

CANADA'S *GENETIC NON-DISCRIMINATION* ACT: FALSE SECURITY FOR CUSTOMERS OF DIRECT-TO-CONSUMER GENETIC TESTING SERVICES

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In the late twentieth century, Direct-to-Consumer Genetic Testing (DTC-GT) companies appeared in the market, selling “at home” genetic tests. These tests require customers to collect their DNA sample and mail it to the DTC-GT company for analysis. Upon analyzing the customer’s DNA, the DTC-GT company sends the customer a report outlining his or her genetic risk of developing a particular disease. The popularity of these companies has increased rapidly in the past few years. However, customers, researchers, and public health officials have expressed concerns about the privacy risks associated with ordering a DTC genetic test.

La fin du vingtième siècle a vu l’apparition d’entreprises qui vendent des tests génétiques offerts directement aux consommateurs (TG-ODC) dont le prélèvement se fait chez soi. Pour effectuer ces tests, les clients sont obligés de prélever un échantillon d’ADN et de l’envoyer à l’entreprise TG-ODC pour analyse. Suite à ladite analyse, l’entreprise TG-ODC fournit un rapport qui résume les risques génétiques du développement de certaines maladies. La popularité de ces entreprises s’est rapidement accrue au cours des dernières années. Cependant, les clients, les chercheurs et les responsables de la santé publique ont expri-

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The main concern is that insurance companies and employers access consumers' genetic testing results and use this information to discriminate against them. This can happen when insurance companies and employers either directly contract with DTC-GT companies or require individuals disclose their genetic testing results as a condition for insurance coverage or employment. Fortunately, in 2017, Canada enacted the *Genetic Non-Discrimination Act (GNDA)*, partly in response to these concerns. The Act prohibits both insurers and employers from using genetic testing results to discriminate against individuals. In this article, I argue that while the *GNDA* helps tackle the main privacy concerns associated with DTC-GT companies, there remain gaps in the legislation that leave customers of DTC-GT services vulnerable to genetic discrimination. Specifically, the definition of "genetic tests" under the Act is too narrow. The *GNDA* is not clear on the nature of consent that must be obtained to collect the results of an individual's genetic test or the permissible uses of the genetic test. The *GNDA* also does not address the varying accuracy of genetic testing technology. This article recommends amending the *GNDA* to better safeguard customers of DTC-GT services.

mé des inquiétudes quant aux risques pour la vie privée associés à la commande d'un TG-ODC. La préoccupation principale concerne les compagnies d'assurance et les employeurs qui accèdent aux résultats des tests génétiques des consommateurs et utilisent ces informations à des fins discriminatoires. Cela peut se produire si les compagnies d'assurance et les employeurs contractent directement avec les entreprises de TG-ODC ou s'ils exigent que les consommateurs de ces tests génétiques divulguent leurs résultats afin de bénéficier d'un contrat d'assurance ou d'emploi. Heureusement, en 2017, le Canada a promulgué la *Loi sur la non-discrimination génétique (LNDG)*, en partie en réponse à ces préoccupations. Cette loi interdit aux assureurs et aux employeurs d'utiliser les résultats des tests génétiques à des fins discriminatoires. Dans cet article, je soutiens que si la *LNDG* contribue à la résolution du principal problème de protection de la vie privée associé aux entreprises de TG-ODC, il reste des lacunes dans la législation qui rendent les consommateurs de services de TG-ODC vulnérables à la discrimination génétique. Plus précisément, la définition des "tests génétiques" au sens de la loi est trop étroite. La *LNDG* n'est pas claire sur la nature du consentement qui doit être obtenu pour recueillir les résultats d'un test génétique. De plus, la *LNDG* n'aborde pas la variabilité de la précision de la technologie des tests génétiques. Le présent article préconise l'amendement de la *LNDG* afin de mieux protéger les consommateurs de services de TG-ODC.

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I. INTRODUCTION

In today's digital era, where data drives technology, genetic information arguably emerges as one of the most valuable and sensitive types of personal information. Genetic information is defined as the "biological identity of an individual" and can be extracted from an individual's skin, hair, blood, or saliva.¹ It can be used to identify an individual and can reveal information about the individual's current or future health state, along with the identity and health status of family members who share similar genetic variants.² Unlike other types of personal information, such as a credit card number, genetic information cannot easily be changed.³ For these reasons, genetic information is considered one of the most sensitive types of personal information.⁴

¹ See Mete Akgün et al, "Privacy preserving processing of genomic data: A Survey" (2015) 56 *J Biomedical Informatics* 103 at 103–04.

² See Imke Christiaans et al, "Obtaining insurance after DNA diagnostics: a survey among hypertrophic cardiomyopathy mutation carriers" (2010) 18 *European J Human Genetics* 251 at 251. This article provides an example of the type of additional personal information that can be extracted from genetic data, specifically how DNA testing can be used to determine one's risk of developing hypertrophic cardiomyopathy (a hereditary heart disease). See also Melissa Gymrek et al, "Identifying Personal Genomes by Surname Inference" (2013) 339:6117 *Science* 321.

³ See Catherine Roberts, "Your Genetic Data Isn't Safe" (23 July 2020), online: <consumerreports.org> [perma.cc/98EA-MZ6Q]. Genetic information generally remains stable during one's lifetime, but DNA can be mutated as a result of replication errors or exposure to some chemicals or ultraviolet light and somatically edited to treat disease (see Suzanne Clancy, "Genetic Mutation" (2008) 1(1):187 *Nature Education*, online: <nature.com> [perma.cc/MX3R-EMRT]; Raymond Ching-Bong Wong et al, "Somatic Cell Gene Editing for Treating Diseases" (2021) 9:828195 *Frontiers in Cell & Developmental Biology* 1).

⁴ See Office of the Privacy Commissioner of Canada, "Direct-to-consumer genetic testing and privacy" (last modified 4 December 2017), online: <priv.gc.ca> [perma.cc/23TL-S6UA]. See generally, Luca Bonomi, Yingxiang Huang & Lucila Ohno-Machado, "Privacy challenges and research opportunities for genomic data sharing" (2020) 52:7 *Nature Genetics* 646. See generally Bradley A Malin, "An evaluation of the current state of genomic data privacy protection technology and a roadmap for the future" (2005) 12:1 *J Am Medical Informatics Assoc* 28.

Concerns about the improper use of genetic information arose in the 1990s, at the start of the Human Genome Project.⁵ The Human Genome Project was an international collaborative research project with the goal of mapping out the entire human genome.⁶ The project uncovered the structure and organization of genes in the body and identified genetic variants in human DNA that can be used to predict the onset of disease.⁷ As a result of the project's findings, along with advancements in genetic testing technology, clinicians became able to collect and sequence patients' DNA to identify the presence of genetic variants associated with diseases.⁸ Outside of traditional healthcare settings, millions of people worldwide have obtained genetic tests from Direct-to-Consumer Genetic Testing (DTC-GT) companies.⁹ DTC-GT companies sell genetic testing services online to customers and require those customers to collect and mail their DNA samples to the company for analysis.¹⁰ While the popularity of these companies has increased rapidly in the past few years, many researchers, public health officials, and customers

⁵ Kathleen Hammond, "Unnecessary and Redundant? Evaluating Canada's *Genetic Non-Discrimination Act*, 2017" (2020) 98 Can Bar Rev 480 at 483. See also Annet Wauters & Ine Van Hoyweghen, "Global trends on fears and concerns of genetic discrimination: a systematic literature review" (2016) 61:4 Journal of Human Genetics 275 at 275.

⁶ National Human Genome Research Institute, "The Human Genome Project" (last modified 07 September 2023), online: <genome.gov> [perma.cc/6WSZ-J4KX]. "The genome is the entire set of DNA instructions found in a cell" (see National Human Genome Research Institute, "GENOME" (last modified 9 March 2024), online: <genome.gov> [perma.cc/VT2K-676A]).

⁷ Rachele M Hendricks-Sturup & Christine Y Lu, "What motivates the sharing of consumer-generated genomic information?" (2020) 8 SAGE Open Medicine 1 at 1.

⁸ See e.g. Francis S Collins, "Shattuck Lecture – Medical and Societal Consequences of the Human Genome Project" (1999) 341:1 New England J Medicine 28 at 32. See generally Asude Alpman Durmaz et al, "Evolution of Genetic Techniques: Past, Present, and Beyond" (2015) 2015:461524 BioMed Research Intl 1 at 4.

⁹ Antonio Regalado, "More than 26 million people have taken an at-home ancestry test" (11 February 2019), online: <technologyreview.com> [perma.cc/28CR-MD6S].

¹⁰ See e.g. Megan A Allyse et al, "Direct-to-Consumer Testing 2.0: Emerging Models of Direct-to-Consumer Genetic Testing" (2018) 93:1 Mayo Clinic Proceedings 113 at 115.

have expressed concerns about the privacy risks associated with the companies' collection, use, and disclosure of genetic data.¹¹ Specifically, major concerns center on the potential disclosure of genetic data to third parties such as insurance companies and employers, which could lead to genetic discrimination.¹² In 2017, Canada passed the *Genetic Non-Discrimination Act (GNDA)*.¹³ The *GNDA* responded to evidence which showed that some Canadians were opting against taking genetic tests due to fear of genetic discrimination.¹⁴

In this article, I will explore the main privacy concerns associated with ordering from DTC-GT companies and how the *GNDA* has helped to tackle these concerns. Specifically, I will discuss DTC-GT companies' secondary uses of their customers' genetic data along with the consumers' use of their genetic testing results and the resulting privacy risks associated with these uses, namely, genetic discrimination by third parties such as insurers or employers. I will then discuss Parliament's enactment of the *GNDA* and how the *GNDA* has helped mitigate the risk of genetic discrimination. I argue that although the *GNDA* is a step in the right direction to help protect consumers of DTC-GT services, three main gaps in the legislation leave

¹¹ Mwenza Blell & M A Hunter, "Direct-to-Consumer Genetic Testing's Red Herring: 'Genetic Ancestry' and Personalized Medicine" (2019) 6:48 *Frontiers in Medicine* 1 at 1. See generally Sarah Gollust, Benjamin Wilfond & Sara Chandros Hull, "Direct-to-consumer sales of genetic services on the Internet" (2003) 5:4 *Genetics in Medicine* 332.

