Date of Hearing: July 1, 2021

ASSEMBLY COMMITTEE ON PRIVACY AND CONSUMER PROTECTION
Jesse Gabriel, Chair
SB 41 (Umberg) – As Amended June 17, 2021

SENATE VOTE: 38-0

SUBJECT: Privacy: genetic testing companies

SUMMARY: This bill would establish the Genetic Information Privacy Act, a comprehensive legal framework to regulate the collection, use, maintenance, and disclosure of genetic data collected or derived from a direct-to-consumer (DTC) genetic testing product or service, including enhanced notice and opt-in consent requirements. Specifically, **this bill would**:

1) Require a DTC genetic testing company to provide clear and complete information regarding the company's policies and procedures for the collection, use, maintenance, and disclosure, as applicable, of genetic data, including all of the following:

   - a summary of its privacy practices, written in plain language;

   - a prominent and easily accessible privacy notice that includes, at a minimum, complete information about the company's data collection, consent, use, access, disclosure, maintenance, transfer, security, and retention and deletion practices, as well as information clearly describing how to file a complaint alleging a violation of the provisions of the bill; and

   - a notice that the consumer's deidentified genetic or phenotypic information may be shared or disclosed to third parties for research purposes in accordance with the federal policy for the protection of human subjects (i.e., "The Common Rule").

2) Require a DTC genetic testing company to obtain a consumer's express consent for the collection, use, and disclosure of the consumer's genetic data, including, at a minimum, separate express consent for each of the following:

   - the use of the genetic data collected through the genetic testing product or service offered to the consumer, including who has access to genetic data, how genetic data may be shared, and the specific purposes for which it will be collected, used, and disclosed;

   - the storage of a consumer's biological sample after the initial testing requested by the consumer has been fulfilled;

   - each use of genetic data or the biological sample beyond the primary purpose of the genetic testing product or service and inherent contextual uses;

   - each transfer or disclosure of the consumer's genetic data or biological sample to a third party other than a service provider, including the name of the third party to which the consumer's genetic data or biological sample will be transferred or disclosed; and

- the marketing or facilitation of marketing to the consumer based on the consumer's genetic data, or the marketing or facilitation of marketing by a third party based on the consumer having ordered, purchased, received or used a genetic testing product or service, except as specified.

3) Require a DTC genetic testing company to implement and maintain reasonable security procedures and practices, and to develop procedures and practices to enable a consumer to access their genetic data, delete their account and genetic data, and have their biological sample destroyed.

4) Require a company subject to the consent requirements of the bill to provide effective mechanisms, without any unnecessary steps, for a consumer to revoke their consent, at least one of which utilizes the primary medium through which the company communicates with its consumers; and require a company to honor a consumer's request to revoke consent as soon as practicable, but not later than 30 days after the consumer revokes consent, in accordance with the Common Rule, and to destroy a consumer's biological sample within 30 days of receipt of the revocation of consent to store the sample.

5) Prohibit a person or public entity from discriminating against a consumer because the consumer exercised any of their rights under this chapter, as specified.

6) Prohibit a DTC genetic testing company from disclosing a consumer's genetic data or biological sample to any entity responsible for administering or making decisions regarding health insurance, life insurance, long-term care insurance, disability insurance, or employment, or to any entity providing advice to an entity responsible for those functions, except as specified.

7) Subject any person who negligently violates the provisions of the bill to civil penalties not to exceed $1,000 plus court costs, as determined by the court, and any person who willfully violates the provisions of the bill to civil penalties in an amount not less than $1,000 and not more than $10,000 plus court costs, as determined by the court.

8) Specify that court costs recovered pursuant to enforcement of this bill shall be paid to the party or parties prosecuting the violation, and that penalties recovered shall be paid to the individual to whom the genetic data at issue pertains.

9) Provide that the provisions of the bill shall be prosecuted exclusively by the Attorney General, a district attorney, a county counsel, a city attorney, a city prosecutor, as specified, in the name of the people of the State of California upon their own complaint, upon the complaint of a board, officer, person, corporation, or association, or upon the complaint of a person who has suffered injury in fact and has lost money or property as a result of the violation.

10) Render any provision of a contract or agreement between a consumer and a person governed by the bill that has or would have the effect of delaying or limiting access to legal remedies for violation of the bill inapplicable to the exercise of rights or enforcement pursuant to the bill.

11) Exclude from its provisions any medical information governed by the Confidentiality of Medical Information Act (CMIA); any protected health information that is collected,

maintained, used, or disclosed by a covered entity or business associate governed by the privacy, security, and breach notification rules established pursuant to the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the federal Health Information Technology for Economic and Clinical Health (HI-TECH) Act; scientific research and educational activities conducted by nonprofit postsecondary educational institutions, as specified, in accordance with federal and state regulations for the protection of human subjects; tests conducted exclusively to diagnose whether an individual has a specific disease, to the extent that all genetic information is treated as medical information or protected health information; and the California Newborn Screening Program.

