Giving away more than your genome sequence?: Privacy in the Direct-to-Consumer Genetic Testing Space

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Direct-to-consumer genetic testing (DTCGT) is an example of recent technology that poses challenges for privacy and security. The industry is centred around the provision of genetic tests directly to the public. Typically, DTCGT services involve several key steps. A consumer purchases a genetic test online, the company will then send the consumer a collection kit, which allows her to take a saliva sample, which she then sends back to the company for analysis. The company performs genetic sequencing on the individual's bodily fluids, and then returns results, which might be partial raw genomic sequence data or interpreted data, eg. for disease risk predisposition. The company may also store both the physical sample and the sequenced genetic data and often performs secondary research, which the consumer may not know about. Some companies allow consumers to engage in social networking on their websites and this differs from other forms of social media in that consumers are encouraged to share health information not just about themselves, but also about their families online. Each of these steps involves digital data or physical material, each of which raises privacy and security issues. The most significant issues applicable to all types of DTCGT tests are: whether these services are fit for their claimed purposes; whether the genetic data and other personal information collected from consumers is being stored securely; whether companies provide sufficient protection for consumers' privacy in genetic and other types of personal information; whether companies are being sufficiently transparent about the respective benefits and limitations of their services; whether consumers have sufficient understanding of disease risk information; and finally, whether consumers actually understand the contracts they enter into when purchasing these tests.

In the first research study 3000 American, Australian and United Kingdom respondents were asked how confident they were that, within the DTCGT testing context, their personal genetic information would only be shared with other people with their permission. Overall, these potential consumers are reasonably confident that, as a consumer of these services, they themselves control the privacy and release of their genetic information. The research showed that this belief is a key driver of potential participation in DTCGT research as well as increasing the likelihood of sharing test results online. Who owns the genetic data and how it can be used is detailed in the contracts consumers enter into and how DTCGT companies protect consumers' privacy is detailed either in the contracts or in separate privacy policies. The contracts used by DTCGT companies resemble those used by web-based companies more generally and are often not tailored to adequately deal with the issues raised by the DTCGT industry specifically. The second study has examined the contracts of DTCGT companies providing health testing. Overall, it was found that

many contracts contain clauses that might raise concern from a consumer protection perspective. The project was focussed on UK law and it is suggested that several terms commonly included in DTCGT contracts might be deemed to be unfair terms and unenforceable under UK law.

Why does this matter?

When it comes to privacy and privacy breaches stored genetic data differs from other forms of personal data in that, unlike say a hacked bank password, it cannot be changed and the privacy breach extends beyond the affected individual to their genetic relatives. With the increasing use of biometrics in security systems, insecure storage of genetic data may pose as yet unforeseen risks for consumers. In the future, there may be an incentive for hackers to target genetic databases in order to acquire data than can be used in financial or identity fraud. There are a number of other risks associated with the use of genetic data, including: targeted marketing of drugs to individuals and family groups; potential genetic discrimination resulting from sharing genetic information with third parties; and sharing with law enforcement or government agencies without appropriate consent.

At present, the DTCGT industry occupies a regulatory grey area. Our research is timely because the industry is developing rapidly and the law is not keeping pace with its development. While there is a lack of specific legal regulation, contracts are being used as the dominant governance mechanism, which raises a number of issues. The lack of traditional gatekeepers, such as clinicians and genetic counsellors who have generally assisted people with understanding genetic test results is also problematic. There is an overall issue of whether many tests offered are fit for purpose. This presentation aims to stimulate discussion and suggest regulatory reform.