¹² See e.g. Juli Murphy Bollinger, Robert C Green & David Kaufman, "Attitudes About Regulation Among Direct-to-Consumer Genetic Testing Customers" (2013) 17:5 *Genetic Testing & Molecular Biomarkers* 424 at 427; Simone Zhang et al, "Public attitudes toward genetic risk scoring in medicine and beyond" (2021) 274:113796 *Soc Science & Medicine* 1 at 2. See generally Aviad E Raz et al, "Transparency, consent and trust in the use of customers' data by an online genetic testing company: an exploratory survey among 23andMe users" (2020) 39:4 *New Genetics & Society* 459.

¹³ Canadian Human Rights Commission & Office of the Privacy Commissioner of Canada, News Release, "New genetic non-discrimination law will promote privacy and human rights in Canada" (5 May 2017), online: <priv.gc.ca/> [perma.cc/TU6F-KXHN] [CHRC & OPC]; *Genetic Non-Discrimination Act*, SC 2017, c 3 [*GNDA*].

¹⁴ Julia Kalinina, "Genetic Non-Discrimination Act Reference: What's the difference between genetic test and biopsy?" (22 October 2019), online: <thecourt.ca> [perma.cc/W9NX-87HN].

consumers of DTC-GT services vulnerable to genetic discrimination by third parties. First, the definition of “genetic tests” under the Act is too narrow, and, as a result, does not cover all the genetic testing services offered by DTC-GT companies. Second, the *GNDA* is not clear on the nature of consent that must be obtained to collect, use, or disclose the results of an individual’s genetic test, resulting in the possibility of uninformed consent. Third, the *GNDA* does not address the varying accuracy of genetic testing technology, which could result in third parties relying on inaccurate data to make decisions about consumers of DTC-GT services.

II. DIRECT-TO-CONSUMER GENETIC TESTING (DTC-GT) COMPANIES

In the late twentieth century, DTC-GT companies emerged, increasing the accessibility of genetic testing.¹⁵ “Genetic testing” is a type of medical test that involves the sequencing and analysis of DNA to identify mutations or variants that may prove to be pathological.¹⁶ Traditionally, genetic testing takes place at a hospital and is initiated and carried out by medical professionals.¹⁷ DTC-GT companies allow customers to purchase genetic tests online, typically without the involvement of a physician.¹⁸ Unlike traditional genetic testing, whereby a medical professional extracts a DNA sample from the patient in a clinical setting, DTC-GT companies send customers a “DNA collection kit.”¹⁹ This testing kit instructs the customer to either

¹⁵ See Allyse et al, *supra* note 10 at 113. See also Caitlin G Allen et al, “The impact of raw DNA availability and corresponding online interpretation services: A mixed-methods study” (2018) 8:1 Translational Behavioral Medicine 105 at 105; Andelka M Phillips, “Only a click away — DTC genetics for ancestry, health, love...and more: A view of the business and regulatory landscape” (2016) 8 Applied & Translational Genomics 16 at 16; Canadian Medical Association, “CMA Policy: Direct-to-Consumer-Genetic Testing” (2017), online (pdf): <cma.ca> [perma.cc/HT6R-5URS].

¹⁶ Mayo Clinic, “Genetic testing” (14 April 2020), online: <mayoclinic.org> [perma.cc/UZY4-ZY26].

¹⁷ Bermseok Oh, “Direct-to-consumer genetic testing: advantages and pitfalls” (2019) 17:3 Genomics & Informatics 1 at 1.

¹⁸ Phillips, *supra* note 15.

¹⁹ Paul Sanfilippo et al, “Current landscape of direct-to-consumer genetic testing and its role in ophthalmology: a review” (2015) 43:6 Clinical & Experimental Ophthalmology 578 at 580.

spit in a test tube or swab the inside of their cheek to collect a DNA sample to be mailed back to the company.²⁰ Upon receiving the DNA sample, the company sequences the DNA and analyzes the customer's genetic variants to provide the customer with a report outlining their genetic risk of developing common diseases such as breast cancer or Alzheimer's.²¹ It is important to note that the genetic tests sold by DTC-GT companies are not diagnostic, meaning they do not tell the individual if he or she currently has a particular condition or disease.²² These genetic tests are predictive, identifying the genetic mutations in an individual's DNA that are associated with an increased risk of developing a particular condition or disease in the future.²³

Piecing together information from a variety of sources, it is estimated that, to date, over one hundred million people worldwide have purchased a DTC genetic test.²⁴ The major players in the industry are located in the United States and offer their services to both Americans and Canadians.²⁵ The majority of DTC-GT consumers are white females with high socioeconomic status (SES), in overall good health, more likely to possess health insurance, less likely to smoke, and less likely to be overweight or obese than the average individual.²⁶ Despite the popularity of DTC-GT services,

²⁰ Oh, *supra* note 17 at 1.

²¹ *Ibid* at 2.

²² *Ibid*. See also Medline Plus, "What do the results of direct-to-consumer genetic testing mean?" (last modified 21 June 2022), online: <medlineplus.gov> [perma.cc/L76U-J7CW].

²³ Oh, *supra* note 17 at 2.

²⁴ Jaime Rosenberg, "As DTC Genetic Testing Grows Among Consumers, Insurers Are Beginning to Get on Board" (22 April 2019), online: <ajmc.com> [perma.cc/A9SN-8UHC].

²⁵ Zion Market Research, "Direct-To-Consumer (DTC) Genetic Testing Market Trend, Share, Growth, Size and Forecast 2030" (30 August 2023), online: <zionmarketresearch.com > [perma.cc/R9EH-LKM9]; Emergen Research, "Direct-To-Consumer Genetic Testing Market, By Test Type (Carrier Testing and Predictive Testing), By Technology (Targeted Analysis and Whole Genome Sequencing), and By Region Forecast to 2030" (September 2022), online: <emergenresearch.com> [perma.cc/WG48-E9DA].

²⁶ J Scott Roberts et al, "Direct-to-Consumer Genetic Testing: User Motivations, Decision Making, and Perceived Utility of Results" (2017) 20:1 Public Health Genomics 36 at 40–41. Note that these findings are relative to the general US adult population.

there are many privacy concerns associated with the companies' secondary uses of genetic data.²⁷ Furthermore, there are privacy risks associated with DTC-GT customers sharing their genetic testing results on third-party platforms after receiving their results from DTC-GT companies.²⁸ These concerns will be analyzed in the following section.

A. Privacy concerns

The privacy concerns associated with purchasing a genetic test from DTC-GT companies arise from the companies' secondary uses of their customers' genetic data along with customers sharing their genetic testing results online. DTC-GT companies allow customers to "opt-in" (i.e., consent) to allow the DTC-GT company to use their genetic information for secondary purposes.²⁹ Studies that have analyzed the fate of customers' genetic information upon "opting in" found that many DTC-GT companies disclose their customers' genetic data to various third-party organizations. DTC-GT companies have contracted with research institutions, non-profit organizations that conduct scientific research, pharmaceutical companies, insurance companies, Spotify,³⁰ and law enforcement agencies, granting them access to their customers' genetic data.³¹ Some DTC-GT companies partner with

²⁷ See e.g. Nola Ries, *Analysis of Privacy Policies and Practices of Direct-to-Consumer Genetic Testing Companies: Private Sector Databanks and Privacy Protection Norms* (Edmonton: Health Law Institute, University of Alberta, 2010) 1 at 6–7.

²⁸ See e.g. Christi Guerrini et al, "Who's on third? Regulation of third-party genetic interpretation services" (2020) 22:1 *Genetics in Medicine* 4; Lauren Badalato, Louiza Kalokairinou & Pascal Borry, "Third party interpretation of raw genetic data: an ethical exploration" (2017) 25:11 *European J Human Genetics* 1189.

²⁹ Raz, *supra* note 12 at 465.

³⁰ In 2018, AncestryDNA teamed up with Spotify to offer users a playlist curated based on their DNA (see "Spotify wants your DNA to decide what you listen to", CBC Radio (19 October 2018), online: <cbc.ca> [perma.cc/X85J-QR73]).

³¹ See Alexander Nill & Gene Lacznia, "Direct-to-Consumer Genetic Testing and Its Marketing: Emergent Ethical and Public Policy Implications" (2020) *J Bus Ethics* 669 at 680. See generally Bonomi, Huang & Ohno-Machado, *supra* note 4.

research institutions that perform the DNA sequencing and analysis that is needed to provide customers with their genetic testing results.³² Additionally, DTC-GT companies may contract with research institutions and share genetic data to research the causes of genetic disease, which frequently leads to scientific publications.³³ For example, AncestryDNA, a U.S.-based DTC-GT company, entered a three-year contract with Calico, a Google spinoff company, to grant Calico access to their databases for research on “the role of genetics and its influences in families experiencing unusual longevity.”³⁴ In 2018, 23andMe signed a \$300 million (USD) deal with the pharmaceutical company, GlaxoSmithKline, allowing GlaxoSmithKline to use 23andMe’s consumers’ genetic information to develop therapeutics for genetic disease treatments.³⁵ Law enforcement agents have also been granted access to DTC-GT companies’ databases to search for DNA profiles that match genetic data from bodily samples found at crime scenes.³⁶ For example, in 2018, the “Golden State Killer” was identified using the stored genetic data of the killer’s relatives obtained from the publicly accessible

³² See e.g. James W Hazel & Christopher Slobogin, “Who Knows What, and When: A Survey of the Privacy Policies Proffered by U.S. Direct-to-Consumer Genetic Testing Companies” (2018) 28:1 Cornell JL & Pub Pol’y 35 at 55.

