

By: Capriglione

H.B. No. 2545

A BILL TO BE ENTITLED

AN ACT

relating to the use of an individual's genetic data by certain genetic testing companies for commercial purposes; authorizing a civil penalty.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle A, Title 11, Business & Commerce Code, is amended by adding Chapter 503A to read as follows:

CHAPTER 503A. DIRECT-TO-INDIVIDUAL GENETIC TESTING COMPANIES

Sec. 503A.001. DEFINITIONS. In this chapter:

(1) "Biological sample" means a material part of the human body, or a discharge or derivative part of the body, including tissue, blood, urine, or saliva that is known to contain DNA.

(2) "Deidentified data" means data not reasonably linked to and that cannot reasonably be used to infer information about an identifiable individual.

(3) "Direct-to-individual genetic testing company" means an entity that:

(A) offers genetic testing products or services directly to individuals; or

(B) collects, uses, or analyzes genetic data that results from a direct-to-individual genetic testing product or service and that an individual provides to the entity.

(4) "DNA" means deoxyribonucleic acid.

(5) "Express consent" means an individual's

1 affirmative response to a clear and meaningful notice regarding the
2 collection, use, or disclosure of genetic data for a specific
3 purpose.

4 (6) "Genetic data" means any data, regardless of
5 format, concerning an individual's genetic characteristics. The
6 term:

7 (A) includes:

8 (i) raw sequence data derived from
9 sequencing all or a portion of an individual's extracted DNA;

10 (ii) genotypic and phenotypic information
11 obtained from analyzing an individual's raw sequence data; and

12 (iii) health information regarding the
13 health conditions that an individual self-reports to a company and
14 that the company:

15 (a) uses for scientific research or
16 product development; and

17 (b) analyzes in connection with the
18 individual's raw sequence data; and

19 (B) does not include deidentified data.

20 (7) "Genetic testing" means a laboratory test of an
21 individual's complete DNA, regions of DNA, chromosomes, genes, or
22 gene products to determine the presence of the individual's genetic
23 characteristics.

24 (8) "Person" means an individual, partnership,
25 corporation, association, business, or business trust or the legal
26 representative of an organization.

27 Sec. 503A.002. APPLICABILITY. (a) This chapter applies to

1 a direct-to-individual genetic testing company that:

2 (1) offers its products or services to individuals who
3 are residents of this state; or

4 (2) collects, uses, or analyzes genetic data that
5 results from the company's products or services and was provided to
6 the company by an individual who is a resident of this state.

7 (b) This chapter does not apply to:

8 (1) an entity only when they are engaged in
9 collecting, using, or analyzing genetic data or biological samples
10 in the context of research, as defined by 45 C.F.R. Section 164.501,
11 that is conducted in accordance with:

12 (A) the federal policy for the protection of
13 human subjects (45 C.F.R. Part 46);

14 (B) the good clinical practice guidelines issued
15 by the International Council for Harmonisation of Technical
16 Requirements for Pharmaceuticals for Human Use (ICH); or

17 (C) the United States Food and Drug
18 Administration policy for the protection of human subjects (21
19 C.F.R. Parts 50 and 56); or

20 (2) genetic data that is protected health information
21 collected by a covered entity or business associate, as defined by
22 45 C.F.R. Part 160, subject to the privacy, security, and breach
23 notification rules under the Health Insurance Portability and
24 Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.).

25 Sec. 503A.003. REQUIREMENTS FOR CERTAIN USES OF
26 DEIDENTIFIED DATA. (a) Except as otherwise provided by this
27 chapter or other law, a direct-to-individual genetic testing

1 company that possesses an individual's deidentified data shall:

2 (1) implement administrative and technical measures
3 to ensure the data is not associated with a particular individual;
4 and

5 (2) publicly commit to maintaining and using data in
6 deidentified form and refraining from making any attempt to
7 identify an individual using the individual's deidentified data.

8 (b) If a direct-to-individual genetic testing company
9 shares an individual's deidentified data with another person, the
10 company shall enter into a legally enforceable contractual
11 obligation prohibiting the person from attempting to identify an
12 individual using the individual's deidentified data.

