Leggo My Genome: What Ethical Requirements Should Govern the Communication of Direct-to-Consumer Genetic Test Results?

Lora Arduser

University of Cincinnati, lora.arduser@uc.edu

Follow this and additional works at: https://lib.dr.iastate.edu/sciencecommunication

Part of the Communication Commons


This Event is brought to you for free and open access by the Conferences and Symposia at Iowa State University Digital Repository. It has been accepted for inclusion in Iowa State University Summer Symposium on Science Communication by an authorized administrator of Iowa State University Digital Repository. For more information, please contact digirep@iastate.edu.
Leggo My Genome: What Ethical Requirements Should Govern the Communication of Direct-to-Consumer Genetic Test Results?

LORA ARDUSER

Department of English, Professional and Technical Writing
University of Cincinnati
PO Box 210069 Cincinnati Oh 45221-0069
USA
Lora.arduser@uc.edu

ABSTRACT: Scholars in scientific communication have shared a growing concern about the ethical implications of approaches to direct-consumer genetic testing. To add to this evolving conversation, this paper addresses the debate about the ethics of communicating genetic testing results through a rhetorical inquiry of the 23andMe controversy.

KEYWORDS: direct-to-consumer genetic testing communication, ethics, rhetorical inquiry

1. INTRODUCTION

For just $99 and about five minutes online, I started my journey of self-discovery. The kit arrives by mail within a few weeks and gives step-by-step instructions on just how to supply your sample -- which might not be as easy as it sounds. The slogan on the box states, "Welcome to You", and to get started you have to hand over a literal part of yourself for analysis. In a plastic vial known as the Saliva Collection Kit and Personal Genome Service, I filled as much saliva as my mouth would allow. This process lasted at least five minutes. Once you reach the "fill line" you snap the cap, shake it up, and send it off. For two to four weeks, while I anxiously awaited the results, 23andMe logged my DNA into their database. They then extracted DNA cells from my saliva and made copies for a pretty extensive analysis. (Spindle, 2013, n.p.)

In 2006, when 23andMe opened for business, the company positioned its product as a “fun way to learn a little genetics using yourself as a test subject” (Seife, 2013). The goal, the company stated on its website in 2007, “is to connect you to the 23 paired volumes of your own genetic blueprint (plus your mitochondrial DNA), bringing you personal insight into ancestry, genealogy, and inherited traits.” As time passed, however, 23andMe put less emphasis on the ancestral component of its service and began to emphasize marketing their services as a way of “predicting and even preventing health problems” (Seife, 2013).

As an in vitro diagnostic device (IVD), a device “intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or conditions arising from a disease” (Shuren, 2010), 23ndMe’s genetic test kit (as well as the test kits of other companies offering this service) comes under the authority of the U.S. Federal Drug Administration (FDA) in accordance with the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act.

Such direct-to-consumer (DTC) genetic testing, testing marketed directly to consumers through television, print advertisements, or the Internet, has been gaining prominence over the past several years (Javitt, Stanley, & Hudson, 2004). In fact, the global DTC genetic testing market is projected to reach the size of more than $230 million by 2018 (Global Industry
As more companies offer these products and more consumers purchase them, the FDA has increasingly been grappling with how to regulate these tests, including how information is communicated to consumers. As a part of these efforts, the FDA has sent numerous warning letters to companies offering DTC genetic testing. In the summer of 2010, 17 companies received letters in which the FDA argued that the personal genome services these companies were offering were medical devices and, therefore, required FDA review and approval before they could be offered on the market. The company 23andMe received its warning letter on November 22, 2013. The letter directed the company to immediately discontinue marketing the 23andMe Saliva Collection Kit and Personal Genome Service (PGS) “until such time as it receives U.S. Food and Drug Administration (FDA) marketing authorization for the device” (FDA, 2013).