³³ Jane Kaye, “The Tension Between Data Sharing and the Protection of Privacy in Genomics Research” (2012) 13 Annual Rev Genomics & Human Genetics 415 at 420. *Ibid* at 55–56.

³⁴ Ancestry Corporate, “AncestryDNA and Calico to Research the Genetics of Human Lifespan” (21 July 2015), online: <ancestry.com> [perma.cc/Y84H-TE2Q].

³⁵ Jamie Ducharme, “A Major Drug Company Now Has Access to 23andMe’s Genetic Data: Should You Be Concerned?” *Time Magazine* (26 July 2018), online: <time.com> [perma.cc/XGG8-4EQW].

³⁶ Chris Phillips, “The Golden State Killer investigation and the nascent field of forensic genealogy” (2018) 36 Forensic Science Intl Genetics 186 at 186; Matthew Haag, “FamilyTreeDNA Admits to Sharing Genetic Data With F.B.I.” (4 February 2019), online: <nytimes.com> [perma.cc/W9AP-SET9]. See also Nathan Scudder et al, “Policy and regulatory implications of the new frontier of forensic genomics: direct-to-consumer genetic data and genealogy records” (2019) 31:2 Current Issues in Crim Justice 194 at 206–207. See generally Nina F de Groot, Britta C van Beers & Gerben Meynen, “Commercial DNA tests and police investigations: a broad bioethical perspective” (2021) 47:12 J Medical Ethics 788. Note that it is not entirely clear how often the police access these databases.

repository of GEDmatch.³⁷ In 2019, FamilyTreeDNA (another DTC-GT company) disclosed its consumers' genetic information (without obtaining their consent) to the Federal Bureau of Investigation (FBI), granting the FBI access to their database of over two million genetic records.³⁸

DTC-GT companies provide third parties with their customers' genetic data, generally in a "de-identified" state, through the removal of personal identifiers.³⁹ In 2020, more than 80% of the 10 million consumers of 23andMe, one of the leading DTC-GT companies, consented to the use of their de-identified data in research.⁴⁰ However, studies have found that even if genomic data is stripped of personally identifiable information, crossing de-identified genomic information with publicly available data can result in the re-identification of an individual.⁴¹ As a result, genetic information can never truly remain anonymized.

The collection and transfer of genetic data from DTC-GT companies to various organizations increases the risk that unintended third parties may obtain access to this information, depending on the data privacy mechanisms put in place by all parties holding the genetic data. The unintended third parties include, but are not limited to, insurers or employers who access customers' genetic testing results, either through contracting with DTC-

³⁷ Phillips, *supra* note 35. GEDmatch is a DNA interpretation website which allows customers of DTC-GT companies to upload their genetic testing results for further analysis (see GEDmatch, "About GEDmatch" (last accessed 25 June 2024), online: <gedmatch.com> [perma.cc/SQ5Y-6MMB]).

³⁸ Haag, *supra* note 35.

³⁹ Hazel, *supra* note 31 at 44.

⁴⁰ Mary A Majumder, Christi J Guerrini & Amy L McGuire, "Direct-to-Consumer Genetic Testing: Value and Risk" (2020) 72 Annual Rev Medicine 151 at 152.

⁴¹ See Dov Greenbaum et al, "Genomics and Privacy: Implications of the New Reality of Closed Data for the Field" (2011) 7:12 PLoS Computational Biology 1 at 2–3. See also George Annas & Sherman Elias, *Genomic Messages: How the Evolving Science of Genetics Affects Our Health, Families and Future* (New York: HarperCollins, 2015) at 191–215; Zhiyu Wan et al, "Sociotechnical safeguards for genomic data privacy" (2022) 23:7 Nature Rev Genetics 429 at 431.

GT companies, data breaches, or direct requests that customers of DTC-GT companies disclose their genetic testing results.⁴²

DTC-GT companies have in fact experienced data breaches. 23andMe was the target of a five-month-long data breach affecting about seven million customers, where hackers stole personal information from customers profiles, including raw genetic data and health reports such as reports about disease predisposition or wellness and carrier status for certain diseases.⁴³ As a result of this breach, multiple class actions lawsuits have been filed against 23andMe, accusing the company of breaching California's privacy and genetic information laws.⁴⁴ In 2018, a DTC-GT company called MyHeritage was hacked, and the personal information of more than 92 million users was exposed.⁴⁵ In addition, consumers of DTC-GT services may publicly share the results of their genetic tests on third-party interpretation websites⁴⁶ and on their Facebook profiles, which may be publicly available depending on the individual's privacy settings.⁴⁷

More recently, on June 16, 2023, the Federal Trade Commission (FTC) announced an enforcement action on a San Francisco genetic testing com-

⁴² Jennifer Cacchio, "What You Don't Know Can Hurt You: The Legal Risk of Peering into the Gene Pool with Direct-to-Consumer Genetic Testing" (2018) 87:1 UMKC L Rev 219 at 225–28.

⁴³ Laura French, "23andMe: Raw genetic data stolen in months-long cyberattack" (26 January 2023), online: <scmagazine.com> [perma.cc/8J7R-CLZ2]. "Raw genetic data" provided by 23andMe informs customers of the base pairs (combinations of adenine, thymine, guanine and cytosine) found at specific gene marker locations on their chromosomes.

⁴⁴ *Ibid.*

⁴⁵ MyHeritage Admin, "MyHeritage Statement About a Cybersecurity Incident" (4 June 2018), online: blog.myheritage.com <blog.myheritage.com> [perma.cc/25KK-H4LA].

⁴⁶ Third party interpretation websites allow customers to upload their raw genetic data obtained from DTC-GT companies to get a second opinion on what their genetic data reveals about their genealogy and future health state (see Tobias Haeusermann et al, "Open sharing of genomic data: Who does it and why?" (2017) 12:5 PloS One 1 at 3–4).

⁴⁷ Sandra Soo-Jin Lee et al, "Attitudes towards Social Networking and Sharing Behaviours among Consumers of Direct-to-Consumer Personal Genomics" (2013) 3:4 J Personalized Medicine 275 at 280–81.

pany called 1Health.io for failing to protect its clients' privacy.⁴⁸ Specifically, 1Health.io did not ensure that the third-party laboratory hired to analyze customers' DNA samples had a policy in place to destroy the samples after analysis.⁴⁹ Without notifying their consumers, 1Health.io also retroactively changed their privacy policy to expand the types of third parties with whom they could share consumers' data to include supermarket chains as well as nutrition and supplement manufacturers.⁵⁰ Furthermore, about 2,400 health reports, along with the raw genetic data of at least 227 consumers, were stored in publicly accessible "buckets" on Amazon Web Service's cloud storage.⁵¹ This data was not encrypted, and access to the data was neither restricted nor logged or monitored.⁵² Even though 1Health.io was warned at least three times over two years that they were storing unencrypted health, genetic, and personal information in publicly accessible places, they did not change their practices.⁵³ The FTC ordered the company to strengthen their protection measures for genetic information and instruct third-party contract laboratories to destroy consumer DNA samples after 180 days.⁵⁴ This case further highlights the pressing privacy concerns surrounding DTC-GT companies' handling of their consumers' genetic information.

Inadequate protection measures employed by DTC-GT companies to protect consumer genetic information along with the widespread sharing of genetic testing results both by DTC-GT companies and their customers can lead to genetic discrimination. Genetic discrimination is defined as "the denial of rights, privileges, opportunities, or other adverse treatment based solely on genetic information, including family history or genetic test results."⁵⁵ A top concern reported by consumers of DTC-GT services is that

⁴⁸ Federal Trade Commission, Press Release, "FTC Says Genetic Testing Company 1Health Failed to Protect Privacy and Security of DNA Data and Unfairly Changed its Privacy Policy" (16 June 2023), online: <ftc.gov> [perma.cc/M2SQ-E4K6].

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

⁵¹ *Ibid.*

⁵² *Ibid.*

⁵³ *Ibid.*

⁵⁴ *Ibid.*

⁵⁵ Cheryl Erwin et al, "Perception, experience, and response to genetic discrimi-

employers or insurance companies will obtain access to their genetic testing results and discriminate against them.⁵⁶ For instance, employers may discriminate against individuals who have a higher risk of developing a disease to avoid higher insurance costs, reduce turnover, or limit liability related to occupational health and safety.⁵⁷ Similarly, insurers may use genetic testing results to increase premiums or deny coverage based on disease risk.⁵⁸ The fear of genetic discrimination has also been found to exist in the general Canadian population, resulting in a reluctance to take genetic tests despite their potential health benefits.⁵⁹ The Supreme Court of Canada (SCC) has also recognized this phenomenon, noting that the fear of genetic discrimination has led many Canadians to forego testing that might help them improve their health and contribute to improving public health.⁶⁰

III. THE *GENETIC NON-DISCRIMINATION ACT (GNDA)*

The *Genetic Non-Discrimination Act (GNDA)* is a Canadian federal law that was passed on May 4th, 2017.⁶¹ Parliament indicated that Canadians “should not have to choose between potential discrimination and taking a genetic test, especially if such tests could improve their health and well-

nation in Huntington disease: The international RESPOND-HD study” (2010) 153B:5 *American J Medical Genetics Part B: Neuropsychiatric Genetics* 1081 at 1082, cited in Hammond, *supra* note 5 at 486.

