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Reading the fine print when buying your genetic self online: direct-to-consumer genetic testing terms and conditions

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Contracts are ubiquitous online. Clickwrap and browsewrap agreements are to be encountered on almost every website a person engages with when accessing services online. Through these documents, people enter into binding contractual relationships, often without reading and sometimes without noticing these documents, when they engage with a wide variety of services online. This article discusses the use of contracts by the direct-to-consumer genetic testing (DTCGT) industry, as the dominant means of industry self-regulation. To date limited attention has been paid to these contracts. This article reviews the contracts of 71 companies that provide a variety of tests for health purposes. It considers these contracts from a consumer protection standpoint and identifies a number of problematic terms that may be challengeable under the UK's consumer legislation and concludes by discussing the recent work potential for the UK's Competition & Markets Authority to establish and enforce clear standards for DTCGT contracts.

Keywords: direct-to-consumer genetic testing; regulation; contract; unfair terms; clickwrap; informed choice

Introduction

We are living in the digital age and we are also living in the age of digital contracts. The Internet has become part of the fabric of everyday life for many people. It is used to document our lives, to access a myriad of services, including now the purchase of genetic testing services. However, almost every website you visit is subject to a contract in some form, often appearing as terms of use, terms and conditions, or terms of service, and these contracts do have important legal implications. They govern relationships between businesses and consumers and they may limit rights to redress if something goes wrong. The average person active online today will enter more contracts in a year than their grandparents did in a lifetime (Felten 2011, D8; Hoffman 2016, 1596). This paper discusses the use of

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contracts online and their role in regulation in a particular context, that of direct-to-consumer genetic testing (DTCGT). It focuses on the contracts of companies that provide tests for health purposes. This paper will address two research questions: from the perspective of consumer protection, what are the problems with these contracts; and how might UK law be used to improve contracts so that they afford better protection for consumers?

The DTCGT industry can be viewed as an example of disruptive innovation (see paper by Curnutte 2017 in this issue) and also an example of a shift from patient to consumer healthcare, as it allows the purchase of genetic tests online without a medical intermediary, bringing them into the consumer space and also into the domestic space, as people can order tests online from their homes. It should be noted that the consumer space differs significantly from the medical space, but in the context of health-related testing it is also not clear that DTCGT services ought to be viewed as consumer services and not medical services (Offit 2008). The term "direct-to-consumer" has primarily developed in the context of advertising and sale of pharmaceutical drugs (Pines 1999). DTCGT can either be advertised to the public but only available through an intermediary (normally a medical practitioner), or it can be both advertised directly and available for order directly by a consumer, normally over the Internet, sometimes also with the involvement of a medical practitioner (Hogarth, Javitt, and Melzer 2008, 163–164). The process normally involves the provision of a test kit by the company which the consumer uses to collect a DNA sample, which is in turn sent back to the company, which then carries out some form of genetic analysis service and then ultimately provides the consumer with test results in digital form. A wide range of health tests are available, ranging from predisposition and pre-symptomatic testing for serious diseases to carrier tests, pharmacogenetic tests (concerned with assessing an individual's responsiveness to particular drugs or therapies) (HGC 2010, 2–3), and also nutrigenetic tests (deals with associations between nutrients and metabolism and genes). Companies that provide testing for health purposes are generally making services available that have previously been offered in a medical setting. There is considerable scientific and clinical skepticism about the accuracy of tests purporting to provide genetic risk assessment for common, complex diseases.

Fourteen years have passed since the first major UK policy report on the regulation of the DTCGT industry (HGC 2003). The HGC also developed *A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services* (2010) and this Framework set out in article 6 that "Clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons" (2010). (Clinical validity and utility were also stressed by the Association for Molecular Pathology in their 2015 Position Statement.)

A small number of prominent companies: DeCODE's DeCODEme; 23andMe; Navigenics; Pathway Genomics; and Knome have been the subject of much of the academic literature. However, there is a greater number and diversity of

firms, and the potential now for DTCGT services to be accessible more widely. If there is a corresponding wider consumer uptake of these services, the issues the industry raises are likely to increase in importance over time. 23andMe has been valued at a market cap of $1 billion (Krol 2015). Furthermore, a recent study by Research and Markets suggests that the "global predictive genetic testing & consumer/wellness genomics market is anticipated to reach USD 4.6 billion by 2025" (2017). Whether or not this estimate will prove to be accurate, if the industry does continue to grow there is likely to be significant consumer uptake of these services and this will include consumers who may be considered vulnerable in some way (see the Unfair Commercial Practices Directive; the Directive on Consumer Rights; and the General Product Safety Directive). The law does make distinctions between ordinary or average consumers and vulnerable consumers. The European Commission's 2016 report explores consumer vulnerability and while acknowledging the lack of a universal definition, it identifies five core dimensions to vulnerability (xviii, and 39–40). Vulnerability is a spectrum and a person may become vulnerable due to a change in their circumstances, but "some personal characteristics can imply that vulnerability remains an enduring characteristic for particular groups of consumers" (xviii).

While, DTCGT often involves feedback of results to individuals without any intermediary, in a clinical setting, a UK patient contemplating genetic testing would normally be provided with genetic counseling both prior to the test and after the test. The provision of counseling services assist patients with understanding what genetic test results mean for them and should assist them with understanding the benefits, risks, and limitations of test results. Article 8 of the HGC's *Framework* set out information requirements for people undergoing genetic testing and suggested that those undergoing "predictive genetic tests" should receive genetic counseling. Drawing upon this, it would be beneficial if companies did provide genetic counseling to consumers.

For genetic tests carried out in a clinical setting, patients are normally required to give informed consent and the rights of patients to refuse treatment are also strongly protected. Indeed Article 9(1) of the HGC's *Framework* specified that a genetic test should only be carried out "after the person concerned has given free and informed consent to it." The importance of informed consent has also been stressed in a number of policy guidance documents to date (European Society of Human Genetics 2010; OECD 2007). However, in the online environment consumers are often deemed to have consented to the terms and conditions of websites through use or viewing of a website and there is a need to improve consent mechanisms for DTCGT health services. It is also important to recognize that informed consent in a medical setting is different to how consent is treated in contract law, but not all DTCGT companies have separate consent documents and consent and agreement or acceptance of terms are often treated synonymously in the DTCGT space.

This article focuses on the regulation of the industry from a consumer protection perspective, but it should be noted that these services do raise significant issues

regarding consumer privacy and data protection. Furthermore, as highlighted by Christofides and O'Doherty's (2016) recent study, consumers' expectations regarding privacy practices of DTCGT providers, may be at odds with actual practices and disclosure policies. In relation to privacy and security risks in this context, an analogy can also be made with wearable fitness monitors. Citizen Lab and Open Effect's report highlighted a number of vulnerabilities in common wearable devices (2016), and given the nature of sequenced genetic data and the difficulties in preventing re-identification of individuals on the basis of such data, the significance of privacy risks in this context should not be underestimated (Ayday *et al*. 2015; Erlich and Narayanan 2014; Nuffield Council 2015). As companies are often engaging in research on consumers' data and collecting other forms of personal and potentially sensitive data, more research on the potential for data linkage and re-identification is also needed.

In the UK, some marketing of DTCGT tests has been permitted and 23andMe has been selling their test kits through Superdrug both via the Superdrug website and in their stores (Meikle 2015; Wallace 2015). This has been possible, because their test kits have a Conformité Européene (CE) mark meaning that the kit has been approved as safe for the purposes of collecting saliva. This certification though is only an assessment of the test kit's safety as a collection device. It does not provide an assessment of the quality of the genetic testing service provided or of any accompanying analysis or interpretation services.

