want to share their genetic information. At the very least this would require DTC companies to clearly and understandably inform consumers about who might get to see their data, instead of hiding it in a lengthy contract. Like so many web-privacy agreements, a careful reading will likely reveal that potentially anyone might get access to their genetic data.

Issue 13: The Dangers of Corporate Ownership of DNA

Without much public discussion, it became very common that DTC GT companies take ownership of the genetic information of their customers. While some companies like 23andME are rather clear about the issue, many other companies are less forthcoming in the information they provide. Unsurprisingly, according to a recent survey, almost all of the respondents willing to use DTC GT services had concerns about the testing company "owning" their DNA profile (Friend et al. 2018). Once the DNA sample and the information retrieved from it become the property of the company (usually via an online contract), then the company is free to sell or transfer it to third parties just like any other commodity (Nordgren 2014; Gurwitz and Bregman-Eschet 2009).

Unbeknownst to most customers, many DTC companies sell the genetic information of customers to third parties. For example, the business model of 23andMe is to sell genetic data to researchers, insurers, and pharmaceutical companies. The proceeds of these sales allow the company to steeply subsidize the cost of its tests offered to individual consumers (Eissenberg 2017). Since 23andMe *owns* the genetic information it collects from its customers, any monetary benefit derived from it is not being shared with the customer. Another example is the "free" mobile app MyGeneRank, which estimates users' polygenetic risk for heart attack and stroke. While the app does not charge money for its insights, customers have to provide their genetic data which, in turn, the company can monetize by selling to third parties.

Interestingly, on the one hand, DTC companies have been proposing that people should have the right to unrestricted access to their genetic information because genetic information is a fundamental element of a person's body, identity, and individuality (Popovsky 2010). On the other hand, despite arguing that genetic information is a fundamental element of a person's body, the same companies claim ownership of this information and sell or share it at their discretion.

Following most basic concepts of natural rights, every person has the inherent right to control his/her own body. This is also expressed in the AMA's value respect that asks for acknowledging the basic human dignity of all stakeholders, which, arguably, includes a person's unalienable right to her body and all parts of it. Assuming that genetic information is a fundamental element of a person's body, it becomes morally questionable when companies buy and sell a person's DNA. There is a strong ethical argument to be made that the commercialization of DNA information without clear permission from its owner is a grave violation of the AMA's principle of Human Dignity and the American Medical Association's ethics code[5] concerning Commercial Use of Human Biological Materials (2020c). Despite a dearth of public awareness, ownership of DNA information is likely one of the most severe ethical issues affecting all types of genetic tests. Clearly, public discussion (and public policy) of this vital topic is called for.

Ethical Implications and Possible Guidelines for Regulators and DTC GT Companies

As is common with many quickly emerging technological developments, adequate guidelines and/or regulations dealing with the ethical and societal issues that manifest themselves lag the current application of the technology. As shown in our analysis of ethical issues, DTC GT is certainly

[4] The American Medical Association's ethics code specifically suggests:

"*Protecting information gathered in association with the care of the patient is a core value in health care*".

[5] The American Medical Association's ethics code specifically suggests:

(a) Disclose potential commercial applications to the tissue donor before a profit is realized on products developed from biological materials.

(b) Obtain informed consent to use biological materials in research from the tissue donor. Human biological materials and their products may not be used for commercial purposes without the consent of the tissue donor.

(c) Share profits from the commercial use of human biological materials with the tissue donor in accordance with lawful contractual agreements.

Table 1 Cross-link between type of test and ethical issues

Ethical issues		Non-medical		Mix of medical and non-medical			Medical		
		Ancestry	Relatedness	Nutrigenetic	Talent	Prenatal	Diagnostic	Personalized medicine	Carrier
1	Empowerment	P	NA	P	P	NA	P	NA	P
2	Improved Health	NA	NA	P	NA	NA	P	P	NA
3	Personal Identity	P	NA	NA	P	NA	Min	NA	Mod
4	Reliability and Validity	Mod	Mod	S	S	Mod	S	S	S
5	Equal access	Mod	Min	Mod	Min	Min	S	S	Min
6	Discrimination	Min	Min	Min	Min	Min	Mod	Min	Mod
7	Parental Decisions	NA	NA	NA	S	S	NA	NA	S
8	Psychological Impact	Min	S	Min	S	S	S	S	S
9	Uninformative Deceptive Ads	Mod	Mod	S	S	Mod	Mod	Min	Min
10	Interpretation	Min	Min	S	S	S	S	S	S
11	Data Security	S	S	S	S	S	S	S	S
12	Privacy	S	S	S	S	S	S	S	S
13	Ownership	S	S	S	S	S	S	S	S

Ranking of ethical concerns: Minimal (Min), Moderate (Mod), Sever (S), Does not Apply (NA),

Please note that in some cases the issues also come with potential benefits to consumers. This is indicated with Positive (P)

no exception. Indeed, a meaningful societal dialogue about the use and abuse potential of DTC GT is still in its infancy. While many of the ethical issues discussed above are not restricted to DTC GT, this new technology also poses some new and difficult challenges. It is those new ethical challenges that are in most need of a fruitful societal dialogue.