Keywords: direct-to-consumer genetic testing, consumer protection, contracts, disease risk, privacy, security

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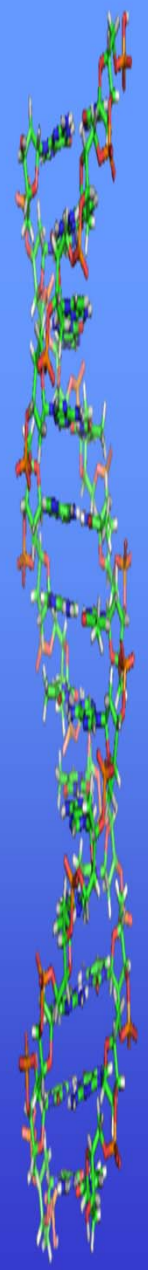
Genetic Testing: Privacy Concerns



- Characteristics of genetic data
  - Most intimate of personal data: unique identifier of both an individual & their family groups
- Inherently identifiable
  - NOT possible to fully *de-identify* genetic data to make it impossible to *re-identify*
- Irrevocable
  - Once breached, it cannot be changed

Direct-to-Consumer Genetic Testing

- Traditional genetic testing
  - Occurs within each country's healthcare system
  - 'Patient' – enlivens professional/regulatory oversight & established legal duties of care
- Direct-to-consumer genetic testing
  - Commercial transaction
  - Occurs in the marketplace, typically online
  - 'Consumer' – enlivens consumer protection legislation & actions such as contract & negligence

General Public's View: Privacy & DTC

- Australia: GP or DTC?
  - Privacy concerns key constraint (also intention to biobank)
- 'Sharing' in the DTC space
  - Potential to extend beyond consumer-company
- Online panel of 3000 American, Australian and UK respondents (+ Japan)
  - 10% actual consumers; 90% potential consumers

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Privacy & DTC

- Private = not shared; Shared = not private
- Privacy issues arise from sharing
  - Privacy = control over sharing
- Providing permission to share means individuals control personal genetic information
  - Permission = control over privacy

Privacy & DTC Engagement

- If consumers *believe* genetic data will only be shared with permission (*perceived* control)
  - More likely to purchase DTC tests
    - especially if have actually shared with family or online
  - Much more likely to participate in DTC research
    - initially permission-based (non-specific/enduring consent)
    - more likely to have actually shared & more likely to purchase

Sharers are Sharers

- More likely to share DTC results with family (not friends)
- More likely to share with doctors
  - DTC results for 'research, informational & educational use only' – not diagnosis
  - 'It would be 'a very brave' GP who relied on the results of a DTC gene test to manage a patient.' Prof Suther, RCPA
- More likely to share in online health communities & with genetic counselors

Does *perceived* control = *actual* control?

- DTC is a commercial transaction
  - Governed by contracts, terms of service & privacy policies (same for online interpretation & sharing sites)

- Australian DTC companies & their privacy policies
  - Privacy policies do NOT comply with *Privacy Act 1988* (Cth) or *Enhanced Privacy Protection Act* (in force 2014)

Click Here Now:
DTC Contracts & Privacy Policies

- Study examined DTC contracts and privacy policies of companies providing tests for health purposes

- These govern:
  - Purchase of genetic tests
  - Use of DTC websites
  - Participation in DTC research

Contracting Online & Consumer Behavior

- When active online we often have ‘inattentional blindness’
- Consumers may not realise they are entering into a contract
- This is particularly relevant to both wrap contracts and privacy policies
  - Consumers often may not even notice, let alone read them

Privacy Risks

- Sharing or sale of sequenced genetic data
- Sharing or sale of other types of personal data
- Possible discrimination on the basis of an individual's genetic makeup

More Privacy Risks

- There is potential for hacking of genetic databases for purposes of:
  - Identity theft
  - Targeted marketing (e.g. pharmaceutical drugs)
  - Discrimination in insurance or employment
  - More remotely, the creation of synthetic DNA

DTC Contracts & Privacy Policies

- Often contracts and privacy policies are not industry specific
- Contracts online more generally often use very similar wording
- Several terms commonly included might be deemed unfair and unenforceable under UK and European Union law

Common Terms

- Consent or agreement with terms **OFTEN DEEMED** through use or viewing of the website or use of services

- Clauses allowing unilateral alteration of terms without notice to consumers

  - Companies could make significant changes to policies on use, storage, sharing, & sale of data without telling consumers.