⁵⁶ Gratien Dalpé et al, “Genetic discrimination views in online discussion forums: Perspectives from Canadian forumites” (2021) 30:6 *J Genetic Counseling* 1613 at 1616–18.

⁵⁷ See Trudo Lemmens, Daryl Pullman & Rebecca Rodal, *Revisiting Genetic Discrimination Issues in 2010: Policy Options for Canada* (Ottawa: Genome Canada, 2010) 1 at 3; Eric Feldman, “The Genetic Information Non-Discrimination Act (GINA): Public Policy and Medical Practice in the Age of Personalized Medicine” (2012) 27:6 *J Genetic Internal Medicine* 743.

⁵⁸ Jessica Roberts, “The Genetic Information Non-Discrimination Act as an Anti-Discrimination Law” (2011) 86:2 *Notre Dame L Rev* 597 at 603.

⁵⁹ Dalpé, *supra* note 55 at 1614.

⁶⁰ *Reference re Genetic Non-Discrimination Act*, 2020 SCC 17 at para 43 (Abella, Karakatsanis and Martin JJ) [*Reference re GNDA*].

⁶¹ *GNDA*, *supra* note 13.

being.”⁶² These concerns constituted a “threat to public health” and as a result, the *GND*A was passed under the federal government’s criminal law power.⁶³

The main objective of the *GND*A, as stated in its preamble, is “to prohibit and prevent genetic discrimination.”⁶⁴ The *GND*A makes it a criminal offence for any person to require an individual to take a genetic test or disclose the results of existing genetic testing results when providing goods or services, entering into contractual agreements, or offering specific terms or conditions in a contract.⁶⁵ Furthermore, a person cannot refuse to engage in any of the previously listed activities because the individual has refused to undergo a genetic test or disclose the results of a genetic test.⁶⁶ The *GND*A also lists exceptions. The results of an individual’s genetic test can be collected, used, or disclosed if the individual provides written consent.⁶⁷ Furthermore, the Act does not apply to physicians, pharmacists or other healthcare practitioners who are providing health services to an individual, or pharmaceutical or scientific researchers who are conducting a scientific study in which the individual is a participant.⁶⁸ As the *GND*A is a criminal statute, penalties include fines of up to \$1,000,000 and imprisonment of up to 5 years.⁶⁹ The *GND*A also amends the *Canadian Human Rights Act* to add “genetic characteristics” to the list of prohibited grounds of discrimination and the *Canada Labour Code* to prohibit federally-regulated employers

⁶² Office of the Privacy Commissioner of Canada, Press Release, “Policy statement on the collection, use and disclosure of genetic test results” (4 December 2017), online: <priv.gc.ca> [perma.cc/Z5M9-KZJX].

⁶³ *Reference re GND*A, *supra* note 59 at paras 96–103.

⁶⁴ *GND*A, *supra* note 13.

⁶⁵ *Ibid*, ss 3(1), (4)(1).

⁶⁶ *Ibid*, ss 3(2), 4(2).

⁶⁷ *Ibid*, s 5.

⁶⁸ *Ibid*, s 6.

⁶⁹ Penalties for a conviction on indictment include a fine not exceeding \$1,000,000 or imprisonment up to five years or both, whereas summary conviction can result in a maximum fine of \$300,000 or imprisonment for a maximum of twelve months or both (see *ibid*, s 7).

from requiring employees to undergo or disclose the results of a genetic test.⁷⁰

IV. PROS AND CONS OF THE *GENETIC NON-DISCRIMINATION ACT (GNDA)* FOR CUSTOMERS OF DTC-GT COMPANIES

A. *The GNDA tackles some, but not all, of the privacy concerns associated with DTC-GT companies*

The *GNDA* helps tackle the main privacy concerns associated with DTC-GT, that is, genetic discrimination that could result in denied employment or an increase in insurance premiums. The Act applies to both insurance companies and employers as they engage in one or more of the following activities: “providing goods or services,” “entering into or continuing a contract or agreement,” and/or “offering or continuing specific terms or conditions in a contract or agreement.”⁷¹ As a result, if third parties such as insurance companies or employers obtain access to the genetic testing results of consumers of DTC-GT services, they are prohibited from using the results without the individual’s written consent.⁷² In addition, third parties are prohibited from forcing an individual to take a genetic test⁷³ or refusing insurance or employment because the individual refused to undergo a genetic test or disclose the results of their genetic test.⁷⁴ Furthermore, while applicants for insurance can voluntarily disclose genetic and other health information as part of their risk assessment to determine their insurability, the provisions appear to prohibit offering incentives to those who voluntarily disclose genetic testing results. This would amount to requiring disclosure of genetic testing results “in order to offer specific terms or conditions” of an insurance or employment contract, which is prohibited under the Act.⁷⁵

⁷⁰ *Ibid*, ss 8–10; *Canadian Human Rights Act*, RSC 1985, c H-6, ss 3(1)(a), 3(1)(c); *Canada Labour Code*, RSC 1985, c L-2, s 247.98

⁷¹ *Ibid*, s 3(1).

⁷² *Ibid*, s 5.

⁷³ *Ibid*, ss 3(1).

⁷⁴ *Ibid*, ss 3, 4(2).

⁷⁵ *Ibid*, s 3(1)(c); See also Hilary Young & Colleen Thrasher, “Genetic Privacy in Employment and Insurance in Canada” in Lara Khoury, Adelle Blackett &

Therefore, insurance companies or employers cannot reward individuals for disclosing their genetic testing results or punish those who do not. These provisions, on their face, provide evidence that the *GND*A protects DTC-GT customers from insurance companies and employers' use of their genetic testing results. However, there remain gaps in the legislation that make DTC-GT customers vulnerable to genetic discrimination by employers, insurance companies, or other third parties.⁷⁶

***B. Legislative gaps in the GND*A leave customers of DTC-GT services vulnerable to genetic discrimination**

Three main gaps in the *GND*A leave customers of DTC-GT companies vulnerable to genetic discrimination. First, the definition of “genetic tests” in the *GND*A is too narrow and does not include new methods utilized by DTC-GT companies to determine disease risk. Second, the *GND*A is unclear on the nature of consent that must be obtained to collect, use, or disclose an individual's genetic testing results and the permissible uses of an individual's results. Third, the *GND*A does not address the varying accuracy of genetic testing technology. Each gap will be addressed respectively.

1. The definition of “genetic tests” in the GNDA is too narrow and does not include new methods utilized by DTC-GT companies to determine disease risk

Under the *GND*A, a “genetic test” is defined as “a test that analyzes DNA, RNA, or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis.”⁷⁷ The definition is underinclusive and does not cover emerging predictive biological factors analyzed by DTC-GT companies, such as epigenetic mark-

Lukas Vanhonnaeker, eds, *Genetic Testing and the Governance of Risk in the Contemporary Economy* (Cham: Springer, 2020) 115 at 117 [Young].

⁷⁶ The *GND*A does not prevent law enforcement from accessing DTC-GT companies' databases. This gap is likely an infringement on individual's privacy rights and is not a genetic discrimination concern. See Gabrielle Samuel et al, “A response to the forensic genetics policy initiative's report ‘Establishing Best Practice for Forensic DNA Databases’” (2018) 36:1 *Forensic Science Intl Genetics* e19 at e19.

⁷⁷ *GND*A, *supra* note 13 at s 2.

ers, proteomic, microbiomic, and metabolomic data.⁷⁸ Epigenetic information includes modifications to gene expression that do not involve a change in the DNA sequence but alter how genes are read, and, in turn, can influence the production of proteins in the body.⁷⁹ Epigenetic modification has been linked to the onset of cancer, autoimmune disorders, and neurological disorders such as Fragile X syndrome and Parkinson's disease.⁸⁰ In addition, many diseases result from protein modifications such as protein misfolding or protein aggregation in specific areas of the body.⁸¹ For example, the build-up of the beta-amyloid protein in the brain has been linked to the onset of Alzheimer's disease.⁸² Furthermore, a person's microbiome can influence their susceptibility to gastrointestinal diseases such as Crohn's disease,⁸³ and metabolic dysregulation can increase one's risk of developing diseases such as diabetes, cardiovascular disease, and neurological diseases.⁸⁴

One can argue that these biological factors are “non-genetic” biomarkers, and as a result, the analysis of these factors cannot be considered a “genetic test.” This argument is one advanced by proponents of genetic

⁷⁸ See generally Yann Joly et al, “Looking Beyond GINA: Policy Approaches to Address Genetic Discrimination” (2020) 21:1 *Annual Rev Genomic & Human Genetics* 491 at 503.

⁷⁹ See e.g. Mark Rothstein, “Epigenetic exceptionalism” (2013) 41:3 *JL Med & Ethics* 733 at 733 [Rothstein]; Charles Dupras et al, “Epigenetic Discrimination: Emerging Applications of Epigenetics Pointing to the Limitations of Policies Against Genetic Discrimination” (2018) 9:1 *Frontiers in Genetics* 1 at 1.

⁸⁰ See e.g. Azam Moosavi & Ali Motevalizadeh Ardekani, “Role of Epigenetics in Biology and Human Diseases” (2016) 20:5 *Iranian Biomedical J* 246 at 250–51.

⁸¹ See e.g. Tapan Chaudhuri & Subhankar Paul, “Protein-misfolding diseases and chaperone-based therapeutic approaches” (2006) 273:7 *FEBS J* 1131 at 1132.

⁸² Yun Zhang et al, “Amyloid β -based therapy for Alzheimer's disease: challenges, successes and future” (2023) 8:243 *Signal Transduction & Targeted Therapy* 1 at 1, 3–6.