In the US, the Food and Drug Administration (FDA) has recently altered its stance regarding DTCGT services (see paper by Curnutte 2017 in this issue). In April 2017 the FDA approved 23andMe's Genetic Health Risk tests for 10 conditions to be marketed in the US. This may lead to wider availability of DTCGT services for health purposes in the US from other DTCGT providers as well, as the FDA intends "to exempt additional 23andMe GHR tests from the FDA's premarket review, and GHR tests from other makers may be exempt after submitting their first premarket notification" (FDA 2017). Significantly, the FDA will be requiring consumer comprehension tests (FDA Letter 2017), but this does not require comprehension tests of the online contracts used on DTCGT websites and as contracts do govern the relationship between DTCGT companies and consumers, there is also a need to ensure that consumers understand the content of these contracts.

Considerable attention has been paid to the potential for consumer harm arising from the profound asymmetries of information between companies and consumers arising in the context of a fast-moving and highly complex field of biomedical science. Policy reports in the USA and Europe have expressed concerns that the public may be misled by promotional hype because they lack the scientific knowledge to assess the veracity of companies' claims. A number of academic studies have examined the websites of DTCGT genetics companies and identified problems with the quality of information offered to consumers. Hennen, Sauter, and Cruyce (2009) undertook a review of 38 companies, assessing the quality of information provision using 12 criteria established by Datta *et al*. (2008). They found

that 55% of companies complied with four or fewer of the 12 criteria, concluding that such "fundamental information deficits [had] . . . possibly far-reaching consequences for consumers." Surveys by Geransar and Einsiedel (2008) and Sterling (2008) have drawn similar conclusions.

More recently, there has been growing interest in the issues of privacy, security, and transparency in provision of information in the context of DTCGT services (Christofides and O'Doherty 2016). Laestadius, Rich, and Auer study (2016) analyzed 30 websites offering health and ancestry tests and examined "the extent to which DTCGT-GT companies are complying with international guidance on the transparent provision of information related to confidentiality, privacy, and secondary use of the genetic samples and data they collect" (2). They found that although there have been some improvements in industry practices since earlier studies, such as an increase in the number of DTCGT companies having terms and conditions and privacy policies publicly available there are still weaknesses that need to be addressed. One area where there is particular need for improvement is the provision of information "regarding the risks and benefits of" DTCGT services and they cite Singleton *et al.*'s work which argued that this "lack of transparency" violates "the ethical principle of informed choice" (2012, 6). The Singleton study used frameworks "based on two core components of an informed choice: (1) the decision-maker has relevant, high-quality information which presents the various alternatives and outcomes; and (2) it is consistent with the decision-maker's values" (Singleton *et al*. 2012, 2). They found that

> in the main pages of these websites, consumers are exposed to an average of 6 times as many benefits as risks and limitations. Therefore, consumers who only read the main web pages may be getting a skewed picture of the benefits, risks, and limitations of testing. (2012, 5)

They recommended the need for companies to consider providing more educational information on their websites to assist consumers.

There have been a large number of proposals for policy action, but such initiatives have tended to focus on the regulation of health-related tests, and the role of medical device regulators in premarket evaluation of tests. It is important to note though that many types of DTCGT services, such as ancestry, talent identification or nutrigenetic testing will not be covered by these regulations, and even for tests covered by medical device regulation, not all aspects of the contractual relationship between company and consumer would be addressed, so alternative or supplementary mechanisms are required (Kalokairinou, Howard, and Borry 2014). The potential role of consumer legislation has been advocated by some as a preferred mechanism to address "fraudulent, deceptive, and unfair business practice" even for health-related tests (Wright, Hall, and Zimmern 2011) and the Human Genetics Commission (HGC) envisaged a role for consumer protection mechanisms in its 2003 report, along with an increased role for the Medicines and Healthcare Products Regulatory Agency (MHRA) (HGC 2003). In the same year, Martin and

Frost provided an early attempt to map a taxonomy of different types of DTCGT services on to a range of legal and regulatory remedies, including consumer law (2003). In the US, as well as the American College of Medical Genetics and Genomics (ACMG), the American Society for Human Genetics (ASHG) has also been active in this area and released a *Statement on Direct-to-Consumer Genetic Testing in the United States* (2007). This Statement recommended that the Centers for Medicare and Medicaid Services (CMS) "create a genetic-testing specialty under CLIA, to ensure the analytic validity of tests and the quality of genetic testing laboratories" and also that "CMS should ensure that all DTCGT genetic-testing laboratories are certified under CLIA and should maintain a publicly accessible list containing the certification status of laboratories." It went on to recommend that, "FDA and the FTC should work together to develop guidelines for DTCGT testing companies to follow, to ensure that their claims are truthful and not misleading and that they adequately convey the scientific limitations for particular tests." It also stressed the importance of the following: transparency in companies' practices; that they should provide appropriate information regarding the risks and benefits of DTCGT; and also that professional medical organizations should provide further education to their members, so that physicians can adequately interpret and understand DTCGT services and results. However, despite some focus on consumer protection remedies, thus far scholars have paid limited attention to the contracts that bind DTCGT companies to their customers.

There is a growing literature that examines the consumer contracts used by online businesses more generally (Ayres and Schwartz 2014; Clapperton and Corones 2007; Loos and Luzak 2015). The level of notice and transparency of these contracts to consumers varies: clickwrap contracts typically force a consumer to scroll through a document before clicking on a box labeled I agree or I accept; whereas browsewrap contracts allow for consumers to access the terms via a hyperlink and it is not necessary to click on the link in order to be held to have entered into the contract (Kim 2013, 39–41, 41–43; Manwaring 2011). Although a clickwrap contract does afford more opportunity to read, in reality consumers often do not read either clickwrap or browsewrap agreements or privacy policies and while there may be an opportunity to read, these documents tend to be extremely lengthy. In the versions of contracts examined herein, 23andMe's Terms of Service is 9081 words, and its Privacy Statement is 32 pages long and 15,807 words long; while Gene By Gene's DNA DTCGT Terms and Conditions is 3645 words and its consent document is 4718, which can be contrasted with the lengths of the iTunes agreement, which is 19,972 words long and Amazon's Terms and Conditions which is 36,275 words long (Wigley 2015).

McDonald and Cranor's (2008) study "estimated that it would cost the average American Internet user 201 hours or the equivalent of $3534 a year to read the privacy policies of each website that he or she visits" (562). Also, where consumers do choose to read such contracts there is evidence to suggest they will not necessarily understand their content due to the complex nature of the legal language used,

which may require a high level of education to comprehend (Ayres and Schwartz 2014; Loos and Luzak 2015). It also may be difficult for a consumer to locate terms on a website. Another study by Reidenberg, McDonald *et al*. investigated "the differences in interpretation among expert, knowledgeable, and typical users and explores whether these groups can understand the practices described in privacy policies at a level sufficient to support rational decision-making" (2015, 42). This study found discrepancies in understanding, including among experts, showing

> a number of areas where website privacy policies are too ambiguous to be meaningful and reveal a need to clarify specific data practices. The research demonstrates that policies describe websites' data sharing practices poorly. Experts could not reach consensus on interpretation of data sharing practices generally and agreed even less as to the various nuances of data sharing. (2015, 83)

While this study focused on the privacy policies of 6 US news and shopping websites (55–56), the study's findings are relevant to thinking about how consumers interact with contracts and privacy policies in the DTCGT context. Given that the nature of DTCGT services for health can involve the dissemination of quite complex genetic and health information, discrepancies in people's understanding of privacy policies for less complex services should lend support to a need to improve both contracts and privacy policies in order to enhance consumer understanding and support decision-making.

