

Genomic Privacy and Direct-to-Consumer Genetics

Big Consumer Genetic Data – What’s in that Contract?

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Abstract— This is a brief position paper providing a summary of current research on the legal regulation of Direct-to-Consumer Genetic Testing (DTCGT), focussing on the contracts used by DTCGT companies. The overall aim of the larger project has been to explore the existing legal mechanisms for the protection of the rights of consumers in their sequenced genetic data in the context of DTCGT. There are several areas of law which could be drawn upon to regulate the industry or which may have relevance for the protection of consumers (data protection, medical device regulation, consumer protection, product liability, and human rights). However, the current mechanism governing the transaction between the consumer and company when an individual purchases a genetic test from a DTCGT company is that website’s contract, normally to be found on websites as Terms of Use, Terms of Service, Terms and Conditions, Privacy Policy or Privacy Statement.

Keywords— contract, direct-to-consumer genetic testing, health, privacy, consumer

I. INTRODUCTION

This is a brief position paper providing a summary of current research on the legal regulation of Direct-to-Consumer Genetic Testing (DTCGT), focussing on the contracts used by DTCGT companies. The overall aim of the larger project has been to explore the existing legal mechanisms for the protection of the rights of consumers in their sequenced genetic data in the context of DTCGT. There are several areas of law which could be drawn upon to regulate the industry or which may have relevance for the protection of consumers (data protection, medical device regulation, consumer protection, product liability, and human rights). However, the current mechanism governing the transaction between the consumer and company when an individual purchases a genetic test from a DTCGT company is that website’s contract, normally to be found on websites as Terms of Use, Terms of Service, Terms and Conditions, Privacy Policy or Privacy Statement.

The DTCGT field is evolving rapidly with companies entering or leaving the market, including via mergers and acquisitions. For instance, Gene By Gene’s FamilyTreeDNA has also acquired DNA Heritage¹ and DNA-Fingerprint,² and MyHeritage has partnered with both Family Tree DNA and 23andMe.³

Starting from (October 2011) until (November 2014), a catalogue of companies in this sector was compiled as follows:

* An Internet search engine (Google) and 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) were used to identify English language web sites for potential DTCGT companies (228 companies). This procedure was repeated on a semi-regular basis.

* In conducting these searches reference was also made to the work conducted by the Human Genetics Commission (HGC), the Government Accountability Office (GAO) and the Genetics and Public Policy Center (GPPC) at Johns Hopkins.

* Each candidate web site was inspected manually to confirm that it was for a DTCGT company (228 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); ancestry; paternity; non-consensual; DNA dating; child talent; athletic ability; misc.

* 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 tables briefly summarise the services offered by each company and also classify the companies into groups based on the type of services they offer.

* All companies identified were tabulated with one master table (228 companies) and then tables of the various categories running to 481 pages.

* The web sites 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 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.

* Common clauses have been tabulated and the tabulation runs to 468 pages.

* The online contracts were read to ascertain similarities, differences and overall trends.

II. FEATURES OF THE DTCGT INDUSTRY

A. *The shift from patient to consumer*

DTCGT is one development in the field of personalised medicine which is challenging traditional conceptions of what it means to be a patient and what it means to be a consumer. Under UK, EU, and USA law the rights of patients are protected and doctors in a qualifying relationship will owe duties to their patients. These include: a duty of care; keeping patients' information confidential; making decisions that are in a patient's best interests; and seeking to cure or treat their condition.⁴

In contrast, the consumer has traditionally been conceptualised in a commercial context and much of the literature has centred on the importance of autonomy and the exercise of the consumer's free will. While there are existing protections for consumers in the form of consumer protection legislation, legislation on unfair terms in contracts, product liability, and regulation of advertising, there has also been much opposition to increasing such protection and generally the obligations a company owes to its consumers will be less than those of a doctor to their patients. However, there is growing interest in the concept of the vulnerable consumer and this debate has relevance in the DTCGT context, as it is possible to argue that at least some DTCGT consumers should be viewed as vulnerable.⁵ This will be explored further in subsequent work.