⁸³ Rachel Gowen et al, “Modulating the Microbiome for Crohn's Disease Treatment” (2023) 164:5 *Gastroenterology* 828 at 829. See also Ohad Manor et al, “Health and disease markers correlate with gut microbiome composition across thousands of people” (2020) 11:1 *Nature Communications* 1 at 2–7.

⁸⁴ See e.g. Kai Mi et al, “Construction and Analysis of Human Diseases and Metabolites Network” (2020) 8:1 *Frontiers in Bioengineering & Biotechnology* 1 at 2.

exceptionalism who hold the belief that genetic information is “special” and, as a result, should be treated differently from other types of medical tests.⁸⁵ A “genetic test” as defined by the Centers for Disease Control and Prevention (CDC), refers to the analysis of changes in DNA and does not include the analysis of epigenetic markers, microbiomic, metabolomic, or proteomic data.⁸⁶ Proponents of genetic exceptionalism would view expanding the definition of genetic tests to include non-genetic biomarkers as undermining the rationale of legislation meant to only deal with genetic tests.⁸⁷ Furthermore, it would contradict their belief that genetic information derived from genetic tests holds exceptional status and merits distinct treatment from other medical data. Once protection is extended to non-genetic factors, there is no reason to refuse to expand the definition to include all physical traits. For example, protection would be provided for individuals who are obese (but do not have a genetic predisposition to obesity), and are therefore, at higher risk for a myriad of diseases.⁸⁸ The line must be drawn somewhere, or else the legislation becomes arbitrary.

Opponents of genetic exceptionalism argue that the distinction between “genetic” and “non-genetic” tests is artificial.⁸⁹ Many genetic tests are accompanied by the analysis of biological factors, such as the measurement of protein levels in the body or modifications that are attached to DNA (epigenetic markers) but do not involve the direct examination of DNA itself.⁹⁰

⁸⁵ Note that genetic exceptionalism has been criticized by many scholars over the past decades (see Dupras, *supra* note 78 at 2).

⁸⁶ Centers for Disease Control and Prevention, “Genetic Testing” (23 March 2020), online: <cdc.gov> [perma.cc/EX2Q-DF7V].

⁸⁷ See Sonia Suter, “The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?” (2001) 79:3 Wash ULQ 669 at 711, 721–22.

⁸⁸ See generally Xavier Pi-Sunyer, “The Medical Risks of Obesity” (2009) 121:6 Postgraduate Medicine 21 at 21.

⁸⁹ Jon Beckwith & Joseph Alper, “Reconsidering Genetic Antidiscrimination Legislation” (1998) 26:3 JL Med & Ethics 205 at 207–208; Rothstein, *supra* note 78 at 735. See generally Mark A Rothstein, “Why Treating Genetic Information Separately is a Bad Idea” (1999) 4:1 Tex Rev L & Pol 33 at 33–34. See also Michael J Green & Jeffrey R Botkin, “‘Genetic Exceptionalism’ in Medicine: Clarifying the Differences Between Genetic and Nongenetic Tests” (2003) 138:7 Annals Internal Medicine 571.

⁹⁰ Beckwith & Alper, *supra* note 88 at 207. Note that susceptibility to genetic dis-

It would be arbitrary to distinguish these types of tests as “genetic” versus “non-genetic” because the results are indirectly determined by the individual’s DNA sequence.⁹¹ For example, protein levels are indirectly associated with an individual’s DNA because protein synthesis is directed by gene expression.⁹² Genes are made up of DNA, and their expression depends on the individual’s DNA sequence.⁹³ In simple terms, consider DNA as the first domino in a chain reaction, and protein levels as a domino further down the chain. The specific levels of proteins are influenced by the DNA sequence because protein synthesis is directed by genes which are made up of DNA.⁹⁴ The medical expert may decide to perform an analysis on a specific domino in the chain reaction because it is easier to analyze, or more research has been done on how a specific domino in the chain reaction is associated with disease.⁹⁵ However, all medical disease predisposition tests, even if they are not targeted specifically at DNA, RNA, or chromosomes, have an underlying genetic contribution.⁹⁶ The inclusion of these factors will not make the line drawing exercise of what constitutes a “genetic test” arbitrary, because it will be limited to the current tests utilized by DTC-GT companies and medical professionals to determine disease onset. Including tests that involve the analysis of epigenetic markers, microbiomic, metabolomic, and proteomic data will thus not open the door to include all physical traits relating to disease onset. In addition, the blurred distinction between “genetic” and “non-genetic” factors is further exemplified upon analysis of the definition of “genetic tests” in the American *Genetic Information Non-Discrimination Act (GINA)*. The *GINA* defines “genetic tests” as the “analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes.”⁹⁷

eases can also be discerned through other factors not considered by DTC-GT companies such as an individual’s health record or family history.

⁹¹ Suzanne Clancy & William Brown, “Translation: DNA to mRNA to Protein” (2008) 1(1):101 *Nature Education*, online: <nature.com> [perma.cc/87G9-UQQH].

⁹² *Ibid.*

⁹³ *Ibid.*

⁹⁴ Beckwith & Alper, *supra* note 88 at 207.

⁹⁵ *Ibid.*

⁹⁶ *Ibid.*

⁹⁷ *Genetic Information Nondiscrimination Act of 2008*, Pub L No 110-233, 42

Furthermore, broadening the definition of “genetic tests” to include the analysis of epigenetic markers, microbiomic, metabolomic, and proteomic data does not conflict but rather furthers the purpose of the *GNDA*. In the 2020 SCC decision, *Reference re Genetic Non-Discrimination Act*, Justice Karakatsanis, as part of the majority, classified the pith and substance of the Act to “protect individuals’ control over their detailed personal information disclosed by genetic tests in the areas of contracting and the provision of goods and services in order to address fears that individuals’ genetic test results will be used against them and to prevent discrimination based on that information.”⁹⁸ Justices Moldaver and Côté, although part of the five-justice majority, more broadly classified the pith and substance as “protect[ing] health by prohibiting conduct that undermines individuals’ control over the intimate information revealed by genetic testing.”⁹⁹ The *GNDA* “may encourage individuals to undergo genetic testing...[that] may in turn produce health benefits, including by enabling earlier detection of health problems.”¹⁰⁰ Since part of the purpose of the *GNDA* is to encourage individuals to undergo testing to enable earlier detection of health problems and to protect individuals’ control over their personal information, one should not draw an arbitrary distinction between what types of disease predisposition tests are worthy of protection. Not all genetic information comes from genetic tests or DNA analysis.¹⁰¹ Genetic information also comes from clinical evaluations, family and medical history, and non-genetic tests.¹⁰² Therefore, regardless of the type of disease predisposition test utilized, individuals should have control over the resulting sensitive information relating to their health. Distinguishing between the different disease predisposition tests on the market would effectively result in an individual being subject to genetic discrimination based on the type of disease predisposition test the individual took. For example, if an individual found out that he or she had an increased risk of developing cancer from a protein synthesis analysis, an insurance company or employer would be able to use this information to discriminate against that individual. However, if the insurance company found out that the individual had an increased risk of developing cancer

USC §101(d)(7)(A), 122 Stat 881 at 885.

⁹⁸ See *Reference re GNDA*, *supra* note 59 at para 65.

⁹⁹ *Ibid* at para 136.

¹⁰⁰ *Ibid* at para 56.

¹⁰¹ Suter, *supra* note 86 at 702.

¹⁰² *Ibid*.

from a test that detected the presence of a genetic variant in the individual's DNA, the individual would be protected against genetic discrimination under the Act.¹⁰³ Individuals should be protected regardless of the specific component of the body that is analyzed to estimate future disease risk. To state otherwise would go against one of the main objectives of the legislation, which, as previously stated, is to encourage individuals to undergo testing to enable earlier detection of health problems.¹⁰⁴

In addition, expanding the scope of "genetic tests" will not affect the constitutional validity of the *GND*A. As previously mentioned, the *GND*A was held as a valid exercise of the federal criminal law power and is therefore constitutional under section 91(27) of the Constitution Act, 1867.¹⁰⁵ The SCC has held that a valid federal criminal law depends on its public purpose, such as "public peace, order, security, health, [or] morality."¹⁰⁶ A valid federal law must include a prohibition, penalty and criminal law purpose that is directed at "some evil, injurious or undesirable effect upon the public" and represent Parliament's attempt "to suppress the evil or to safeguard the interest threatened."¹⁰⁷ The SCC found that the *GND*A fulfilled the first two criteria, as it prohibits genetic discrimination and is backed by penalties in the form of fines or jail time.¹⁰⁸ Regarding the criminal law purpose, the SCC held that the character of the prohibitions under the *GND*A safeguarded "autonomy, privacy and the fundamental social value of equality, as well as public health," which are public interests traditionally protected by the criminal law.¹⁰⁹ In reaching this conclusion, Justice Karakatsanis reasoned that the conduct prohibited by sections 1 to 7 of the *GND*A posed a risk of harm to "two facets of autonomy and personal privacy because individuals have an interest in deciding whether or not to access the detailed genetic information revealed by genetic testing and whether or not to share

¹⁰³ *GND*A, *supra* note 13, s 5.

¹⁰⁴ *Reference re GND*A, *supra* note 59 at para 56.

¹⁰⁵ *Ibid* at para 4.

¹⁰⁶ *Reference re Validity of Section 5(a) Dairy Industry Act*, [1949] SCR 1 at 50, 1948 CanLII 2 (SCC).

¹⁰⁷ *Ibid* at 49.

¹⁰⁸ *Reference re GND*A, *supra* note 59 at para 68.