Another matter, which needs further consideration is the design of the contracting environment online and the way consumers behave online. It has been suggested that in the online world people are becoming habituated to clicking (Kim 2013, 59–60) and may even be "click-happy" (Kim 2013, 61; Hillman 2005, 4). In Frischmann and Salinger's recent article they "develop an original argument that the electronic contracting environment should be understood as a techno-social tool for engineering human beings to behave automatically, like simple machines. . . . " They

> describe the problem in Taylorist terms, as a system of scientific management that's directed toward consumers. This view emphasizes how consumers, like laborers in Taylorist workplaces, are conditioned (and possibly deskilled) to behave in ways that are largely determined by system designers who optimize environments to meet efficiency standards. (2016, 2)

They suggest that the electronic contracting environment "conditions human beings to behave like simple stimulus-response machines" and that if this is case there may be a need for significant reform for a number of reasons, but especially in the interests of protecting "human autonomy and sociality" (2016, 3). Frischmann and Salinger's work is useful when we think about the use of contract to govern the purchase of DTCGT tests for health purposes. If we think about this in a more traditional medical context where protection of patient autonomy is often given significant protection the idea that the way people behave online may be

diminishing their autonomy especially in relation to decision-making in the context of the purchase of DTCGT tests is worthy of further scrutiny.

This paper details a number of ways in which current industry reliance on standard "wrap" contracts (defined below) falls short of basic requirements for consumer protection. Having described the problem, the paper goes on to offer a regulatory solution, advocating a more active role for consumer protection agencies in governing the DTCGT industry, and in particular, exploring the potential role of the Competition & Markets Authority (CMA) in the UK context. Given the nature of DTCGT services and the importance of privacy and security issues raised by these services, the conclusion notes there is also a potential role in the UK for the Information Commissioner's Office (ICO) and the Human Tissue Authority (HTA), as well as scope for similar bodies in other countries in improving regulation of the industry.

Method

This paper draws on findings from on-going research on the DTCGT industry and its regulation that encompasses the diverse range of DTCGT services on offer (book forthcoming). These now include tests for ancestry, health, diet and lifestyle, genetic relatedness (most often paternity), child talent, and infidelity tests. However, this article focuses on the use of contracts by 71 DTCGT companies that provide tests for health purposes, highlighting specific types of terms commonly included in DTCGT contracts, which are likely to be problematic from a consumer protection standpoint. This draws upon a review conducted between 2011 and 2015 on DTCGT wrap contracts obtained from DTCGT company websites, which had their contracts publicly available. The present article does not include quotations from specific contracts, but uses figures based on the overall frequency of these terms. This article uses the term "wrap contract" in the same manner as Nancy Kim, that is:

> a blanket term to refer to a unilaterally imposed set of terms which the drafter purports to be legally binding and which is presented to the nondrafting party in a nontraditional format. Nontraditional in this context means that the contracting form wasn't commonly used prior to 1980 and includes electronic media and offline mediums. (2013)

As part of this research a database of companies was created (Phillips 2015a). This was done through the performance of searches using an Internet search engine (Google) and using the following terms: order genetic test online, order disease risk genetic test, genetic test diet, order genetic predisposition test, genetic test for athletic ability, genetic paternity test, genetic test for drug response, genetic test nutrition, genetic test metabolism, DNA diet test, DNA health risk test, infidelity DNA test, genetic test for Warfarin, genetic test for statin, genetic test for prostate cancer, genetic test for breast cancer risk, genetic carrier test, ancestry DNA

test, genetic ancestry test. These searches were used to identify English language websites for potential DTCGT companies (229 companies – the list is continuing to be updated and the most current figure is 269 (as of April 2017). This procedure was repeated on semi-regular (one to three times a year) basis. In conducting these searches, reference was also made to the work conducted by the HGC, the Government Accountability Office, Genetics and Public Policy Center at Johns Hopkins (GPPC), and all websites of companies listed in the work of these organizations were examined (The Genetics and Public Policy Center 2011; Kutz 2010).

Each candidate website was inspected manually to confirm that it was for a DTCGT company (229 companies). Each DTCGT company was assigned to one of the following categories: health (subdivisions of pharmacogenetic; predisposition; pre-symptomatic; nutrigenetic; carrier testing; and testing available through physicians) – 102 companies in total; ancestry – 68 companies; paternity – 85 companies; non-consensual – 34 companies; DNA dating – 4 companies; and child talent and athletic ability – 29 companies. All companies identified were tabulated with one master table and then tables of the various categories running to 481 pages. The tables briefly summarize the services offered by each company and also classify the companies into groups based on the type of services they offer (Phillips 2015a, 2015b). If a company's website was no longer functioning or the company ceased to operate this was also recorded.

In compiling the list of health-related testing companies, those companies, which market their services to physicians and/or allow consumers to order through physicians were also included for the sake of comprehensiveness. The websites of DTCGT companies in the health category (102 companies) were examined to identify those whose terms and conditions were available to the public (71 companies). The health category includes providers of: pharmacogenetic; predisposition; pre-symptomatic; nutrigenetic; carrier testing; and testing available through physicians The online contracts and privacy policies of health-related DTCGT companies were saved as electronic documents (PDF files). Where available the contracts and privacy policies were also saved for all other categories of testing and these will be examined in future research.

Findings: potentially unfair terms in DTCGT contracts

It is important to recognize that whenever an individual is active online they are likely to be forming contractual relationships in a wide variety of contexts. While this may not seem problematic if nothing is going wrong, the use of contracts in the online environment can have a significant impact on an individual's rights, as businesses often use their contracts to govern not only their relationship with consumers, but also the use of their websites, and services.

While the DTCGT industry is quite diverse, there is much commonality in the structure of DTCGT contracts, the types of terms that are included and the language used by companies. DTCGT contracts appear on websites normally as terms and

conditions, terms of use, or terms of service and are sometimes combined with privacy policies or statements. Companies use these contracts to govern their relationship with consumers and also to govern the use of their services and the use of their websites, including social networking functions. In the DTCGT context this means that these contracts can be used to govern participation in research and social networking functions on DTCGT websites.

For the most part, DTCGT wrap contracts closely resemble the forms used in electronic commerce more generally. For instance, many of the terms commonly found in DTCGT contracts are also found in the contracts of Amazon, Twitter, and Google and the language used is also very similar (Loos and Luzak 2015). Typically, a DTCGT contract is likely to include: a clause allowing the company to unilaterally alter its terms; clauses indicating that services are provided for informational purposes and do not constitute medical advice; a clause governing consent; a clause governing acceptance of the contract; exclusion clauses disclaiming liability; clauses requiring consumers to indemnify the company; clauses disclaiming warranties; clauses governing intellectual property; clauses governing disclosure of data; clauses making arbitration compulsory; clauses proscribing the choice of law or jurisdiction for setting disputes; and clauses limiting remedies and damages.

Several of these terms as they are currently framed are problematic from a consumer protection standpoint and may be open to challenge on the grounds of potential unfairness under UK law. Consequently, some of these terms and some contracts in their entirety may not in fact be enforceable against UK consumers. The terms, which seem most likely to be challengeable on the grounds of unfairness, are:

- clauses allowing for unilateral variation of the contract;
- exclusion clauses purporting to disclaim liability for fitness for purpose or for personal injury caused by the company's negligence;
- clauses limiting scope of purpose, such as those specifying that services are not provided for medical purposes;
- clauses purporting to bind the consumer to resolve any disputes in another jurisdiction;
- and consent clauses.