At the center of the controversy over how DTC genetic testing should be used and regulated are a set of contested values and expectations about the ethics of technological innovation, how these technologies should be regulated, and how test results from these technologies should be publicly communicated. Such testing may allow people to be more proactive in their health care, but because this type of testing may also provide an “interpretation” of genetic information without necessarily involving a doctor in the process, members of the scientific and medical community are concerned that people are vulnerable to being misled by the results and may make important decisions about treatment or prevention based on inaccurate, incomplete, or misunderstood information about their health. The marketing of these products over the Internet has been seen as particularly troublesome due to the easy access to genetic tests results without the intervention of a health care professional because “even the clinically available genetic tests, which may provide legitimate test results, can be difficult to interpret without genetic counseling” (NHGRI, 2004, n.p.).

Scholars in scientific communication have shared the growing concern about the ethical implications of approaches to DTC advertising (Lynch, 2011; Majdik, 2009; Nordgren, 2010; William-Jones, 2006), and as much of the discussion involves the communication of genetic testing results, science communication scholars are likely to place a large role in this evolving situation. To add to this emergent conversation, I approach what Segal refers to as questions posed prior to the questions of researchers in health and medicine: “Projects in rhetoric of health and medicine, in general, aim to be useful. Their usefulness often lies in their ability simply to pose questions that are prior to the questions typically posed by health researchers” (2009, p. 228). She offers the example of questions in cosmetic surgery: “[B]efore we ask the more obvious medical/health questions—for example, “How can it be performed most safely?” and “Should it be covered by health insurance plans?”—we might ask, “How are people persuaded to see themselves as improvable by cosmetic surgery in the first place?”” (Segal, 2009, p. 228).

I argue that deliberations about how (or if) to regulate DTC genetic testing and the communication of testing results should be prefaced by similar types of questions, including “What ethical requirements should govern the communication of DTC genetic test results?” Stakeholders involved in shaping regulatory and risk communication practices could be better informed in designing these practices if, as Thompson (2012) argued, explicit attention is paid to the ethical framework(s) they were adopting as a part of these practices. To take up Thompson’s (2012) call, in this paper I offer the beginnings of an inquiry into how to build an ethical framework to inform decisions about communicating DTC genetic test results. To do so I draw on McKeon’s work with commonplaces and pluralistic interpretation (Farrell, 2000; McKeon, 1987). I start by providing a brief background on the existing literature on DTC genetic
testing then move directly into the identification of six commonplaces in the texts I examined, which included the FDA’s March 8-9, 2011, public hearing, the 23andMe website, and information from 73 customer reviews of 23andMe’s test kit on Amazon. The commonplaces I will discuss are: 1) safety, 2) reliability, 3) the ability to understand complex information, 4) innovation, 5) privacy, and 6) empowerment/participation. After providing examples of these commonplaces in the texts, I close with an early attempt to create an ethical schematic that can help inform decisions about communicating testing results.

2. DTC GENETIC TESTING

Rhetoricians of science, medicine, and health have long been interested in the discourse of genetics. Condit’s 1999 landmark text *The Meaning of the Gene: Public Debates about Human Heredity* set the stage for what happens when genetics moved out of the lab and into the public. Much of the work that followed Condit also focused on laypeople’s understandings and perceptions of genetics and genetic health messages. More than a decade later, for example, Gronnvoll and Landau (2010) examined metaphors for genes used by the American public. Smerecnik, Mesters, de Vries and de Vries (2011) examined genetic health messages to gauge the public’s understanding of these messages, and Leeming looked at “how information gathering and representation broadened steadily to accommodate genetic diagnostic tests” (2011, p. 415). R. Parrott, Volkman, Ghetian, Weiner, Raup-Krieger, and J. Parrott also argued that in the “relatively little is known about lay audience recollection of images and messages about genes and health, or their perceptions about the role of genetics research for health, and what diseases are inherited” (2008, p. 8). Work that has focused specifically on DTC genetic testing has mirrored this other work in some ways. For example, focusing specifically on genetic testing for the breast cancer genes (BRCA 1 and 2) Perez, D. G. Cruess and S. Cruess (2011) examined attitudes toward DTC and online testing for BRCA. Pearson and Liu-Thompkins similarly addressed the direct-to-consumer marketing of medical genetic tests and the increasing need to better understand the ethical and public policy implications of such products, arguing that “the complexity of genetic tests raises serious concerns about whether consumers possess the knowledge to make sound decisions about their use” (2012, p. 42). Finally, Majdik analyzed how providers of DTC genetic tests communicate abstract, technical science with nonexpert audiences and argued that direct-to-consumer genetics “reveals a stasis in public discourse over where legitimate agency for interpreting genetic test results, judging their meaning, and making decisions in response to them should rest” (2009, p. 571).

