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TO: Members of the Legislative Commission on Data Practices and Personal Data Privacy

FROM: Nathan Hopkins, Legislative Analyst 651-296-5056

RE: Consumer Privacy and Direct-to-Consumer Genetic Testing

I. Background

The nucleus of a typical human cell contains 23 pairs of chromosomes. These chromosomes are made of the deoxyribonucleic acid (DNA) that comprises the human genome.¹ Our DNA contains the information our cells need to make the proteins that form the structure of our bodies. A gene, which is composed of DNA, is the basic physical and functional unit of heredity; we inherit them from our parents, and pass (half of) them down to our children. Most genes are the same in all people, but a small fraction of our genes—less than one percent of the total—are slightly different between people. These small differences make each individual's genetic blueprint unique.²

Genetic or genomic tests are performed on an individual's DNA, which is typically derived from a sample of blood, hair, tissue or saliva.³ Genetic tests have been developed for many heritable traits as well as thousands of diseases. Some genetic tests focus on a single gene or genetic mutation that is directly linked to a specific disease disorder—for example, the genes BRCA1 and BRCA2, which are responsible for some hereditary breast and ovarian cancers. But other genomic technologies have been developed to examine multiple genes that may increase or decrease a person's risk of common diseases, such as cancer or diabetes. However, because researchers have yet to pinpoint most of the genetic components that cause diseases, genetic testing does not always provide a complete or definitive result.⁴

¹ See *Fact Sheets: Chromosomes*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, <https://www.genome.gov/26524120/chromosomes-fact-sheet/> (last updated June 16, 2015).

² See *Help Me Understand Genetics: Cells and DNA*, U.S. NATIONAL LIBRARY OF MEDICINE, <https://ghr.nlm.nih.gov/> (published November 13, 2018).

³ Genetic tests focus on an individual's inheritance of a single gene, while genomic tests (such as genetic panels or whole genome sequencing) look at an individual's wider inheritance of various genetic traits. For the purposes of this memorandum, I use the more common phrase "genetic testing" to refer to both genetic and genomic testing.

⁴ See *Public Health Genomics: Genomics and Health*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/genomics/public/index.htm> (last updated July 19, 2017).

A. What is Direct-To-Consumer Genetic Testing?

Traditionally, genetic testing is ordered by a person's healthcare provider, such as a physician, nurse practitioner, or genetic counselor. The healthcare provider determines which test is needed, orders the test from a laboratory, collects and sends the DNA sample, interprets the test results, and shares the results with the patient. The involvement of a healthcare provider helps strengthen the test's clinical utility—i.e., whether the test provides helpful information about diagnosis, treatment, management, or prevention of a disease. Also, a health insurance company often covers part or all of the cost of this clinical testing.⁵

Direct-to-consumer (DTC) genetic testing, however, is done without the involvement of a person's healthcare provider. Instead, a company markets a genetic test directly to customers. Tests can be purchased online or in stores. The customer sends the company a DNA sample, the company processes and analyzes the sample, and then sends the customer the results.⁶

Dozens of companies offer DTC genetic testing. Companies may focus their testing on ancestry/genealogy, health predictions, or both. The number of people who have ordered a DTC genetic genealogy test more than doubled during 2017 and now exceeds 12 million, according to industry estimates. In early 2018, the genealogy company Ancestry.com, based in Utah, announced that it has tested more than seven million people, including two million during the last four months of 2017. The company's customer rolls exceed those of all competitors combined. The second-largest player, 23andMe, has tested more than three million, followed by MyHeritage and FamilyTreeDNA.⁷

B. What Privacy Concerns Arise from DTC Genetic Testing?

A person's genome represents permanent and comprehensive information about his or her unique biological identity. The genome reveals a person's family connections, susceptibility to certain diseases, and a host of other physical characteristics. In the absence of strong regulation of DTC genetic testing, each company's own terms and conditions documents control what happens to customers' genetic information when they turn it over. Company practices vary: some may be very transparent, maximize consumer autonomy, and be very privacy-oriented; others less so. The Future of Privacy Forum recently published a set of suggested "best practices" for the DTC genetic testing industry,⁸ but these have no legal force.