It is also possible that several DTCGT contracts overall may fail transparency requirements.

Exclusion clauses and fitness for purpose

In reviewing DTCGT contracts, it was found that exclusion clauses were extremely common, with 80% of companies including such a clause. Fourteen percent of DTCGT company contracts examined disclaim liability for personal injury or

death caused by their negligence. This is a term of a type that is blacklisted in section 65 of the UK's Consumer Rights Act (CRA) 2015 and is consequently automatically void and unenforceable.

While much of the policy guidance on DTCGT to date has stressed the importance of clinical validity, companies often state that their services are provided on an "as is" basis and also attempt to avoid liability for tests being fit for purpose. In total, 38% of companies disclaim liability for fitness for purpose and 44% specify that their services are provided on an "as is" basis and 30% also specify that they provide "no warranty" for their services (Phillips, *Genomic Privacy* 2015a). It is quite likely that many of the terms of this type would be deemed to be unfair in accordance with the CRA. Specifically, the CRA implies certain terms into consumer contracts which include that contract for either the supply of services, goods, or digital content must in fact be "fit for purpose" clauses disclaiming liability for "fitness for purpose" are likely to be unenforceable. Section 10 requires that goods must be fit for a particular purpose and section 31 includes this as a type of liability that cannot be excluded in section 31 (1)(b).

While in the context of DTCGT conducted for purposes that are not health related, it may appear reasonable that a company is not providing medical advice or medical information, the situation is less clear where tests are carried out for health purposes. This is accentuated when DTCGT companies are also engaged in medical research, which is true of the most prominent DTCGT companies.

Of the 71 contracts examined, 51% have clauses of this type. Of these 12 companies specifically state that their services are provided for "informational purposes." Forty-five percent of companies overall include a statement indicating that they do not provide or intend to provide medical advice with 15% also stating that their services are not intended to be a substitute for medical advice and 27% indicate in some way that their services are not intended as medical advice.

It is likely that such terms may be deemed to be unfair under the CRA, as the Act implies obligations into contracts for services and the supply of digital content. Specifically, digital content, which in this case would include genetic test results, should be fit for purpose (section 35), should match description (section 36), and should be of satisfactory quality (section 34). In relation to scope of purpose clauses section 36, which requires digital content to match description is key. In the context of DTCGT companies providing health tests, where website content encourages consumers to believe they are buying tests that have a medical purpose or will be relevant for medical treatment decisions, a scope of purpose clause suggesting that services are not for medical purposes may be deemed to be unfair.

Variation clauses

Clauses allowing DTCGT companies to alter their terms are particularly common with 72% of the contracts examined including such a clause (Phillips, *Genomic*

Privacy 2015a). Of these companies 39% include a term which allows them to alter their terms "at any time," while 32% allow for alteration of terms "from time to time." Only a very small minority of companies with variation clauses, 6%, will notify consumers of changes by email. Furthermore, 30% of companies will deem acceptance to altered terms through continued use of the website. Twenty-eight percent recommend that the customer checks their website periodically to ascertain whether changes have been made to their terms or privacy policy. Clauses of this type are very likely to be construed as being unfair according to the CMA's *Draft Guidance* (2015) and its *Unfair Contract Terms Guidance (Final Guidance)* (2015a). These are also covered in the CRA's Gray List in sections 10 and 11 of Schedule 2, but the CMA in its *Unfair Terms Explained* also suggests that these may be blacklisted under Part 1 of the CRA (July 2015b). It should be stressed that variation clauses in the DTCGT context could also have far reaching impact, as DTCGT companies often combine their privacy policies with their terms and conditions, this means that a variation clause may allow companies to significantly alter their privacy policies. This means that where a company includes a clause indicating that they will not sell or share personal data if they also include a clause which allows for unilateral alteration, they could in the future decide to sell and share that data and a consumer's options for redress may be quite limited. Consumers need to be able to make decisions about test purchase with greater certainty about what will be done with their data and how it will be stored, shared, or sold.

Consent in the DTCGT context

In a clinical setting when a patient undergoes genetic testing there are strict requirements for consent. This is quite different from a commercial scenario, as where terms are agreed upon in a contract, the emphasis in contract law has been on demonstrating assent or acceptance of the terms of the contract and what constitutes that assent or acceptance. Consent and assent or acceptance are often treated interchangeably in DTCGT contracts. This is problematic, because they have different meanings in law. Thirty-one percent of the contracts reviewed do not have specific clauses addressing consent. While the remaining 69% (49 companies) do have some clause addressing consent or acceptance of terms (Phillips, *Genomic Privacy* 2015a), consent and assent are often treated as synonymous and this is problematic. For instance, of the 49 companies that do include a clause addressing consent or acceptance in some form, 53% deem either acceptance, agreement or consent to their terms merely through use or viewing of the website (this is representative of 35% of the total 71 contracts examined). Twenty-two percent have clauses deeming acceptance or agreement and 13% have clauses deeming consent.

In the context of DTCGT where test results may have relevance for a person's health, it seems unacceptable for companies to deem consent merely through use or visiting of the website, as visiting a website does not necessitate viewing of

terms. In line with previous policy guidance and the FDA's introduction of tests for consumer comprehension, more information and resources to assist with understanding contractual terms should be provided and doing this on the web is not difficult or particularly costly. There are several issues, which need to be considered in examining acceptance and consent mechanisms in the DTCGT context. These include: the level of consumers' understanding of terms in DTCGT contracts; whether they have in fact given consent to the contract; the limits of their consent – for instance have they provided adequate consent for their data be used in research and shared by the company with third parties; and whether the consumer has capacity to consent – for instance as genetic information is shared between family members, ought all relevant family members to give their consent before one individual is tested; and also whether they have in fact given valid assent or acceptance of terms.

The current practice of deeming either acceptance or consent through viewing or visiting a website provides insufficient protection for consumers and unnecessarily favors companies. While in more conventional e-commerce this may be permissible to some extent DTCGT companies are collecting large amounts of potentially sensitive information from their consumers including information that would more usually be recorded in a patient's medical records.

Whether these contracts are adequate to comply with UK law is questionable. For instance, such contracts may not satisfy the requirements for consent for genetic tests set out in the UK's Human Tissue Act 2004. In the context of tests provided for health purposes the recent UK Supreme Court decision of *Montgomery v Lanarkshire Health Board* ((Scotland) [2015] UKSC 11; Campbell 2015) reinforces the importance of providing patients with adequate information (Kaye *et al*. 2015), so that they are able to make informed decisions about treatment options. If a dispute were to arise between a UK consumer and a DTCGT company providing health testing, a court might hold that the company is required to provide consumers with more information about the respective risks and benefits of undergoing testing and possible risks relating to potential misuse of data, especially in the context of on-going health research using consumers' data (Hofmann, Solbakk, and Holm 2009).

Furthermore, in accordance with the provisions of the CRA, it is likely that deemed consent or assent clauses might be deemed to be unfair terms in accordance with the Gray List in Schedule 2, as such terms seem to be within the remit of section 10 which deals with terms that have "the object or effect of irrevocably binding the consumer to terms with which the consumer has had no real opportunity of becoming acquainted before the conclusion of the contract."