Other scholars have focused on concerns similar to those expressed by the FDA. For example, in a special issue of the Journal of Science Communication (JCOM) that focused on the communication and marketing practices used by private companies selling DTC genetic testing, Delfanti examined the consequences of putting technology that has the ability “to decide about our life choices in our hands, as well as help solve crucial health problems by preventing the insurgence of diseases” (2011, p. 1) in the hands of private companies in a free market.

Research focusing specifically on 23andMe has investigated the research division of 23andMe in an analysis of a variety of documents associated with the company to argue that the notion of gift exchange in the participatory culture the company and its customers engage in is used to draw attention away from the free, clinical labour which drives the profitability of 23andMe (Harris, Wyatt, & Kelly, 2013). Arribas-Ayllon, Sarangi, and Clarke (2011) also examined three DTC genetic testing company websites (Navigenics, deCODEme and 23andMe)
to uncover the rhetorical and discourse devices employed to assess how personalized healthcare is promised to the public. They found that the approach of 23andMe implied a democratic/consumerist register based on “unmediated access to genetic information,” (p. 56) that encouraged sharing and an emphasis on community empowerment.

3. COMMONPLACES IN THE 23ANDME CONTROVERSY

In writing about the history of rhetoric and its relationship to philosophy McKeon argued for rhetoric as an architectonic art systemized through schematization (McKeon, 2005, p. 198). While his system of analysis is so encompassing that it can be difficult to extract what Farrell referred to as a “committed practice of rhetoric” (2000, p. 190), nevertheless, it can be productive to reformulate McKeon’s work into a more praxis-centered approach, such as the one I begin to offer here. As McKeon himself wrote, “Rhetoric provides the devices by which to determine the characteristics and problems of our times and to form the art by which to guide actions for the solutions of our problems and the improvement of our circumstances” (1987, p. 11).

In order to help resolve the ‘new problem’ of ethically communicating DTC genetic test results, I offer a schematic based on McKeon’s work with commonplaces in architectonic rhetoric. A productive architectonic art, McKeon wrote, “produces subject matters and organizes them in relation to each other and to the problems to be solved” (1987, p. 3). Furthermore, commonplaces can be used to focus on a problem “and move from the battle of schools to common inquiry from different points of view” (2005, p. 136).

McKeon takes his definition of commonplaces from its various definitions throughout the history of rhetorical theory.

The history of commonplaces is marked by degradations, narrowings, transformations, and novel applications. When applied to memory, the commonplaces threatened to become as numerous as the things remembered. Commonplaces moved from meaning an empty place, as an aid in the ordering of things, to meaning a special matter, or subject, to be discussed. As instruments of discovery, commonplaces have shifted back and forth, from devices used for discovering something unknown to formulae used for recalling stock quotations to be applied in a familiar manner. (Backman, 1987, p. xviii)

In and of themselves commonplaces do not get us far, but as instruments of invention they can move us toward solving particularly thorny, complex problems. When used in conjunction with a rhetorical schema, commonplaces can help us arrive at “uninterpreted but suggestive relations of terms that might open up possibilities for subsequent interpretation and development in discourse.” (Enos, 2009, p. 426). McKeon’s own schematic, as described in “Philosophic Semantics and Philosophic Inquiry,” was developed for the discovery of meaning in all discourses, but a similar exercise may lead beyond compromise between individual motives to collective solutions for interdisciplinary problems such as the one at hand by taking what can be sources of ambiguities to generate questions to move toward a solution.