12) Define, for the purposes of this bill, the following terms: affirmative authorization, biological sample, consumer, dark pattern, deidentified data, direct-to-consumer genetic testing company, express consent, genetic data, genetic testing, person, and service provider.

13) Clarify that nothing in the bill shall be construed to affect access to information made available to the public by the consumer.

14) Make legislative findings and declarations relating to the unique sensitivity of genetic information.

EXISTING LAW:

1) Provides, pursuant to the California Constitution, that all people have inalienable rights, including the right to pursue and obtain privacy. (Cal. Const., art. I, Sec. 1.)

2) Prohibits discrimination on the basis of genetic information under the Unruh Civil Rights Act and the Fair Employment and Housing Act (FEHA). (Civ. Code Sec. 51; Gov. Code Sec. 12920 et seq.)

3) Prohibits, pursuant to federal law under the Genetic Information and Nondiscrimination Act (GINA), discrimination based on genetic information in group health plan coverage and employment. (Pub. Law 110-233.)

4) Subjects any person who improperly discloses genetic test results contained in a health care service plan applicant or enrollee's medical records, or pursuant to a genetic test requested by an insurer, to civil and criminal penalties. (Civ. Code Sec. 56.17; Ins. Code Sec. 10149.1.)

5) Subjects any provider of health care, health care service plan, pharmaceutical company, or contractor, who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of written or electronic medical records, to damages in a civil action or an administrative fine, as specified. (Civ. Code Sec. 56.36.)

6) Specifies, under HIPAA, privacy protections for patients' protected health information and generally prohibits a covered entity, which includes a health plan, health care provider, and health care clearing house, from using or disclosing protected health information except as specified or as authorized by the patient in writing. (45 C.F.R. Sec. 164.500 et seq.)

7) Prohibits, under CMIA, providers of health care, health care service plans, or contractors, as defined, from sharing medical information without the patient's written authorization, subject to certain exceptions. (Civ. Code Sec. 56 et seq.)

8) Defines "medical information," for purposes of CMIA, to mean individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. (Civ. Code Sec. 56.05(g).)

9) Establishes the California Consumer Privacy Act of 2018 (CCPA), which grants consumers certain rights with regard to their PI (personal information), including enhanced notice, access, and disclosure when their PI is collected; the right to deletion; the right to restrict the sale of information; and protection from discrimination for exercising these rights. It places attendant obligations on businesses to respect those rights. (Civ. Code Sec. 1798.100 et seq.)

10) Provides consumers the right, pursuant to the CCPA, to request that a business that sells the consumer's PI, or that discloses it for a business purpose, provide certain disclosures to the consumer, and enables a consumer, at any time, to restrict a business from selling that PI to third parties. (Civ. Code Secs. 1798.115 and 1798.120.)

FISCAL EFFECT: According to the Senate Appropriations Committee, "[t]he Department of Justice (DOJ) reports ongoing annual costs of $357,000 for 1.0 Deputy Attorney General and 1.0 Legal Secretary for enforcement workload associated with this measure[;…and] unknown, potentially-significant workload cost pressures to the courts to adjudicate alleged violations of this measure."

COMMENTS:

1) **Purpose of the bill**: This bill seeks to create a comprehensive, workable legal framework for the collection, use, maintenance, and disclosure of genetic data by DTC genetic testing companies in order to protect consumers' sensitive information and their reasonable expectations pertaining to transactions involving their PI. This bill is author-sponsored.

2) **Author's Statement**: According to the author, "[t]he Pentagon recently sent out a memo asking service members to not use DTCs due to, 'the increased concern in the scientific community that outside parties are exploiting the use of genetic materials for questionable purposes…without their [consumers'] authorization or awareness.' Furthermore, a study reported by Business Insider showed that 40 to 60 percent of genetic data is re-identifiable when compared against public databases. The evidence is clear; the laws regulating DTCs are inadequate and need to be strengthened to better protect consumers. Currently, at least [four] other states have enacted similar legislation due to the importance of protecting consumers' most sensitive information. By passing the Genetic Information Privacy Act, California will protect its consumers' most sensitive data."

3) **Direct-to-consumer genetic testing**: In 1990, the United States Department of Energy's Office of Science and the United States National Institutes of Health formally launched the Human Genome Project, an international scientific research collaboration aimed at mapping the human genome in its entirety. The fruits of this project were realized in 2003 when the

project was declared complete. Since that time, there have been dramatic advancements in the ease and efficiency with which genetic data can be collected and analyzed.