Significant Clauses

- Clauses stating services are provided for ‘research, informational and educational use only’ &/or ‘recreation’
- Clauses stating company may share data with law enforcement
- Clauses stating company can share with third parties

Need For Reform Of Contracts & Privacy Policies

- Contracts and privacy policies should be drafted so that they can
  - Be easily understood by the consumer
  - Allow for consumers to make informed decisions & have control over their data
    - e.g. could include more opt-ins for specific uses of data
  - Consent should not be deemed through visiting a website

Thank you!

For further information, please contact

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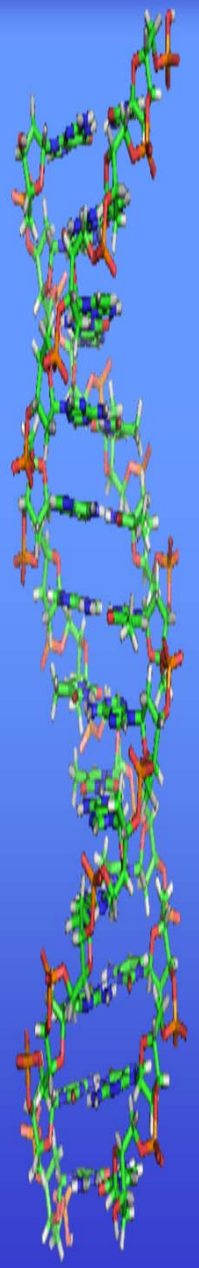

Graphics: DNA available at Google Images, origin not attributed

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GENEWATCH

FROM THE LAB TO THE MARKET
By Andelka M. Phillips, Jan Charbonneau

from *GeneWatch* 28-3 | Oct-Dec 2015

With traditional genetic testing, doctors collect DNA samples, explain test results and advise patients on treatment options. With direct-to-consumer (DTC) genetic testing, private companies provide genetic tests and results in commercial transactions. Consumers provide DNA samples directly to DTC genetic testing companies, with results provided back directly to consumers, typically online and usually without involving doctors.[1] Direct-to-consumer genetic tests range from health-related tests with significant healthcare implications (e.g. disease predisposition) to the so-called recreational genomics with no discernible implications (e.g. earwax consistency).[2]

Of particular concern has been the offering of health-related tests outside the traditional medico-legal environment. Questions have been raised about the quality of health-related direct-to-consumer genetic tests and whether results are understandable by the average consumer. Concern has also been expressed about the appropriate regulation of the DTC genetic testing industry; at present DTC genetic testing purchases are normally governed by corporate contract and privacy policies. It is questionable whether consumers are giving valid consent for the tests and participation in DTC genetic testing research. Finally, there is a consensus that consumers often have insufficient understanding that the terms and conditions they agree to on DTC genetic testing websites (when they click "I agree") are legally binding agreements.

While debatable, let's assume health-related DTC genetic testing tests are accurate and valid, meaning laboratories conducting tests are accredited and tests identify genetic variations with scientifically established links to health-related conditions. For tests to provide personal utility - information someone can do something with - consumers must be able to first understand their test results.

Direct-to-consumer genetic tests are not medical tests, with the industry emphasizing they are for 'research, information and education' only and not to be considered as a diagnosis. Interpretation of DTC genetic testing results, presented by companies in standardized numeric form, and their use in healthcare decision-making is left to consumers. While many companies actively suggest consumers consult their doctors or genetic counselors, that also is left to the consumer.

