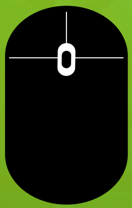
THINK BEFORE YOU CLICK

ORDERING A GENETIC TEST ONLINE



BY ANDELKA M. PHILLIPS

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Most of us click "I agree" multiple times a day. I normally begin my day by turning on my computer and checking my email. Often my computer will ask me to install software updates. Prior to installation, it will normally ask me to agree to terms and conditions, but how many of us read these documents? The answer is *very few*. We access a myriad of services online, but very rarely pause to read the fine print in all those clickwrap and browsewrap agreements. I am not saying online commerce is bad—the Internet has made so many things more accessible to so many people—but the use of online contracts is challenging many of the traditional conceptions of what a contract ought to be. My current research analyzes the contracts and privacy policies used by direct-to-consumer genetic testing companies (DTCGT). The overall aim of this project is to examine the current legal mechanisms for protection of the rights of consumers in their genomic sequence data and to suggest possible reforms. However, examining DTCGT contracts has forced me into the depths of online contract law, and this in turn has made me think more carefully whenever I am faced with an option to click away. I now do pause and wonder what exactly I am agreeing to. Most of the time it is more than I bargained for. This article will provide a brief overview of the world of online contracts in the context of DTCGT.

Before proceeding further, it is necessary to explain briefly what DTCGT is. DTCGT, also sometimes referred to as personal genome testing (PGT), is a new industry, which has developed as a consequence of the recent advances in genetic and genomic science. DTCGT companies offer a variety of services, but their normal procedure is to allow people to order a genetic test from their website. Customers then receive a kit in the mail and use the kit to take a sample of their DNA, normally in the form of saliva. The sample is then returned to the company.[1] After the sample has been analyzed, the company will convey the results of the test to the consumer and sometimes provide ongoing updates on the individual's health information. A web-based interface is the primary mode of delivering this information to consumers, often without recourse to genetic counseling (although some states, including California, require DTCGT companies to offer genetic counseling).

In conducting my research, I have so far compiled a list of 227 companies offering genetic testing services online. The primary focus of my current research is on those companies that offer health-related testing services, but in the future I hope to explore issues raised by other categories of testing. (Approximately 100 companies offer some form of health-related testing, with half of these based in the United States. Companies that offer testing services via physicians have been included for the sake of comprehensiveness.) The category of health-related testing itself covers a wide range of services, and it is possible to further classify companies within this category into subcategories, namely: pharmacogenetics or pharmacogenomics; nutrigenetics or nutrigenomics; predisposition/susceptibility; carrier; and presymptomatic. Currently, DTCGT companies primarily offer either genetic testing for specific conditions and, less commonly, whole genome scans. It is likely that in the near future these companies will offer whole genome sequencing at very competitive rates. Gene by Gene's DNA DTC currently performs a whole genome sequencing service for $7,395 (US).[2] DTCGT differs from clinical genetic testing services in that it is marketed either directly to consumers or to consumers and their physicians.

For health-related testing, the most common services are predisposition, presymptomatic, and carrier testing. Predisposition testing provides an indication of an individual's absolute lifetime risk and/or relative risk of developing a particular condition,[3] while presymptomatic testing evaluates whether a healthy asymptomatic individual "has a high probability of developing a condition."[4] Carrier testing aims to identify whether a person is a carrier for a particular condition.[5] One type of testing that shows particular promise for personalized medicine is that of pharmacogenetics, which is concerned with assessing an individual's responsiveness to particular drugs or therapies.[6] Some companies now offer data-only services, which means that they only provide their customers with the raw sequenced data. (Gene By Gene's DNA DTC and 23andMe are good examples of this.)

Taking a wider view of the industry as a whole, there is a broad spectrum of services available, ranging from ancestry testing to nonconsensual ('infidelity') testing. There are approximately 85 companies offering paternity testing services, 62 offering ancestry testing, 27 offering tests for child talent and athletic ability, and 34 conducting nonconsensual testing.

The companies which first rose to prominence in this field were: DeCODE (which became DeCODEme); 23andMe; and Navigenics. Both DeCODEme[7] and Navigenics have since been sold to life sciences research companies and are no longer offering DTC services, although very recently DeCODE has resumed operating in Iceland.[8]

Most DTCGT companies' contracts and privacy policies take the form of either clickwrap (click-through) or browsewrap agreements. These contractual forms have developed from shrinkwrap agreements and are now ubiquitous in all forms of online commerce. These contracts are mass-consumer standard form contracts. Most afford no opportunity for the consumer to negotiate and are drafted by the company heavily in its favor. Whenever you buy a product online, participate in an online auction, update computer software, or access content from a plethora of websites, you may at some point be asked to agree to corresponding terms and conditions. Most of the time you will do this without reading and sometimes without even glancing at these terms and conditions. It is also possible that even when you have not been asked, your use of the website will be deemed as acceptance

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of the website's terms. Several questions arise here. Why do we not read them? Is it a matter of trust? Is it a matter of lack of time? Do we simply not care? Unfortunately, the reality is that many of us do not have sufficient time to read these contracts. There is also a strong element of trust here. Many of us do trust companies to a certain extent, and we also tend to think that harm befalls other people and not us.