¹⁰⁹ *Ibid* at para 80.

their test results with others.”¹¹⁰ In terms of safeguarding equality, the SCC found that “genetic discrimination threatens the fundamental social value of equality by stigmatizing and imposing adverse treatment on individuals because of their inherited, immutable genetic characteristics, and, in particular, the characteristics that may help to predict disease or disability.”¹¹¹ Expanding the definition of “genetic tests” to include all disease predisposition tests on the market furthers the legislative initiative to protect individuals from emerging threats to privacy, autonomy, and equality by providing them with control over their personal information generated from a larger range of health tests that provide them with disease predisposition information.

Therefore, in order to address the struggle of justifying a fine-line demarcation between genetic and non-genetic factors’ role in predicting disease onset, the *GND*A should adopt a broader definition of “genetic tests” to include emerging disease predisposition tests that are on the market to fully protect consumers of DTC-GT services against discrimination along with threats to privacy, autonomy and equality. Currently, the definition provided in the *GND*A of “genetic tests” is underinclusive, leaving unprotected a great deal of relevant and significant genetic information. It is important to note that there is currently no other legislation in Canada that fills this gap. Without a broader definition, consumers of DTC-GT services may be vulnerable to genetic discrimination, depending on the type of disease predisposition test purchased from DTC-GT companies.

2. The *GND*A is unclear on the nature of consent that must be obtained to collect, use, or disclose an individual’s genetic testing results and the permissible uses of the genetic testing results

The *GND*A states that “written consent” must be obtained from the individual to collect, use or disclose the results of the individual’s genetic test.¹¹² However, the Act does not explicitly state that there must be fully informed consent or what the written consent entails.¹¹³ Information relating to the use of an individual’s genetic data may be buried in boilerplate

¹¹⁰ *Ibid* at para 84.

¹¹¹ *Ibid* at para 90.

¹¹² *GDNA*, *supra* note 13, s 5.66, s5.

¹¹³ *Ibid*; Elizabeth Adjin-Tettey, “Striking the Right Balance: Does the Genetic

language in such a way that the individual does not understand that they are allowing someone to use their genetic testing results. As a result, DTC-GT customers could be misled into providing what is qualified as written consent under the Act but is not truly informed consent.

Canada's federal privacy legislation, the *Personal Information Protection and Electronic Documents Act* (*PIPEDA*), helps to clarify the nature of consent that must be obtained to collect, use, or disclose an individual's genetic testing results under the *GNDA* in some circumstances. *PIPEDA* sets out general rules that govern the "collection, use and disclosure" of "personal information" by private sector organizations.¹¹⁴ Under *PIPEDA*, "personal information" is defined as "information about an identifiable individual," i.e., "information that on its own or combined with other pieces of data can identify an individual."¹¹⁵ Personal information including an individual's DNA sample or genetic testing results would be classified as "personal information" under *PIPEDA*.¹¹⁶ *PIPEDA* applies to organizations that are engaged in commercial activities across Canada along with applicants to and employees of federally regulated businesses, except for those in provinces that have substantially similar private sector privacy laws.¹¹⁷ Under *PIPEDA*, "the knowledge and consent of the individual are required for the collection, use or disclosure of personal information."¹¹⁸ Furthermore, an "explicit form of consent" must be obtained for the collection, use or disclosure of "sensitive" personal information, which includes genetic

Non-Discrimination Act Promote Access to Insurance?" (2020) 14:2 McGill JL & Health 145 at 162.

¹¹⁴ Office of the Privacy Commissioner of Canada, "PIPEDA fair information principles" (last modified 31 May 2019), online: <priv.gc.ca> [perma.cc/L56B-VMN3].

¹¹⁵ *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5, s 2(1) [*PIPEDA*]; Office of the Privacy Commissioner of Canada, *Summary of privacy laws in Canada* (last modified 31 January 2018), online: <priv.gc.ca> [perma.cc/99RW-4RJ7] [OPC, "Summary"].

¹¹⁶ Office of the Privacy Commissioner of Canada, *PIPEDA in brief* (last modified 31 May 2019), online: <priv.gc.ca> [perma.cc/P85P-T9GX].

¹¹⁷ *PIPEDA*, supra note 115, s 4(1)(b); Office of the Privacy Commissioner of Canada, *Enforcement of PIPEDA* (last modified 20 April 2017), online: <priv.gc.ca> [perma.cc/J86T-E7WY]. Note that Quebec, Alberta, and British Columbia each have their own legislation to cover the private sector.

¹¹⁸ *PIPEDA*, supra note 115, s 5(1), Schedule 1, principle 4.3.

data.¹¹⁹ Consent is only considered valid “if it is reasonable to expect that an individual to whom the organization’s activities are directed would understand the nature, purpose, and consequences of the collection, use and disclosure of the personal information to which they are consenting.”¹²⁰ *PIPEDA*’s “consent provisions” can guide legislators on the type of criteria that should be adopted and explained in the *GND*A to qualify “valid” consent.¹²¹ Since *PIPEDA* does not apply to all organizations collecting genetic data, the *GND*A should specifically refer to informed consent and explain how “valid” consent can be obtained to provide further safeguards against deceptive or coercive practices employed by organizations or employers of companies not caught under *PIPEDA* such as not-for-profit political parties and associations.¹²²

Furthermore, the *GND*A does not explicitly prevent an organization from using the genetic testing results of an individual who provides written consent to make decisions about that individual’s family members.¹²³ Genetic testing results reveal the health information of both the individual who took the genetic test and their family members who share similar genetic variants.¹²⁴ Therefore, whenever a person chooses to allow an organization to use their genetic data, they are implicitly allowing the organization to learn more sensitive information about their relatives.¹²⁵ This fact is particularly problematic if a consumer of DTC-GT services consents to disclose their results to an insurance company to help determine their insurance cost. The insurance company would likely have an interest in using the individual’s genetic data to learn about relatives who also have or seek insurance from the company and may use that information to increase premiums or

¹¹⁹ *Townsend v Sun Life Financial*, 2012 FC 550 at para 25; *PIPEDA*, *supra* note 115, s 5(1), Schedule 1, principle 4.3.6.

¹²⁰ *PIPEDA*, *supra* note 115, s 6(1).

¹²¹ *Ibid*, s 5.1, Schedule 1, principles 4.3.1–4.3.7.

¹²² OPC, “Summary”, *supra* note 115.

¹²³ Young, *supra* note 74 at 117.

¹²⁴ See also Christiaans, *supra* note 2.

¹²⁵ Julian Segert, “Understanding Ownership and Privacy of Genetic Data” (28 November 2018), online (blog): <sitn.hms.harvard.edu> [perma.cc/WT9F-JRTC].

deny coverage to the individual's family members based on their risk of developing a disease.¹²⁶

Fortunately, *PIPEDA* requires organizations collecting personal information to identify the purposes for which the personal information is being collected by the organization before or at the time of collection.¹²⁷ The Office of the Privacy Commissioner (OPC) of Canada has published guidance on how organizations can meet this requirement, noting that the purposes for collecting personal information should be defined "as clearly and narrowly as possible."¹²⁸ In addition, subsection 5(3) of *PIPEDA* provides a legal boundary that protects individuals from inappropriate data practices. It states that "an organization may collect, use or disclose personal information only for purposes that a reasonable person would consider are appropriate in the circumstances."¹²⁹ Therefore, *PIPEDA* makes it clear that an individual's consent is not a free pass for organizations to use personal information for whatever purpose they want. The analysis of whether stated purposes are appropriate in the circumstances must be conducted "in a contextual manner" with attention given to the particular circumstances surrounding the collection, use and disclosure, "all of which suggests flexibility and variability in accordance with the circumstances."¹³⁰ Given the sensitivity of genetic testing results and the aforementioned section 5(3) of *PIPEDA*, it seems it would be illegal for an insurer to use an individual's genetic testing results to underwrite family members without their consent. The OPC has published a list of purposes for the collection, use, or disclosure of personal information that would generally be considered "inappropriate" by a reasonable person, known as "No-Go zones."¹³¹ Unfortunately,

¹²⁶ Roberts, *supra* note 57 at 604, 617.

¹²⁷ *PIPEDA*, *supra* note 115, s 5(1), Schedule 1, principle 4.2.

¹²⁸ Office of the Privacy Commissioner of Canada, *PIPEDA Fair Information Principle 2 - Identifying Purpose* (last modified 13 August 2020), online: <priv.gc.ca> [perma.cc/K6N6-C4FY]. See also Office of the Privacy Commissioner of Canada, *PIPEDA Self-Assessment Tool* (13 August 2021), online: <priv.gc.ca> [perma.cc/BJ4W-3DRU].

¹²⁹ *PIPEDA*, *supra* note 115, s 5(3).

¹³⁰ *Eastmond v Canadian Pacific Railway*, 2004 FC 852 at para 131.

¹³¹ Office of the Privacy Commissioner of Canada, "Guidance on inappropriate data practices: interpretation and application of subsection 5(3)" (last modified 24 May 2018), online: <priv.gc.ca> [perma.cc/4RHV-WVTQ].

the “No-Go zones” published by the OPC do not address using genetic data from one individual to make decisions about others. That said, the OPC notes that “it is [their] intention to periodically revisit and update the list of “No-Go zones” as warranted. The popularity of DTC-GT services provides a strong incentive for the OPC to add “using personal information of one individual to make decisions about a family member of that individual” to the “No-Go zones” list. An inclusion such as this would be broad enough to cover genetic information obtained from genetic tests along with information such as health records and family medical history that can also be used to predict disease onset.¹³² Alternatively, the *GNDA* could explicitly state the scope of allowable uses of the individual’s genetic information. For example, the *GNDA* could specifically state that consent should be limited in that it only extends to the genetic information being used in relation to the consenting individual and not to that individual’s family members.¹³³

3. The *GNDA* does not address the varying accuracy of genetic testing technologies

Under the *GNDA*, there is an underlying presumption that all genetic testing results are accurate and reliable. This is supported by the provisions which state that genetic testing results may be used if an individual consents in writing to its use, along with the healthcare practitioner and researcher exception and the absence of any provision disqualifying certain types of genetic tests.¹³⁴ However, there is clear evidence of deficiencies in the genetic testing results obtained by DTC-GT companies. More specifically, studies have found that some DTC-GT companies’ tests are not clinically and/or analytically valid.¹³⁵

¹³² See generally Stephany Tandy-Connor et al, “False-positive results released by direct-to-consumer genetic tests highlight the importance of clinical confirmation testing for appropriate patient care” (2018) 20:12 *Genetics in Medicine* 1515 at 1520.