As genetic sequencing becomes increasingly inexpensive and accessible, it is also becoming more ubiquitous. In addition to various medical applications, the past several years have seen the rise of a growing industry for direct-to-consumer (DTC) genetic testing products. Businesses such as 23andMe and Ancestry.com market these products as opportunities to better know oneself, based on their capacity to reveal individual traits, medical predispositions, ethnicities and nations of origin, and blood relationships to others. When purchased, DTC genetic testing products provide a kit through which a sample, typically saliva, can be collected and mailed to the company for analysis. The company then provides results to the consumer, generally online, through landing pages where consumers can access their raw genetic data as well as inferences drawn from those analyses. The information that can be extrapolated or inferred from these data continues to grow each year, as the scientific understanding of genetics and genomics improves, and new uses for databases of such genetic information continue to emerge.

4) **The unique sensitivity of genetic data**: In April of 2018, police arrested Joseph James DeAngelo, alleging that he was the "Golden State Killer" suspected of at least 13 murders, 50 rapes, and 100 burglaries in California between 1974 and 1986. After decades of active investigation, the break in the case arose from law enforcement's use of publicly available genetic data supplied to the freely accessible genealogical database GEDMatch, to which users upload their genetic data received from DTC genetic tests in order to identify familial matches among other users. Using the killer's DNA profile collected from a rape kit, investigators submitted the killer's genetic information to GEDMatch and identified ten to twenty relatives who shared the killer's great-great-great grandparents. Investigators then reconstructed a putative family tree using this information, ultimately identifying two prime suspects, one of which was exonerated by a family member's submitted genetic data; the other, DeAngelo, was a genetic match with the killer.

   The arrest of the alleged Golden State Killer has been hailed as an exemplary use of consumer genetic data in the investigation of crimes, but it also spotlighted the issue of genetic privacy and the unforeseen uses of commercially obtained genetic data. As of 2019, over twenty-six million people had used some form of DTC genetic testing service, and that number continues to grow as new companies enter the market.[1] 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."[2]

   The capacity to reveal sensitive information about family members is not limited to the law enforcement context. A genetic test has the potential to uncover information about biological parentage and about inherited genetic traits that could reveal sensitive health conditions of parents or other relatives. Genetic data also derive particular sensitivity from the potential information that can be inferred about an individual. Already several genes associated with

---

[1] Antonio Regalado, "More than 26 Million People Have Taken an At-Home Ancestry Test," *MIT Tech. Rev.*, Feb. 11, 2019, https://technologyreview.com//s/612880/more-than-26-million-people-have-taken-an-at-home-ancestry-test, accessed Jul. 23, 2020.

[2] Yaniv Erlich, et al., "Identity inference of genomic data using long-range familial searches," *Science*, 362, 690-694, (2018).

certain health conditions and behavioral traits have been identified, including some genotypes that have extremely high probabilities of leading to certain diseases later in life. Unlike usernames, passwords, credit card numbers, and other identifying information, genetic data cannot be changed or divorced from the individual in the event it falls into the wrong hands. This immutability extends the lifespan of compromised genetic information indefinitely, increasing the scope and duration of possible exploitation, and further amplifying its already considerable sensitivity. In support of SB 41, a coalition of privacy and consumer rights advocacy organizations consisting of ACLU California Action, Consumer Action, Consumer Federation of America, Electronic Frontier Foundation, Privacy Rights Clearinghouse, and Access Humboldt, explains:

> Genetic data is especially intimate because it is a unique and immutable personal identifier, potentially contains medical information, and has implications not only for the individual but for the individual's relatives who have not chosen to take these tests. All results from genetic testing should be private by default, yet DTC companies currently can and do use consumer data for purposes other than providing results to consumers – including company-sponsored research, and selling consumer data to third parties without consumer knowledge or consent. SB 41 would put sensible safeguards around this highly private data to ensure consumers have control over their genetic information. […]
>
> Inappropriate use of this highly sensitive data can deeply affect consumers. Genomic data can be used to uniquely identify an individual and never expires, making it impossible for consumers to fully undo inappropriate sharing of this information as they might do for other personal information. The highly distinguishable and stable aspects of genetic information also make it incredibly valuable to marketers, data brokers, and insurers. Access to long-term care insurance, for example, can be impacted by the results of genetic testing. SB 41 would ensure that Californians have better control over who has access to their sensitive genetic information, including ensuring that people and companies administering insurance may not access DTC genetic testing results.

Taken together, the fact that genetic data is immutable, specific to an individual, revealing of sensitive information about kin and kinship, of ever-increasing informational value, and capable of revealing sensitive health information, renders this data unique even among categories of PI in its sensitivity. Consequently, it is critical that privacy and consumer protection laws treat these data accordingly.