Since not all types of genetic tests offered in the market today raise all the ethical issues that have been discussed above, it is prudent to formulate potential guidelines specific for each type of GT test. Thus, we cross-link likely ethical issues and various genetic tests in order to provide preliminary guidance for regulators and marketers (see Table 1). Our motivation for this approach is that it is unhelpful to treat the sale and marketing of all genetic tests as the same regardless of its specific ethical challenges.

Ancestry

As discussed above, ancestry tests are fully non-medical and are recognized as such by most consumers. Consumers are not likely to expect the same high level of accuracy for ancestry tests, they are expecting for medical services. At the present state of the technology, ancestry tests resemble an educational form of entertainment, which are similar to other consumer services. As pointed out in Table One, relative to other tests, *there are few ethical concerns with ancestry tests that would warrant additional regulation.* This is not to say that current laws and regulations (including self-regulation) are always sufficient. For example, data security (Issue 11) and privacy (Issue 12) pose many unresolved issues for all consumers, companies, and regulators (Laczniak and Murphy 2006; Ferrell 2016). The point is that these issues are not unique to ancestry tests and, therefore, are not in need of specific regulation. Ownership rights over data (Issue 13) represents one of the most severe issues for all GTs but, arguably, the degree of severity depends on the amount of data collected. At the present moment, most DTC companies use only a small part of a person's DNA for ancestry tests. However, in most cases, the genome is still collected and could potentially be analyzed at a later point in time. As discussed, a societal dialogue of how to deal with the ownership rights issue of genetic data is desperately needed.

Finally, while not a high likelihood outcome, the expanded marketing promises to consumers about the value of ancestry testing may lead to the expansion of race-related debates about various ethnic superiorities (Issue 6). DTC companies could mitigate this potential problem by providing clear and unbiased information. Overall however, from an ethical perspective, any ban or intrusive restrictions of the sale of ancestry tests directly to the consumer does *not* seem to be warranted.

Relatedness

While also being non-medical, relatedness tests hardly offer innocuous entertainment. Indeed, the disruptive psychological impact (Issue 8) of these tests can be enormous. Further, *since many of these tests are being offered without the informed consent of the person whose DNA is being analyzed, relatedness tests potentially constitute an extraordinary violation of the person's privacy rights* (Issue 12).

Applying our first ethical test, which is based on a utilitarian calculus, the potential disadvantages and risks of these tests seem to outweigh potential benefits. Further, relatedness tests are not in line with the AMA's value of respect, which implies to do no harm. Therefore, from an ethical perspective, a ban on selling these genetic tests directly to the consumer might be justified.

Nutrigenetic

Since the majority of these tests claim to potentially improve consumers' health by "optimizing" their diet based on the person's individual genetic makeup, they blur the line between medical and non-medical tests. At present, most of the recommendations derived from these tests lack scientific basis, which means their validity must be questioned (Issue 4) (Webborn et al. 2015). One of the main ethical concerns is that consumers might misinterpret these tests (Issue 10) as medical advice and fall prey to sometimes misleading advertisements (Issue 9) (Phillips 2016).

The supplement industry in the U.S., which is regulated by the Dietary Supplement Health and Education Act of 1994 (DSHEA) and falls under the purview of the FDA, faced similar criticism. Under the DSHEA, supplement companies are prohibited from making any medical claims and are also regulated in making 'qualified' health claims (DSHEA, 2020). *If nutrigenetic tests were to be regulated in a similar way—perhaps under DSHEA guidelines—the main ethical concerns* (Issue 4, 9, 10) *could be sufficiently ameliorated* so that it is ethically responsible to continue selling these tests directly to the consumer. That is, with proper regulation, these tests might offer net benefits to consumers from a utilitarian perspective without violating core values propagated by the AMA statements.

Talent and Athletic Ability

Similar to nutrigenetic, these tests, which generally lack clinical utility (Issue 4) (Phillips 2016), often blur the line between medical and non-medical tests by making scientifically unsubstantiated claims (Issue 4) that are easily misinterpreted by consumers as "medically sound advice" (Issue 9). *Clearly, from an ethical standpoint, more regulation (industry or otherwise) is needed to avoid misleading consumers with GTs that purportedly predict athletic talents or aptitude.* Further, at the present state of technology, the overall benefits of these tests do not reach much further than providing entertainment and possibly, a better acceptance of self-limitations (Issue 3,[6] 4). However, the abuse potential of these tests specifically for minors is substantial. Whether it is due to misinterpretation or due to misleading and false information provided by the DTC vendor, parents might be inclined to steer their children in a constrained direction academically and/or athletically. In such cases, taking a utilitarian perspective, the potential harm being done is likely to outweigh the potential benefits. Therefore, it might be warranted to prohibit the direct-to-consumer sale of these tests for minors. If parents want to have their kids' potential talent and athletic ability tested, they should have to go through a licensed genetic counselor. Such regulation might help to prevent the most harmful abuse potential of these tests.

