

BILL ANALYSIS

C.S.S.B. 315
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Trade, Workforce & Economic Development
Committee Report (Substituted)

BACKGROUND AND PURPOSE

The bill sponsor has informed the committee that the growing interest in DNA-based products in the marketplace has increased concerns over a person's ownership over their DNA and genetic makeup, as DNA testing and direct-to-consumer testing kits have given private companies access to a person's genetic makeup with minimal oversight. The bill sponsor has also informed the committee that there is limited privacy and protection against what is done with an individual's DNA once it is in the company's possession or outsourced to a third party, which exacerbates worries over political and enforcement abuses, as the entities that purchase or share genetic information are rarely known to the consumer, as well as ethical concerns regarding polygenic scores, also known as genetic risk scores, used to predict disease and intelligence. The bill sponsor has further informed the committee that in 2023, 23andMe experienced a data breach affecting nearly seven million users who had provided DNA to the company after which the company's entire board resigned, except for the CEO, and 40 percent of the company's employees were laid off, according to *The Guardian*, raising further concerns regarding what happens to a person's DNA once a company dissolves. C.S.S.B. 315 seeks to address this issue by establishing a property right in DNA, by providing for injunctive relief and a civil penalty, and creating a criminal offense.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill expressly does one or more of the following: creates a criminal offense, increases the punishment for an existing criminal offense or category of offenses, or changes the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

C.S.S.B. 315 amends the Property Code to establish that an individual has an exclusive property right in the individual's unique DNA, defined by the bill as deoxyribonucleic acid, subject to the bill's provisions. The bill prohibits a person, without the informed, written consent of the individual or the individual's legal guardian or authorized representative, from doing the following:

- collecting a DNA sample from an individual;
- performing a genetic test on an individual's DNA sample;
- retaining an individual's DNA sample;
- altering or modifying an individual's DNA;
- selling or otherwise transferring to another person an individual's DNA sample; or
- making available or allowing to be made available to another person an individual's DNA sample.

The bill defines the following terms for the bill's purposes:

- "DNA sample" as a blood sample or other biological sample or specimen provided by an individual for the purpose of conducting DNA analysis or storage;
- "genetic characteristic" as a scientifically or medically identifiable genetic or chromosomal variation, composition, or alteration that predisposes an individual to a disease, disorder, or syndrome;
- "genetic test" as a presymptomatic laboratory test of an individual's genes, products, or chromosomes that analyzes the individual's DNA, RNA, proteins, or chromosomes and that is performed to identify a genetic characteristic; and
- "RNA" as ribonucleic acid.

C.S.S.B. 315 establishes that the bill's provisions do not apply to the following:

- a DNA sample collected or received for the following:
 - the purpose of medical diagnosis and treatment;
 - the purpose of determining paternity;
 - law enforcement purposes, including the identification of a perpetrator, the investigation of a crime, or the identification of a missing, unidentified, or deceased person;
 - medical examiner purposes, including the performance of an inquest to determine the cause or circumstance of death under Code of Criminal Procedure provisions relating to medical examiners;
 - research, defined by reference to applicable federal regulations relating to the privacy of individually identifiable health information, that is conducted in accordance with the following:
 - the federal policy for the protection of human subjects under applicable federal regulations;
 - the good clinical practice guidelines issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH); or
 - the FDA policy for the protection of human subjects under applicable federal regulations relating to the protection of human subjects and to institutional review boards;
 - use, analysis, storage, or transfer by a public institution of higher education or a private or independent institution of higher education, as those terms are defined by the Higher Education Coordinating Act of 1965; or
 - any other similar use under the laws of the state or another jurisdiction; or
- to an entity that, as follows:
 - is a covered entity or business associate, defined by reference to federal regulations relating to general administrative requirements for public welfare purposes, subject to the privacy, security, and breach notification rules under the federal Health Insurance Portability and Accountability Act of 1996;
 - offers genetic testing products or services through a health care provider; or
 - is a health care provider.

C.S.S.B. 315 makes a person who violates an individual's property right to the individual's unique DNA liable to the state for a civil penalty not to exceed the amount of any profits that are attributable to the violation. The amount of profits may be established by showing the gross revenue attributable to the unauthorized use minus any expenses that the person who committed the unauthorized use may prove. Subject to these provisions, the amount of the civil penalty must be based on the following:

- the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation;
- the economic harm caused by the violation;
- the history of previous violations;
- the amount necessary to deter a future violation;

- efforts to correct the violation; and
- any other matter that justice may require.

The bill authorizes the attorney general, if it appears that a person has violated the bill's provisions relating to an individual's property right to the individual's unique DNA, to institute an action for a civil penalty, injunctive relief, or both and to recover reasonable attorney's fees and expenses and court costs incurred in recovering a civil penalty or obtaining injunctive relief under these provisions.

C.S.S.B. 315 creates a Class A misdemeanor offense for a person who, with criminal negligence, violates the bill's provisions relating to an individual's property right to the individual's unique DNA.

C.S.S.B. 315 does not apply to the use or retention of a DNA sample collected or provided before the bill's effective date.

EFFECTIVE DATE

September 1, 2025.

COMPARISON OF SENATE ENGROSSED AND SUBSTITUTE

While C.S.S.B. 315 may differ from the engrossed in minor or nonsubstantive ways, the following summarizes the substantial differences between the engrossed and committee substitute versions of the bill.

The engrossed and the substitute both establish that the bill's provisions do not apply to a DNA sample collected for certain purposes, but differ in the following respects:

- the substitute includes in that exemption a DNA sample received for those purposes, which the engrossed did not include;
- whereas the engrossed version included emergency medical treatment among those exempted purposes, the substitute instead includes medical diagnosis and treatment;
- the substitute includes the following among those exempted purposes, which the engrossed did not include:
 - medical examiner purposes, including the performance of an inquest to determine the cause or circumstance of death under the applicable Code of Criminal Procedure provisions;
 - research, defined by reference to applicable federal regulations relating to the privacy of individually identifiable health information, that is conducted in accordance with the following:
 - the federal policy for the protection of human subjects under applicable federal regulations;
 - the good clinical practice guidelines issued by ICH; or
 - the FDA policy for the protection of human subjects under the applicable federal regulations; and
 - use, analysis, storage, or transfer by a public institution of higher education or a private or independent institution of higher education, as those terms are defined by the applicable Education Code provisions; and
- the substitute includes a provision, absent from the engrossed, establishing that the bill's provisions do not apply to an entity that, as follows:
 - is a covered entity or business associate, defined by reference to the applicable federal regulations, subject to the privacy, security, and breach notification rules under the federal Health Insurance Portability and Accountability Act of 1996;
 - offers genetic testing products or services through a health care provider; or
 - is a health care provider.

The substitute omits the provision of the engrossed that established that a research entity that obtains an individual's informed, written consent in accordance with the general requirements for informed consent under U.S. Department of Health and Human Services policy for the protection of human research subjects, as follows:

- may collect and use a DNA sample from the individual for a purpose disclosed to the individual in a written disclosure provided to the individual during the informed consent process; and
- may not use a DNA sample collected from the individual for a purpose other than a purpose disclosed to the individual in a written disclosure provided to the individual during the informed consent process.