⁵ See *What is direct-to-consumer genetic testing*, U.S. NATIONAL LIBRARY OF MEDICINE, <https://ghr.nlm.nih.gov/primer/dtcgenetic/directtoconsumer> (last reviewed May 2018).

⁶ See *id.*

⁷ Antonio Regalado, *2017 was the Year Consumer DNA Testing Blew Up*, MIT TECHNOLOGY REVIEW, Feb. 12, 2018 (available at <https://www.technologyreview.com/s/610233/2017-was-the-year-consumer-dna-testing-blew-up/>).

⁸ See *Privacy Best Practices for Consumer Genetic Testing Services*, FUTURE OF PRIVACY FORUM, July 31, 2018 (available at <https://fpf.org/wp-content/uploads/2018/07/Privacy-Best-Practices-for-Consumer-Genetic-Testing-Services-FINAL.pdf>).

Specific privacy concerns that have been highlighted regarding DTC genetic testing include:

- **Transparency:** Are the company's policies and conditions regarding privacy transparent, accessible, and understandable to the average customer? Does the company have any ability to unilaterally change its privacy policies, or is customer notice and consent required?
- **Access:** Will the customer's genetic information be made available in any way to persons other than the customer (e.g. through an ancestry or genealogy database)?
- **Dissemination and transfer:** Does the company sell, transfer, or otherwise make an individual's *identifiable* genetic information available to third parties such as: pharmaceutical companies, marketing companies, academic researchers, insurance companies, employers, educational institutions, government entities, law enforcement, etc.? What about de-identified genetic information? Does the customer have any ability to opt-out of or restrict this kind of dissemination?
- **Retention and deletion:** For how long does the company retain the customer's genetic information and/or sample? Does the customer have any ability to limit retention or require deletion/destruction of the information?
- **Security:** Does the company maintain security protocols that protect genetic information against unauthorized, inappropriate, or unintended disclosure?
- **Breach notification:** Will the company notify customers of any security breach that may have compromised the security of the customers' genetic information?
- **Law enforcement access:** Will the company disclose genetic information to law enforcement? Does the company require a warrant or subpoena prior to such disclosure? Will the company notify a customer if his or her genetic information has been disclosed in response to a warrant or subpoena?
- **Business associates:** Does the company require that its business associates (e.g. outside vendors, service providers, consultants, etc.) with access to customer genetic information abide by the same privacy standards as the company itself?

II. Minnesota Law

A DTC genetic testing company doing business in Minnesota is subject to the state's general consumer protection laws, which prohibit consumer fraud, unlawful and deceptive trade practices, and false advertising. Minnesota does not, however, have a statute specifically regulating direct-to-consumer genetic testing. Nevertheless, there are several other sections of law that are applicable or relevant in discussing the privacy concerns arising from DTC genetic testing.

A. Minnesota Statutes, section 13.386: Treatment of Genetic Information Held by Government Entities and Other Persons

Section 13.386 of the Minnesota Government Data Practices Act (GDPA) regulates how both governmental entities *and non-governmental entities* can use and disseminate genetic information. Subdivision 3 states:

- (a) Unless otherwise expressly provided by law, genetic information about an individual:
 - (1) may be collected by a government entity, as defined in section 13.02, subdivision 7a, *or any other person*⁹ only with the written informed consent of the individual;
 - (2) may be used only for purposes to which the individual has given written informed consent;
 - (3) may be stored only for a period of time to which the individual has given written informed consent; and
 - (4) may be disseminated only:
 - (i) with the individual's written informed consent; or
 - (ii) if necessary in order to accomplish purposes described by clause (2).

