

Genetics goes online – privacy in the world of personal genomics

Dr Andelka M. Phillips discusses the risks in processing and storing genetic data – potentially indefinitely.

The direct-to-consumer genetic testing (DTC aka personal genomics) industry has brought DNA tests out of the clinic and into the domestic space. A number of companies offer family-finder features and will try to connect people with unknown relatives. It is important to note that genetic data can serve both as a unique identifier for an individual and, given the shared nature of our DNA, it is possible to identify a person's relatives through access to one person's genetic data.

Today's world is one of ever-increasing monitoring, where we are all subject to complex data mining and profiling. We can be tracked across platforms, through our phones, our computers, and wearable fitness monitors. Many new data driven products and services are coming to market with relatively little specific industry regulation and this article provides a brief introduction to the complex world of DTC genetic testing services, and key privacy and data protection issues raised by the industry.

NATURE OF DTC GENETIC TESTS

Simply put, DTC services provide genetic tests directly to the public normally for order through a website. DTC companies typically send their customers a test kit, which is used to collect a DNA sample. This is usually a saliva sample or cheek swab. This sample is sent back to the company for processing and the individual tested will be able to access their results through a web-based interface. The industry has emerged in the last two decades, with University Diagnostics launching a mail order service in 1996, and it now consists of a broad spectrum of services with the present research identifying 288 companies offering some form of DNA test online. There are tests available for various health purposes, as well as ancestry tests (a field which is seeing

particular growth – for example, AncestryDNA in the period between Black Friday and Cyber Monday 2017 sold 1.5 million test kits). There are also tests for more dubious purposes and which have not been well validated, such as tests for child talent, matchmaking, and infidelity (which is non-consensual).

At present, the industry lacks harmonised standards and it is possible to obtain contradictory results for tests from different health test providers. This is due to a number of factors. Scientific understanding of how genes function and their association with human health is still developing and tests for many complex diseases have not yet been standardised. Understanding of how epigenetic factors¹ contribute to health is also continuing to develop and there is also growing interest in the impact of the microbiome² on human health. Also, some tests offered by DTC companies have not been validated and may have limited utility. Most DTC companies are currently not offering services that sequence a whole genome or whole exome (the protein coding part of the genome) and have tended to focus on targeting Single Nucleotide Polymorphisms (SNPs)³.

Also, DTC companies frame their populations in their databases differently. Recent research has also demonstrated that there is a relatively

high incidence of false positives in genetic test results provided by DTC companies. It should be noted though that it is also possible to obtain different ethnicity estimates from ancestry test providers and also that certain groups, such as Indigenous Peoples are underrepresented even in the largest DTC databases. More informational and educational resources are needed to assist consumers in understanding what their individual test results mean for them and to support them to make informed decisions in this context.

GOLDEN STATE KILLER AND GEDMATCH

This topic is timely given the recent media coverage of the genetic genealogy database GEDmatch's involvement in investigations of the Golden State Killer case. This case highlights the broad potential for genetic databases to be used for secondary purposes. This case related to a large number of murders, rapes, and burglaries carried out in the US in the 1970s and 1980s. A process known as Familial DNA searching allows for the tracing of relatives through searching existing records of genetic data. (Normally this is done relying on existing criminal databases). GEDmatch allows people to upload genetic data and crucially it does allow for sharing with law enforcement in its site policy. Currently, some of the details of the process followed by law enforcement are still emerging, but a profile on GEDmatch was created based on DNA samples collected at crime scenes 30 or 40 years ago. The database was then searched in order to find people who could be potential relatives. This process is controversial and it needs to be borne in mind that this type of searching does mean that police are examining databases of innocent people in order to potentially track down a possible suspect. It has now emerged that a DTC company

INFORMATION

This article follows on from the Genetics session at the Privacy Laws & Business 31st Annual International Conference *Navigating GDPR: The art of the possible*. The speakers in this session were: Helga Þórisdóttir, Commissioner, Data Protection Authority, Iceland; and Dr Andelka M Phillips. This article is based on Phillips' ongoing research and the forthcoming book, *Buying Your Self On the Internet: Wrap Contracts and Personal Genomics*, which will be published by Edinburgh University Press in 2019 as part of their Future Law series.

