

BRIAN E. FROSH
Attorney General

WILLIAM D. GRUHN
Chief
Consumer Protection Division

ELIZABETH F. HARRIS
Chief Deputy Attorney General

CAROLYN QUATTROCKI
Deputy Attorney General



STATE OF MARYLAND
OFFICE OF THE ATTORNEY GENERAL
CONSUMER PROTECTION DIVISION

March 9, 2022

TO: The Honorable Delores G. Kelley, Chair
Finance Committee

FROM: Hanna Abrams, Assistant Attorney General

RE: Senate Bill 766 – Genetic Information Privacy – SUPPORT WITH
AMENDMENTS

The Consumer Protection Division of the Office of the Attorney General (the “Division”) supports Senate Bill 766 (“SB 766”), sponsored by Senator Sydnor, with the amendments outlined below. SB 766 requires direct-to-consumer genetic testing (“DTC-GT”) companies to provide consumers with information about the collection, use, and sharing of genetic data, as well as obtain consumer consent for these activities. SB 766 addresses the important issue of genetic privacy, and with the Division’s proposed amendments, will provide consumers with necessary protections.

The amendments the Division proposes aim to:

- 1) Strengthen SB 766 by ensuring that entities, such as for-profit educational institutions that do not conduct research, are not unnecessarily exempted from its scope;**
- 2) Amend the definition of genetic data to clarify that SB 766 protects information that can be inferred from the genetic information, such as information about relatives;**
- 3) Eliminate or restrict the exemption for de-identified data because it has been established that de-identified data *can* be re-identified.**

Genetic information constitutes the most sensitive and personal of information: it uniquely identifies an individual, reveals their propensity to develop certain diseases, and exposes genetically related family members. Given the sensitive nature of genetic information, however, there are growing privacy concerns regarding DTC-GT company data practices. Traditional genetic testing is administered through healthcare providers who are extensively regulated, but DTC-GT companies market directly to consumers and currently are subjected to very little state or federal regulation. DTC-GT companies can use, sell, or disseminate the genetic information they have gathered with few limitations. For example, 23andMe collected the genetic information of its customers, and in July 2018, sold access to this information to the drug company

GlaxoSmithKline (GSK) for \$300 million.¹ To protect genetic information, the Division proposes the following amendments:

- **Limit the Carve-Outs:** Section 14-4402 carves out all education institutions, whether public, private, nonprofit, or for-profit, as well as any entity owned or operated by these institutions from the scope of SB 766.² If the intent of this language is to permit academic research, this exemption is ill-conceived and overbroad. One of the hallmarks of for-profit educational institutions is the lack of academic research.³ There is therefore no need to craft an exemption encompassing for-profit educational institutions. Moreover, to the extent that research is conducted by entities covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) or their business associates, they are already exempted.⁴ The Division recommends eliminating subsections 2 and 3.⁵
- **Amend Definition of Genetic Data:** Genetic data is personal data relating to inherited or acquired genetic characteristics of a person and their family members acquired through DNA or RNA analysis. The definition of “genetic data” should be modified to include information extrapolated, derived, or inferred from the genetic analysis.⁶ Recall that in 2018, a suspect for the Golden State Killer was identified from crime scene DNA based on a DNA match uploaded to a database by distant family members.⁷
- **Remove or Further Limit the Exemption for De-identified Data:** Section 14-4401(g)(3) excludes de-identified data from the definition of genetic data entirely, a blanket exclusion that is overbroad. To de-identify data, a DTC-GT company supposedly removes

¹ Press Release, *GSK and 23andMe Sign Agreement to Leverage Genetic Insights for the Development of Novel Medicines*, Jul. 25, 2018; Jamie Ducharme, *A Major Drug Company Now Has Access to 23andMe’s Genetic Data. Should You Be Concerned*, TIME (July 26, 2018), <http://time.com/5349896/23andme-glaxo-smith-kline/> [<https://perma.cc/BU23-DE6S>].

² § 14-4402(2) excludes institutions of higher education as defined by Education Article § 10-101. Subsection (h) of this article defines this as “an institution of postsecondary education that generally limits enrollment to graduates of secondary schools, and awards degrees at either the associate, baccalaureate, or graduate level” and expressly includes “public, private nonprofit, and for-profit institutions of higher education.”

³ Kinser, Kevin. “Faculty at Private For-Profit Universities: The University of Phoenix as a New Model?” *Private Higher Education*, pp. 273-276 (2005), available at https://www.prophe.org/cache/0633066_p13_14_Kinser.pdf.

⁴ § 14-4402(1).

⁵ At the very least, subsection 2 should be amended to read: “a public or private nonprofit institution of higher education as defined in § 10-101 of the Education Article[.]” and subsection 3 should be eliminated entirely. § 14-4402(3) excludes from the application of SB 766 any “entity owned or operated by an institution of higher education, as defined in § 10-101 of the Education Article.”

⁶ For example, the California Genetic Information Privacy Act defines “genetic data” as “any data, regardless of its format, that results from the analysis of a biological sample from a consumer, or from another element enabling equivalent information to be obtained, and concerns genetic material. Genetic material includes, but is not limited to, deoxyribonucleic acids (DNA), ribonucleic acids (RNA), genes, chromosomes, alleles, genomes, alterations or modifications to DNA or RNA, single nucleotide polymorphisms (SNPs), uninterpreted data that results from the analysis of the biological sample, and any information extrapolated, derived, or inferred therefrom.” Section 56.18(b)(7) of the California Civil Code (Chapter 2.6. Genetic Privacy).

