

**SB-318**

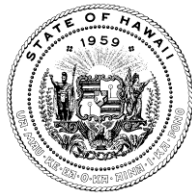
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Testimony for CPN on 1/28/2025 9:30:00 AM

Submitted By	Organization	Testifier Position	Testify
Andrew Crossland	Individual	Oppose	Written Testimony Only

Comments:

**I STRONGLY OPPOSE** individuals' genetic information being made available for use by the State, and I urge all Committee members to **VOTE NO** on this Bill.



**JOSH GREEN, M.D.**  
GOVERNOR | KE KIA'ĀINA

**SYLVIA LUKE**  
LIEUTENANT GOVERNOR | KA HOPE KIA'ĀINA

**STATE OF HAWAII | KA MOKU'ĀINA 'O HAWAI'I**  
**OFFICE OF THE DIRECTOR**  
**DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS**  
**KA 'OIHANA PILI KĀLEPA**  
335 MERCHANT STREET, ROOM 310  
P.O. BOX 541  
HONOLULU, HAWAII 96809  
Phone Number: (808) 586-2850  
Fax Number: (808) 586-2856  
cca.hawaii.gov

**NADINE Y. ANDO**  
DIRECTOR | KA LUNA HO'OKELE

**DEAN I HAZAMA**  
DEPUTY DIRECTOR | KA HOPE LUNA HO'OKELE

## **Testimony of the Department of Commerce and Consumer Affairs**

### **Office of Consumer Protection**

**Before the**  
**Senate Committee on Commerce and Consumer Protection**  
**Tuesday, January 28, 2025**  
**9:30 AM**  
**Conference Room 229 & Videoconference**  
**State Capitol**  
**415 South Beretania Street**

**On the following measure:**  
**S.B. 318, RELATING TO GENETIC INFORMATION**

Chair Keohokalole and Members of the Committee:

My name is Mana Moriarty, and I am the Executive Director for the Department of Commerce and Consumer Affairs' (Department) Office of Consumer Protection (OCP). The Department opposes this bill.

The purpose of this bill is to require the Department of Commerce and Consumer Affairs to adopt rules establishing privacy requirements for direct-to-consumer genetic testing in the State and require the Department's rules to specify whether consumers' genetic information may be used for purposes of investigative genetic genealogy.

The OCP provides the following comments highlighting concerns with the bill as drafted; including (1) that the Health Breach Notification Rule, 16 C.F.R. Part 318, as amended, ("the Rule") provides consumers privacy protections that apply to businesses

offering direct-to-consumer genetic testing; (2) that the Federal Trade Commission brought groundbreaking actions to enforce the Rule in 2023 to protect consumers who purchased prescription drug and telehealth services on a direct-to-consumer web and mobile platforms; (3) that confusion may result if Hawaii's law sets a lower "floor" for consumer protections than federal law; and (4) the bill leaves stakeholders with insufficient clarity on key terms such as "investigative genetic genealogy" to meaningfully participate in a rulemaking process.

The bill requests the Department of Commerce and Consumer Affairs to enact rules establishing privacy requirements for direct-to-consumer genetic testing, citing gaps in the privacy protections afforded by federal law to persons who procure genetic testing commercially. Section 1 of the bill acknowledges that the federal Health Insurance Portability and Accountability Act provides privacy protections in medical settings. Under the Health Breach Notification Rule, a rule adopted by the Federal Trade Commission under Section 18 of the Federal Trade Commission Act, federal law also provides privacy protections for consumers who use health apps, connected devices, or procure services from "any other entity furnishing health care services or supplies." 2024-10855 (89 F.R. 47028).

First among the department's concerns, the Health Breach Notification Rule already requires certain organizations (both businesses and nonprofits) not covered by HIPAA to notify their customers, the Federal Trade Commission, and in some cases, the media, if there's a breach of unsecured, individually identifiable health information. [Complying with FTC's Health Breach Notification Rule | Federal Trade Commission](#). The bill does not acknowledge the Rule, its nationwide scope and application to health apps and importantly businesses that offer direct-to-consumer genetic testing. The Rule applies to a vendor of personal health records (PHRs), a term that encompasses any entity "that offers or maintains a personal health record." 16 C.F.R. 318.2. The July 2024 amendments make clear that makers of health apps, connected devices, and similar products must comply with the Rule.

Breaches of “PHR identifiable health information” trigger the notification requirements of the Rule. PHR identifiable health information includes information that “is created or received by a covered health care provider,” which in turn includes “any other entity furnishing health care services or supplies.” 16 C.F.R. 318.2. “Health care services or supplies” mean **“any online service such as a website, mobile application, or internet-connected device that provides mechanisms to track diseases, health conditions, diagnoses or diagnostic testing, treatment, medications, vital signs, symptoms, bodily functions, fitness, fertility, sexual health, sleep, mental health, genetic information, diet, or that provides other health-related services or tools.”** 2024-10855 p. 535, available at <https://www.federalregister.gov/d/2024-10855/p-535>.”

Second among the department’s concerns, the Health Breach Notification Rule has already been enforced by the Federal Trade Commission (FTC), the nation’s consumer protection agency, which enforces Section 5 of the FTC Act. Section 5 of the FTC Act prohibits companies from misleading consumers or engaging in unfair practices that harm consumers. In addition, the FTC enforces the Health Breach Notification Rule. In 2023, the Commission brought its first enforcement actions under the Rule against vendors of personal health records. In February 2023, the Commission brought an enforcement action alleging a violation of the Rule against GoodRx Holdings, Inc. (“GoodRx”), a digital health company that sells health-related products and services directly to consumers, including prescription medication discount products and telehealth services through its website and mobile applications.

The Office of Consumer Protection routinely brings actions to enforce state consumer protection laws, including Hawaii Revised Statutes section 480-2, which prohibits companies from misleading consumers or engaging in unfair or deceptive trade practices. In construing section 480-2 and its prohibitions, courts and this office are required to “give due consideration to the rules, regulations, and decisions of the Federal Trade Commission and the federal courts interpreting section 5(a)(1) of the Federal Trade Commission Act.” Section 480-2(b). The Office of Consumer Protection gives due consideration to the Health Breach Notification Rule, with falls within section 480-2(b)’s ambit.

Third among the department's concerns, Section 2(a) of the bill requests that the Department of Commerce and Consumer Affairs establish privacy requirements for direct-to-consumer genetic testing limited to testing "that is administered or processed in the State." A rule adopted pursuant to this could not protect a Hawaii resident subjected to harm on whom a genetic test was performed outside of Hawaii's borders if the test was neither "administered" nor "processed" in the State. A Hawaii resident who visits another state and procures and administers a genetic test while there, should not be left unprotected by a rule adopted for the purpose of protecting the consumer public in Hawaii. This situation would be highly unsatisfactory for Hawaii consumers, for whom federal law should represent a "floor" for consumer protection. Laws enacted, and rules adopted, in Hawaii for the purposes of consumer protection should protect consumers at least as much as federal laws and rules.

Fourth and finally, is that the bill requests the department to specify in its rules whether genetic data may be used for "investigative genetic genealogy." Although "investigative genetic genealogy" appears central to the bill's mandate, it is undefined. Rulemaking, particularly when contested, has the potential to be a lengthy, costly process in terms of public time. The central premise of the rulemaking should be clear to the stakeholders weighing in on a proposed rule, but the scope and nature of "investigative genetic genealogy" is unclear.

Thank you for the opportunity to testify on this bill.