Consent and authorization models discussed in the academic literature in relation to biobanks, such as Hofmann, Solbakk, and Holm's suggestions for conditional authorization drawing upon Greely and Arnason's work (2009), or HeLEX's dynamic consent model (Kaye *et al*. 2015), may provide useful guidance here. The use of short summary notices, or perhaps short summary contracts drawing

upon the work of Good *et al*. (2007) might also be beneficial for consumers. In the short term though, it is desirable that the CMA works with the DTCGT industry to improve their contracts.

Improving consumer contracts – a role for the UK CMA

What role might consumer legislation play in providing a regulatory framework to address these problems? In the UK, legislation on unfair terms has recently been reformed with the enactment of the new CRA 2015 and there is also a new consumer regulator, the CMA. The CRA consolidates previous UK legislation governing unfair terms in business to consumer contracts as well as implementing EU directives. Namely, it essentially replaces the Unfair Contract Terms Act 1977, the Unfair Terms in Consumer Contracts Regulations 1999 (UTCCR); and implements aspects of the Consumer Rights Directive and the Unfair Contract Terms Directive. The Act applies to both contract terms and notices. It is likely that the legislation will be interpreted in a similar way to the previous legislation and if this is the case, then "there are three different contexts in which a challenge to the fairness of a contractual term may arise" (Bright 2007).

The CMA was formed in 2014 and it has taken over some of the functions of the Office of Fair Trading and the Competition Commission. Under the CRA, the CMA has authority to take enforcement actions against companies, which are using unfair terms or notices. It can apply to a court for an injunction against specific companies. However, it cannot take on individual cases on behalf of individual consumers, which means that in practice if consumers seek redress their options may be limited It is hoped that the CMA will monitor DTCGT companies' practices where they offer services to UK based consumers.

Since its formation the CMA has released a number of documents dealing with unfair terms and unfair business practices and also engaged in a public consultation on unfair terms. Early in 2015, it released a short guide for businesses, entitled *Unfair Contract Terms Explained* (2015b) and draft guidance, entitled *Draft Guidance on Unfair Contract Terms – Consultation Document* (2015), for which it conducted a guidance document on the CMA's consumer powers was released in May 2016 with a further update in August 2016.

CMA's compliance review on cloud computing

The CMA has recently completed a review of cloud service providers and has released its report entitled *Consumer Law Compliance Review: Cloud Storage* (2016). This review assessed whether cloud storage providers' contractual terms and business practices are in compliance with UK consumer protection law. It should be noted that the report has already had some degree of success with improving terms, as several cloud service providers have made commitments to

improve their terms (CMA, Cloud Compliance Review homepage 2017). This includes Amazon, Apple, Microsoft, BT, Dropbox, and Google (CMA homepage 2017; Competition & Markets Authority 2016b).

The report is very relevant to the discussion of improving regulation of the DTCGT industry, as it indicates the types of terms and business practices, which the CMA is likely to view as problematic and potentially unfair. For each of the terms that the CMA finds problematic, it also makes recommendations on how terms and business practice might be improved. Some of these suggestions could usefully be adapted to the DTCGT context. In paragraph 5.2 of the report, which summarizes the effect of Part 1 of the CRA, the CMA states that:

> in relation to contracts for the supply of goods, digital content and services (or any combination of these), in particular: a service must be performed with reasonable skill and care; anything said or written about the service by or on behalf of the trader and which is taken into account by the consumer, is to be treated as a term of the contract (subject to certain conditions). (2016)

In relation to unilateral variation clauses, the report indicates that several clauses of this type may cause consumer detriment (CMA, Cloud Storage 2016, para 5.24) and that the CMA views such clauses as unfair under the CRA (5.25). Relevant here is that this includes terms that "allow the provider to change the terms or the service in any way for any reason and at any time" or those that "do not require providers to give consumers notice of changes" are of concern (5.37). In order to address its concerns relating to unilateral variation clauses the CMA makes a number of recommendations. Significantly, they recommend that cloud service providers should

> only be able to make changes to the terms or the service for valid reasons that are clearly set out in the contract, so that consumers understand how the changes might affect their rights and obligations under the contract. This is particularly important for fixed-term contracts where the scope to make changes should be limited. (5.37)

They also recommend that providers "should ensure that consumers receive adequate notice of changes, so that they can consider their position and decide whether to accept the changes," and that steps should be taken to "ensure that consumers who do not wish to accept changes can cancel the contract, obtain a refund for any services not yet provided (including, where relevant, any additional services they have purchased) and retrieve their data" (5.37). If the CMA were to take a similar approach towards DTCGT companies it seems likely that many unilateral variation clauses would be deemed to be unfair and that it would be useful for DTCGT companies to apply a similar approach to that recommended for cloud computing providers.

The report also deals with choice of law clauses and the CMA suggests that terms may be unfair in a number of ways. These include: requiring legal proceedings to be brought in countries outside the consumer's home jurisdiction; specifying that

the contract is to be governed by the law of another country; and clauses that use "legal jargon that is likely to confuse consumers about which courts have jurisdiction and which laws will apply (e.g. 'without prejudice to mandatory law provisions')."

In relation to these clauses, the CMA recommended that providers should: "ensure consumers are able to bring legal proceedings in their local courts"; "ensure the contract is subject to the consumer's local law"; and "clearly explain that the consumer's local courts will have jurisdiction and their local law will apply" (5.72). This might indicate that clauses in DTCGT contracts, which purport to apply the law of another jurisdiction may not be enforceable against UK consumers and are likely to be deemed unfair. Again, the CMA's recommendations here could be usefully adapted to apply to the DTCGT context.

In relation to exclusions of liability, in the context of cloud computing, the CMA indicated that a number of different types of terms might be open to challenge on the grounds of unfairness. They also suggested that that many exclusion clauses are also likely to be blacklisted under the CRA and that "Blacklisted terms are automatically unenforceable by a trader against a consumer" (CMA, Cloud Storage 2016, para 5.60). These included terms that: "attempt to exclude or restrict a consumer's statutory rights and remedies under the CRA, for example, excluding liability where the provider has failed to use reasonable skill and care when providing the service"; "despite the potential for consumers to have large amounts of data saved or stored, place an unreasonably low cap on liability (outside of a consumer's statutory remedies)"; "contain confusing or contradictory information, so that it is not possible for consumers to know what liability is or is not excluded in any particular situation"; and "include significant amounts of unnecessary 'legal jargon' (e.g. 'mutatis mutandis', 'workmanlike effort', and 'implied warranties of merchantability'). Businesses should, of course, generally avoid using jargon at all in their terms" (5.59). In the context of DTCGT, it would seem likely that certain types of commonly included exclusion clauses are likely to be deemed unfair.

Exclusion clauses purporting to exclude liability for fitness for purpose or limiting the scope of purpose for health tests to non-medical purposes seem particularly likely to be deemed unfair. The CMA also makes practice recommendations in relation to clauses of this type, which could again be useful in improving terms and business practice in the DTCGT context.

Regarding transparency, the CMA expressed concern over a number of matters. Clauses that were not drafted using plain language or were structured in a confusing way, or clauses included in additional documents and not in the main contract are likely to fail transparency requirements (5.24).

Section 68 of the CRA requires both contractual terms and notices to be transparent. Section 68(2) specifies that consumer notices are to be "expressed in plain and intelligible language and it is legible." In the present study of DTCGT contracts, documents were often particularly lengthy and use complex legalese.

Consequently, it is plausible that an ordinary consumer might have difficulty understanding the import of a number of commonly included terms and some DTCGT contracts may fail the CRA's transparency requirements.