13 Sec. 503A.004. REQUIREMENTS FOR CERTAIN USES OR DISCLOSURE
14 OF GENETIC DATA AND BIOLOGICAL SAMPLE. (a) A direct-to-individual
15 genetic testing company shall:

16 (1) develop, implement, and maintain a comprehensive
17 security program to protect an individual's genetic data against
18 unauthorized access, use, or disclosure; and

19 (2) make publicly available:

20 (A) a high-level privacy policy overview that
21 includes basic, essential information about the company's
22 collection, use, or disclosure of genetic data; and

23 (B) a prominent privacy notice that includes
24 information about the company's data collection, consent, use,
25 access, disclosure, transfer, security, retention, and deletion
26 practices.

27 (b) Before collecting, using, or disclosing an individual's

1 genetic data, a direct-to-individual genetic testing company shall
2 provide to the individual information about the company's
3 collection, use, and disclosure of genetic data the company
4 collects through a genetic testing product or service, including
5 information that:

6 (1) clearly describes the company's use of the genetic
7 data;

8 (2) specifies the persons who have access to test
9 results; and

10 (3) specifies the manner in which the company may
11 share the genetic data.

12 (c) A direct-to-individual genetic testing company shall
13 provide a process for an individual to:

14 (1) access the individual's genetic data;

15 (2) delete the individual's account and genetic data;

16 and

17 (3) destroy or require the destruction of the
18 individual's biological sample.

19 Sec. 503A.005. REQUIRED CONSENT. (a) A
20 direct-to-individual genetic testing company engaging in any of the
21 following activities must obtain:

22 (1) an individual's separate express consent for:

23 (A) the transfer or disclosure of the
24 individual's genetic data to any person other than the company's
25 vendors and service providers;

26 (B) the use of genetic data for a purpose other
27 than the primary purpose of the company's genetic testing product

1 or service; or

2 (C) the retention of any biological sample
3 provided by the individual following the company's completion of
4 the initial testing service requested by the individual;

5 (2) an individual's informed consent in accordance
6 with guidelines for the protection of human subjects issued under
7 45 C.F.R. Part 46, for transfer or disclosure of the individual's
8 genetic data to a third party for:

9 (A) research purposes; or

10 (B) research conducted under the control of the
11 company for the purpose of publication or generalizable knowledge;
12 and

13 (3) an individual's express consent for:

14 (A) marketing by the company to the individual
15 based on the individual's genetic data; or

16 (B) marketing by a third party to the individual
17 based on the individual's ordering or purchasing of a genetic
18 testing product or service.

19 (b) For purposes of Subsection (a), "marketing" does not
20 include providing customized content or offers to an individual
21 with whom a direct-to-individual genetic testing company has a
22 first-party relationship on the company's Internet website or
23 through an application or service provided by the company to the
24 individual.

25 Sec. 503A.006. PROHIBITED DISCLOSURES. (a) A
26 direct-to-individual genetic testing company may not disclose an
27 individual's genetic data to a law enforcement entity or other

1 governmental body unless:

2 (1) the company first obtains the individual's express
3 written consent; or

4 (2) the entity or body obtains a warrant or complies
5 with another valid legal process required by the company.

6 (b) A direct-to-individual genetic testing company may not
7 disclose, without first obtaining an individual's written consent,
8 the individual's genetic data to:

9 (1) an entity that offers health insurance, life
10 insurance, or long-term care insurance; or

11 (2) an employer of the individual.

12 Sec. 503A.007. CIVIL PENALTY. (a) A direct-to-individual
13 genetic testing company that violates this chapter is liable to
14 this state for a civil penalty in an amount not to exceed \$2,500 for
15 each violation.

16 (b) The attorney general or a district attorney may bring an
17 action to recover a civil penalty imposed under Subsection (a) and
18 to restrain and enjoin a violation of this chapter. The attorney
19 general or a district attorney may recover reasonable attorney's
20 fees and court costs incurred in bringing the action.

21 SECTION 2. The changes in law made by this Act apply only to
22 genetic information obtained by a direct-to-individual genetic
23 testing company on or after the effective date of this Act.

24 SECTION 3. This Act takes effect September 1, 2023.