5) **Insufficiency of existing genetic privacy laws**: Presently, there are very few protections provided by state and federal laws to limit the use and disclosure of the genetic data collected by DTC genetic testing companies. Pursuant to HIPAA, federal law requires written authorization for a covered entity, including a healthcare provider, a health insurance provider, or a business associate of either, to disclose the protected health information of a patient, which may include genetic testing history and results. (45 CFR 164.500 et seq.) State law, pursuant to CMIA, provides parallel protections, requiring written authorization for a provider of healthcare or of health insurance to disclose a patient's medical information. (Civ. Code Sec. 56 et seq.) CMIA also explicitly provides protections for the disclosure of genetic test results contained in an applicant's or enrollee's medical records by a health care service plan, including penalties for willful or negligent disclosure of that information without a written authorization that conforms to certain specifications. (Civ. Code Sec. 56.17.) The California Insurance Code provides these same protections with respect to

disclosure of the results of a test for a genetic characteristic requested by an insurer. (Ins. Code Sec. 10149.1.) However, because the businesses offering DTC genetic testing are not health care service plans or insurance providers, nor are they generally covered entities under HIPAA, typical protections for medical information or other protected health information do not apply to the test results, including these provisions of CMIA and the Insurance Code.

In 2018, California enacted landmark privacy legislation, the CCPA (AB 375, Chau, Ch. 55, Stats. 2018), giving consumers certain rights regarding their PI, including: (1) the right to know what PI is collected and sold about them; (2) the right to request the categories and specific pieces of PI the business collects about them; and (3) the right to opt-out of the sale of their PI, or opt-in in the case of minors under 16 years of age. The CCPA includes in its definition of PI "biometric information," which it defines to mean "an individual's physiological, biological, or behavioral characteristics, including an individual's deoxyribonucleic acid (DNA), that can be used, singly or in combination with each other or with other identifying data to establish individual identity." (Civ. Code Sec. 1798.140.)

Accordingly, the protections provided by the CCPA are available with respect to genetic data maintained by a DTC genetic testing company to the extent that the data are identifiable. The CCPA also provides a private right of action in the event a consumer's nonencrypted and nonredacted PI is subject to unauthorized access, theft, or disclosure, which would apply if the unauthorized access, theft, or disclosure was the result of negligence by the business. (Civ. Code Sec. 1798.150.) The CCPA provides minimum protections for PI generally, and as such, extends such protections to genetic data, but it explicitly leaves room for further regulation in circumstances in which more extensive protection is necessary.

Both state and federal laws also provide some protection against discrimination on the basis of genetic information. The federal Genetic Information Nondiscrimination Act (GINA; Pub. Law 110-223) prohibits discrimination on the basis of genetic information in group health plan coverage and employment, though it does not extend to other types of insurance coverage. GINA also makes it unlawful for an employer to request, require, or purchase genetic information of employees or their families, though this provision does not apply to private employers with fewer than 15 employees. Although these protections are certainly valuable, the discrimination protections do not apply to most circumstances, and the Act does not limit the nonconsensual collection, use, or disclosure of genetic information by DTC genetic testing companies.

Additionally, under the Fair Employment and Housing Act (FEHA; Gov. Code Sec. 12900 et seq.), California prohibits discrimination in employment and housing contexts on the basis of genetic information, and more generally prohibits discrimination based on genetic information pursuant to the Unruh Civil Rights Act (Civ. Code Sec. 51 et seq.). The latter act defines "genetic information" to include information about the individual's genetic tests, the genetic tests of family members of the individual, or the manifestation of a disease or disorder in family members of the individual, and "includes any request for, or receipt of, genetic services, or participation in clinical research that includes genetic services, by an individual or any family member of the individual." While these prohibitions on discrimination may limit the harms of unbridled disclosure of genetic data by DTC genetic testing companies in some contexts, however, they arguably do little to protect a consumer's general privacy interest in their own genetic data.

6) **SB 41 would provide comprehensive protections for genetic data collected, used, maintained, or disclosed by a DTC genetic testing company**: SB 41, a nearly identical reintroduction of SB 980 (Umberg, 2020; *see* Comment 7), builds upon previous attempts to protect genetic information consistent with the California Constitution's right to privacy. These attempts include SB 1267 (Padilla, 2012) and SB 222 (Padilla, 2014), which would have required written authorization by an individual for their DNA sample to be obtained or analyzed, as well as certain disclosures about the individual's rights to the data and the data collection, maintenance, use, and disclosure practices of the entity handling the sample. Both of these bills borrowed language from CMIA and Insurance Code provisions dealing with the disclosure of genetic information. In the same vein, SB 41 would provide meaningful protections for highly sensitive data that are otherwise under-protected or unprotected. These DTC genetic tests are becoming both more ubiquitous, and more exhaustive, as the techniques for genetic sequencing and related processes become cheaper. As such, the bill would address a significant gap in privacy protections for California consumers, and would do so in a manner appropriate to the unique nature of the data.