¹³³ See generally, Nanibaa’ Garrison et al, “Genomic contextualism: shifting the rhetoric of genetic exceptionalism” (2019) 19:1 *Am J Bioethics* 51.

¹³⁴ *GNDA*, *supra* note 13, ss 5, 6. Note that the exception states that both healthcare practitioners and researchers are allowed to require an individual to undergo a genetic test and use the results of their tests to provide health services or for research purposes, respectively.

¹³⁵ See Stacie D Adams, James P Evans & Arthur S Aylsworth, “Direct-to-Con-

Clinical validity refers to whether the genetic variant of interest is accurately associated with the onset of certain illnesses or diseases.¹³⁶ Most DTC-GT companies are neither closely regulated nor legally subject to any accreditation or certification standards and therefore are not required to prove that their tests are scientifically valid.¹³⁷ As a result, many companies test for genetic variants that have not been scientifically proven to be predictive of a particular health state, and thus provide consumers with unreliable testing results.¹³⁸ One study analyzed forty-nine samples taken from DTC-GT companies that were identified as carrying genetic variants associated with disease.¹³⁹ The study found that some of variants that the DTC-GT companies reported would lead to an “increased risk” of developing a particular disease were classified as benign by clinical laboratories.¹⁴⁰ Similar studies that have analyzed the accuracy of DTC-GT companies’ genetic testing results have found that many DTC-GT companies’ genetic tests have low predictive power, reliability, and validity as the associations between the analyzed genetic variants and the reported disease have not been well-replicated in the scientific literature.¹⁴¹

sumer Genomic Testing Offers Little Clinical Utility but Appears to Cause Minimal Harm” (2013) 74:6 North Carolina Medical J 494; Tandy-Connor et al, *supra* note 132 at 1516, 1518–19; ACJW Janssens, AAM Wilde & IM van Langen, “The sense and nonsense of direct-to-consumer genetic testing for cardiovascular disease” (2011) 19:2 Netherlands Heart J 85; Michael Weedon et al, “Use of SNP chips to detect rare pathogenic variants: retrospective, population based diagnostic evaluation” (2021) 372 BMJ 1 at 5–6.

¹³⁶ Paula Saukko, “State of play in direct-to-consumer genetic testing for lifestyle-related diseases: market, marketing content user experiences and regulation” (2013) 72:1 Proceedings Nutrition Society 53 at 57.

¹³⁷ Justine Horne et al, “A critical examination of legal and ethical considerations for nutrigenetic testing with recommendations for improving regulation in Canada: from science to consumer” (2020) 7:1 JL & Biosciences 1 at 8.

¹³⁸ Saukko, *supra* note 136 at 57.

¹³⁹ Tandy-Connor et al, *supra* note 132 at 1515.

¹⁴⁰ *Ibid* at 1516.

¹⁴¹ See e.g. Rebecca Matthews, Wayne Hall & Adrian Carter, “Direct-to-consumer genetic testing for addiction susceptibility: a premature commercialisation of doubtful validity and value” (2012) 107:12 Addiction 2069 at 2071; A Cecile JW Janssens et al, “A critical appraisal of the scientific basis of commercial genomic profiles used to assess health risks and personalize health interventions” (2008) 82:3 Am J Human Genetics 593 at 598; See Wilde, *supra* note 135 at

Analytical validity refers to whether the technology used by DTC-GT companies can accurately identify the presence or absence of the genetic variant of interest in an individual's genome.¹⁴² Genetic testing technology utilized by most DTC-GT companies tends to differ from that used by medical professionals.¹⁴³ The Whole Genome Sequencing (WGS) technique is a common method used in clinical practice for genetic testing but is only used by a select few DTC-GT companies in North America.¹⁴⁴ With this technique, the whole genome is sequenced to detect and analyze genetic variants,¹⁴⁵ which makes WGS highly accurate at identifying mutations and variants in an individual's genome and results in a high diagnostic rate.¹⁴⁶ In contrast, the most widely used genetic testing technology by DTC-GT companies is Single Nucleotide Polymorphism (SNP) targeting.¹⁴⁷ This technique only analyzes a section of the individual's genome and therefore does not include a comprehensive genome analysis.¹⁴⁸ Multiple studies have concluded that, while SNP targeting is highly predictive in detecting common

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- 86; Teri A Manolio, "Genome-wide Association Studies and Assessment of the Risk of Disease" (2010) 363:2 *New England J Medicine* at 166 at 173.
- ¹⁴² Stacey Hume et al, "CCMG practice guideline: laboratory guidelines for next-generation sequencing" (2019) 56:12 *J Medical Genetics* 792 at 797.
- ¹⁴³ Tandy-Conner et al, *supra* note 132 at 1516, 1519.
- ¹⁴⁴ Hume et al, *supra* note 142 at 793; Frederik Bagger et al, "Whole genome sequencing in clinical practice" (2024) 17:1 *BMC Medical Genomics* 1 at 1, 5; Rachel Horton et al, "Direct-to-consumer genetic testing" (2019) 367:I5688 *BMJ* 1 at 1; Kenza Samlali, Mackenzie Thornbury & Andrei Venter, "Community-led risk analysis of direct-to-consumer whole-genome sequencing" (2022) 100:6 *Biochemistry & Cell Biology* 499 at 500–01.
- ¹⁴⁵ Gregory Costain et al, "Genome sequencing as a diagnostic test" (2021) 193:42 *Can Medical Assoc J* E1626 at E1626. See also Bagger et al, *supra* note 144 at 1, 5.
- ¹⁴⁶ Costain et al, *supra* note 145 at E1628. See also Gregory Costain et al, "Periodic reanalysis of whole-genome sequencing data enhances the diagnostic advantage over standard clinical genetic testing" (2018) 26:5 *European J Human Genetics* 740 at 742.
- ¹⁴⁷ Horton et al, *supra* note 144.
- ¹⁴⁸ *Ibid.*

genetic variants, SNP testing technology yields a high rate of false positives when testing for rare genetic variants associated with a particular disease.¹⁴⁹

Legal protections relating to the accuracy of these tests are currently addressed under *PIPEDA*. Under the “Accuracy Principle” in *PIPEDA*, organizations are responsible for minimizing the use of incorrect information when making a decision about an individual or disclosing information to third parties.¹⁵⁰ To achieve this, they must ensure that all stored personal information is accurate, complete, and up-to-date.¹⁵¹ Principle 4.6.3 of the “Accuracy Principle” states: “[p]ersonal information that is used on an on-going basis, including information that is disclosed to third parties, should generally be accurate and up-to-date, unless limits to the requirement for accuracy are clearly set out.”¹⁵² As previously discussed, the genetic testing results generated by DTC-GT companies are a type of personally identifiable information used on an “on-going” basis by the DTC-GT companies along with the consumers. Some DTC-GT companies sell the consumers’ genetic data to third parties,¹⁵³ use consumers’ DNA for ongoing research,¹⁵⁴ or allow law enforcement agencies to access their databases.¹⁵⁵ In addition, consumers share their genetic testing results with their healthcare providers or other third-party platforms.¹⁵⁶ Therefore, under *PIPEDA*, DTC-GT companies must clearly set out the limitations of their genetic tests.

However, these protections are not sufficient to prevent insurance companies and employers from using inaccurate genetic testing results voluntarily shared by individuals.¹⁵⁷ In practice, DTC-GT companies do not make the information on the accuracy of their genetic tests easily accessible to

¹⁴⁹ Weedon et al, *supra* note 135 at 4, 6.

¹⁵⁰ *PIPEDA*, *supra* note 115, Schedule 1, principle 4.6.

¹⁵¹ *Ibid.*

¹⁵² *Ibid.*

¹⁵³ Janessa Mladucky et al, “Secondary Data Usage in Direct-to-Consumer Genetic Testing: To What Extent Are Customers Aware and Concerned?” (2021) 24:3-4 *Public Health Genomics* 199 at 200.

¹⁵⁴ Bonomi, Huang & Ohno-Machado, *supra* note 4 at 649.

¹⁵⁵ *Ibid.*

¹⁵⁶ See generally, Lee et al, *supra* note 46 at 275, 277, 282, 284.

¹⁵⁷ Brennan Canuteson, “The Risks of Relying on Direct-to-Consumer Genetic

individuals.¹⁵⁸ As a result, consumers of DTC-GT companies are unaware of the limitations of their results and may rely on those results to their detriment.¹⁵⁹ Specifically, studies have found that the content on the DTC-GT companies' main web pages often implies that their genetic tests can inform health decisions, whereas those same companies' privacy policies outline the limitations relating to the accuracy of their genetic testing results.¹⁶⁰ Multiple studies have shown that, in general, the majority of consumers do not read privacy policies or terms of service.¹⁶¹ A 2016 study used eye-tracking methodology to understand how privacy policies are read and found that users who click to read privacy policies only skim through the text.¹⁶² In addition, a 2017 study that analyzed the privacy policies of thirty DTC-GT companies found that the average readability score of these policies is at a college reading level, and, as a result, it is likely that many consumers are

Testing Service Agreements to Protect Genetic Information" (2021) 5:1 Bus Entrepreneurship & Tax L Rev 35 at 35, 38, 47.