To uncover the six commonplaces I discuss in this section I undertook a reading and re-reading of the texts. To discuss the six commonplaces I provide examples of each from the three stakeholder groups: the FDA, 23andMe and customers of 23andMe. Following these illustrations I offer an ethical schematic built upon the commonplaces that may be generative for producing guidance on communicating DTC testing results.
3.1 Safety and Reliability

Examples about concerns the FDA has about safety can be gleaned from text from the transcript from the Town Hall Discussion with the Director of CDRH and Other Senior Center Management on September 22, 2011; the statement of Jeffrey Shuren, Director, Center for Devices and Radiological Health for the FDA before the Subcommittee on Oversight and Investigations in the U.S. House of Representatives on July 22, 2010; the FDA’s Medical Devices Advisory Committee meeting on March 8, 2011; and the FDA’s warning letter to 23andMe.

At the 2011 Advisory Committee meeting, for example, Dan Vorhaus, an attorney with Robinson, Bradshaw & Hinson, stated:

> And the real tensions here are, I think, twofold. One is innovation tensions of balancing public health concerns and concerns for consumer safety against innovation and concerns for consumer access and desire for direct access. And then, again, this fundamental tension of interposing clinical guidance into the process of DTC genetic testing as opposed to safeguarding individual autonomy and giving people the ability to access that information on their own.

In his testimony to the Subcommittee on Oversight and Investigations Committee on Energy and Commerce U.S. House of Representatives Shuren explained concerns about safety with an example: “A false negative result for a hepatitis C virus test (a Class III test) may result in failure to provide appropriate treatment, leading to risk of liver failure due to delayed treatment. In addition, without the knowledge that he or she is infected, the patient may put others at risk by spreading the disease.” Finally, in its warning letter to 23andMe the FDA stated: “The FDA is particularly concerned with people acting on false or erroneous interpretations of data. The FDA notes that the BRCA-related risk assessment for breast or ovarian cancer could lead to “prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions”, in the case of a false positive, “while a false negative could result in a failure to recognize an actual risk that may exist.

Customers of 23andMe who purchased the testing kit through Amazon also raise this concern.

> Having my raw data has allowed me to look further into a genetic condition that runs in my family but isn't something that 23andMe specifically tests for yet. I had a 50/50 chance of inheriting something I didn't want. Now I know I lost that particular genetic lottery. Environmental and lifestyle factors may still keep the disease from manifesting but, armed with the knowledge that it is a real possibility, I can keep a close eye out for symptoms and not make the mistake of writing them off to normal aging. Some people would not want to know, but I did. I can now undergo regular testing, which will allow me to start treatment at the earliest detectable stage of the disease, should it manifest. My doctor tells me that the standard treatment is to first take a "wait and see" approach but, in my case, he won't be doing that. He’s delighted to have the knowledge he needs to treat me more effectively, should the need arise.

While safety seems to be a commonplace of the FDA and 23andMe’s customers, the commonplace of reliability is shared by all three entities. For 23andMe reliability is consistently liked to the affiliations the company has with scientists and the company’s professed adherence to scientific standards and methods. The two areas of the website where this is most apparent is the page entitled “Scientific Standards” and the publication of the company’s advisory board and the board members’ biographies. On the Scientific Standards page, for example, 23andMe lists six standards: 1) laboratory processing, 2) development and curation of scientific databases, 3)
a rigorous review process, 4) scientific and software innovation, 5) expert advice, and 6) scientific progress. Interestingly, the introduction to these standards seems to weave business concerns of reliability such as “quality control” with scientific concerns such as validity and accuracy. The introduction states: “Our scientific processes have been designed with the goal of providing our customers with accurate, high-quality data in a format that is easy to understand and interpret. Each step in our workflow is carefully monitored and validated through quality control measures that ensure your data accurately reflects your genetic makeup.”