Of course, many of us would still not choose to read online contracts, even if we had sufficient time to do so. Furthermore, for the ordinary consumer who chooses to read these documents, the process is not necessarily one of enlightenment. This is in large part due to both the length of online contracts and also the language used, as many contracts use language that requires a high level of education to understand.[9] There is also a significant level of misunderstanding on the part of consumers of the meaning and effect of online privacy policies. More studies are needed, but several studies have found that a high percentage of consumers think that the existence of a privacy policy on a website means that the company cannot share or sell data.[10] This is of course not the case. The current trend against reading contracts has led to a situation where companies, assuming no one will read their contracts, have begun to insert extra clauses, giving them additional advantages that are unrelated to the original consideration given for that contract—a practice that Nancy Kim describes aptly as the use of "crook provisions." [11]

So what does the common DTCGT contract look like? Some of the clauses that can normally be found in these contracts include: compulsory arbitration; choice of law; broad disclaimers of liability, including stating that the company cannot guarantee fitness for purpose; intellectual property; indemnification; change of terms at any time; and clauses stating that the information provided is for informational and research purposes only.

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Just how long are these contracts? 23andMe's Terms of Service is 9,081 words, while Gene By Gene's DNA DTC is 3,645 words. It is common for online contracts generally to be at least 6,000 words in length. If you need an example from outside the DTCGT context, take a look at your iTunes user agreement.

One of the most prominent DTCGT companies, 23andMe, is facing multiple class actions this year in the aftermath of the FDA's warning letter of November 2013.[12] The recent order in *Tompkins v. 23andMe*[13] centered on 23andMe's arbitration clause. However, their contract is by no means unique. Similar clauses have been included in the contracts of many other companies, including those offering services via physicians. They are also to be found in the contracts of companies offering other types of testing, such as ancestry testing.

Some clauses commonly included in DTCGT contracts may not surprise the reader, as it is standard business practice to limit a company's liability wherever possible. However, undergoing genetic testing is not the same thing as purchasing an ordinary consumer product, such as a DVD, television, or book. Once a person's DNA sample has been sequenced, the information is irrevocable—an aspect which several companies mention in their contracts. Sequenced genetic data can also count as personally identifiable information, and it can potentially reveal sensitive information regarding a person's health status and ethnicity. It can also serve as a unique identifier of the person tested, and at the same time it can be used to reveal information about individuals who may be related. A recent article by J. Trevor Hughes discusses the unexpected consequences of undergoing genetic testing. In this instance, the author signed himself and his parents up for genetic testing by 23andMe. 23andMe offers a service that connects people to possibly unknown relatives. In this case, the testing revealed that the author had an unknown half brother. This was a factor in the subsequent divorce of his parents. This type of scenario is likely to only become more common if genetic testing continues to be available DTC.[14]

When an individual undergoes genetic testing in a clinical setting, there are more checks and balances, as well as a strong emphasis on informed consent. Normally the person tested will be provided with genetic counseling both prior to the test's performance and after he/she receives the results. When we move genetic testing outside this setting there are arguably more dangers for the test subject, and it seems advisable for these companies to improve their contracts, and especially their consent mechanisms. This could be done in an innovative and educational way; it need not be harmful for the company. Contracts could be improved by making them more interactive, with attention being drawn to key clauses by bold fonts or other visual aids; by providing more opportunities for customers to opt out of particular services; and by providing more information about use, storage, and disclosure of data. Educational videos about genetic information and the risks of learning unwanted information could also be provided. There have been some successful efforts in the field of genetic counseling that utilize such videos. As many companies do want to conduct medical research based upon data they have collected from consumers, then it would be a two-way street, and the sharing of information would benefit all parties in the long-term.

There is much promise for DTCGT testing

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in the context of preventative medicine and treatment, but more research is needed. Although great advances have been made, researchers are only really beginning to understand the part that genetics plays in the development of complex diseases. Even seemingly simple matters such as the genes associated with height inheritance have proved to be far from simple. For now, with many complex diseases, a genetic predisposition to that disease is only one of numerous factors to be taken into consideration in current medical practice and treatment, and there is growing interest in the effects of the microbiome on human health. There is a general need to improve the understanding of DTCGT and genetics more generally both amongst ordinary medical practitioners and consumers who are considering having a DTCGT test, and it would be extremely helpful for companies to contribute to improving the understanding of their services, as well as the limitations of genetic risk information.