The CMA made a number of recommendations in relation to overall transparency that could also usefully be applied to the DTCGT industry and help to improve DTCGT contracts. In summary, the CMA recommends that companies should: draft contracts in "plain English, using, as far as possible, ordinary words in their normal sense" and minimize the necessity for "consumers to cross-refer to different terms or documents" (5.80). Contracts should also be drafted in a way that makes it easy for consumers to understand legal provisions and their legal rights. Contracts should also be structured clearly and companies should use short sentences and break "up the text of the contract with easily understood subheadings" (5.80). Terms that could be disadvantageous to consumers need to be given prominence and companies should highlight these terms and set "out clearly the obligations and the circumstances in which they arise" (5.80). The majority of contracts reviewed were not in line with these recommendations and consumers would benefit from similar recommendations being applied to the DTCGT industry. However, there may also be a heightened need for the provision of further information, especially for providers of health tests.

Fairness

Section 62 of the CRA requires terms and notices to be fair. It sets out how fairness is to be determined in subsections 4 and 5. "A term is unfair if, contrary to the requirement of good faith, it causes a significant imbalance in the parties" rights and obligations under the contract to the detriment of the consumer.' When assessing fairness of a term the "nature of the subject matter of the contract" and "surrounding circumstances" are to be taken into account. In the context of DTCGT services then, the nature of such services will be relevant and it is possible that the online nature of purchasing and the other content of DTCGT websites may also be relevant in assessing fairness.

In line with the CMA's recent report on cloud computing, it is likely that the following types of terms commonly found in DTCGT contracts might be found to be in breach of consumer protection legislation, and specifically be deemed to be unfair terms. These terms are as follows:

- clauses allowing for unilateral variation of the contract;
- clauses disclaiming liability for fitness for purpose or for personal injury caused by the company's negligence;
- clauses limiting scope of purpose;
- clauses purporting to bind the consumer to resolve any disputes in another jurisdiction;
- and clauses covering consent.

Conclusion

There is a need to improve the regulation of the DTCGT industry in order to afford better protection to consumers and also to allow them to make informed decisions about whether to engage with and utilize DTCGT services. DTCGT services for health purposes can provide consumers with information regarding levels of risk for quite serious diseases and conditions. If this information is to be beneficial for the individuals tested they need to be able to understand what it means for them and they need to be able to make free and informed decisions about engaging with these services. Although the Internet offers great benefits especially in the sense of making services more accessible to a wider number of people regardless of their location, the online environment influences people's behavior to make transactions quickly without reading or understanding a contract. For complex services this can be detrimental to an individual's decision-making processes. DTCGT services for health can provide information about serious health conditions. While this information may have some benefits for individuals, people need to be able to make informed decisions about accessing such services and in order for this information to be beneficial to the individual tested they need to understand the limitations of testing and what results mean for them. Where a person would be required to give informed consent for the same or a similar test in a medical setting, then DTCGT websites need to provide information about their services in a transparent way and it is not acceptable to bury consent clauses in long documents, especially where the clause suggests that consent can be deemed through use or viewing of the website or use of services.

Given the complex nature of test results and the fact that they have previously been restricted to a medical setting we may need to look beyond contract law to improve industry regulation. The issues of transparency, informed choice, and autonomy are significant here. If these services are to be offered as consumer services, then consumers need access to information and support, so that they can make informed and conscious decisions about whether or not to engage with these services.

In the UK the CMA is well placed to take on a more active role in monitoring the terms used by DTCGT companies and it could usefully draw upon its recent work with the cloud computing industry. The CMA should undertake a compliance review of the industry's consumer contracts, which could usefully draw upon its recent compliance review of the cloud computing industry. Consumer protection agencies in other countries are also well placed to play a part in improving the governance of this industry and protecting consumers in their jurisdictions.

In the UK, the ICO, the HTA, and the MHRA may all have roles to play in improving regulation of the industry alongside the CMA. The HTA especially could assist with improving consent mechanisms in this context.

Ultimately though, there is a need for international collaboration not only to improving terms, but also to ensure test quality standards and to foster better

security and privacy enhancing infrastructure. DTCGT companies are amassing large quantities of sequenced genetic data, as well as other forms of personal data and a significant breach of a DTCGT database could have far reaching consequences. However, the new approach taken by the FDA may lead to an increase in health testing offerings, but as it is also at odds with the position of the ACMG it will be interesting to see how this develops.

Harmonizing standards across the industry may also be beneficial for companies, as they should also enable consumers to identify which companies offer higher quality services and which companies are engaging in better business practices. Better standards can also allow for more certainty for businesses so that companies can more easily ascertain what the law allows them to do and to avoid breaching the law. While this article has focused on the UK framework, this framework is very closely linked to the European Union's consumer protection legislation and companies offering services to consumers based in the European Union are likely to find that their contracts may be challengeable on the grounds of unfairness in many of the Member States.

While this article is concerned with the potential unfairness of contract terms, it is important to stress that current business practice by many DTCGT companies is often at odds with much of the policy guidance released to date.

While the industry remains largely self-regulated, then contracts are, de facto, the main governance mechanism for relations between companies and their consumers. Those contracts need to be improved if they are to afford a better balance between the interests of both parties.

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References

ACMG. 2015. "Direct-to-Consumer Genetic Testing: A Revised Position Statement of the American College of Medical Genetics and Genomics." *Genetics in Medicine.* https://www.acmg.net/docs/ACMG%20Revised%20DTCGT%20Statement%20AOP%20Dec%202015.pdf.

Annes, J. P., M. A. Giovanni, and M. F. Murray. 2010. "Risks of Presymptomatic Direct-to-Consumer Genetic Testing." *New England Journal of Medicine* 363: 1100.

Association for Molecular Pathology. 2007. *Position Statement: On Direct Access Genetic Testing (Direct to Consumer Genetic Testing)*.

Association for Molecular Pathology. 2015. *Association for Molecular Pathology Position Statement: Direct Access Genetic Testing (Direct to Consumer Genetic Testing)*. https://www.amp.org/publications_resources/position_statements_letters/documents/AMPpositionstatementDTCtesting-FINAL_002.pdf.

Ayday, E., E. De Cristofaro, J. -P. Hubaux, and G. Tsudik. 2015. "Whole Genome Sequencing: Revolutionary Medicine or Privacy Nightmare?" *Computer* 48: 58–66.

Ayres, I., and A. Schwartz. 2014. "The No-reading Problem in Consumer Contract Law." *Stanford Law Review* 66 (545): 545–610. http://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=5881&context=fss_papers.

Bright, S. 2007. "Unfairness and the Consumer Contract Regulations." In *Contract Terms*, edited by A. Burrows and E. Peel, 173–190, 174. Oxford: Hart.

Cain, Patrick. 2016. "Privacy Risks Lurk in DNA Tests, Experts Warn." *Globalnews.ca*. Accessed September 20, 2016. http://globalnews.ca/news/2879276/privacy-risks-lurk-in-dna-tests-experts-warn/.

Campbell, Mark. 2015. "Montgomery v Lanarkshire Health Board." *Common Law World Review* 44 (3): 222–228.

Christofides, E., and K. O'Doherty. 2016. "Company Disclosure and Consumer Perceptions of the Privacy Implications of Direct-to-Consumer Genetic Testing." *New Genetics and Society* 35 (2): 101–123. doi:10.1080/14636778.2016.1162092.