7. SUCCESSORS AND ASSIGNS
7.1 Successors and Assigns. You may not assign Your rights and duties under this Agreement to any party at any time. This Agreement will enure to the benefit of and will be binding on Us and our respective successors and permitted assigns. In the event of corporate merger, amalgamation, divestiture or asset sale, We will have the right to transfer and assign Our rights and obligations hereunder to any third party (the "Assignee"), upon written notice to You, provided that We cause the Assignee to agree in writing to all the terms contained in this Agreement.
8. UPGRADES
8.1 Upgrades. Other than our obligation under Section 2.4(b), We shall have no other obligations to provide updates or support services to You. Obligations or expectations with regard to product upgrades, enhancements, support or remedies for errors, defects or deficiencies will be limited to those expressly set forth in a separate agreement between Us and You. In the absence of such an agreement between Us and You, We will use reasonable efforts to provide ongoing support and remedies to identified errors and defects, on a timeliness and material basis, at Our then current commercial rates.
9. CONFIDENTIALITY
9.1 Confidentiality. You acknowledge that the existence of this Agreement, the terms and conditions hereof, the transactions contemplated hereby and other information, including, without limitation, customer, technical and financial information that they have received or will receive in connection with this Agreement, is considered private and confidential (the "Confidential Information"). You will use reasonable diligence and in no event less than the degree of care which We use in respect to our own confidential and proprietary information of like nature, to prevent the unauthorized disclosure, reproduction or distribution of such Confidential Information to any other individual, corporation or entity. Such Confidential Information will exclude:
(a) Information that is already in the public domain;
(b) Information already known to the receiving party, as of the date of the disclosure, unless the receiving party agrees to keep such information in confidence at the time of its original receipt;
(c) Information hereafter obtained by the receiving party, from a source not otherwise under an obligation of confidentiality with the disclosing party;
(d) Information that the receiving party is obligated to produce under order of a court of competent jurisdiction, provided that the receiving party promptly notifies the disclosing party of such an event so that the disclosing party may seek an appropriate protective order.
10. TERM
10.1 Term. The term of this Agreement will commence on the date of Your agreement to these terms and shall continue for the same term as the Usage Agreement.
11. GENERAL
11.1 Consents. Any consent required under this Agreement will not be unreasonably withheld.
11.2 Captions. The Article and paragraph headings used herein are for convenience only and are not a part of this Agreement and will not be used in construing it.
11.3 Entire Agreement. This Agreement constitutes the entire agreement of the Parties, and no amendment to the terms of this Agreement will be effective unless in writing and signed by both parties hereto.
11.4 Equitable Relief. You agree that any breach of this Agreement by You would cause irreparable damage, and that, in event of such breach, in addition to any and all remedies at law, We will have the right to an injunction, specific performance or other equitable relief to prevent the continuous violations of the terms of this Agreement.
11.5 Force Majeure. Notwithstanding anything herein to the contrary, We shall not be liable for any delay or failure in performance caused by circumstances beyond Our reasonable control.
11.6 Relationship of the Parties. This Agreement does not constitute a partnership or joint venture, and nothing herein contained is intended to constitute, nor will it be construed to constitute, such a partnership or joint venture. Except as expressly provided in this Agreement, neither We nor You will have any power or authority to act in the name or on behalf of the other party, or to bind the other party to any legal agreement.
11.7 Severability. The provisions of this Agreement are to be considered separately, and if any provision hereof should be found by any court or competent jurisdiction to be invalid or unenforceable, this Agreement will be deemed to have effect as if such provision were severed from this Agreement.
11.8 Number and Gender. Where the context permits, the singular includes the plural, and the masculine includes the feminine and vice versa.
11.9 Notices. All notices and communications required or permitted under this Agreement will be in writing and will be sent by registered or certified mail, postage prepaid, return receipt requested, facsimile transmission (the "Fax"), with confirmed answer back, or electronic mail, with confirmation of receipt, to Us or You at the respective addresses we provide to each other or to such other address
heedlessly just ignore all this and

SIGN HERE

DTC genetic testing results for disease predisposition are essentially two numbers: the consumer's own personal lifetime risk of developing a given disease and the average person's lifetime risk of developing that same disease. So ... it seems that it should be straightforward for a consumer to compare two numbers objectively and determine if their lifetime risk is higher or lower than the average and then, based on this interpretation, make appropriate healthcare decisions.