   Among other provisions, this bill would institute several notice and express consent requirements for collection, use, maintenance, and disclosure of genetic data by DTC genetic testing companies, and would require that any DTC genetic testing company provide a consumer with clear and complete information summarizing its privacy practices. Critically, the bill also requires that a DTC genetic testing company obtain a consumer's separate express consent, and provide a simple mechanism by which to revoke consent, for each of the following: (1) the use of the consumer's genetic data; (2) the storage of the consumer's biological sample after the initial testing; (3) each use of genetic data or the biological sample beyond the primary purpose of the genetic testing service; (4) each transfer or disclosure of the consumer's genetic data or biological sample to a third party other than a service provider; (5) each transfer or disclosure of the consumer's genetic data or biological sample to a governmental agency, except as necessary to comply with a court order; and (6) the marketing or facilitation of marketing based on the consumer's genetic data or their status as a consumer of a genetic testing product, except as specified. The bill specifies that the mechanism for revocation of consent cannot include any unnecessary steps, and must utilize the medium through which the consumer and company typically communicate (e.g., online) in order to avoid logistical and administrative hurdles to exercising that right.

   The bill further requires any DTC genetic testing company to implement and maintain reasonable security procedures and practices to protect against unauthorized access to data, and to develop procedures and practices to enable the consumer to access their genetic data, delete their account and genetic data, and have their biological sample destroyed. The author has prudently defined "DTC genetic testing company" to include any company that collects, uses, maintains, or discloses genetic data collected or derived from a DTC genetic testing product or service or directly provided by a consumer, and has included provisions to prohibit discrimination on the basis of exercising any rights provided by the bill.

   To prevent the use of genetic data for potential discrimination in insurance contexts not covered by existing Insurance Code provisions, the bill prohibits a DTC genetic testing company from disclosing a consumer's genetic data to any entity responsible for administering or making decisions regarding health insurance, life insurance, long-term care insurance, disability insurance, or employment, or any entity that provides advice to an entity that is responsible for performing those functions, unless certain criteria are met to ensure

that the entity does not primarily operate in the insurance space, and that any component of the entity that does manage insurance cannot access the genetic data.

Finally, to avoid complications resulting from inconsistencies or conflicts with existing state and federal laws, the bill excludes from its scope any medical information governed by CMIA, and protected health information that is collected, maintained, used, or disclosed by a covered entity or business associate governed by the privacy, security, and breach notification rules pursuant to HIPAA. These respective statutes already contain fairly robust privacy protections and limitations on disclosure of genetic information (*see* Comment 5), rendering that information sufficiently protected in the absence of the provisions of this bill. The bill also exempts from its definition of "genetic data" data and biological samples subject to the federal policy for the protection of human subjects, otherwise known as the Common Rule, to the extent that the data are collected, used, maintained, and disclosed in compliance with the provisions of the Common Rule. This exemption would prevent logistical compliance complications for genetic researchers, since the Common Rule already includes informed consent and notice provisions, and genetic data used for this purpose would otherwise be subject to two separate, independent standards governing its use. In cases in which an unforeseen conflict between an existing privacy law and the provisions of SB 41 were to occur, the bill specifies that its provisions "shall not reduce a direct-to-consumer genetic testing company's duties, obligations, requirements, or standards under any applicable state and federal laws for the protection of privacy and security," and that "[i]n the event of a conflict between the provisions of [SB 41] and any other law, the provisions of the law that afford the greatest protection for the right of privacy for consumers shall control."

Together, these robust protections, along with thoughtful exemptions to improve workability and practicality, would significantly strengthen the status quo protections for genetic data trafficked in this rapidly growing industry.

7) **SB 41 seeks to resolve concerns related to COVID-19 testing and other diagnostic testing that resulted in the Governor's veto of SB 980**: In 2020, the author of this bill proposed SB 980, which, through extensive stakeholder input and negotiation, along with considerable input from this Committee, arrived at language nearly identical to the language currently in print as SB 41. SB 980 passed out of this Committee 10-0, off of the Assembly Floor 69-0, and off of the Senate Floor 39-0, but was ultimately vetoed by Governor Newsom.

In his veto message, the Governor stated that "the broad language in this bill risks unintended consequences, as the 'opt-in' provisions of the bill could interfere with laboratories' mandatory requirement to report COVID-19 test outcomes to local public health departments, who report that information to the California Department of Public Health. This reporting requirement is critical to California's public health response to the COVID-19 pandemic, and we cannot afford to unintentionally impede that effort."