Prenatal Tests

Traditional prenatal tests, which are used to detect certain disorders such as Down's syndrome or Tay-Sachs disease (Scientific American 2013), clearly fall under the domain of medical tests. Given the far-reaching potential consequences of these tests and most consumers' inability to properly interpret them (Issue 10), *it might be ethically warranted to make prenatal tests only available through a physician.*

From an ethical perspective, even more worrisome is the increasing availability of "whole genome sequencing" that provides information about many aspects of the unborn child's likely physical condition as an adult such as its height, physical strength, and affinity for certain diseases (Issue 7). *Given the tremendous potential for abuse, a societal dialogue is direly needed to sort out how—or if at all—parents should be allowed access to "whole genome" information.* Following the ethical mandate of non-malfeasance—"first, do no harm"—propagated by the AMA and the American Medical Association's code of ethics, it seems prudent to outlaw these tests in their entirety until we, as a society, have a better understanding of how this hitherto unobtainable information can and should be used.

Diagnostic Tests

DTC companies marketing genetic diagnostic tests, which clearly fall under the domain of medical tests, should be held to higher communication standards than traditional consumer advertising whose accepted goal is to persuade customers (Issue 9) (Schaper and Schicktanz 2018; Elwyn et al. 2000). While DTC GT companies cannot replace the role of physicians, the *American Medical Association's* code of medical ethics (AMA Code of Medical Ethics 2020a, b,

[6] Knowing one's talents might be empowering but commercially available talent tests do not (yet?) live up to this promise (Phillips 2016).

c, d) does provide useful guidance for how to communicate with customers ordering medical tests:

> To enable patients to participate meaningfully in decisions about health care, physicians have a responsibility to provide information and help patients understand their medical condition and options for treatment.

A related concern is that most customers of DTC GT firms do not possess the expertise to interpret the GT results they receive (Issue 10). In line with the AMA Code of Medical Ethics, DTC companies should not only make accurate, unbiased, and understandable information available on their websites but also offer more active assistance, for example via providing access to competent genetic counselors.

Equal access (Issue 5) poses another concern that may warrant specific attention from public policy makers and companies. National governments could offer help—financially, legislatively, and otherwise—to have an international institution such as the World Health Organization develop a database that covers people of all ethnic backgrounds. Such efforts would greatly improve the predictive power of medical tests for all races and not only for people of European decent. This would be in line with the ethics code of the American Medical Association and reflects the fairness dimension, which flows from the Rawlsian difference principle analysis.

Finally, more regulation (self-and/or otherwise) is needed to improve the reliability and validity of diagnostic tests (Issue 4). While this is not only a significant issue for DTC but for diagnostic genetic tests in general, the problem is potentially compounded if customers try to evaluate their test results without professional help.

Despite all these challenges, taking a utilitarian perspective, the potential benefits of having direct access to diagnostic GT (Issue 1, 2) likely outweighs potential disadvantages. Therefore, instead of an outright ban on selling these tests directly to consumers, it might be better to focus on addressing the ethical issues raised through industry regulation.

Personalized Medicine

While customizing medical treatment based on a person's DNA is certainly a promising new technology, it is difficult to see how patients could possibly benefit from these tests without the guidance of their physicians or other specialists. Thus, following a utilitarian cost benefit analysis, these tests should only be available when prescribed by a physician.

Carrier Testing

The results of carrier tests are primarily used to assist patients with their reproductive decision-making (Phillips 2016). In a clinical setting, patients undergoing carrier testing receive counseling regarding the consequences of such testing. Given the potentially far-reaching consequences of Carrier tests, the complexity of interpreting them (Issue 10), and their potential for causing emotional distress (Issue 8), the potential benefits of selling these tests directly to the consumer—mainly convenience and access (Issue 1)—might not outweigh their risks. Therefore, it might be ethically warranted to make these tests only available through a physician or genetic counselor.

Summary and Conclusion

The increasing commercialization of genetic tests (GTs), which comes with many potential benefits and also severe concerns, represents an underappreciated, under-debated, and under-researched phenomenon. The primary goal of this analysis is to raise awareness of the intricate ethical and public policy issues embedded in Direct-to-Consumer GTs and their marketing dimensions.

Given the ascendant global ubiquity of DTC genetic tests, a total ban of such business models—as has been suggested in the past by some in the business literature (Liu and Pearson 2008)—is no longer realistic; it is 'too late to put the genie back in the bottle'. Pragmatic ethical principles for GT and its dissemination are needed to harness this new technology for the advancement of humankind. To this end, we offer an initial ethical analysis, using a simplified three-step model.

Based on our initial ethical analysis, we tried to provide preliminary guidelines for public policy decision makers and marketers. The broad spectrum of available genetic tests and their applications—ranging from fairly innocuous entertainment to existentially serious medical advice—require 'test specific' regulations. However, any practical and sustainable attempt to effectively regulate DTC GTs also necessitates a global approach. As discussed, many DTC GT companies do business across borders with data collection, analysis, and customers spanning different countries. Further, as long as customers have access to the internet, they can order GTs—maybe not de jure but de facto—regardless of the jurisdiction they are in. One idea to address this problem is to explore establishing an internationally recognized clearing house that surveils DTC GTs and provides guidance to national regulation. This approach would be somewhat in line with the current practice of the World Health Organization (WHO) overseeing pharmaceuticals (WHO 2020).

We intend that our literature-based discussion and ethical analysis will inspire further research about how to best tackle DTC GTs from a societal and public policy standpoint. As pointed out in our literature review ("Appendix" section), the medical community has been investigating DTC GT issues quite extensively from different angles.

