BIOCOM

September 5, 2018

Governor Jerry Brown
State Capitol
Sacramento, CA 95814

RE: SB 1121 Request for Signature (Dodd)

Dear Governor Brown,

On behalf of Biocom's over 1100 members throughout California, I request your signature on SB 1121 (Dodd). As California's largest and most experienced life science organization, Biocom is a leading voice in the advocacy efforts of the California life science community including biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers.

As you are probably aware, SB 1121 enacts a number of critical technical fixes to the California Consumer Privacy Act of 2018 (AB 375), signed by you earlier this year. Of greatest concern to the life sciences industry, although AB 375 exempts health information protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as well as medical information protected by the California Confidentiality of Medical Information Act (CMIA), the wording of AB 375 is problematic when it comes to aspects of conducting clinical trials in California. The changes in SB 1171 are needed to ensure the validity and integrity of clinical trials.

CCPA, if not further amended, would require trial sponsors to give clinical trial participants the right to access some of the data about themselves in blinded clinical trials, even though this would fundamentally impair the integrity of the study results. Most clinical research trials are "blinded"; that is, the participant (with his or her informed consent) is not told certain information — for example, whether he or she is assigned to the treatment group or the control group — in order to reduce or eliminate conscious or subconscious bias , such as the placebo effect. CCPA, as currently written, does not allow researchers to ensure that studies remain blinded in all cases. Also, CCPA currently allows clinical trial participants to delete some of their data. Deletion of clinical research trial data would impair the integrity of the study results, and, for that reason, is prohibited by U.S. Food and Drug Administration guidelines.

If state law makes it impossible to conduct a scientifically valid research study that complies with federal regulations, then federal research dollars and private research grants will not be awarded to

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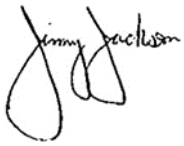
California researchers. In addition, Californians who want to participate in potentially life-saving trials would have to travel to other states for the duration of the trial. According to www.clinicaltrials.gov, there are currently 7,889 active clinical trials in California. An additional 309 studies are approved but not yet recruiting patients. It is important to note that, by federal law, www.clinicaltrials.gov only includes a subset of clinical trials. For example, it does not include Phase I studies. Therefore, these numbers understate the extent of clinical trials now in jeopardy – and do not address future trials.

Biocom is pleased to support this bill, and encourages you to sign it into law. If we may answer any questions, please contact me at jjackson@biocom.org or 858-832-4149 or Biocom's contract lobbyist on this matter, Maureen Higgins, at (916) 930-7182.

Sincerely,



Jimmy Jackson
Senior Vice President & Chief Policy Officer
Biocom