A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent.¹⁰

Accordingly, section 13.386 places restrictions on the collection, use, retention, and dissemination of genetic information. Unusually for the GDPA, these restrictions apply to private companies just as they do to government entities. Note, however, that the restrictions ultimately boil down to the question of whether the data subject has given “informed consent,” which is not defined in the statute.¹¹

Also, notably, this section’s definition of “genetic information” limits it to information “about an identifiable individual.”¹² This means that genetic information which has been genuinely de-identified are not subject to these restrictions.

Finally, although the plain language of this statute includes “persons” in addition to government entities (an unusual feature within the *Government Data Practices Act*), the section is rather toothless against such non-governmental persons. This is because the civil penalties set

⁹ Within Chapter 13, “person” is defined as “any individual, partnership, corporation, association, business trust, or a legal representative of an organization.” See Minn. Stat. § 13.02, subd. 10.

¹⁰ See Minn. Stat. § 13.836, subd. 3 (emphasis added). A copy of this entire section is attached hereto.

¹¹ Under Section 13.05, subdivision 4(d), “[w]hether a data subject has given informed consent shall be determined by rules of the commissioner [of administration].” Under Administrative Rule 1205.1400, “‘Informed consent’ means the data subject possesses and exercises sufficient mental capacity to make a decision which reflects an appreciation of the consequences of allowing the entity to initiate a new purpose or use of the data in question.” It is not clear, however, whether these administrative rules would apply to a private entity that is subject to Section 13.386. Chapter 13 also lays out a specific and more restrictive definition of “informed consent” at Section 13.05, subdivision 4a, but this only applies to government entities when they are disclosing information to insurers. That section has no applicability to private DTC genetic testing companies.

¹² See § 13.836, subd. 1

out in section 13.08 of the GDPR only makes government entities civilly liable for violations of Chapter 13. Accordingly, section 13.386 does not provide an express private right of action against a private company that violates that section. Criminal penalties under section 13.09 could be brought against a private company for violation of section 13.386, but those criminal penalties are only apply to willful violations.

B. Genetic Nondiscrimination in Health Insurance and Employment; Newborn Screening Programs

This subsection discusses three major areas where current Minnesota law protects the privacy of genetic information. None of the statutes discussed in this subsection have any direct application to DTC genetic testing companies. They do, however, provide context regarding the legal treatment of genetic information under current Minnesota law.

1. Genetic nondiscrimination in health insurance

Laws restricting genetic discrimination by health insurance companies exist in the majority of states.¹³ In Minnesota, section 72A.139 prohibits health insurance companies from requiring applicants to submit to genetic testing or from using genetic information to make decisions about eligibility, coverage, premiums, etc.¹⁴ This section also places some requirements on life insurance companies when they require genetic testing. These requirements include: getting informed consent from the applicant; notifying the applicant's physician of test results; and not requiring the applicant to pay for the testing.¹⁵

2. Genetic nondiscrimination in employment

The majority of states also prohibit genetic discrimination in the employment context.¹⁶ In Minnesota, section 181.974 prohibits employers from requesting or requiring genetic testing as a condition of employment or utilizing genetic information to affect current or prospective employees.¹⁷ This section does provide a private right of action for any person aggrieved by a violation. Treble damages, punitive damages, and attorney fees are all authorized.¹⁸

3. Genetic information from newborn screening programs

Under the Newborn Screening Program, hospitals and others in charge of caring for newborn infants are required to take blood from newborn infants and submit the blood spots to

¹³ See *Genetics and Health Insurance State Anti-Discrimination Laws*, NATIONAL CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/research/health/genetic-nondiscrimination-in-health-insurance-laws.aspx> (last updated January 2008).

¹⁴ See Minn. Stat. § 72A.139, subd. 3.

¹⁵ See *id.* at subds. 5–7.

¹⁶ See *Genetic Employment Laws*, NATIONAL CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/research/health/genetic-employment-laws.aspx> (last updated January 2008).

¹⁷ See Minn. Stat. § 181.974.

¹⁸ See *id.* at subd. 3.

the Minnesota Department of Health to undergo genetic testing for heritable and congenital disorders.¹⁹ This program is subject to the restrictions in section 13.386 (discussed above), but also has several unique features.

