IPMPC
International Pharmaceutical &
Medical Device Privacy Consortium

March 8, 2019

Mr. Xavier Becerra
California Department of Justice
ATTN: Privacy Regulations Coordinator
300 S. Spring Street
Los Angeles, CA 90013

By Email to: PrivacyRegulations@doj.ca.gov

Re: CCPA Regulations

Dear Attorney General Becerra,

The International Pharmaceutical & Medical Device Privacy Consortium ("IPMPC") welcomes the opportunity to provide comments on the development of regulations under the California Consumer Privacy Act (CCPA).

The IPMPC is comprised of chief privacy officers and other data privacy and security professionals from a number of research-based, global pharmaceutical companies and medical device manufacturers.[1] The IPMPC is the leading voice in the global pharmaceutical and medical device industries to advance innovative privacy solutions to protect patients, enhance healthcare, and support business enablement.[2]

We welcome the opportunity to provide comments at this preliminary stage of the rulemaking process. We note that the legislature has given the Attorney General broad

[1] IPMPC members may also operate related businesses, including CLIA laboratories.

[2] More information about IPMPC is available at https://www.ipmpc.org/. This filing reflects the position of the IPMPC as an organization and should not be construed to reflect the positions of any individual member.

discretionary authority to adopt regulations "to further the purposes of this title."[3] This may include, but is not limited to, the specific issues enumerated at Civil Code § 1798.185(a). We have focused our comments on the following areas where we believe regulations are needed in order to promote a common understanding of CCPA requirements:

1) What qualifies as a "particular consumer or household" for purposes of the definition of "personal information" at Civil Code § 1798.140(o).
2) The scope of the medical research provision at Civil Code § 1798.145(c)(1)(C).
3) The scope of the HIPAA exemption at Civil Code § 1798.145(c)(1)(A).

I. "Particular Consumer or Household"

The definition of "personal information" at Section 1798.140(o) means "information that identifies, relates to, describes, is capable of being associated with, or could reasonably be linked, directly or indirectly, with *a particular consumer or household*" (emphasis added). It is, therefore, critical for all stakeholders to have a clear understanding of what qualifies as a "particular consumer or household."

As a preliminary matter, it is important to note that the inclusion of "household" in the definition of "personal information" creates considerable confusion. How, for example, would access rights apply in this context? Would all members of a household be entitled to access the information that a business holds that relates to any member of that household? The application of the law would be clearer if the legislature were to delete the reference to "household." If this does not occur, however, it will be necessary for the Attorney General to issue rules that clarify how the Act is intended to operate in this context.

It is clear from the fact that the legislature included a definition of "deidentified" information that the legislature did not intend for all information that "describes" or "relates to" a particular individual or household to be considered "personal information," regardless of the identifiability of such information. To give effect to the apparent legislative intent, it would be prudent to adopt regulations clarifying that (i) "a particular consumer or household" means an identifiable consumer or an identifiable household; (ii) an identifiable consumer is a consumer (as defined in the Act) who can be identified by the business who collects such information, without expending disproportionate efforts or resources, by reference to a name, contact information, or communications device; and (iii) an identifiable household refers to shared users of a personal computer or other personal communications device that can be uniquely identified.

[3] California Civil Code § 1798.185(a) and (b).

The IPMPC believes that this proposed clarification protects individual privacy while recognizing that not all individual-level data raises privacy concerns. If information can be associated with a particular consumer or household by name, address, or other contact information, or if the information can be used to communicate with the consumer or household (such as to deliver advertising messages), then the information may trigger privacy interests. Information that does not meet one of these criteria should not be covered as "personal information."

II. Health Research Exemption

Civil Code § 1798.145(c)(1)(C) states that the CCPA does not apply to "[i]nformation collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule, pursuant to good clinical practice guidelines issued by the International Council for Harmonisation or pursuant to human subject protection requirements of the United States Food and Drug Administration." We understand this exemption to cover health research that is conducted (i) pursuant to the federal Common Rule; or (ii) following ICH E6 GCP standards; or (iii) following FDA human subject protection standards as may be found at 21 C.F.R. Part 50. We would appreciate confirmation of this interpretation.

III. HIPAA Exemption

Civil Code § 1798.145(c)(1)(A) states in relevant part that the CCPA does not apply to "protected health information that is collected by a covered entity or business associate governed by the privacy, security, and breach notification rules issued by the United States Department of Health and Human Services, Parts 160 and 164 of Title 45 of the Code of Federal Regulations." We understand the purpose of this exemption is to recognize that collection, use, and disclosure of patient health information is already regulated at the federal level, and, therefore, to exempt this information from the scope of application of the CCPA. We presume that information that is considered de-identified under HIPAA would not be considered "personal information" under the CCPA. Nevertheless, in the unlikely event HIPAA de-identified health information were viewed by the Attorney General as still constituting "personal information" under the CCPA, then we think it is clear that the legislature intended for this information to be exempt from CCPA requirements pursuant to Section 1798.145(c)(1)(A). We would appreciate confirmation of this interpretation as well.

We are also attaching to these comments, our position paper on "Issues Under the CCPA Needing Further Clarification or Amendment." While some of the issues in the position paper likely

require legislative action, we believe the issues discussed above clearly rest within the Attorney General's rulemaking authority.

We thank you for the opportunity to provide these comments. We applaud your efforts to solicit public input early in the rulemaking process.

Sincerely,

Peter A. Blenkinsop
IPMPC Secretariat

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International Pharmaceutical & Medical Device Privacy Consortium

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Issues Under the CCPA Needing Further Clarification or Amendment

The International Pharmaceutical & Medical Device Privacy Consortium appreciates the efforts of California lawmakers and the Office of the Attorney General to craft legislation and implementing rules that protect the privacy of California consumers while recognizing the legitimate needs of businesses to collect and use personal information. Clarification of the following areas of the California Consumer Privacy Act (CCPA) is needed to ensure that there are no unintended effects of the law and compliance efforts are focused on those issues that pose the greatest privacy risk.

1. References to "research" should be aligned to existing standards for scientific research activity and should permit research activities undertaken by private businesses to develop new products and services, especially in the area of researching and developing new treatments, diagnostics, medical devices, therapies, and cures for diseases and conditions that affect California residents.

2. The definition of "personal information" should more clearly exclude information that cannot be used without disproportionate efforts to identify the subject of the information. The definition of "de-identified" should be modified in a corresponding fashion. In addition, to more closely align with federal law, the definition of "de-identified" should be modified by adding a new sentence, as follows: "For purposes of this title, 'de-identified' shall include information that meets the requirements of 45 C.F.R. 164.514(b) for de-identified information or 164.514(e)(2) for a limited data set."

3. The definition of "publicly available" information should be revised to include both (i) information that is lawfully made available from federal, state, or local government records; and (ii) information manifestly made public by or on behalf of the consumer.

4. If a business maintains personal information in a pseudonymized form, the business should not be obliged to acquire or maintain additional information in order to identify the individual for the sole purpose of complying with a requirement under the CCPA.

5. A "consumer" should be defined as a California resident who purchases or uses a product or service in a personal capacity. "Consumer" should not include individuals acting in their capacity as employees or as professionals.

6. Businesses should be allowed flexibility to decide what mechanism(s) would be most effective for enabling consumers to exercise their rights, provided that at least one mechanism is provided that is easy-to-use and cost-free.

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7. A safe harbor to the private right of action should be included for businesses that have implemented a data security program consistent with recognized industry standards.

8. The CCPA should apply only to personal information collected or disclosed after the effective date of the law. Businesses require adequate time after the promulgation of rules by the Office of the Attorney General to modify their business practices in order to comply.