This accuracy is linked analytical validity, which is part of the framework for genetic test evaluation. The framework takes its name, ACCE, from the four components evaluated: analytical validity, clinical validity, clinical utility and the ethical, legal and social implications of genetic testing. (Kroese, Elles, & Zimmern, 2007). According to Kroese, Elles, and Zimmern, analytical validity of a genetic test defines its ability to measure accurately and reliably the genotype of interest. In response to this need, in 2008 the 23andMe website also contained this statement: “The genotyping services of 23andMe are performed in LabCorp's CLIA-registered laboratory. The results presented in Health and Traits have not been cleared or approved by the FDA but have been analytically validated according to CLIA standards.”

In his testimony to Congress, Jeffrey Shuren also discussed the issue of reliability in terms of analytical validity: “Premarket review of moderate and high risk LDTs would ensure that the tests are evaluated for analytical validity and clinical validity, based on their claimed intended use, and would provide an independent and unbiased assessment of the data used to support analytical and clinical claims for those LDTs.”

For customers, on the other hand, validity is most often discussed in terms of results:

Afterwards I conducted many researches by geneticists on the internet that broadly concludes that these "take at home kits" are not as reliable as people would like then to be. I wash my hands from these tests now and will continue the old fashion way, familiy telling me and genealogical records.

Interestingly, customers were interested in reliability of the company as a business and reacted in responses to experiences with customer service: “This seems to be the best DNA service out there. It has at least as many features as other consumer DNA services and presents the info in a VERY user-friendly way. Plus, they add new features all the time.”

Another customer stated:

This company is obviously investing the money it gets in interest bearing accounts so it can make extra profit on what consumers spend for the extra 5-6 weeks they take to send you your results. How long does it take to run a sample in a machine? It does not take 2 months. My friend works at Genetic. She said they are obviously delaying the process on purpose as 1-2 weeks is tops here. I can't stand companies that legally rip off consumers on purpose. Here is another one.

3.2 Ability/Inability to Understand Complex Information

The ability, or inability, of both customers and primary care doctors to understand the complex information offered in genetic testing results is another commonplace shared by the FDA, 23andMe, and customers. For example, according to Dr. Gulcher’s statement, Chief Scientific Officer and Co-Founder, deCODE Genetics at the March 8, 2011 Advisory Committee meeting:

There are unique issues when it comes to direct-to-consumer testing. We need to be able to communicate the results in layman terms. We need to emphasize that these tests are risk tests. They are
not genetic determinative tests or diagnostic tests like Nancy [Wexler] described with the Huntington's disease gene test.

As stated in Shuren’s testimony to Congress:

Marketing genetic tests directly to consumers can increase the risk of a test because a patient may make a decision that adversely affects their health, such as stopping or changing the dose of a medication or continuing an unhealthy lifestyle, without the intervention of a learned intermediary.

The company 23andMe also saw the need to “translate” results. Although 23andMe’s website has evolved over the time, in 2007, as the home page of the company’s website was a job ad for science writers who could “create well written educational content for the general consumer” and could “convey complex scientific concepts in easily understandable prose for non-scientists.”

Customers, on the other hand, often see themselves as not needing a “translator.” Rather, they interpret the results on their own, as the following examples indicate.

I also found both the so-called health analysis to be pretty much useless. Sure, you're told that people with your genetic markers have a higher percentage than others markers of a certain disease or health risk, but so what? That is totally meaningless as lifestyle, diet, exercise and a host of other factors come into play and serve a far more important determination of what kind of health you have and are going to have.

As for the results, know what you are paying for. It isn't going to tell you, "YOU will get this disease" or "YOU won't get this disease." It tells you based on your genes how you compare to average using research studies to back up their findings. Someone complained that all their results came back "typical" or "average" that doesn't mean that everyone gets those results. This person is lucky, they didn't have any increased risks. One test for someone in my family came back at 51% risk with the typical risk being like 8% so now we know that we should be careful about things that might lead to this issue.