(Family Tree DNA's parent company Gene By Gene) also received a "federal subpoena from the Eastern District of California in March 2017 asking for 'limited information' about a single customer account."⁴ The suspect in this case, James DeAngelo, has been cleared in at least one of the murder cases on the basis that his DNA did not match, which should further highlight the need for a cautious approach to using this method.

However, since the coverage of DeAngelo's arrest there have been several other news stories indicating that GEDmatch is being utilized in a number of other cold case investigations, with Parabon Nanolabs uploading data from "approximately 100 crime scenes on to GEDmatch's database in the hopes of finding further matches."⁵

The past two years have also seen increased attention on the DTC industry with a number of companies engaging in prominent advertising campaigns, most notably 23andMe and AncestryDNA. As well as increased consumer uptake, 2017 and 2018 have seen the revelations of two data breaches at DTC companies, AncestryDNA and MyHeritage. Research has also demonstrated that it is possible to infect DNA data with malware, which may pose other challenges for companies dealing with genetic data in the future. This is an area where there is quite a lot of uncertainty in

terms of future risks, and DTC companies will need to invest in security infrastructure.

PROBLEMS WITH ANONYMISATION

While in the past it was thought that anonymization and de-identification techniques might help to minimise privacy risks in this context, there is growing recognition that it is not really possible to de-identify genetic data in a way that would make it impossible to re-identify an individual. There have been several studies, which have demonstrated that it is possible to re-identify research participants in large genetic studies. Good examples are the work by Gymrek et al and Erlich et al. It has even been demonstrated that identification is possible through reliance on research statistics. This means that the risk of a data leak does not necessarily decrease over time. As Ayday et al note, due to the shared nature of genetic data, potential data leakage is not a matter that will only affect the individual concerned, but their family and genetic data stored in DTC databases if leaked could actually impact upon a large family group.

INDUSTRY GROWTH AND SECONDARY RESEARCH

While in the industry's early days, there was relatively low consumer uptake, a number of prominent companies have now amassed databases of hundreds of thousands, or

even several million, records of consumers' genetic data. Good examples are 23andMe and AncestryDNA, but Gene By Gene's Family Tree DNA, Orig3n, and MyHeritage also have substantial databases. Two companies that were early key players, DeCODE's DeCODEme and Navigenics, which were both sold to other research companies exemplify how easily consumer data can be used for on-going secondary research. DeCODE is an Icelandic company and Iceland's DP Commissioner Þórisdóttir's talk in the same conference session (see the Information box at the end) provided helpful context on the Icelandic experience of genetic research. DeCODE began with a contract to map the genome of the Icelandic population, subsequently developed a DTC offering, known as deCODEme before its subsequent sale to Amgen in 2012.

A number of prominent DTC companies have begun to enter the field of medical research, entering partnerships with other DTC companies and other industries, most often the pharmaceutical sector, but some are also partnering with insurers. The DTC company 23andMe has entered into at least 15 partnerships with third parties (mostly pharmaceutical companies), the most recent venture being with Glaxo-SmithKline, and also purchased Cure-Together in 2012, while Family Tree DNA has acquired DNA Heritage and DNA-Fingerprint, and MyHeritage has partnered with both Family Tree DNA and 23andMe. Meanwhile, Orig3n has recently entered into a partnership with ZhongAn Online P&C Insurance Co., Ltd, which plans to supplement its insurance offerings and provide genetic testing services to its customer base of 500 million people and the wider Chinese market. These examples highlight the potential for genetic data collected from consumers to be used for a wide range of secondary research.

REGULATION OF THE INDUSTRY

In lieu of industry specific legislation, DTC companies have tended to rely on their privacy policies and online contracts to govern their relationships with consumers. These documents

FURTHER READING

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appear on websites and are often linked together and seek to incorporate terms by reference, which means that a consumer needs to read all of a company's documents to fully understand their rights and obligations. As DTC tests are framed as consumer services, DTC companies should be complying with consumer protection legislation (the EU Directive on Consumer Rights and the Unfair Contract Terms Directive are particularly relevant) as well as data protection law. They may also need to comply with the governance framework on medical devices.