Staff notes that SB 980, like SB 41, provided explicit exemptions for medical information subject to CMIA and protected health information subject to HIPAA, and thus would have arguably exempted the COVID-19 testing circumstances the Governor details. According to the California Department of Public Health's (CDPH) FAQ on COVID-19 testing sites:

> California law (BPC section 1288) requires that a clinical or public health laboratory accept assignments for clinical laboratory tests only from persons licensed under the

> provisions of law relating to the healing arts as healthcare providers with a scope of practice that authorizes ordering clinical laboratory tests or their representatives.
>
> Five over-the-counter tests can be performed without an order (pregnancy, glucose level, cholesterol, fecal occult blood, and HIV), but all the tests for SARS-CoV-2 must be ordered by licensed medical personnel authorized to order such tests.[3]

Though Executive Order N-25-20 suspended some of the licensure and certification requirements for testing personnel, it nonetheless required tests to be conducted and analyzed under the supervision of a licensed healthcare professionals, subjecting such tests to existing protections for medical information that would not have fallen under the bill. Even if such data did not fall under the medical information/protected health information exemption, SB 980 specifically accommodated this type of circumstance in its definition for DTC genetic testing company, which specified that the definition included an entity that analyzes genetic data obtained from a consumer "*except to the extent that the analysis is performed by a person licensed in the healing arts for diagnosis or treatment of a medical condition*." The potential inadvertent impacts on COVID-19 testing efforts envisioned by the Governor are accordingly unclear.

Although over-the-counter laboratory tests for COVID-19 are not currently authorized in California, the potential market for such products has not gone unnoticed. According to a May 2021 article in Business Insider:

> Amazon is considering the launch of a new line of business that offers an array of at-home medical tests and a third-party marketplace for general home-diagnostics services, Insider has learned.
>
> The company is in talks to first launch its own COVID-19 testing kit in June […] according to people directly involved in the matter. […] Additionally, Amazon could expand to offer testing kits for infections that lead to respiratory and sexually transmitted diseases. Amazon's long-term goal is to expand into other areas, such as clinical genomics, and launch a third-party marketplace that sells medical tests from other companies, these people said.[4]

Whether existing protections under fairly stringent federal and state medical privacy laws, which permit the sharing of medical information for public health reasons under specified conditions, would apply to these types of tests would depend on the nature and structure of the business. If CMIA and HIPAA did apply in such a case, SB 980 would explicitly have not applied, and in the event CMIA and HIPAA did not apply, arguably some privacy scheme beyond the general privacy protections afforded by the CCPA would be appropriate to protect such sensitive data.

---

[3] California Department of Public Health, "COVID-19 for Laboratories: Frequently Asked Questions (FAQ's): Do I need a doctor's order to get tested?" *Laboratory Field Services*, Updated Apr. 13, 2021, https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19FAQ.aspx, [as of Jun. 26, 2021].

[4] Eugene Kim, "EXCLUSIVE: Amazon plans new 'Diagnostics' brand that offers at-home medical tests for COVID-19, sexually transmitted infections, and clinical genomics," *Business Insider*, May 17, 2021, https://www.businessinsider.com/amazon-diagnostics-new-brand-home-medical-tests-covid-sti-genomics-2021-5, [as of Jun. 26, 2021].

In order to address the Governor's stated concerns with SB 980 while still ensuring any test that may fit the limited set of circumstances described would be sufficiently privacy-protective, the author has amended SB 41 to exempt from its provisions "[t]ests conducted exclusively to diagnose whether an individual has a specific disease, to the extent that all persons involved in the conduct of the test maintain, use, and disclose genetic information in the same manner as medical information or protected health information[…]" This amendment was drafted in consultation with this Committee, CDPH, and stakeholders, and seems to strike an appropriate balance between avoiding unforeseen obstacles to public health objectives on the one hand, and ensuring that resulting genetic information is subject to some privacy protections on the other.

Despite this amendment, opponents argue that the bill's broad definitions with respect to "genetic data" and "direct-to-consumer genetic testing company" may nonetheless interfere with workplace safety and COVID-19 protocols. In an "oppose unless amended" letter, TechNet argues:

> We understand the goal of the author is to place important protections around direct-to-consumer genetic testing data, but we are concerned about the overly broad definitions in the bill which will put in scope information that in fact goes beyond actual genetic data and could add complex challenges as it relates to workplace safety and COVID-19 protocol.
>
> […O]ur concern is that the latest amendments still do not address the issue we raised previously which is that "genetic data" is too broad in that it includes any data derived from results. That, in conjunction with how broadly a direct-to-consumer genetic testing company is defined, means that even a casual conversation in the workplace resulting from a test someone had taken for any genetic test will be in scope. It is certainly helpful that there is that exclusion for disease, but since the definition of genetic data includes data resulting from, etc. it goes beyond just simply the "test". For this reason we posit, is COVID-19 considered a disease but not also considered a condition?