However, as evidenced by the dearth of articles in business journals, research from a business and marketing ethics perspective are scarce. Thus, we encourage business and marketing researchers to get involved in the discussion that, so far, has been dominated by the medical community.

Given the multifaceted nature of ethical issues raised by DTC GTs, more cross-disciplinary research involving specialists from medicine, marketing, economics, law, public policy, and ethics might be warranted. That is, any discipline on its own seems ill-equipped to deal with the intricate and interconnected nature of the issues raised by this new technology.

Further, the different types of tests discussed above do not pose the same ethical and public policy issues. Therefore, future research could start investigating test-specific issues in depth. For example, research germane to privacy and data security issues (Issues 11, 12) could embrace the specific challenges in these areas posed by DTC GTs. For another example, marketing specialists could in tandem with medical ethicists explore the (ab)use of medical communication (issue 9) in marketing DTC GTs.

In the end, the technology of GTs and its myriad application has been advancing more rapidly than the ability of the public to find a consensus about GT usage and its marketing. Some of the most concerning issues addressed—Parental Decisions (7); Privacy (12); Ownership (13)—represent new or barely explored ethical challenges that have not (yet) been sufficiently discussed by society. Thus, a true public dialogue—understood as *"a sustained collective inquiry into the process, assumptions, and certainties that compose everyday experience"* (Isaacs 1993, p. 25)—is achingly needed so that a societal consensus might guide public policy makers and companies pursuing self-regulation.

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Appendix

See Table 2.

Abstracts of three seminal business journal articles:

Table 2 DTC genetic testing in the academic literature

Business and Medical Literature								
Database	ABI + Business Source elite; PubMED							
Search terms	Direct to consumer + genetic test(ing); Genetic test(ing) + consumer							
Business Journals					Time frame			Total
Core Business Journals	Health Journals	Sociology Journals	Other Journals*		2015–2019	2010–2014	Before 2010	
3	22	5	9		9	15	15	39
Medical Journals Major Topical Areas**								
Attitude, Knowledge	Clinical Utility Reliability	Ethical Issues	Regulatory Issues	Other				
192	132	81	88	67	172	195	51	418

*Other disciplines: law, computer sciences

**Journals were categorized by up to two major topical areas per article. For articles that covered more than two topical areas, only the main two were accounted for

1 Analyzing the activities of one of the largest DTC companies (23andMe), Merz (2016) shows the conflation of production and consumption for certain demographic sectors. She argues that by targeting especially African Americans, this 'prosumption' relies for its success on both the labor of African American 'prosumers' and on the prior system of racial signification through which corporeal matter and genetic information appear interesting. Put differently, Black consumers in America are particularly disposed to want to know more about their genetic past. Merz (2016).

2 Reflecting emergent concerns, Liu and Pearson (2008) provide an excellent overview (now over ten years old) of the regulatory environment for DTC GT in the USA. They performed a content analysis of the websites of 46 DTC companies offering predictive genetic tests (tests that determine whether an individual is a carrier and/or if the individual has an increased susceptibility to a disease). Their analysis concludes that "the combination of consumer ignorance, scant government regulation, aggressive marketing practices, and the often-overzealous media attention to genetic testing is a recipe for harm to individual consumers and public health" (Liu and Pearson 2008). Accordingly, they recommend only offering GT through a physician and prohibiting DTC marketing of genetic tests that lack analytic or clinical validity. Liu and Pearson (2008).

3 In a significant study of DTC GT, Berg and Fryer-Edwards (2008) identified and analyzed the websites of 13 companies offering health-related GT directly marketed to consumers. Their study "suggests that biotech companies are not providing balanced information about the risks and benefits of genetic testing; they are not consistently offering genetic counseling services; and some sites are even offering tests with little evidence of clinical value" (Berg and Fryer-Edwards 2008, p. 29). At that time, the authors' three main recommendations to companies for ethical DTC Genetic Test marketing were (1) provide enough information for consumers to make an educated decision, (2) only offer genetic tests with clinical validity, and (3) reduce the potential for misinterpreting results. These guidelines have rarely been followed by the industry. As discussed below, while the number of companies offering DTC GT has dramatically increased since this study was done more than 10 years ago, the overall recommendations of this study are still relevant today. Berg and Fryer-Edwards (2008)

References

Alba, J. W., & Hutchinson, J. W. (2000). Knowledge calibration: What consumers know and what they think they know. *Journal of Consumer Research, 27*(2), 123–156.

Aldhous, P., & Reilly, M. (2009). Special investigation: How my genome was hacked. *New Scientist*. Retrieved April 6, 2019, from https://www.newscientist.com/article/mg20127013-800-special-investigation-how-my-genome-was-hacked/

AMA Code of Medical Ethics. (2020a). Code of Medical Ethics: Consent, communication & decision making. Retrieved January 20, 2020, from https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-consent-communication-decision-making.