Generally, consent for newborn screening is presumed unless parents object to the screening in writing by specifying that they want their child to opt out of the screening. Parents are notified that they may opt out of the tests being performed or have the tests performed without the results stored. The law prohibits use of the blood samples and test results for any other reason than allowed under the law without the written consent of the parent. The law also prohibits the sale of bloodspots, test results, or other data collected during the newborn screening process. Finally, the law allows parents and a person who was tested under the newborn screening program, once that person is 18 years or older, to request that the person's blood samples and test results are destroyed.

III. Law in Other Jurisdictions

A. Federal Law and Regulations

There is no federal law directly addressing consumer privacy as it relates to DTC genetic testing. This section discusses the role that certain federal agencies have in regulating DTC genetic testing companies, and a key federal law regarding the use of genetic information.

Currently, federal regulatory authority over DTC genetic testing falls primarily within the province of the Food and Drug Administration (FDA) under the Medical Device Amendment of the Federal Food, Drug, and Cosmetic Act, and the Centers for Medicaid and Medicare Services (CMS) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).²⁰ These agencies, however, regulate the medical aspects of DTC genetic testing; they do not address consumer privacy issues. Furthermore, unlike genetic testing performed by a healthcare provider, DTC genetic testing is not subject to the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The Federal Trade Commission (FTC) is the agency that would address consumer privacy concerns with DTC genetic testing companies. The FTC is charged with protecting consumers against fraudulent, misleading, or unfair business practices. Section 5 of the Federal Trade Commission Act (FTCA)²¹ prohibits unfair or deceptive acts or practices in or affecting commerce. Section 12 of the FTCA²² specifically prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics.²³ The FTC analyzes the role of

¹⁹ See Minn. Stat. §§ 144.125, 144.128.

²⁰ See Sarah Sunderman, *The Need for Regulation of Direct-to-Consumer Genetic Testing in the United States: Assessing and Applying the German Policy Model*, 12 WASH. U. GLOBAL STUD. L. REV. 357, 368 (2013).

²¹ See 15 U.S.C. § 45.

²² See 15 U.S.C. § 52.

²³ See *Regulation of Clinical Tests: In Vitro Diagnostic (IVD) Devices, Laboratory Developed Tests (LDTs), and Genetic Tests*, CONGRESSIONAL RESEARCH SERVICE, at p. 22–23, last updated April 11, 2017 (available at <https://crsreports.congress.gov/product/pdf/R/R43438>).

advertising in bringing health-related information to consumers, and can bring enforcement actions against false or deceptive advertising, either by administrative process or civil judicial action. This means that, although the FTC isn't setting minimum standards regarding privacy protection, it could investigate a company that violates its own promises to consumers regarding privacy protection. For example, in August of 2017, Uber Technologies Inc. settled an administrative action that the FTC brought against it regarding its customer privacy practices.²⁴ In the settlement, Uber agreed to implement a comprehensive privacy program and undergo regular, independent audits to confirm compliance.

Like Minnesota and many other states, the federal government has also passed a law prohibiting discrimination in health coverage and employment based on genetic information. The Genetic Information Nondiscrimination Act of 2008 (GINA)²⁵ protects the public from discrimination based on genetic information in health insurance and employment. GINA prohibits employers from requesting, requiring, purchasing or using genetic information about an individual or family member in any job-related decision. GINA also prohibits health insurers (both group and individual) from requesting, requiring, or utilizing a person's genetic information for underwriting purposes. In contrast, it does not prohibit insurers' use of such information in underwriting life, disability or long-term care insurance.