The same letter lays out several examples in which antibody tests or tests for proteins indicative of COVID-19 in a workplace context could potentially be captured by the bill. Staff notes, however, that the bill's definition of "genetic data" is unlikely to include antibodies and other proteins. Though genetic material is necessary for the construction of proteins, including antibodies, all material included in the bill's definition of genetic data is constructed from combinations of nucleic acids, or modifications thereto, rather than amino acids, which form the building blocks of proteins. This categorical distinction would mean that the only publicly available COVID-19 testing method that may fall under the bill's provisions would be a test for SARS-CoV-2 viral RNA. No such tests have been approved for direct-to-consumer use. In the event these tests were used for diagnostic purposes in the workplace, the aforementioned amendment would ensure that the provisions of the bill would not apply, so long as any genetic information is treated as medical information. Staff further notes that the same information would be considered medical information were it collected in a medical context rather than in the workplace, suggesting that existing law recognizes the unique sensitivity of this type of data. Accordingly, the author's amendment toward this end seems to effectively balance public health interests with personal privacy.

8) **"Deidentified" data are intentionally excluded from the bill to permit genetic research in a privacy protective manner**: The bill exempts from the definition of genetic data "deidentified data," which it defines to mean "data that cannot be used to infer information about, or otherwise be linked to, a particular identifiable individual, provided that the business that possesses the information" takes certain measures to ensure the information is not reidentified at any point. This definition of "deidentified" is seemingly more stringent than the definition in the CCPA, which defines it to mean "information that cannot *reasonably* identify, relate to, describe, be capable of being associated with, or be linked, directly or indirectly, to a particular consumer, provided that a business that uses deidentified information" takes certain measures to prohibit reidentification.

   Still, it is not entirely clear whether genetic data can ever truly be fully deidentified. While the genetic sequence information can be divorced from PI such as an individual's name or email address, it nonetheless provides information sufficient to specify a particular individual. Notably, the Supreme Court of California has ruled that a unique DNA profile, in the absence of a name, is sufficient to describe a particular person for the purposes of an arrest warrant, holding:

   > For the purposes of the Fourth Amendment, we conclude that the arrest warrant in question, which described the defendant by his 13-loci DNA profile and included an explanation that the profile had a random match probability such that there was essentially not chance of its being duplicated in the human population except in the case of genetically identical sibling [*sic*.], complied with the mandate of our federal constitution that the person seized be described with particularity. (*People v. Robinson* (2010) 47 Cal. 4th 1104, 1130-1134.)

   That being said, omitting an exemption for deidentified data would cause significant logistical problems in the conduct of genetic research, for which secondary deidentified genetic data is often obtained and used for studies. Without attempting to reidentify the data, which would violate federal laws relating to the protection of human subjects in research, it would not be possible for researchers to obtain consent from the individual in accordance with the requirements of this bill. This would effectively preclude the use of these genetic datasets for research purposes.

   As a result, the relatively stringent definition of "deidentified" used in this bill is an attempt to balance these logistical considerations with the bill's preeminent concern of ensuring personal genetic privacy. Considering the inherently identifiable nature of DNA, it remains to be seen what specific deidentification mechanisms must be used to achieve this level of impersonality, but it would ultimately be incumbent on the court to determine whether deidentification attempts were satisfactory to absolve one from liability under this bill.

9) **Double referral and remaining considerations for analysis in subsequent committee**: In 2020, the Assembly opted to single refer all bills, including many that would have otherwise been double-referred, due to logistical constraints on the legislative process imposed by the COVID-19 pandemic, leaving this Committee as the committee of sole referral for SB 980.

   This year, SB 41 has been double-referred to the Assembly Judiciary Committee, where it will be analyzed if passed by this Committee. Accordingly, while those issues were confronted in this Committee with respect to SB 980, they will be only briefly identified

here. Should the bill pass out of this Committee, the Assembly Judiciary Committee may wish to consider certain issues raised by this Committee last year.

Specifically, a central contention with respect to SB 980 revolved around the consent requirement with respect to contextual marketing, or the marketing of products based on the content of the page upon which the advertisement appears. As this Committee's July 27, 2020 analysis of SB 980 described:

> [W]hile the data contextual advertising would rely on in the DTC genetic testing space are not necessarily inherently more sensitive than data used for this purpose by other industries (e.g., non-genetic data), the context in which the advertisements would appear, i.e. alongside sensitive information concerning personal health, wellness, and relationships, would imbue the advertisements with greater potential to mislead or manipulate consumers.