AMA Code of Medical Ethics. (2020b). Direct-to-Consumer Advertisement of Prescription Drugs. Retrieved June 20, 2020, from https://www.ama-assn.org/delivering-care/ethics/direct-consumer-advertisement-prescription-drugs

AMA Code of Medical Ethics. (2020c). Commercial Use of Human Biological Materials. Retrieved June 29, 2020, from https://www.ama-assn.org/delivering-care/ethics/commercial-use-human-biological-materials

AMA Code of Medical Ethics. (2020d). Privacy in Health Care. Retrieved June 30, 2020, from https://www.ama-assn.org/delivering-care/ethics/privacy-health-care

AMA Statement on Ethics. (1984; 1988). American Marketing Association, source: www.marketingpower.com reprinted in: *Ethics in Marketing,* 2nd Ed. (P.E. Murphy, G.R. Laczniak and F. Harris, *eds.*). London: Routledge (2017): 11–12.

Auton, F. (2004). The advertising of pharmaceuticals direct to consumers: A critical review of the literature and debate. *International Journal of Advertising, 23*(1), 5–52.

Ball, J. (2018). Caring or compulsion? The effects of consumer attributions of risk information disclosure in direct-to-consumer prescription drug advertising. *The Journal of Consumer Affairs, 52*(3), 623–654.

Biegler, P. (2014). Placebogenic potential is no reason to favor pharmaceutical advertising. *Journal of Business Ethics, 123*(1), 145–155.

Bloss, C. S., Darst, B. F., Topol, E. J., & Schork, N. J. (2011). Direct-to-consumer personalized genomic testing. *Human Molecular Genetics, 20*(R2), R132–R141.

Bredart, A., Autier, P., Riccardo, A., Audisio, A., & Geraghty, J. G. (2001). Psychosocial dimensions of BRCA testing: an overshadowed issue. *European Journal of Cancer Care, 10*(2), 96–99.

Berg, C., & Fryer-Edwards, K. (2008). The ethical challenges of direct-to-consumer genetic testing. *Journal of Business Ethics, 77*(1), 17–31.

Bowie, N. (2002). Ethical reasoning in practice: A Kantian approach to business ethics. In T. Donaldson, P. H. Werhane, & M. Cording (Eds.), *Ethical issues in business: A philosophical approach* (pp. 61–71). New Jersey: Prentice Hall.

Burke, W., Atkins, D., Gwinn, M., Guttmacher, A., Haddow, J., Lau, J., et al. (2002). Genetic test evaluation: information needs of clinicians, policy makers, and the public. *American Journal of Epidemiology, 156*(4), 311–318.

Burke, W. (2004). Genetic testing in primary care. *Annual Review of Genomics and Human Genetics, 5*, 1–14.

Calfee, J. (2002). Public policy issues in direct-to-consumer advertising of prescription drugs. *Journal of Public Policy and Marketing, 21*(Fall), 174–193.

Carere, D.A., VanderWeele, T., Moreno, T.A., Mountain, J.L., Roberts, J.S., Kraft, P., Green, R.C., and PGen Study Group. (2015). The impact of direct-to-consumer personal genomic testing on perceived risk of breast, prostate, colorectal, and lung cancer: Findings from the PGen study. *BMC Medical Genomics, 8*(1), 63.

