SENATE COMMITTEE ON APPROPRIATIONS
Senator Anthony Portantino, Chair
2021 - 2022 Regular Session

SB 1500 (Committee on Health) - Biologics: investigational use

Version: April 20, 2022
Urgency: No
Hearing Date: May 9, 2022
Policy Vote: HEALTH 10 - 0
Mandate: No
Consultant: Samantha Lui

Bill Summary: Senate Bill 1500 would exempt biologic drugs from state licensing requirements when the biologic drug is part of a new investigational drug trial.

Fiscal Impact: Staff notes unknown, potentially significant revenue generator as this bill would allow for the continued flow of federal funding. Absent this bill, there would be cost pressures on the General Fund (low millions) as there are several biologic projects at risk, over multi-years, the University of California would no longer be able to participate in. Clinical trial funding is typically from sponsor, industry, or the federal National Institutes on Health. To the extent that funding is no longer secured from either of these entities, this would be a cost pressure on the General Fund to fund the continuance of research trials.

The Department of Public Health notes no fiscal impact.

Background: The Sherman Food, Drug, and Cosmetic Law regulates drugs and devices, including requiring a manufacturer to be licensed by the Department of Public Health (CDPH). Drugs and devices must be approved under the Sherman Law, or the federal Food and Drug Administration (FDA) has approved a new drug, new biologic, or a new device. A "biologic" is a type of drug, manufactured in a living system such as a microorganism, or plant or animal cells. Most biologics are very large, complex molecules or mixtures of molecules. A non-biologic is typically manufactured through chemical synthesis, made by combining specific chemical ingredients in an ordered process. Biologic drugs are subject to the same federal approval pathways for their use in clinical trials as non-biologic drugs, a robust process that results in the FDA's grant of an Investigational New Drug (IND) application prior to their use in humans.

Before a drug may be administered to humans, the FDA, pursuant to an IND application, must approve the use of the drug. The FDA treats biologic and non-biologic drugs the same, in that both are subject to the same oversight provisions, including the right of the FDA to terminate or put a hold on the study, setting forth responsibilities of sponsors and investigators, meeting requirements relating to institutional review boards, and obtaining informed consent for investigational uses. Currently, the biologic-specific portion of the existing law has no exemption for uses of biologics in investigational studies, contrary to the exemption under the Sherman Law for non-biologics.

Proposed Law: SB 1500 would:

- Exempt human whole blood or human whole blood derivatives intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices from the requirement to have a human whole blood or blood derivatives license issued by CDPH, if the

investigation is conducted in accordance with provisions of federal law governing FDA approval of an IND application.

- Add to the list of scenarios when a person can engage in the production of biologics other than human whole blood and human whole blood derivative, if the production of biologics, as specified, is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices, and if the investigation is conducted in accordance with provisions of federal law governing FDA approval of an IND application.

- Exempt tissue intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices from the requirement to have a tissue bank license issued by CDPH, if the investigation is conducted in accordance with provisions of federal law governing FDA approval of an IND application.

Staff Comments: The UC Office of the President states their researchers are currently running more than 4,600 clinical trials investigating treatments for more than 2,400 conditions. There are several ongoing biologic trials across the campuses, including University of California, Irvine, of $11.5 million through 2025 and University of California, Davis, of $2.3 million from 2016 to present.

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