¹⁵⁸ Gregory Kutz, *Direct-to-Consumer genetic tests: misleading test results are further complicated by deceptive marketing and other questionable practices* (Washington, DC: US Government Accountability Office, 2010) at 1–2, 8.

¹⁵⁹ *Ibid* at 8.

¹⁶⁰ See e.g. Kutz, *supra* note 158 at 15; Canadian Medical Association, *supra* note 15; Christina Lachance et al, "Informational content, literacy demands, and usability of websites offering health-related genetic tests directly to consumers" (2010) 12:5 Genetics in Medicine 304 at 304; Amanda Singleton et al, "Informed choice in direct-to-consumer genetic testing (DTCGT) websites: a content analysis of benefits, risks, and limitations" 21:3 (2011) J Genetic Counseling 433 at 433–34, 436–437; Norman P Lewis et al, "DTC genetic testing companies fail transparency prescriptions" (2011) 30:4 New Genetics & Society 291 at 299, 301, 303.

¹⁶¹ See Alessandro Acquisti & Jenns Grossklags, "Privacy and Rationality in Individual Decision Making" (2005) 3:1 IEEE Security & Privacy 26 at 30; Julio Angulo et al, "Towards usable privacy policy display and management" (2012) Information Management & Computer Security 4 at 4–5; Jonathan A Obar & Anne Oeldorf-Hirsch, "The biggest lie on the internet: Ignoring the Privacy Policies and terms of service policies of social networking services" (2020) 23:1 Information Communication & Society 128 at 129–30; Connie K Varnhagen et al, "How Informed Is Online Informed Consent?" (2005) 15:1 Ethics & Behaviour 37 at 38, 44.

¹⁶² Nili Steinfeld, "'I agree to the terms and conditions': (How) do users read privacy policies online? An eye-tracking experiment" (2016) 55:1 Computers in Human Behavior 992 at 998.

not able to comprehend them.¹⁶³ The discrepancy between the claims made by DTC-GT companies about the accuracy of their tests on their main web-pages and those in their privacy policies suggests that consumers may be led to believe the information obtained from certain genetic tests will accurately predict their risk of developing a disease in the future. As a result, consumers may use this information for insurance and employment purposes. This is problematic because even if an individual voluntarily shares their genetic testing results with an insurer or employer, insurers and employers should not use the information shared by that individual unless this information is accurate. Reliance on inaccurate genetic tests will result in inaccurate predictions of disease onset. Further legal protection is therefore warranted to protect the decisions made by the consumers of DTC-GT services after they purchase a genetic test.

Two approaches can be adopted to tackle this problem. The first is based on the U.S. approach to ensuring the accuracy of DTC-GT services. In the U.S., the Food and Drugs Administration (FDA) is charged with regulating the accuracy of genetic tests. More specifically, the FDA is tasked with assessing both the clinical and analytical validity of DTC-GT services on the market along with the claims made by these companies about the accuracy of their tests.¹⁶⁴ Currently, DTC-GT companies operating in Canada are not regulated or accountable to any governing body, and therefore, as previously stated, there is no assurance that genetic testing results are accurate.¹⁶⁵ Powers should be granted to a governing body in Canada, such as Health Canada's Health Product and Food Branch to regulate the use of these services to ensure scientifically sound practices. This will certify that consumers who purchase from these companies obtain accurate genetic tests. Additionally, the *GNDA* can be amended to specify the type of genetic tests that can be used by employers, insurance companies, or other third parties once

¹⁶³ Linnea I Laestadius, Jennifer R Rich & Paul L Auer, "All your data (effectively) belong to us: data practices among direct-to-consumer genetic testing firms" (2017) 19:5 *Genetics in Medicine* 513 at 518.

¹⁶⁴ US Food and Drug Administration, "Direct-to-Consumer Tests" (last modified 20 December 2019), online: <fda.gov> [perma.cc/W29E-DK4K].

¹⁶⁵ See Genetics Education Canada, "Direct-to-Consumer Genetic Testing" (last modified October 2017), online (pdf): <geneticseducation.ca> [perma.cc/VQ9Q-SQHC]; Office of the Privacy Commissioner of Canada, "Direct-to-consumer genetic testing and privacy" (4 December 2019), online: <priv.gc.ca> [perma.cc/7AQP-2ZLZ]; Canadian Medical Association, *supra* note 15.

the individual's written consent is obtained. Canada can look to the United Kingdom for guidance.

The United Kingdom's "Code on Genetic Testing and Insurance" (the Code) is a voluntary agreement between the UK government and the Association of British Insurers on how insurers in the United Kingdom can use genetic information in determining life, critical illness, and income protection insurance.¹⁶⁶ The Code permits insurance companies to collect and use the results of genetic tests to make underwriting decisions in limited circumstances.¹⁶⁷ Specifically, the Code prohibits insurance companies from asking for the result of a predictive genetic test when an individual is applying for insurance unless that individual is applying for life insurance valued over £500,000 and has undergone a predictive genetic test for Huntington's disease.¹⁶⁸ This is understandable because the predictive test for Huntington's disease is highly accurate, and there is a high probability that those with the gene variant will develop the condition.¹⁶⁹ The Code also states that an individual is not required to disclose the results of a predictive genetic test (including for Huntington's disease) if the test was done as part of scientific research, the individual's relative or spouse has had the test, or the individual has the test after he or she has taken out insurance.¹⁷⁰ With these aforementioned provisions of the Code as guidance, the *GNDA* should therefore specify that only certain genetic tests that have high predictive ability, such as genetic testing results for single gene disorders, can be collected and used to make decisions about an individual if the individual consents to its use.¹⁷¹ Like the Code, the *GNDA* can further specify the types of insurance, such

¹⁶⁶ Association of British Insurers, "Code on Genetic Testing and Insurance" (2023), online: <abi.org.uk> [perma.cc/7KSZ-FCK4].

¹⁶⁷ UK Government & Association of British Insurers, *Code on Genetic Testing and Insurance* (London, UK: United Kingdom Department of Health and Social Care, 2018), commitments 2, 4–6 [UK Code on Genetic Testing and Insurance].

¹⁶⁸ *Ibid* at commitment 2.

¹⁶⁹ Association of British Insurers, "Consumer Guide: Code on Genetic Testing and Insurance" (July 2023) 1 at 7, online (pdf): <abi.org.uk> [perma.cc/GL3J-MRMR].

¹⁷⁰ *Ibid* at 5; UK Code on Genetic Testing and Insurance, *supra* note 167, commitment 3.

¹⁷¹ See Leah Hutt, Elaine Gibson & Erin Kennedy, "Call for Action: Provinces and Territories Must Protect our Genetic Information" (2021) 44:2 Dal LJ 1 at 4.

as life insurance over a specified amount, for which genetic tests can be collected with the individual's consent. This will allow individuals the opportunity for insurance regardless of their genetic conditions, subject to certain limitations, such as genetic testing results related to Huntington's disease. Further narrowing the type of genetic testing results that can be voluntarily shared with insurance companies based on their accuracy will help to lessen the possibility of genetic discrimination.

Federal law must recognize that genetic tests are becoming more popular and can be obtained outside traditional methods. As a result, some genetic tests may be less accurate than others based on the technology used by the company performing the analysis.¹⁷² Inaccurate genetic testing results that are voluntarily disclosed to insurers have significant impacts on the individual. It can result in higher premiums, or in the case of employment can cause employers to refuse to hire individuals because of an individual's chance of developing a particular condition.¹⁷³ This would especially be the case if the genetic test reveals a predisposition to a disease that cannot be managed or avoided with modern medicine or lifestyle changes. Regulating the accuracy of DTC genetic tests and developing indicators of accuracy as preconditions for insurers and employers to accept and use genetic testing results will help advance one of the previously discussed objectives of the *GND*A, namely, encouraging individuals to undergo genetic testing.¹⁷⁴ These strategies should be combined with public education about the risks and limitations of DTC-GT services.

V. CONCLUSION

Scientific and technological advancements are changing the landscape of healthcare. DTC-GT companies provide individuals with a convenient way to order genetic tests. However, ordering from DTC-GT companies poses a risk to genetic privacy. The main privacy concern is the risk that insurance companies and employers will obtain access to DTC-GT customers' genetic testing results and use this information to discriminate against them. Fortunately, the *GND*A mitigates this risk, but it is far from perfect.

¹⁷² Weedon et al, *supra* note 135 at 4–5.

¹⁷³ Sandra Soo-Jin Lee & Emily Borgelt, "Protecting Posted Genes: Social Networking and the Limits of GINA" (2014) 14:11 Am J Bioethics 32 at 40.

¹⁷⁴ *Reference re GND*A, *supra* note 59 at para 56.

The *GND*A should expand its definition of “genetic tests” to cover emerging predictive biological factors analyzed by DTC-GT companies to fully protect customers of DTC-GT companies against genetic discrimination. Furthermore, the *GND*A should include specific guidelines as to what qualifies as valid consent and define the scope of allowable uses of an individual’s genetic testing results to ensure fully informed consent is obtained from individuals. Lastly, the *GND*A should only permit the use of accurate genetic testing results to make decisions about an individual. Considering the highly sensitive nature of genetic data, the *GND*A should be amended to further encourage individuals to undergo genetic testing so that early intervention can be sought if an individual learns that he or she is at an increased risk of developing a disease.