Carey, N. (2012). *The epigenetics revolution*. London: Icon Books Ltd.
Covolo, L., Rubinelli, S., Ceretti, E., & Gelatti, U. (2015). Internet-based direct-to-consumer genetic testing: a systematic review. *Journal of Medical Internet Research, 17*(12), e279.
Curran, K. (2019). Living in the brave new genomic era. Retrieved July 6, 2019, from https://www.risingtidebio.com/review-dna-genetic-testing/
Delbanco, S. (2018). 4 reasons employers should pay attention to genetic testing. *Employee Benefit News (Online),* New York (Jul 18, 2018).
Dohany, L., Gustafson, S., Ducaine, W., & Zakalik, D. (2012). Psychological distress with direct-to-consumer genetic testing: a case report of an unexpected BRCA positive test result. *Journal of Genetic Counseling, 21*(3), 399–401.
DSHEA. (2020). Dietary Supplement Health and Education Act of 1994. Retrieved January 15, 2020, from https://www.fda.gov/food/dietary-supplements.
Duster, T. (2009). Ancestry testing and DNA: Uses, limitations and caveat emptor. *GeneWatch Bulletin of the Council for Responsible Genetics*. Retrieved April 18, 2019, from https://www.councilforresponsiblegenetics.org/pageDocuments/O7HIKRKXYB.pdf#page=1&zoom=auto,-150,271
Eissenberg, J. (2017). Direct-to-consumer genomics: Harmful or empowering? *Missouri Medicine, 114*(1), 26–32.
Elwyna, G., Grayb, J., & Clarkeb, A. (2000). Shared decision making and non-directiveness in genetic counselling. *Journal of Medical Genetics, 37*(2), 135–138.
Eveleth, R. (2015). Genetic testing and tribal identity. *The Atlantic*. Retrieved April 28, 2019, from https://www.theatlantic.com/technology/archive/2015/01/the-cultural-limitations-of-genetic-testing/384740/
FDA. (2017). FDA allows marketing of first direct-to-consumer tests that provide genetic risk information for certain conditions. *FDA News Release*, Retrieved July 10, 2019, from https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-tests-provide-genetic-risk-information-certain-conditions
FDA. (2020). Background on Drug Advertising. Retrieved June 20, 2020, from https://www.fda.gov/drugs/prescription-drug-advertising/background-drug-advertising
Ferrell, O. C. (2016). Broadening marketing's contribution to data privacy, *Journal of the Academy of Marketing Science*, published online 08 October 2016. *DOI*. https://doi.org/10.1007/s11747-016-0502-9.
Florko, N. (2017). FDA Lowers marketing hurdles for direct-to- consumer genetic tests. *InsideHealthPolicy.com's Daily Brief*, (Nov 7, 2017).
Friend, L., O'Neill, J., Rivlin, A., & Browne, R. (2018). Direct to consumer genetic testing: Opportunities and risks in a rapidly evolving market. *KPMG International*. Retrieved June 30, 2019, from https://assets.kpmg/content/dam/kpmg/xx/pdf/2018/08/direct-to-consumer-genetic-testing.pdf
FTC. (1984). FTC Policy Statement on Deception, 103 F.T.C. 110, 174. Retrieved August 16, from https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf
GAO. (2010). Direct-To-Consumer Genetic Tests. United States Government Accountability Office, GAO-10–847T, Retrieved June 28, 2019, from https://www.gao.gov/assets/130/125079.pdf
Global Market Insights. (2019). Direct-to-Consumer Genetic Testing Market will achieve 15%+ CAGR up to 2025. Retrieved August 9, 2019, from https://www.globenewswire.com/news-release/2019/06/19/1870948/0/en/Direct-to-Consumer-Genetic-Testing-Market-will-achieve-15-CAGR-up-to-2025-Global-Market-Insights-Inc.html
Gollust, S., Hull, S., & Wilfond, B. (2002). Limitations of direct-to-consumer advertising for clinical genetic testing. *Journal of the American Medical Association, 288*(14), 1762–1767.
Gordon, E., Griffin, G., Wawak, L., Pang, H., Gollust, S., & Bernhard, B. (2011). "It's not like judgment day": public understanding of and reactions to personalized genomic risk information. *Journal of Genetic Counsel, 21*, 423–432.
Green, R., & Farahany, N. (2014). The FDA is overcautious on consumer genomics. *Nature, 505*, 286–287.
Gurwitz, D., & Bregman-Eschet, Y. (2009). Personal genomics services: whose genomes? *European Journal of Human Genetics, 17*, 883–889.
Gymrek, M., McGuire, A., Golan, D., Halperin, E., & Erlich, Y. (2013). Identifying personal genomes by surname inference. *Science, 339*(6117), 321–324.
Hall, M., & Rich, S. (2000). Laws restricting health insurers' use of genetic information: Impact on genetic discrimination. *American Journal of Human Genetics, 66*, 293–307.
Harmon, A. (2019). James Watson had a chance to salvage his reputation on race. He made things worse. *The New York Times*, January 1, 2019. Retrieved April 16, 2019, from https://www.nytimes.com/2019/01/01/science/watson-dna-genetics-race.html.
Hudson, K., Javitt, G., Burke, W., & Byers, P. (2007). ASHG statement on direct-to-consumer genetic testing in the United States. *American Journal of Human Genetics, 81*(3), 635–637.
Hunt, S. D., & Vitell, S. J. (1986). General theory of marketing ethics. *Journal of Macromarketing, 6*(Spring), 5–15.
Isaacs, W. (1993). Dialogue, collective thinking and organizational learning. *Organizational Dynamics, 22*(Fall), 24–39.
Javitt, G. (2007). In search of a coherent framework: Options for FDA oversight of genetic tests. *Food and Drug Law Journal, 62*, 617–652.
Jonas, H. (1985). *Technik, Medizin und Ethik: Zur Praxis des Prinzips Verantwortung*. Frankfurt am Main: Insel.
Kido, T., Kawashima, M., Nishino, S., Swan, M., Kamatani, N., & Butte, A. (2013). Systematic evaluation of personal genome services for Japanese individuals. *Journal of Human Genetics, 58*, 734–774.
Klug, W., Cummings, M., Spencer, C., Palladino, M., & Killian, D. (2019). *Concepts of genetics* (12th Edn.). U.S. Pearson Education ISBN 987-0-134-60471-8.
Korthals, M., & Komduur, R. (2010). Uncertainties of nutrigenomics and their ethical meaning. *Journal of Agricultural and Environmental Ethics, 23*, 435–454.
Krimsky, S., & Johnston, D. (2017). Ancestry DNA testing and privacy: a consumer guide. Council for Responsible Genetics, Retrieved April 18, 2019, from https://www.councilforresponsiblegenetics.org/img/Ancestry-DNA-Testing-and-Privacy-Guide.pdf
Lalkhen, A., & McCluskey, A. (2008). Clinical tests: Sensitivity and specificity, continuing education in anaesthesia. *Critical Care & Pain, 8*(6), 221–223.
Laczniak, G., & Murphy, P. (1993). *Ethical marketing decisions: The higher road*. Toronto: Allyn and Bacon.
Laczniak, G. R., & Murphy, P. E. (2006). Marketing, consumers and technology: Perspectives for enhancing ethical transactions. *Business Ethics Quarterly, 16*(3), 313–321.
Laczniak, G., & Murphy, P. (2008). Distributive justice: Pressing questions, emerging directions, and the promise of Rawlsian analysis. *Journal of Macromarketing, 28*(1), 5–11.
Lee, T., & Brennan, T. (2002). Direct-to-consumer marketing of high-technology screening tests. *New England Journal of Medicine, 346*(7), 529–531.
Leighton, J., Valverde, K., & Bernhardt, B. (2012). The general public's understanding and perception of direct-to-consumer genetic test results. *Public Health Genomics, 5*, 11–21.