To address these concerns, the author adopted amendments to SB 980 that would have allowed contextual advertising without the consumer's express consent only under the specified circumstances, including where the advertisement ***is not intended to*** result in disparate exposure to advertising content on the basis of any protected characteristic, as described in the Unruh Civil Rights Act (Civ. Code Sec. 51).

Identical language to the aforementioned amendment is included in the bill in print. While SB 41 accordingly does not suffer from many of the same shortcomings with respect to contextual marketing that were identified in SB 980, demonstrating *intent* to present advertisements in a manner that discriminates based on protected characteristics for the purpose of legal action may be remarkably difficult. As the Equal Justice Society, a non-profit dedicated to strengthening anti-discrimination protections, explains, "because contemporary discrimination is frequently structural in nature, unconscious, and/or hidden behind pretexts (despite the fact that a tangible harm has resulted from their actions), the showing of 'intent' becomes a near impossible burden for plaintiffs."[5]

Additionally, similar to the enforcement mechanisms available in the CMIA and Insurance Code provisions concerning unlawful disclosure of genetic test results, SB 41 would subject any person who negligently or willfully violates its provisions to civil penalties, to be paid to the individual whose genetic information was affected. In the event of a negligent violation, a civil penalty of up to $1,000 would be assessed, and in the event of a willful violation, a civil penalty of not less than $1,000 and not more than $10,000 would be assessed. Unlike the CMIA and Insurance Code provisions, however, the bill lacks a private right of action, and actions for relief can only be prosecuted by the Attorney General, a district attorney, a county counsel, a city attorney, or a city prosecutor, "upon their own complaint or upon the complaint of a board, officer, person, corporation, or association, or upon a complaint by a person who has suffered injury in fact and has lost money or property as a result of the violation of" the bill's provisions. This language permits prosecution upon the complaint of a person, or upon complaint of a person who has suffered injury in fact as a result of the violation, making it unclear whether a person must demonstrate injury in fact resulting from the violation in order to bring a complaint. If this is indeed the case, such a standard may be

---

[5] *Equal Justice Society*, "Intent Standard," https://equaljusticesociety.org/law/intentdoctrine/, [as of Jun. 27, 2021].

difficult to achieve, as demonstrating injury in fact resulting in the loss of money or property is notoriously difficult in cases in which an individual's privacy has been breached.

Additionally, the bill would direct the court costs recovered to the prosecuting party or parties, and the civil penalties to the individual. This would offset the cost of prosecution to the agency, and encourage enforcement. Still, with civil penalties paid to the individual, the incentive for an agency to bring an action may nonetheless be insufficient to drive robust enforcement.

Though these provisions may benefit from additional clarity, the bill in print nonetheless builds on existing privacy laws to provide extensive, thoughtful protections for this uniquely sensitive data, and would significantly advance the State's interest in protecting the privacy and security of the personal information of its residents.

10) **Related legislation**: AB 825 (Levine) would add "genetic data" to the definition of PI for purposes of the laws requiring businesses and public agencies to report data breaches to affected parties, and laws requiring businesses to implement and maintain reasonable security procedures and practices to protect PI they own, license, or maintain. This bill passed out of this Committee unanimously and is currently in the Senate Appropriations Committee.

11) **Prior legislation**: AB 2301 (Levine, 2020) was substantially similar to AB 825 (Levine). This bill was not set for hearing in the Assembly Privacy and Consumer Protection Committee.

SB 980 (Umberg, 2020) *See* Comment 7.

SB 180 (Chang, Ch. 140, Stats. 2019) requires a person selling a gene therapy kit in California, such as CRISPR-Cas9 kits, to include a notice to the consumer on their website prior to the point of sale, and to place the notice on a label on the package containing the gene therapy kit, in plain view and readily legible, stating that the kit is not for self-administration.

AB 1130 (Levine, Ch. 750, Stats. 2019) expanded definitions of PI in various consumer protection statutes to include additional sensitive information, including biometric data and certain identification numbers.

SB 222 (Padilla, 2014) *See* Comment 6.

SB 1267 (Padilla, 2012) *See* Comment 6.

SB 559 (Padilla, Ch. 261, Stats. 2011) prohibited discrimination on the basis of genetic information, including in housing and employment contexts.

REGISTERED SUPPORT / OPPOSITION:

Support

23andMe
Access Humboldt
ACLU California

Ancestry
Consumer Action
Consumer Federation of America
Consumer Reports
Electronic Frontier Foundation
Oakland Privacy
Privacy Rights Clearinghouse
University of California

Opposition

TechNet (unless amended)

Analysis Prepared by: Landon Klein / P. & C.P. / (916) 319-2200