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February 13, 2024

The Honorable Pamela Beidle, Chair
Senate Committee on Finance
Miller Senate Office Building, 3 East Wing 11 Bladen St., Annapolis, MD 21401 – 1991

Re: SWA SB 0541, *Maryland Online Data Privacy Act of 2024*

Dear Chair Beidle and Members of the Committee:

On behalf of the Biotechnology Innovation Organization (BIO) and our members, we thank you for the opportunity to submit written testimony for SB 541, the Maryland Online Data Privacy Act of 2024 establishing the manner in which consumer's personal data may be processed and authorizing a consumer to exercise certain rights in regard to their data.

About BIO

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

SB 541

After reviewing the bill, we were pleased to see provisions included that balance patient rights to privacy while maintaining the important public policy goal of promoting biomedical innovation and research in the state of Maryland.

However, in order to facilitate and maintain biomedical research efforts, we encourage you to consider including in the definition of "de-identified data" data that is de-identified pursuant to HIPAA standards.

The existing framework under HIPAA minimizes unnecessary data gathering, allows patients to exercise appropriate levels of autonomy over their PHI, and facilitates healthcare research and innovation. Bill SB 541 captures and preserves a number of elements of the HIPAA legislation, with the exception of the de-identification standard, which our members rely on to harmonize data collection practices for research purposes.

Maintaining current HIPAA and research requirements that BIO members are already adhering to is critical. HIPAA creates clear guidelines for the appropriate use and disclosure of PHI, while also recognizing the critical role PHI plays in research and healthcare innovation. HIPAA recognizes the careful balance between protecting patient privacy and facilitating research.

The HIPAA de-identification standard establishes rules and mechanisms such that the individual to whom protected health information applies cannot be identified nor can the information be re-identified. This allows for safe, secure, and private use of health care data for research purposes.

Failure to include this standard would result in significant operational challenges for companies conducting or looking to initiate biomedical research in Maryland. Many other states in the country with privacy legislation include the HIPAA deidentification standard (see e.g. Virginia H2037(2021) and Colorado Sb190 (2021)).

To address this concern, please consider the amendment below, which makes no substantive changes to the original de-identification data definition, and only adds an additional provision by which one would be able to classify their de-identification practices to be consistent with the Maryland legislation:

14-4601

(P) "DE–IDENTIFIED DATA" MEANS DATA THAT CANNOT REASONABLY BE USED TO INFER INFORMATION ABOUT OR OTHERWISE BE LINKED TO AN IDENTIFIED OR IDENTIFIABLE CONSUMER, OR A DEVICE THAT MAY BE LINKED TO AN IDENTIFIED OR IDENTIFIABLE CONSUMER,
(1) IF THE CONTROLLER THAT POSSESSES THAT INFORMATION:
(i) TAKES REASONABLE MEASURES TO ENSURE THAT THE INFORMATION CANNOT BE LINKED WITH A CONSUMER;
(ii) COMMITS IN PUBLICLY AVAILABLE TERMS AND CONDITIONS OR IN A PUBLICLY AVAILABLE PRIVACY POLICY TO MAINTAIN AND USE THE INFORMATION IN DE–IDENTIFIED FORM; AND
(iii) CONTRACTUALLY OBLIGES ANY RECIPIENTS OF THE INFORMATION TO COMPLY WITH ALL PROVISIONS OF THIS SUBSECTION;
OR
(2) the requirements for de-identification set forth in 45 CFR 164.514 that is derived from individually identifiable health information as described in the Health Insurance Portability and Accountability Act (HIPAA) (P.L. 104-191) or personal information consistent with the human subject protection requirements of the United States Food and Drug Administration are met.

Thank you for your consideration of this change. If you have any questions, please do not hesitate to contact me.

Sincerely,
/s/
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