3.3 Innovation (and Privacy)

The fourth commonplace, innovation, has been discussed by the medical and public health community as a balancing act that needs to be carefully poised with concepts about patient safety: “As the science of genetics changes, science policy also changes, and there is an increasing need for “finding a level of regulation for genetic tests that both protects patients and encourages innovation” (Hamburg & Collins, 2010, p. 1). Elizabeth Mansfield, Officer of In Vitro Diagnostic Devices at the FDA echoed this concern in the 2011 Advisory Committee meeting: “In addition, the regulatory apparatus must keep pace with rapidly advancing technology and scientific knowledge, as discussed on the previous slide. We must be able to assess new technologies and promote high-quality innovation, while protecting patients.”

Other examples of this commonplace from this meeting follow from Dan Vorhaus.

So I don't think we're talking about whether there should be any additional oversight. I think the question that we're talking about is what kind of oversight should we have, and how do we provide effective oversight without stifling innovation in personal genomics and personalized medicine?...And, again, Dr. Hogarth mentioned this earlier, but we're talking about oversight, not necessarily prescriptions. So I don't think, again, anybody wants to have completely hands off, and I don't think anybody's saying let's ban everything. Well, I don't think very many people, I should say, based on what we've heard. But I don't think very many people are saying let's just ban everything that involves sending genetic information to consumers. The question is how to do it responsibly, again, to preserve
and protect public health, while also balancing that against the need for access to data for innovation and concerns like that.

The position of 23andMe on innovation can be found both on the company’s website and in the transcription of the presentation by Ashley Gould, 23andMe’s lawyer, at the Advisory Committee meeting in which she stated:

In conclusion, I leave you with 23andMe’s requests for your consideration: First, continue to allow informed consumers to freely learn about their own DNA. Adopt thoughtful policy [her emphasis] that promotes innovation and is flexible enough to evolve with new technologies and research developments….Through a cross-sector working group, effectively define clinical validity [her emphasis] specific to genetic testing. Finally, focus on establishing requirements [her emphasis] for analytical and clinical validity, analytical standards and transparency that apply to all genetic testing services. Genetic information provided directly to consumers should be held to the same standards as genetic information provided in a clinical setting.

Customers who bought 23andMe’s testing kit on Amazon also embrace innovation: “The 23andMe Genetic test is well worth the money. The product will become even more useful as more people are tested. It is the beginning of a new era in medical technology.” Several customers, however, want this innovation to be balanced with honoring the use of their privacy and data:

I have tested my DNA at 23andMe, FTDNA, and Ancestry.Com. (I will review the other companies too.) 23andMe is geared toward a health agenda. Which is fine. I am more interested in genealogy. I saw 23andMe advertised on a genealogy site, and therefore assumed that they would care about the experience of their customer base whose interests are along those lines. They do not. Even though they focus on health, in exchange for them using my data, I expected them to meet certain needs of mine as a customer. Most anything about genealogy and genealogical improvements goes unanswered by them on their message boards and direct emails about genealogical improvements are vague and manufactured, while they are quick to answer many other things. I think it is an awful way to treat a large part of their customer base. I also think they couldn't care less because they have my data already. Which angers me a lot. It is not like I am asking for something for free. I paid money, and it was implied that I would get a certain level of genealogical satisfaction. And they are using my data to further an agenda that I have no interest in. It is a very one-sided relationship.

3.4 Empowerment (and Participation)

The company 23andMe has always heralded customer empowerment on its website, but by 2010 this theme shifted from a more paternalist stance of the company helping the customer to the customer being in control by taking action. The empowerment theme is evident in text such as “choose the DNA test that’s right for you,” “take charge of your health,” and “choose to have it all.” The need for action is also apparent in the directives “choose” and “take charge.” This “doing” ethos continued through 2011 as the site was actually transformed into a set of instructions with steps. These steps are: “1 Get Your Kit,” 2 “Provide Your Saliva,” “3 Learn About Yourself,” and “4 Get Monthly DNA Discoveries.”