B. *Consumer driven research*

Companies promise consumer empowerment and patient centred research. Sequenced genomic data collected from consumers is being used by several companies in ongoing research and potentially shared or sold on to third parties, such as insurance providers or pharmaceutical companies or law enforcement agencies. The industry is dependent on receiving a physical sample of DNA, normally in the form of saliva and the DNA acquires value for the company once it has been sequenced. It is the sequenced genetic data that is the asset for the company and the business model of DTCGT companies is dependent on the samples of consumers. All the most prominent DTCGT companies have research branches, most notably 23andMe,⁶ Navigenics,⁷ and DeCODEme,⁸ but also Gene By Gene,⁹ myDNA,¹⁰ and Map My Genome¹¹ to name a few. Navigenics and DeCODEme have already been sold on to other entities, meaning that the data collected from consumers is being used in ongoing research.¹²

There is potential for DTCGT to contribute to the advancement of scientific research and lead to improvements in human health. However, as sequenced genetic data is irrevocable, potentially sensitive and can serve both as a unique identifier for an individual and also identify related individuals, there is a need for careful scrutiny of companies' practices regarding processing, use, storage, and sharing of both genetic data and other types of personal data they collect. As highlighted in the Nuffield Council's recently released report, there is growing public concern about the use of data in research.¹³ There is also growing concern over dataveillance more generally in the wider online context.

Some have expressed concern about possible harms resulting from undergoing testing through a DTCGT company. Much of this concern stems from the potential harm that may ensue when an individual receives test results indicating that she has a genetic predisposition to develop a particular condition, although this is debated. There is some evidence suggesting that individuals may in fact not be significantly affected by receiving knowledge of their disease risk, but there is also a possibility that people will experience psychological harm. A good example of this is where a person tests positive for either of the BRCA 1 or 2 mutations, which have a strong association with breast cancer. Even in a clinical setting it has been found that people who receive this type of information may undergo some form of psychological harm.¹⁴ Although this experience may be temporary, it is important that consumers who undergo genetic testing using DTCGT are protected and this harm could be minimised by providing adequate genetic counselling services and conducting such tests only through accredited laboratories. Another area of concern relates to prenatal testing and the testing of children and minors and companies offering such services need to be carefully monitored.¹⁵

III. THE TYPICAL CONTRACT

All the DTCGT contracts and privacy policies examined herein are either clickwrap (click-through) or browsewrap agreements. These are two types of online contract, which are common to all forms of online commerce. The consumer purchases the test online and will normally manifest their consent or assent by clicking 'I Agree'. These types of contract are familiar to many of us and unfortunately, a large proportion of consumers have become accustomed to clicking 'I Agree' without necessarily ever reading the contents of the relevant contract. In a conventional commercial setting this is arguably not problematic, but in the DTCGT context it is important to consider what consumers are actually agreeing to and what rights they may unknowingly be relinquishing. It is hoped that this short paper can provide some brief insight into the types of terms likely to be encountered when purchasing a DTCGT test.

These are mass consumer standard form contracts, which are normally lengthy and densely worded. These contractual forms will be encountered by many people on an almost daily basis and it is increasingly the case that companies operate on the assumption that the majority of their consumers will not read their contracts or privacy policies. In turn, this has given rise to the practice of including additional clauses in contracts that bear no relation to the original purpose of the contract and are intended to give the company additional advantages.¹⁶ Perhaps the most extreme example was GameStation's inclusion of a clause, which purported to compel you to relinquish your immortal soul to the company, although this was actually included as an experiment.¹⁷

While there is much commonality in the language used in these contracts this is not necessarily beneficial to the consumer. These contracts are one sided with no opportunity for consumers to negotiate and they are heavily biased in the company's favour. While this may be permissible to a certain degree, DTCGT services differ from ordinary commercial services in important ways.

A. Consent vs Assent

Current practice It should be noted that consent, assent, and acceptance or agreement with contractual terms are quite separate things. Consent and assent or acceptance are often conflated in the contracts and privacy policies of DTCGT companies. This conflation is another factor highlighting the consequences of the paradigm shift from patient to consumer in the DTCGT context. Also, several companies do not have any clause governing consent. Please refer to Table 1.

Recommended practice The adequacy of consent in the DTCGT context is worthy of careful scrutiny. Consent does mean different things in different contexts and DTCGT services provided for health related purposes are more akin to medical services provided online, which could be viewed as either medical treatment or medical research and thus, they do differ substantially in nature from other common types of online commercial services. The difference is that potentially at one and the same time you have a consumer service, medical treatment, and medical research all happening in the one transaction and traditionally different standards have applied to those three contexts.