Clapperton, D. M., and S. G. Corones. 2007. "Unfair Terms in 'Clickwrap' and Other Electronic Contracts." *Australian Business Law Review* 35: 152–180.

CMA. Consumer Law Compliance Review: Cloud Storage para 5.2. 5.24, 5.25, 5.37, 5.67, 5.72, 5.60, 5.59, 5.74, 5.80.

Competition & Markets Authority. 2015. *Draft Guidance on Unfair Contract Terms Consultation Document*. Competition & Markets Authority, CMA37con.

Competition & Markets Authority. July 2015a. *Unfair Contract Terms Guidance – Guidance on the Unfair Terms Provisions in the Consumer Rights Act 2015*. Competition & Markets Authority, CMA37.

Competition & Markets Authority. July 2015b. *Unfair Contract Terms Explained*. Competition & Markets Authority, CMA37(a):13–4, paras 65–68.

Competition & Markets Authority. 2016a. *Consumer Law Compliance Review: Cloud Storage*. Findings Report. Accessed May 29, 2016. https://assets.digital.cabinet-office.gov.uk/media/57472953e5274a037500000d/cloud-storage-findings-report.pdf.

Competition & Markets Authority. 2016b. *CMA Secures Better Cloud Storage Deals' Press Release*. Accessed November 4, 2016. https://www.gov.uk/government/news/cma-secures-better-cloud-storage-deals.

Competition & Markets Authority. 2017. "*Cloud Storage: Consumer Compliance Review" homepage*. Accessed July 25, 2017. https://www.gov.uk/cma-cases/cloud-storage-consumer-compliance-review.

Competition & Markets Authority. CMA37(a).

Cornel, M. C., C. G. van El, and P. Borry. 2014. "The Challenge of Implementing Genetic Tests with Clinical Utility While Avoiding Unsound Applications." *Journal of Community Genetics* 5 (1): 7–12.

Council Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety.

Council Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 Concerning Unfair Business-to-Consumer Commercial Practices in the Internal Market and Amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (Unfair Commercial Practices Directive).

Council Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on Consumer Rights, Amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and Repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council.

Curnutte, M. 2017. "Regulatory Controls for Direct-to-Consumer Genetic Tests: A Case Study on How the FDA Exercised its Authority." *New Genetics and Society* 36 (3): 209–226.

Datta, A. K., T. J. Selman, T. Kwok, T. Tang, and K. S. Khan. 2008. "Quality of Information Accompanying On-Line Marketing of Home Diagnostic Tests." *Journal of the Royal Society of Medicine* 101: 34–38. http://journals.sagepub.com/doi/full/10.1258/jrsm.2007.070150.

Erlich, Y., and A. Narayanan. 2014. "Routes for Breaching and Protecting Genetic Privacy." *Nature Reviews Genetics* 15: 409.

European Commission. 2016. *Consumer Vulnerability across Key Markets in the European Union*. http://ec.europa.eu/consumers/consumer_evidence/market_studies/vulnerability/index_en.htm.

European Society of Human Genetics. 2010. "Statement on Direct-to-Consumer Genetic Testing for Health-related Purposes." *European Journal of Human Genetics* 18 (12): 1271–73. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3002858/.

Felten, E. 2011. "Postmodern Times: Are We All Online Criminals?." *Wall Street Journal*, D8 November 18.

Food and Drug Administration. 2017. "FDA Allows Marketing of First Direct-to-Consumer Tests That Provide Genetic Risk Information for Certain Conditions." News Release April 6. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm551185.htm.

Food and Drug Administration. 2017. *Letter to 23andMe, Inc. c/o Ms. Lisa Charter*, April 6. https://www.accessdata.fda.gov/cdrh_docs/pdf16/DEN160026.pdf.

Frischmann, B. M., and E. Salinger. September 2016. *Engineering Humans with Contracts*. Cardozo Legal Studies Research Paper No. 493. https://ssrn.com/abstract = 2834011.

The Genetics and Public Policy Center. 2011. *Table – Tested Listed by Disease Category*, August 11. http://www.dnapolicy.org/news.release.php?action = detail&pressrelease_id = 145.

Geransar, R., and E. Einsiedel. 2008. "Evaluating Online Direct-to-Consumer Marketing of Genetic Tests: Informed Choices or Buyers Beware?" *Genetic Testing* 12 (1): 13–23, 21.

Gollust, S. E., E. S. Gordon, C. Zayac, G. Griffin, M. F. Christman, R. E. Pyeritz, L. Wawak, and B. A. Bernhardt. 2012. "Motivations and Perceptions of Early Adopters of Personalized Genomics: Perspectives from Research Participants." *Public Health Genomics* 15: 22–30.

Good, N. S., J. Grossklags, D. K. Mulligan, and J. A. Konstan. 2007. "Noticing Notice: A Large-scale Experiment on the Timing of Software License Agreements." In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems ACM 607-616*.

Hennen, L., A. Sauter, and E. Cruyce. 2009. "Direct to Consumer Genetic Testing: Final Report." Bonn: European Technology Assessment Group, 38. http://www.tatup-journal.de/downloads/2009/tatup091_hesa09a.pdf

Hillman, R. A. 2005. *On-line Consumer Standard-form Contracting Practices: A Survey and Discussion of Legal Implications*. Cornell Law Faculty Publications, Paper 29. http://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article = 1028&context = lsrp_papers.

Hilts, A., C. Parsons, and J. Knockel. 2016. *Every Step You Fake: A Comparative Analysis of Fitness Tracker Privacy and Security.* Open Effect Report. https://openeffect.ca/reports/Every_Step_You_Fake.pdf.

Hoffman, D. A. 2016. *From Promise to Form: How Contracting Online Changes Consumers*. Faculty Scholarship. 1730. http://scholarship.law.upenn.edu/faculty_scholarship/1730.

Hofmann, B., J. H. Solbakk, and S. Holm. 2009. "Consent to Biobank Research: One Size Fits All?." In *The Ethics of Research Biobanking*, edited by Jan Helge Solbakk, Sore Holm, and Bjorn Hoffman, 17–20. Springer. https://link.springer.com/chapter/10.1007/978-0-387-93872-1_1

Hogarth, S., G. Javitt, and D. Melzer. 2008. "The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues." *Annual Review of Genomics and Human Genetics* 9: 161–182. http://www.cienciaviva.eu/projectos/2ways/artigo1.pdf

Hudson, K., Gail Javitt, Wylie Burke, and Peter Byers. 2007. "ASHG Statement on Direct-to-Consumer Genetic Testing in the United States." *American Journal of Human Genetics* 81: 635.

HGC (Human Genetics Commission). 2003. *Genes Direct: Ensuring the Effective Oversight of Genetic Tests Supplied Directly to the Public*. London, UK: Department of Health.

HGC (Human Genetics Commission). 2007a. *More Genes Direct*. London, UK: Department of Health.

HGC (Human Genetics Commission). 2007b. *More Genes*, 16. London, UK: Department of Health.

HGC (Human Genetics Commission). 2010. *A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services*. London, UK: Department of Health.

Kalf, R., Raluca Mihaescu, Suman Kundu, Peter de Knijff, Robert C. Green, A. Cecile J. W. Janssens. 2014. "Variations in Predicted Risks in Personal Genome Testing for Common Complex Diseases." *Genetics in Medicine* 16: 85.

Kalokairinou, L., H. C. Howard, and P. Borry. 2014. "Changes on the Horizon for Consumer Genomics in the EU." *Science* 346: 296.