In 2015, three thousand potential and actual DTC genetic testing consumers in the United States, Australia and the United Kingdom were asked to interpret sample DTC genetic testing disease pre-disposition results. Analysis revealed that for some consumers, interpretation of these two numbers is anything but objective. Some consumers presented with a personal lifetime risk numerically lower than the average person's believed their risk was actually higher or much higher; some presented with numerically higher than average risk believed their risk was actually lower or much lower. Others presented with a personal lifetime risk significantly higher than the average felt their risk was 'about the same' as the average person's. This diversity of interpretation was driven by a range of factors, including the individual's assessment of their own health and lifestyle, family disease history, general health numeracy skills and even their beliefs about the role genes play in disease.[3]

Does this matter? How the numbers are interpreted was found to have an impact on consumers' emotional states and behavioral intentions. For example, worry and anxiety increased if personal risk was interpreted by the consumer as higher, with relief increasing if personal risk was interpreted as lower than the average - perfectly normal responses if tests and interpretation are accurate but capable of generating unnecessary stress or a false sense of security if not. With regard to what consumers might do, those interpreting their disease risk as higher than average, regardless of the actual numbers, were more likely to, for example, monitor their health more closely, change their diet and visit their doctors - all positive health behaviors regardless of actual results. Of course, those interpreting their risk as lower, again regardless of the actual numbers, were less likely to make such positive health-related changes.

At its core, consumer genomics is about consumer empowerment - allowing consumers to access their own genetic information and use that information in health related decision-making. However, for DTC genetic testing offerings to deliver on this, consumers must be able to accurately interpret test results and make appropriate decisions. This research suggests that DTC genetic testing companies' assumption of 'objective interpretation' of results may not be the case, suggesting the 'one size' approach to returning results may not 'fit all.'

How should we regulate the industry? At present, DTC genetic testing sits outside existing regulation. Several areas of law have relevance (medical devices regulation, consumer protection, and privacy), but specific regulation is needed in the U.S., where many of these companies are based. The FDA's renewed interest in DTC genetic testing as of November 2015[4] also may we hope lead to more specific industry guidance being developed.

Moving DNA testing away from the clinic means that many of the traditional safeguards that might apply in a medical setting are not present in the DTC genetic testing context. With the direct-to-consumer model, genetic testing has moved outside the doctor-patient relationship to that of a relationship between a consumer and company. In lieu of specific regulation, companies rely on the terms of service, terms of use and privacy policies that appear on their websites to govern transactions.

An in-depth review was conducted of the contracts of DTC genetic testing companies providing health testing[5] as well as the existing regulatory landscape. As with many web-based industries, DTC genetic testing contracts are often lengthy, complex documents. And the behavior of consumers in this context resembles their behavior regarding online contracting more generally. That is, it seems that consumers may not actually read the documents they have 'agreed' to when active online. We often tend to click 'I Agree' without considering the legal implications of this. In the DTC genetic testing context this raises questions regarding the validity of consumers' consent for genetic tests and for participation in research.

Even ignoring the non-reading problem, there is an issue of whether a person can ever really agree to terms that are not available at the time of entering into a contract. For instance, many contracts include a unilateral change of terms clause. Such clauses often allow companies to change their terms without direct notice to the consumer. And these contracts often deem consent to altered terms through continued use or visiting of a website, which is often possible without ever encountering terms. This is problematic as it may impact upon the purposes for which stored genetic data may be used. For example, an individual might agree to participate in research conducted by the DTC genetic testing company for certain purposes, but those purposes might change if the terms were subsequently altered.

These contracts often include broad indemnity and exemption clauses which consumers are not likely to expect or understand. For instance, it is common to include a clause disclaiming liability for fitness for purpose. It is possible that some of these terms could be deemed 'unfair terms' and unenforceable under UK and EU law. It may also be possible to challenge some of the terms under American or Australian law. For health related testing, tests really ought to be fit for their claimed purpose and there ought not to be a discrepancy between website claims and contract content.

DTC genetic testing contracts are also generally not industry specific, meaning that they resemble the wrap

contracts used more generally by many online industries and large Internet Service Providers. Briefly, a wrap contract can be defined as 'a unilaterally imposed set of terms which the drafter purports to be legally binding.[6] The two most common forms used on the Internet are clickwrap and browsewrap. Clickwrap contracts are presented in a form where a person can scroll through terms and click "I Agree" at the end,[7] while browsewrap normally have terms available on a hyperlink,[8] so that it is possible to click "I Agree" without viewing the terms at all. In online contracting more generally, companies frequently borrow terms from each other,[9] which means there is much uniformity amongst them.