Normally in a clinical setting, the emphasis is normally on informed consent and a patient will be asked to provide appropriate consent before undergoing any form of medical treatment. In the UK, in order for an individual to give adequate consent, she/he must have capacity to make the relevant decision; must be provided with sufficient information to be able to make the decision; and the decision must be voluntary.¹⁸ (Similar requirements apply in the US). Likewise, a research participant is also required to give adequate consent to participate in research. Prior to the advent of DTCGT patients were also expected to provide informed consent before undergoing genetic testing and also undergo pre and post-test genetic counselling. This continues to be a requirement of genetic testing carried out in a clinical setting.

In contrast, in a commercial setting where terms are agreed upon in a contract, the emphasis in contract law has been on demonstrating assent or acceptance or agreement with the terms of the contract and what constitutes that assent or acceptance. In the context of DTCGT where test results may have relevance for a person's health, it may be inappropriate for companies to deem consent merely through use or visiting of the website, as visiting a website does not necessitate viewing of terms and the validity of consent provided merely through visiting a website is open to challenge.

There are several issues that need to be considered in examining acceptance and consent mechanisms in the DTCGT context and these will be considered in more depth in subsequent writing. These include: the level of consumers' understanding of terms in DTCGT contracts; whether they have in fact given adequate consent or assent to the contract; the limits of their consent or assent – for instance have they provided adequate consent for their data be used in research and shared by the company with third parties; whether the consumer has capacity to consent; and as genetic information is shared between family members it may be advisable for companies offering disease risk tests to explain the implications of testing for family members for consumers with

family histories of diseases, which are highly heritable, such as Huntington's.

B. Disclaimer and Warranty

Current practice In online contracts it is common to include broad disclaimers of warranties and liabilities. These include statements that the company does not guarantee their services are fit for purpose and that services are provided on an 'as is' basis. Please refer to Table 1.

Recommended Practice In the context of tests that are carried out for health related purposes, the inclusion of such clauses seems inappropriate as it often directly contradicts how these services are marketed and what the services appear to be for. Such terms might be construed as unfair and ineffective under EU and UK law, where legislation provides implied terms into consumer contracts, which include that they will be 'fit for purpose'. It is possible that terms disclaiming liability for fitness for purpose would be deemed to be unfair under UK and EU law.¹⁹ Disclaiming liability in this manner seems problematic in light of the ongoing medical research conducted by DTCGT companies and fits in with broader concerns about clinical validity and clinical utility. If companies are to continue to disclaim liability for fitness for purpose then it is desirable that they are more transparent about this on their websites. It would be preferable that the practice was discontinued and more DTCGT services were subject to pre-market review.²⁰

C. Change of Terms

Current practice A common practice in online contracts more generally is the inclusion of a clause allowing the company broad discretion to alter their terms or privacy policy and many DTCGT companies include clauses of this type. Please refer to Table 1.

Recommended Practice Such clauses are understandable from a company's perspective, but if these are to be included, then companies should highlight these terms, so that the consumer is fully aware of their significance and can decide whether she wishes to proceed. (They may also be deemed to be unfair under EU law). Furthermore, deeming acceptance to changes in terms through continued use of the website is not appropriate in this context, as consumers can normally access a website without ever viewing the terms and conditions and so it would be advisable if all companies notified consumers of changes to their policies via email.

D. Privacy

Current practice DTCGT companies either have separate privacy policies or include their privacy policy in their contract. Many DTCGT companies' privacy policies focus more on data that may be collected on a website via the use of cookies, rather than what is done with genetic data specifically. Almost half allow for sharing of either personal information or genetic information with third parties. Only a small minority specify that they will destroy the physical sample either immediately after sequencing or after communicating results. Please refer to Table 1.

Recommended Practice DTCGT companies need to improve their privacy policies. These policies should

comprehensively cover the use, storage and sharing of personal information and specifically cover the use, storage, and sharing of genetic data as well as procedures for destruction of the physical DNA sample. Increasingly, DTCGT companies offer social networking functions and contracts commonly give the companies licenses to use user generated content in a similar manner to more traditional social networking websites, such as Facebook and MySpace. However, while consumers may arguably benefit from utilizing some social networking functions, consumers need to be made aware of the possible risks which posting genetic data publically together with other health information may entail.