As a term the commonplace of participation is difficult to uncover in the FDA texts, but their process itself is participatory: the FDA invited DTC genetic testing companies to come and talk with them, they held public hearings that included not only representatives from the FDA and 23andMe but customers and medical professionals.
In the Amazon reviews customers of 23andMe were split in terms of whether or not this information was empowering. If the customer did not think the testing was valid or accurate, the person did not feel empowered by the information: “Well, to sum it up: if you do this test, you will be informed that you are related to EVERYBODY and if you are hoping to see just a very general summation: you will be ok, but anything other than knowing you are Asian, African, European will be no help. Save your money and go get a massage.”

Customers who did find the information accurate and useful, on the other hand did.

On the health side, it gives you info about: your genetic predisposition and carrier status (or lack of) for diseases, how well your body will likely respond to certain drug treatments, and your probable genetic traits. On the ancestry side, it gives you info about: your ancestor’s geographic regions, (if you opt-in and your family joins) you can compare DNA with relatives to see which lines you got which traits from, (if you opt-in) you can also find (and, if you like, contact) close or distant relatives. It’s awesome for those trying to find out more about their genealogy. I found the ancestry stuff totally fascinating and the health stuff very useful. WORTH EVERY PENNY.

4. FROM COMMONPLACES TO SCHEMATICS

As Z. H. McKeon noted in her introduction to the second volume of R. McKeon’s selected writings:

    data, or single terms, can be pointed to but meaningful discourse arises only when two terms are combined in interpretation, three or more in method where extended connections or arguments are constructed, and many terms in structures or theories which warrant the connections and anchor them in principle in a systemic account of reality. (Z. K. McKeon, 2005, p.6)

To put this another way, for terms to be meaningful, they must be contextualized in order to not only to create meaning but to be useful. Ethical frameworks are the same, and a universally valid ethical theory that has “all acceptable moral standards, of every time and place” (Winkler & Coombs, 1993, p. 2) may be impossible to obtain. Contextualism, on the other hand “adopts the general idea that moral problems must be resolved within the interpretive complexities of concrete circumstances, by appeal to relevant historical and cultural traditions, with reference to critical institutional and professional norms and virtues, and by relying primarily upon the method of comparative case” (Winkler & Coombs, 1993, p. 4).

Over the course of his life, McKeon worked on a schematic that fits with this notion of contextualism that was meant to account for a plurality of meanings, which have been effective force in action and in formation of policy. In examining the texts from 23andMe, the FDA and 23andMe customers, I attempt an early version of a schematic (Table 1) based on these ideas about applied ethics and contextualism and McKeon’s work with commonplaces and theorizing philosophy. To create this schematic I use the commonplaces I identified as a starting point and note each of the stakeholders using the commonplace. I then conflate McKeon’s categories of interpretations and method based on an argument that a worldview determines method, or as Farrell puts it, “methods are invented too” (2000, p. 195). Finally, I layer one of the three ethical standpoints McKeon discusses onto the interpretation of the commonplace.

There is an ethics of virtues related to considerations of the nature, powers, and ends of men; it borrows from the language of physics and psychology. There is an ethics of precepts related to the duties and obligations of man relative to himself and to others; it borrows from the language of law. There is an ethics of responsibility which is determined by reciprocities in the actions of men, and which relates
virtues and precepts preserving their differences in their indifference; it borrows from the language of art and technique. (McKeon, 2005, p. 252)