Lippi, G., Favarolo, E. J., & Plebani, M. (2011). Direct-to-consumer testing: more risks than opportunities. *International Journal of Clinical Practice, 65*, 1221–1229.

Liu, Q., Liu, H., & Kalwani, M. (2020). See your doctor: the impact of direct-to-consumer advertising on patients with different affliction levels. *Marketing Letters, 31*(1), 37–48.

Liu, Y., & Pearson, Y. E. (2008). Direct-to-consumer marketing of predictive medical genetic tests: Assessment of current practices and policy recommendations. *Journal of Public Policy & Marketing, 27*(2), 131–148.

Mappes, T. A., & DeGrazia, D. (2006). *Biomedical ethics* (6th ed.). Boston, MA: McGraw Hill.

Mapmygene.com. (2019). Inborn Talent Genetic Test. Retrieved July 2, 2019, from https://www.mapmygene.com/

Marchant, G. (2014). The use and misuse of genetic data. *GPSolo, 31*(2), 64–65.

Marteau, T. M., French, D. P., Griffin, S. J., Prevost, A. T., Sutton, S., Watkinson, C., et al. (2010). Effects of communicating DNA-based disease risk estimates on risk-reducing behaviors. *Cochrane Database Systematic Review, 6*(10), CD00725.

McCabe, L., & McCabe, E. (2004). Direct-to-consumer genetic testing: Access and marketing. *Genetics in Medicine, 6*(1), 58–59.

McPherson, E. (2006). Genetic diagnosis and testing in clinical practice. *Clinical Medicine & Research, 4*(2), 123–129.

Merz, S. (2016). 'Health and ancestry start here': Race and prosumption in direct-to-consumer genetic testing services. *Ephemera: Theory & Politics in Organization, 16*(3), 119–140.

Mill, S. J. (1979). *Utilitarianism*. (Original publication 1863). Indianapolis: Liberal Arts Press.

Mintz, C. (2009). What's next? (the answer may surprise you), *Life Science Leader*. Retrieved January 3, 2020, from https://www.lifescienceleader.com/doc/what-s-next-the-answer-may-surprise-you-0001

Miron-Shatz, T., Hanoch, Y., Doniger, G., Omer, Z., & Ozanne, E. M. (2014). Subjective but not objective numeracy influences willingness to pay for BRCA1/2 genetic testing. *Judgment and Decision Making, 9*(2), 152–158.

Motluk, A. (2005). Anonymous sperm donor traced on internet. New Scientist, Issue2524: 6. Retrieved August 17, 2019, from https://www.donorsiblingregistry.com/sites/default/files/images/docs/Anonymous_Sperm_Donor_Traced_on_the_Internet.pdf

Murphy, P. (1999). Character and virtue ethics in international marketing: An agenda for managers, researchers and educators. *Journal of Business Ethics, 18*(1), 107–124.

Murphy, P., Laczniak, G., Bowie, N., & Klein, T. (2005). *Ethical marketing*. Upper Saddle River, NJ: Pearson Education.

Nelson, A., & Robinson, J. (2014). The social life of DTC genetics: The case of 23andMe. In D. Kleinman & K. Moore (Eds.), *Routledge handbook of science, technology and society* (pp. 108–123). New York: Routledge.

Newman, T., & Freitag, J. (2011). Personalized medicine development. *Applied Clinical Trials, 20*(7), 30–33.

NHGRI. (2019). National Human Genome Research Institute. Genetic Testing. Retrieved July 17, 2019, from https://ghr.nlm.nih.gov/primer/testing/uses.

NIH. (2020). National Institute of Health. Bioethics. Retrieved June 17, 2020, from https://www.niehs.nih.gov/research/resources/bioethics/index.cfm

Nill, A., Laczniak, G., & Thistle, P. (2018). The use of genetic testing information in the insurance industry: An ethical and societal analysis of public policy options. *Journal of Business Ethics*. https://doi.org/10.1007/s10551-017-3554-y.

Nill, A., & Schibrowsky, J. (2007). Marketing ethics research: A systematic review of the literature. *Journal of Macromarketing, 27*(2), 256–273.

Nordgren, A. (2014). Neither as harmful as feared by critics nor as empowering as promised by providers: Risk information offered direct to consumer by personal genomics companies. *Journal of Community Genetics, 5*, 59–68.

Nordgren, A. (2008). Genetics and identity. *Community Genetics, 11*, 252–266.

Pence, G. E. (2007). *The elements of bioethics*. Boston, MA: McGraw Hill.

Phillips, A. (2016). Only a click away—DTC genetics for ancestry, health, love…and more: A view of the business and regulatory landscape. *Applied & Translational Genomics, 8*, 16–22.

Phillips, K., Deverka, P. A., Hooker, G., & Douglas, M. (2018). Genetic test availability and spending: Where are we now? Where are we going? *Health Aff (Millwood), 37*(5), 710–716.