E. Indemnity

Current practice Online contracts also often include indemnity clauses and these are also a feature of DTCGT company contracts. This sometimes includes indemnification against any third party action which may arise from a person sharing their test results. For instance sharing with a healthcare professional would be covered by this. Please refer to Table 1.

Recommended Practice The inclusion of such clauses may be understandable from a company’s perspective, but these clauses are currently too broad in scope and it is desirable that such clauses are omitted in future.

TABLE I. TABLE OF PRELIMINARY RESULTS OF ANALYSIS OF THE CONTRACTS OF DTCGT COMPANIES THAT PROVIDE HEALTH RELATED TESTING

Number of companies analyzed: 71 Date Survey performed: Oct 11 - Nov 14			
Subject Matter	Content of Clause	No. of companies including clause	%
Consent and Acceptance	Deemed consent or acceptance through use or viewing of website	25	35%
Consent and Acceptance	Deem acceptance or agreement	16	22%
Consent and Acceptance	Deem consent	9	13%
Consent and Acceptance	Do not have a specific clause covering consent	22	31%
Disclaimer of Liability	Include disclaimer clauses	57	80%
Disclaimer of Liability	Disclaim liability for fitness for purpose	27	38%
Disclaimer of Liability	Disclaim liability for injury caused by their negligence	10	14%
Disclaimer of Liability	Specify that their services, their website, and products or information are all provided on an ‘as is’ basis.	31	44%
Disclaimer of Liability	Specify that they provide ‘no warranty’ for their services.	21	30%
Privacy	Have clauses covering disclosure of data	26	37%
Privacy	State that they will not sell data	20	28%
Privacy	State that they may disclose data to law enforcement agencies, to comply with law or court order or health oversight agencies	18	25%
Privacy	Allow for disclosure of personal data or genetic data to third parties in certain circumstances	34	48%
Privacy	Will destroy physical sample either immediately after sequencing or after communicating test results	7	10%

Number of companies analyzed: 71 Date Survey performed: Oct 11 - Nov 14			
Subject Matter	Content of Clause	No. of companies including clause	%
Indemnity	Requires consumer to indemnify the company	31	44%
Indemnity	Indemnification against third party action which might arise through sharing genetic test results with a healthcare professional	26	37%
Change of terms	Allowing company right to change terms	51	72%
Change of terms	Change terms ‘at any time’	28	39%
Change of terms	Change terms ‘from time to time’	23	32%
Change of terms	Allow for change of terms ‘at any time’ (...) ‘without notice’	17	23%
Change of terms	Will notify consumer of changes by email	4	6%
Change of terms	Continued use of website is deemed acceptance of changes to terms	21	30%
Exclusion	Specify their services are provided for informational, recreational, or educational purposes only.	36	51%

IV. CONCLUSION

More specific regulation for the DTCGT industry is needed, but reform of DTCGT contracts is also necessary and feasible in the short term. It is hoped that this paper highlights that some terms commonly included in DTCGT contracts may not be of a nature likely to be anticipated by the consumer.

Overall there is a need for greater transparency about the respective risks and benefits of DTCGT testing. Currently, some terms commonly included in DTCGT contracts could be construed as unfair or unconscionable in the UK and EU, and also possibly in some US states. As the industry is dependent on consumer data then there is a need for and an opportunity for companies to educate consumers. If consumer data is to be used in ongoing medical research then providing more comprehensive mechanisms for providing consent seems desirable. Privacy policies also need to be more comprehensive and address the issues of data sharing, sale, storage, and security in much greater depth and explicitly draw consumers’ attention to companies’ privacy practices.

It is desirable that prominent DTCGT companies do take the lead and reform their contracts. Contracts could be framed as shorter documents using easily understood language with attention being drawn to key clauses. They could be made more interactive with more opportunities for consumers to opt out of particular clauses. Companies could look to models of consent used in other contexts, such as HeLEX’s dynamic consent.²¹ They could also provide some short videos explaining their terms in a similar vein to the videos provided by some companies that provide genetic counselling.

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