⁷ Jocelyn Kaiser, *We Will Find You: DNA Search Used to Nab Golden State Killer can Home In on About 60% of White Americans*, SCIENCE, Oct. 11, 2018, available at <https://www.science.org/content/article/we-will-find-you-dna-search-used-nab-golden-state-killer-can-home-about-60-white>.

identifying details from the data, commits to never re-identifying it, and contractually obligates third parties to the same. But once the DTC-GT company engages in this de-identification process, consumers will no longer be able to control the data's use or require its deletion, and DTC-GT companies will be able to sell it or use it in any way it chooses. If the data were truly anonymized and unable to be traced back to the consumer the exemption might be justifiable, but the problem with permitting this exclusion is that study after study has shown that de-identification is a misnomer—*de-identified data can be re-identified*.⁸

Numerous studies have demonstrated that it is possible to re-identify data that has been de-identified according to current regulatory standards set forth in HIPAA, using limited information such as birth year and state of residency or through information publicly available through the Internet.⁹ This has led the American Medical Association to conclude that “[i]n terms of privacy, increasingly it has been recognized that genetic data *cannot* be de-identified . . . A DNA profile alone may be adequate to identify most individuals even in the absence of other identifying information, including individuals that have not previously participated in genetic testing.”¹⁰ Even if the data can be adequately de-identified with today's technology, there is no guarantee that it will not be re-identifiable in the future because “de-identification is a moving-target—data that could not be linked back to an individual at the time of its release could become identifiable over time, as new datasets and new re-identification techniques become available.”¹¹

- **Expand the Disclosure Prohibition to Include Disability Insurance:** Section 14-4405(d) prohibits DTC-GT companies from disclosing a consumer's genetic information to entities offering health insurance, life insurance, or long-term care insurance absent consent.¹² These are important prohibitions, but absent from the list is disability insurance. The Division recommends entities offering disability insurance be added to the list of prohibited disclosures.
- **CPD Opposition to Proposed PhRMA Amendments:** The pharmaceutical industry has proposed amendments to SB 766 that would (a) exempt genetic data that is disclosed to

⁸ Exec. Office of the President, *Big Data: Seizing Opportunities, Preserving Values*, 8 (2014) (discussing re-identification), at 51 (discussing harms including financial loss, intrusion into private life, reputational damage and societal harms).

⁹ See, e.g., Melissa Gymrek, *Identifying Personal Genomes by Surname Inference*, 339 SCI. 321, 321 (2013); Jeantine E. Lunshof et al., *From Genetic Privacy to Open Consent*, 9 Nature Revs. Genetics 406, 406 (2008) (“Developments in both medical informatics and bioinformatics show that the guarantee of absolute privacy and confidentiality is not a promise that medical and scientific researchers can deliver any longer.”); Amy L. McGuire & Richard A. Gibbs, *No Longer De-Identified*, 312 Science 370, 370 (2006).

¹⁰ American Medical Association Board of Trustees Report 12, Resolution 207-A-19, Nov. 2021 (emphasis added). A 2018 publication in the leading academic journal Science indicated that “a genetic database needs to cover only 2% of the target population to provide a third-cousin match to nearly any person.”

¹¹ *A Practical Path toward Genetic Privacy*, at 26, Future on Privacy Forum, Apr. 2020, available at https://fpf.org/wp-content/uploads/2020/04/APracticalPathTowardGeneticPrivacy_April2020.pdf.

¹² § 14-4405(d).

DTC-GT companies in the context of research; and (b) would dramatically expand the definition of de-identified data. The Division opposes these amendments because they would undermine the consumer privacy rights SB 766 strives to protect.

First, permitting a blanket exemption for genetic data collected under the guise of research undermines the very protections that SB 766 intends to provide consumers in a largely unregulated space. SB 766 governs DTC-GT companies who do not bear the burdens and accompanying obligations imposed by HIPAA and other federal rules and regulations.

Second, allowing genetic data that was de-identified in conformance with HIPAA and other federal regulations¹³ to be considered de-identified under SB 766 would effectively gut several key requirements that currently exist in SB 766 to protect de-identified data—namely, a public commitment by the business to maintain and use the data in a de-identifiable form and not attempt to re-identify the data and a requirement that businesses legally bind recipients of genetic data from attempting to re-identify it. Leading organizations – such as the NIH and the International Cancer Genome Consortium – emphasize that de-identification practices should include contractual controls such as those required by SB 766.¹⁴ This is a minimal, but necessary protection for genetic data, particularly when collected by largely unregulated entities such as DTC-GT companies. We strongly oppose further weakening the de-identification requirements introduced by the sponsor.

Accordingly, the Consumer Protection Division respectfully requests a favorable report on SB 766 with the amendments described herein.

Cc: Members, Finance Committee
The Honorable Charles E. Sydnor

¹³ The most frequently used form of deidentification in healthcare is known as the “safe harbor.” This method involves removing 18 enumerated individual identifiers. In today’s data rich environment, numerous studies have demonstrated that the HIPAA safe harbor standard is not a sufficient privacy guard. Requiring public and legal commitments not to re-identify provides an additional level of necessary protection when dealing with DTC-GT companies.

¹⁴ *A Practical Path toward Genetic Privacy*, at 24, Future on Privacy Forum, Apr. 2020, available at https://fpf.org/wp-content/uploads/2020/04/APracticalPathTowardGeneticPrivacy_April2020.pdf.