Popovsky, M. (2010). Exaggerated benefits and underestimated harms: the direct-to-consumer genetic test market and how to manage it going forward. *Dartmouth Law Journal, 8*, 65–87.

Powell, K. P., Christianson, C. A., Cogswell, W. A., Dave, G., Verma, A., Eubanks, S., et al. (2012). Educational needs of primary care physicians regarding direct-to-consumer genetic testing. *Journal of Genetic Counseling, 21*(3), 469–478.

PR Newswire. (2017). Predictive genetic testing and consumer/wellness genomics market by application (cancer, diabetic screening, parkinsonism, cardiovascular, orthopedic & musculoskeletal, nutria genetics, skin & metabolism genetics) and trend analysis from 2013 to 2025. *PR Newswire*, New York, 23 February 2017. Retrieved June 29, 2019, from https://ezproxy.library.unlv.edu/login?url=https://search.proquest.com/docview/1871339529?accountid=3611

Preston, L. E., & Post, J. E. (1975). *Private management and public policy*. Englewood Cliffs, NJ: Prentice-Hall.

Rawls, J. (1971). *A theory of justice*. Cambridge, MA: Harvard University Press.

Radetzki, M., Radetzki, M., & Juth, N. (2003). *Genes and insurance*. Cambridge: Cambridge University Press.

Regaldo, A. (2018). 2017 was the year consumer DNA testing blew up. *MIT Technology Review*. Retrieved March 29, 2019, from https://www.technologyreview.com/s/610233/2017-was-the-year-consumer-dna-testing-blew-up/

Ricoeur, P. (1990). On John Rawls' A theory of justice: Is a pure procedural theory of justice possible? *International Social Science Journal, 42*(4), 553–564.

Rothstein, M. (2013). Epigenetic exceptionalism. *Journal of Law, Medicine & Ethics, 41*(3), 733–736.

Schaper, M., & Schicktanz, S. (2018). Medicine, market and communication: Ethical considerations in regard to persuasive communication in direct-to consumer genetictesting services. *Medical Ethics, 19*(56), 1–11.

Scientific American. (2013). Beware the destiny test. *Scientific American, 308*(2), 12.

Sobel, S., & Cowan, B. (2003). Ambiguous loss and disenfranchised grief: The impact of DNA predictive testing on the family as a system. *Family Process, 42*(1), 47–57.

Solberg, L. (2009). Over the counter but under the radar: Direct to consumer genetic tests and FDA regulation of medical devices. *Vanderbilt Journal of Entertainment and Technology Law, 11*, 711–742.

Swan, E. L., Dahl, A. J., & Peltier, J. W. (2019). Health-care marketing in an omni-channel environment. *Journal of Research in Interactive Marketing, 13*(4), 602–618.

Tandy-Connor, S., Guiltinan, J., Krempely, K., LaDuca, H., Reineke, P., Gutierrez, S., et al. (2018). False-positive results released by direct-to-consumer genetic tests highlight the importance of clinical confirmation testing for appropriate patient care. *Genetics in Medicine, 20*(12), 1515–1521.

Taylor, M., Edwards, J., & Ku, L. (2006). Lost in transition: Challenges in the expanding field of adult genetics. *American Journal of Medical Genetics: Part C: Seminars in Medical Genetics, 142*(4), 294–303.

Torkamani, A., & Topol, E. (2018). Your genome, on demand. *MIT Technology Review, 121*(6), 20–21.

Van de Pol, P., & de Bakker, F. (2010). Direct-to-consumer advertising of pharmaceuticals as a matter of corporate social responsibility? *Journal of Business Ethics, 94*(2), 211–224.

Vorhaus, D. (2011). The FDA and DTC Genetic Testing: Setting the Record Straight. *The Privacy Report.* Retrieved July 9, 2019, from https://theprivacyreport.com/2011/03/11/the-fda-and-dtc-genetic-testing-setting-the-record-straight/

Walker, F. (2007). Huntington's disease. *Lancet, 369*(9557), 218–228.

Webborn, N., Williams, A., McNamee, M., Bouchard, C., Pitsiladis, Y., Ahmetov, I., et al. (2015). Direct-to-consumer genetic testing for predicting sports performance and talent identification: Consensus statement. *British Journal of Sports Medicine, 49*(23), 1486–1491.

Welch, B., Harvey, J., O'Connell, N., & McElligot, J. (2017). Patient preferences for direct-to-consumer telemedicine services: A nationwide survey. *BMC Health Services Research, 17*, 2–7.

Wen, J. (2015). An incongruent picture of direct-to-consumer advertising of genetic tests: Qualitative framing analysis on newspapers and 23andMe's press releases. *Journal of Medical Marketing, 15*(3–4), 69–80.

Winslow, R. (2007). Is there a heart attack in your future? Genetic tests promise to map your personal health risks, but some question usefulness. *Wall Street Journal*, Eastern edition; New York, N.Y.: D.1

WHO. (2020). Pharmaceutical products. Retrieved July 4, 2020, from https://www.who.int/topics/pharmaceutical_products/en/

Zwart, H. (2015). Human genome project: History and assessment. *International Encyclopedia of the Social & Behavioral Sciences, 11*(2), 311–317.