Kaye, J. 2012. "The Tension Between Data Sharing and the Protection of Privacy in Genomics Research." *Annual Review of Genomics and Human Genetics* 13: 415–431.

Kaye, Jane, Jessica Bell, Linda Briceno, and Colin Mitchell. 2016. "Biobank Report: United Kingdom." *The Journal of Law, Medicine & Ethics* 44 (1): 96–105, 102.

Kaye, J., E. A. Whitley, D. Lund, M. Morrison, H. Teare, and K. Melham. 2015. "Dynamic Consent: A Patient Interface for Twenty-first Century Research Networks." *European Journal of Human Genetics* 23 (2): 141–146.

Kim, N. S. 2013. *Wrap Contracts: Foundations and Ramifications*. Oxford: Oxford University Press.

Krol, A. 2015. "Open Humans Aims to Be the Social Network for Science Volunteerism." *Bio IT World*. Accessed April 13, 2015. bio-itworld.com/2015/4/9/open-humans-aims-social-network-science-volunteerism.html.

Krol, A. 2015. "What Comes New for Direct-to-Consumer Genetics?" *Bio IT World*. Accessed July 18, 2015. bio-itworld.com/2015/7/16/what-comes-next-direct-consumer-genetics.html.

Kutz, G. 2010. *Direct-to-Consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices: Congressional Testimony.* Washington, DC: DIANE Publishing. http://www.gao.gov/assets/130/125079.pdf

Laestadius, L. I., Jennifer R. Rich, and Paul L. Auer. 2016. "All Your Data (Effectively) Belong to Us: Data Practices among Direct-to-Consumer Genetic Testing Firms." *Genetics in Medicine*. doi:10.1038/gim.2016.136.

Loos, M., and J. Luzak. 2015. *Wanted: A Bigger Stick. On Unfair Terms in Consumer Contracts with Online Service Providers*. Centre for the Study of European Contract Law Working Paper Series, January 8.

Manwaring, K. 2011. "Enforceability of Clickwrap and Browsewrap Terms in Australia: Lessons from the U.S. and the U.K." *Studies in Ethics, Law, and Technology* 5 (1). doi:10.2202/1941-6008.1102.

Martin, P., and R. Frost. 2003. "Regulating the Commercial Development of Genetic Testing in the UK: Problems, Possibilities and Policy." *Critical Social Policy* 23 (2): 186–207.

McDonald, A. M., and L. F. Cranor. 2008. "The Cost of Reading Privacy Policies." *I/S A Journal of Law and Policy for the Information Society* 4: 562.

Meikle, James. 2015. "Superdrug Criticised by Doctors for Stocking Genetic Self-testing Kits." *The Guardian*, March 31. www.theguardian.com/science/2015/mar/31/superdrug-criticised-doctors-genetic-self-testing-kits.

Nelson, Tanya N., L. Armstrong, J. Richer, J. Evans, J. Lauzon, B. McGillivray, H. Bruyere, and S. Dougan. 2012. "CCMG Statement on Direct-to-Consumer Genetic Testing." *Clinical Genetics* 81 (1): 1.

Nuffield Council on Bioethics. 2015. *The Collection, Linking and Use of Data in Biomedical Research and Health Care: Ethical Issues*. February 2015, UK. https://nuffieldbioethics.org/wpcontent/uploads/Biological_and_health_data_web.pdf

OECD Guidelines for Quality Assurance in Molecular Genetic Testing. 2007. http://www.oecd.org/sti/biotech/38839788.pdf.

Offit, K. 2008. "Genomic Profiles for Disease Risk: Predictive or Premature?" *JAMA: The Journal of the American Medical Association* 299: 1353.

Phillips, Andelka M. 2015a. *Genomic Privacy and Direct-to-Consumer Genetics: Big Consumer Genetic Data – What's in that Contract?* Security and Privacy Workshops (SPW), 2015 IEEE.

Phillips, A. M. 2015b. "Think Before You Click Ordering a Genetic Test Online." *Scitech Lawyer* 11 (2): 8.

Phillips, A. M. 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.

Pines, Wayne L. 1999. "A History and Perspective on Direct-to-Consumer Promotion." *Food & Drug Law Journal* 54: 489.

Plaut, V. C., and R. P. Bartlett III. 2012. "Blind Consent? A Social Psychological Investigation of Non-readership of Click-through Agreements." *Law and Human Behavior* 36: 293.

Ray, T. 2017. "ACMG Guidelines at Odds with FDA Green Light for 23andMe Health Risk Tests." *Genomeweb*, April 11. https://www.genomeweb.com/regulatory-news/acmg-guidelines-odds-fda-green-light-23andme-health-risk-tests.

Reidenberg, J. R., L. F. Cranor, B. French, A. Grannis, J. T. Graves, F. Liu, A. McDonald, *et al*. 2015. "Disagreeable Privacy Policies: Mismatches Between Meaning and Users' Understanding." *Berkeley Technology Law Journal* 31 (1): 39–88. http://btlj.org/data/articles2015/vol30/30_1/0039-0088_Reidenberg_et_al_WebPdf.pdf.

Research and Markets. 2017. Predictive Genetic Testing and Consumer/Wellness Genomics Market by Application and Trend Analysis from 2013 to 2025, January. http://www.researchandmarkets.com/research/26mxz4/predictive.

Singleton, A., Lori Hamby Erby, Kathryn V. Foisie, and Kimberly A. Kaphingst. 2012. "Informed Choice in Direct-to-Consumer Genetic Testing (DTCGT) Websites: A Content Analysis of Benefits, Risks, and Limitations." *Journal of Genetic Counseling* 21: 433–439. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3348288/pdf/nihms353182.pdf.

Spector-Bagdady, Kayte. 2015. "Reconceptualizing Consent for Direct-to-Consumer Health Services." *American Journal of Law & Medicine* 41 (4): 568–616.

Spector-Bagdady, Kayte. 2016. "Why You Should Worry about the Privatization of Genetic Data." *The Conversation*, September 8. Accessed September 26, 2016. https://theconversation.com/why-you-should-worry-about-the-privatization-of-genetic-data-62591.

Staff Reporter. 2017. "FDA Authorizes Direct-to-Consumer Access for Multiple 23andMe Health Risk Tests." *Genomeweb*, April 6. https://www.genomeweb.com/regulatory-news/fda-authorizes-direct-consumer-access-multiple-23andme-health-risk-tests.

Sterling, R. 2008. "The On-line Promotion and Sale of Nutrigenomic Services." *Genetics in Medicine* 10 (11): 784–796, 794.

US Food and Drug Administration. 2013. *Warning Letter of November 22, 2013*. Accessed May 23, 2014. http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm.

Wallace, H. 2015. "GeneWatch UK PR: Shoppers Warned Not to Buy Gene Tests from Superdrug." *GeneWatch UK*. Accessed April 5, 2015. genewatch.org/article.shtml?als%5Bcid%5D = 406259&als%5Bitemid%5D = 575612.

Wigley + Company Solicitors. 2015. *To read or not to read … Online Ts and Cs. Or Hamlet*. Wigley + Company Solicitors. Accessed July 7. wigleylaw.com/assets/Uploads/To-read-or-not-to-read.pdf.

Williams-Jones, B. 2003. "Where There's a Web, There's a Way: Commercial Genetic Testing and the Internet." *Community Genetics* 6: 46–57.

Wright, Caroline F., Alison Hall, and Ron L. Zimmern. 2011. "Regulating Direct-to-Consumer Genetic Tests: What Is All the Fuss about?" *Genetics in Medicine* 13 (4): 295–300.