In my review of DTC company contracts, a number of clauses were identified, which are open to challenge under consumer protection law in the UK and EU on the basis of qualifying as unfair terms. The UK's Competition and Markets Authority has previously conducted a compliance review of contract terms in the cloud storage context and has given guidance on terms it views as problematic. In the review of DTC contracts, a number of similar terms were identified and it was suggested that several terms are open to challenge on the grounds of unfairness. Two examples are: clauses that allow a company to unilaterally alter their terms without notice to the consumer; and clauses that purport to bind the consumer to bring any claims for legal redress in a jurisdiction outside their home jurisdiction. It is possible that some of these clauses could also be challenged in other jurisdictions, such as the US, Australia, and New Zealand.

The work of the Australian consumer regulator, the Australian Competition and Consumer Commission (ACCC) also has relevance here, as they have recently had success in a case they brought against the American game company Valve. The *ACCC v Valve* case was concerned with clauses included in Valve's Subscriber Agreement and whether they "breached the Australian Consumer Law (ACL) by making false and misleading representations to Australian consumers." Australia's Federal Court found that Valve "had engaged in misleading or deceptive conduct and made false or misleading representations"⁶ and fined Valve three million Australian dollars. This decision is a victory for the

enforcement of Australian consumer protection law over international companies offering services to Australian consumers. The ACCC has also brought an enforcement action against the wearable device manufacturer Fitbit and obtained an enforceable undertaking in 2018.

Companies offering DTC tests to consumers based in the European Union should now be complying with the GDPR. Significantly, genetic data is included both within the GDPR's definition of personal data and also in the prohibition on processing of special categories of personal data in Article 9. Genetic data is also included in the prohibition on processing of special categories of personal data as set out in Article 9. There are two relevant exceptions set out in article 9(2). These are: (a) "explicit consent" of data subject; and (j) the so-called research exemption. Thus, a significant element of compliance is obtaining the necessary consent from the individual tested and it is likely that businesses will need to obtain separate consents for additional research.

The GDPR also sets out requirements in relation to privacy notices and privacy policies. Article 13 sets out the types of information that should be provided to data subjects in relation to processing of information and there is also a transparency requirement set out in Article 12(1). Article 12(7) also requires that information that is provided to a data subject be provided in a meaningful way, including that the information presented is "easily visible, intelligible and clearly legible." There are similar requirements set out for consumer contracts under European consumer protection law.

Compliance with the GDPR may prove challenging for some businesses and it may be that more reform is needed to assist with governance of new technologies. However, creating privacy policies that are user friendly and assist data subjects in understanding how their data is used can also be seen as an opportunity. Businesses should consider how to give more control to consumers, so that individuals are able to choose how their data is used. Particularly for services that deal with sensitive information, such as genetic data, developing consumer

trust could allow for a competitive advantage. It would be useful if Data Protection Authorities and Consumer regulators could develop more model privacy policies and contracts for specific industries. It is also desirable for industry codes of conduct to be developed. Overall, there is a need for better protection of the rights of individuals, including more informational resources so that people are able to make more informed choices about whether to engage with such services.

AUTHOR

Dr Andelka Phillips is a Research Associate at the University of Oxford's Centre for Health, Law and Emerging Technologies (HeLEX). She will be a Senior Lecturer at Te Piringa Faculty of Law, The University of Waikato, New Zealand from early 2019.

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- 2 Microbiome comprises all of the genetic material within a microbiota (the entire collection of microorganisms in a specific niche, such as the human gut). See <https://www.nature.com/subjects/microbiome>
- 3 The most common type of genetic variation among people.
- 4 P Aldhous, 'Cops Forced A Company To Share A Customer's Identity For The Golden State Killer Investigation' *BuzzFeed* (1 May 2018) www.buzzfeednews.com/article/peteraldhous/family-tree-dna-subpoena-golden-state-killer#.kIPB3w6vpm; P Shanks, 'Forensic DNA and the "Golden State Killer"' *Center for Genetics and Society* (2 May 2018) www.geneticsandsociety.org/biopolitical-times/forensic-dna-and-golden-state-killer
- 5 AM Phillips, *Buying Your Self on the Internet* (forthcoming 2019) chapter 4 citing Peter Aldhous, 'DNA Data From 100 Crime Scenes Has Been Uploaded To A Genealogy Website — Just Like The Golden State Killer' *BuzzFeed News* (17 May 2018) <<https://www.buzzfeednews.com/article/peteraldhous/parabon-genetic-genealogy-cold-cases>>
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