Table 1. An Ethical Schematic for Communicating DTC Genetic Testing Results

<table>
<thead>
<tr>
<th>Ethics/Principle</th>
<th>Stakeholder</th>
<th>Interpretations</th>
<th>Commonplaces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virtue</td>
<td>FDA</td>
<td>Trust us</td>
<td>Safety</td>
</tr>
<tr>
<td>Responsibility</td>
<td>FDA</td>
<td>Risk of acting on info</td>
<td></td>
</tr>
<tr>
<td>Responsibility</td>
<td>Customer</td>
<td>Acting on personal risk information as prevention</td>
<td></td>
</tr>
<tr>
<td>Duty</td>
<td>FDA/23andMe</td>
<td>Analytical validity</td>
<td>Reliability</td>
</tr>
<tr>
<td>Virtue</td>
<td>Customer</td>
<td>Honesty</td>
<td></td>
</tr>
<tr>
<td>Duty</td>
<td>Customer/FDA</td>
<td>Fact – does it work</td>
<td></td>
</tr>
<tr>
<td>Responsibility</td>
<td>FDA/23andMe</td>
<td>Need translator</td>
<td>Expertise/understand complex info</td>
</tr>
<tr>
<td>Virtue</td>
<td>23andMe/Customer</td>
<td>Be translator</td>
<td></td>
</tr>
<tr>
<td>Responsibility</td>
<td>Customer/FDA</td>
<td>Don’t need translator</td>
<td></td>
</tr>
<tr>
<td>Virtue</td>
<td>All</td>
<td>Promote</td>
<td>Innovation</td>
</tr>
<tr>
<td>Responsibility</td>
<td>Customer/FDA</td>
<td>Transparency</td>
<td>Privacy</td>
</tr>
<tr>
<td>Virtue</td>
<td>FDA/23andMe</td>
<td>--owner” of data</td>
<td></td>
</tr>
<tr>
<td>Responsibility</td>
<td>23andMe/Customer</td>
<td>--business</td>
<td></td>
</tr>
<tr>
<td>Virtue</td>
<td>All</td>
<td>Participate</td>
<td>Empower</td>
</tr>
<tr>
<td>Responsibility</td>
<td>23andMe/Customer</td>
<td>--regulatory process</td>
<td></td>
</tr>
<tr>
<td>Virtue</td>
<td>Customer</td>
<td>Learn</td>
<td></td>
</tr>
<tr>
<td>Responsibility</td>
<td>All</td>
<td>Community</td>
<td></td>
</tr>
</tbody>
</table>

5. CONCLUSION

McKeon said that some problems in science require simultaneously the “transformation of concepts, the invention of language and symbols, and the determination of facts” (2005, p. 244). Condit also argued that, “the movement of genetic information and technology out of the scientific research laboratory and into general commerce was accompanied by a substantial increase in the quantity of ethical debates about the applications of genetic information” (1999, p. 188).

I would add that these ethical discussions should take place prior to and in conjunction with discussions about communicating DTC genetic testing results and risk. To make this argument, in this paper I have focused on the discourse surrounding the 23andMe controversy because controversies can provide an opportunity to examine commonplaces as productive ambiguities that are a basis for discussion leading to further questions rather than unifying interpretations into a single voice (McKeon, 2005). By “adjusting a bolt or two” (Farrell, 2000, p. 195) of McKeon’s work with commonplaces and schematics, I have suggested that mapping
out the commonplaces of this controversy can be a productive strategy to engage in dialogue about the ethics of communication in this particular setting.

As Jeremy Gruber, President of the Council for Responsible Genetics, said at the 2011 Advisory Committee meeting:

As the science progresses, it has become clear that the major challenge for the future won't be sequencing technologies and broad public access to them, but rather the cost and difficulty of interpreting and applying the huge amounts of data that they generate. We are still only at the beginning of this genetic revolution, and it's certainly our hope that this new synthesis of genetics and information technology can empower individual self-knowledge and promote health access across a wide variety of platforms.

Issues of communication and interpretation will be at the center of these challenges. As such, science communicators will continue to play a pivotal role in the complex field of genetic testing, and as I have suggested in this paper, this role can be one that helps generate the questions that inform actions and policy.

ACKNOWLEDGEMENTS: The author would like to thank Christa Teston for her early input on this project and Jean Goodwin for her work on the symposium and the proceedings.

REFERENCES


Gulcher, J. (March 8, 2011). Comment made during public meeting of the Medical Devices Advisory Committee on the Molecular and Clinical Genetics Panel. Washington, D.C.


Mansfield, E. (March 8, 2011). Comment made during public meeting of the Medical Devices Advisory Committee on the Molecular and Clinical Genetics Panel. Washington, D.C.