The proposed way forward does not have to be detrimental for the DTC industry. It is possible for contracts to be improved without severely disadvantaging companies. If DTC is to live up to its promises and assist the cause of personalized medicine, it would be beneficial for contracts to be more fairly balanced and to empower consumers through providing adequate information in a comprehensible form. If DTC genetics is to have a real connection with consumer empowerment and enabling people to take charge of their genetic information, then consumers need more tools to do this. If DTC companies want to conduct participatory research projects, then consumers ought to be able to participate knowingly and more actively.

Regulatory reform is also needed, but improving contracts and privacy policies would be a cost-effective and useful strategy in the short-term. I am monitoring the FDA's work in this area (especially its *Anticipated Details of the Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories* and the recently released Draft Guidance for public comment) together with reform of the medical devices regulatory framework in the EU (two Draft Regulations: Medical Devices Regulation and IVD Regulation) with interest. My work is currently ongoing, and I hope to use the compiled data to create a publicly available database that records information about the industry. ◆

Endnotes

1. A. Harris, S. Wyatt & S. E. Kelly, *The Gift of Spit (And the Obligation to Return It)*, 16 Information, Communication & Society 2 (2012), at 1–22.

2. Gene By Gene, *Whole Genome Sequencing* (2014), *available at* https://www.genebygene.com/pages/research.

3. Approximately 64 companies offer this type of testing.

4. Human Genetics Commission, *A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services* (Department of Health, 2010), Tables 1(2) and 1(5).

5. Approximately 24 companies offer this type of testing.

6. Approximately 26 companies offer this type of testing.

7. D. Vorhaus, *Implications of Amgen/deCODE Deal for Genetic Testing Consumers* (2012), *available at* http://www.genomicslawreport.com/index.php/2012/12/10/implications-of-amgendecode-deal-for-genetic-testing-consumers/.

8. Pete Shanks, *Genomic Controversy in Iceland: Déja Vu All Over Again*, Center for Genetics and Society (2014), *available at* http://www.biopoliticaltimes.org/article.php?id=7778.

9. Thomas J. Maronick, *Do Consumers Read Terms of Service Agreements When Installing Software?—A Two-Study Empirical Analysis*, 4 Int'l J. Bus. & Soc. Res. 137 (2014); Susan E. Gindin, *Nobody Reads Your Privacy Policy or Online Contract: Lessons Learned and Questions Raised by the FTC's Action Against Sears*, 8 Nw. J. Tech. & Intell. Prop. 2 (2009) at 1; Robert A. Hillman, *On-line Consumer Standard-Form Contracting Practices: A Survey and Discussion of Legal Implications*, Cornell Law Faculty Publications, Paper 29 (2005) at 1; Ian Ayres & Alan Schwartz, *The No-Reading Problem in Consumer Contract Law*, 66 Stan. L. Rev. 545 (2014).

10. Allyson W. Haynes, *Online Privacy Policies: Contracting Away Control Over Personal Information*, 111 Penn St. L. Rev. 611 (2006); Jacqueline J. Kacen et al., *Bricks Or Clicks? Consumer Attitudes Toward Traditional Stores and Online Stores*, 18 Global Econ. & Mgmt. Rev. (2013) at 1; David Thompson, *I Agreed to What—A Call for Enforcement of Clarity in the Presentation of Privacy Policies*, 35 Hastings Comm. & Ent. L.J. 199 (2012).

11. Nancy S. Kim, Wrap Contracts: Foundations and Ramifications (OUP. 2014) 51-2; Nancy S. Kim, *Contract's Adaptation and the Online Bargain*, 79 U. Cin. L. Rev. 1327 (2010).

12. US Food and Drug Administration, Warning Letter of November 22, 2013, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm. This stated that 23andMe's kit had not received appropriate "marketing clearance or approval in violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act)." It classified the kit as a "device within the meaning of section 201(h) of the FD&C Act, 21 U.S.C. 321(h), because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body."

13. Tompkins v. 23andMe, Inc., No. 5:13-CV-05682-LHK (N.D. Cal. June 25, 2014) (order granting omnibus motion to compel arbitration), *available at* https://cases.justia.com/federal/district-courts/california/candce/5:2013cv05682/272617/109/0.pdf?ts=1403776223.

14. J. Trevor Hughes, *Consent and Forgetting: What Privacy Pros Can Learn From One Family's Unexpected Experience* (2014), *available at* https://privacyassociation.org/news/a/consent-and-forgetting-what-privacy-pros-can-learn-from-one-familys-unexpected-experience/.

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