Why does this matter? It matters because DTC genetic testing companies are often not tailoring their contracts and privacy policies to address the specific issues raised by this industry. The two most pressing issues here are the related issues of privacy and information security.

Consumers need to be more aware that their stored sequenced DNA can be used to identify them and also their families. For example, an individual's sequenced genetic data can serve as a unique identifier for that individual and stored data will remain inherently identifiable. And as families share much of their DNA, an individual's stored data poses potential risks for their family, as it is possible to re-identify quite large family groups. Several studies have now indicated that complete anonymization is not possible - even if data is "de-identified," it is re-identifiable.[10]

Some sites offer social networking functions and consumers may also choose to engage with other online platforms that allow sharing of genetic test results and health information, such as CureTogether, owned by DTC genetic testing company 23andMe.[11] When consumers engage with either social networking on a company's website or on a sharing platform, they may also be agreeing to give the company a license to use user generated content. This is concerning, as in this context this content may include personal, lifestyle, and medical data that might normally be considered to be sensitive.

Genetics is a rapidly evolving field with each day bringing new insight into the role genes and their interaction with environmental factors play in disease predisposition and progression and the impact of the microbiome on human health. Even in clinical research there is debate over the role of particular genes and their association with disease.

Health-related genetic testing is complex in nature, even for medical professionals. DTC genetic testing adds additional layers of complexity. At present, many tests offered by companies have not been standardized and standards are not harmonized across the DTC genetic testing industry. The net result is that consumers choosing to purchase tests for the same conditions from different companies may get contradictory results.

Even assuming the tests are accurate, consumers are left to interpret results themselves and then decide what to do with that information, information that might have serious personal and family implications. Consumers may choose to take their DTC genetic testing results to their physicians; however, many general practitioners have indicated they are not yet confident in interpreting genetic tests. Consequently, if consumers are going to benefit from these services, it is vital that physicians have sufficient information to assist them in interpreting DTC genetic testing results.

Ultimately, when engaging with DTC genetic testing companies, consumers have to realize they are entering into legally binding contracts and agreeing to privacy policies involving the most intimate of personal and family information: their DNA.

It appears that with DTC genetic testing it is still very much a case of 'caveat emptor' - let the buyer beware.

***Andelka M. Phillips**, has recently passed her viva for the degree of doctor of philosophy in law in the Faculty of Law at the University of Oxford. Her research focuses on regulation of DTC genetic testing and the protection of consumers' rights in their genetic information in the context of DTC genetic testing.*

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ENDNOTES

[1] The DTC genetic testing industry has been evolving in terms of business models and modes of distribution. Some companies now require, or offer the option, of return of results to consumers' healthcare professionals. 23andMe's UK branch also supplies tests through Superdrug, a pharmaceutical chain.

[2] For information on the range of non-health related DTC genetic testing tests on offer, especially some of the more questionable types of testing, see A. Phillips, 'Only a Click Away - DTC Genetics for Ancestry, Health, Love...and More: A View of the Business and Regulatory Landscape' in Applied & Translational Genomics - forthcoming 2016.

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[5] This involved compiling a list of the DNA testing companies with English language websites. 248 have been identified and there are 102 websites that have offered testing for health purposes in the last four years. Please also see Andelka M Phillips, 'Genomic Privacy and Direct-to-Consumer Genetics - Big Consumer Genetic Data - What's in that Contract?' (2015 IEEE CS Security and Privacy Workshops); and Andelka M Phillips, Think Before You Click ? Ordering a Genetic Test Online' (2015) 11 Scitech Lawyer 8.

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THINK BEFORE YOU CLICK

ORDERING A GENETIC TEST ONLINE

BY ANDELKA M. PHILLIPS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There is much promise for DTCGT testing

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

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

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

Endnotes

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

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

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

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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 mechanims 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 mechanims 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 Heritage[1] 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.

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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 Genome[11] 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 permissable 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 Huntingdon'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 pofessional	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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