B. Alaska's Genetic Privacy Act

As discussed above, the majority of states (as well as the federal government) have laws prohibiting genetic discrimination in health insurance and employment.²⁶ Alaska, however, has a genetic privacy law that has been described by one privacy advocacy organization as "exemplary" and "comprehensive."²⁷

The Alaska Genetic Privacy Act²⁸ was passed into law in 2004. The state statute requires written informed consent for the collection, analysis, retention, or disclosure of DNA samples and test results. The statute also declares that a DNA sample and the results of any genomic analysis are the "exclusive property of the person sampled or analyzed."²⁹ There are both civil and criminal enforcement mechanisms for the statute. A private right of action is authorized, allowing someone who was affected by a violation of the statute to sue the responsible party.³⁰ In addition to damages, the statute imposes a civil penalty of \$5,000 to \$100,000, depending on the

²⁴ See *Uber Settles FTC Allegations that It Made Deceptive Privacy and Data Security Claims*, FEDERAL TRADE COMMISSION, <https://www.ftc.gov/news-events/press-releases/2017/08/uber-settles-ftc-allegations-it-made-deceptive-privacy-data> (published August 15, 2017).

²⁵ P.L. 110-233, 122 Stat. 881.

²⁶ A helpful collection of state statutes related to genomics is maintained by the National Human Genome Research Institute. See *Genome Statute and Legislation Database*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, <https://www.genome.gov/policyethics/legdatabase/pubsearch.cfm> (last updated Nov. 5, 2018).

²⁷ See *State Genetic Privacy Policy*, ELECTRONIC PRIVACY INFORMATION CENTER (accessed Nov. 15, 2018), <https://www.epic.org/state-policy/genetic-privacy/>.

²⁸ AK ST § 18.13.010 et seq.

²⁹ *id.* § 18.13.010(a)(2).

³⁰ *id.* § 18.13.020.

circumstances. Another provision criminalizes knowing violations as a class-a misdemeanor,³¹ which carries a maximum prison sentence of one year,³² and (for a corporation) a maximum fine of \$500,000 or three times any pecuniary gain realized as a result of the offense, whichever is greater.³³

In 2014, a lawsuit was filed in federal district court in Alaska against Gene by Gene, Ltd. (the parent company of Family Tree DNA) for violation of Alaska's Genetic Privacy Act.³⁴ The plaintiff Michael Cole purchased a DTC genetic testing kit from Family Tree DNA and sent in his DNA sample using the supplied cheek swab. Like other customers, Cole was given the option of joining "projects" to connect to potential relatives. Cole alleges in his complaint that when a customer joins certain "projects," Family Tree DNA automatically publishes the full results of the customer's DNA to publicly available websites without the customer's written consent in violation of Alaska law.³⁵ As part of its defense in the case, Gene by Gene argued that Alaska's Genetic Privacy Act had unconstitutionally vague uses of terms including "genetic characteristic," "disclose," and "informed consent."³⁶ The district court, however, rejected all of Gene by Gene's vagueness arguments.³⁷ The lawsuit remains pending.

IV. Conclusion

DTC genetic testing companies doing business in Minnesota are subject to the state's existing consumer protection laws. Also, Minnesota Statutes, section 13.386 already provides privacy protections for individual's genetic information. In considering future legislation on this topic, section 13.386 is a good foundation to build upon. The major problem with this section, however, is that (as a result of its placement in Chapter 13), it lacks an enforcement mechanism against private entities like DTC genetic testing companies. Accordingly, members may want to consider including a private right of action against non-governmental entities within section 13.386.

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Attachment: Minn. Stat. § 13.386

³¹ *Id.* § 18.13.030.

³² *Id.* § 12.55.135.

³³ *Id.* § 12.55.035.

³⁴ See *Cole v. Gene by Gene, Ltd.*, No. 1:14-CV-00004-SLG (D. Alaska). The plaintiff's attempt to certify the lawsuit as a class action was denied by the district court; on appeal, the Ninth Circuit affirmed the denial. See *Cole v. Gene by Gene, Ltd.*, 735 F. App'x 368, 369 (9th Cir. 2018).

³⁵ See *Cole v. Gene by Gene, Ltd.*, No. 1:14-CV-00004-SLG, 2017 WL 5992467, at *1 (D. Alaska July 28, 2017) (denying defendant's motion for summary judgment).

³⁶ *Id.* at *4.

³⁷ See *id.*