Date of Hearing: June 28, 2022

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
SB 1500 (Committee on Health) – As Amended June 13, 2022

SENATE VOTE: 39-0

SUBJECT: Public health: federal regulation.

SUMMARY: Aligns state law governing biologic drugs with state law governing all other drugs by exempting biologic drugs from state licensing requirements when the biologic drug is part of a new investigational drug trial. Makes other non-controversial changes to existing law regarding investigational/scientific use of whole blood, and extending the sunset date on an exemption for home medical device retail facility inspections. Specifically, **this bill**:

1) Exempts from existing licensure requirements 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 if they investigation is conducted in accordance with provisions of federal law governing Food and Drug Administration (FDA) approval of an Investigational New Drug (IND) application (if the investigation is conducted in accordance with the federal Abbreviated New Drug Application or Investigational Device Exemption application).

2) Exempts the production of biologics other than human whole blood or human whole blood derivatives from the requirement to have a biologics license issued by the Department of Public Health (DPH), if the biologics are 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.

3) Exempts from existing licensure requirements tissue intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the federal Abbreviated New Drug Application or Investigational Device Exemption application.

4) Extends to January 1, 2028 the exemption for home medical device retail facility from annual inspections if they are accredited by an accrediting body approved by the Centers for Medicare and Medicaid Services.

EXISTING LAW:

1) Regulates drugs and devices under the Sherman Food, Drug, and Cosmetic Law (Sherman Law), including requiring a license from DPH to manufacture any drug or device in California.

2) Prohibits selling, delivering, or giving away any new drug or new device unless DPH has approved a new drug or device application under the Sherman Law, as specified, or the FDA has approved it as a new drug, new biologic, or a new device, as specified.

3) Exempts drugs and devices from the licensing requirement under the Sherman Law if the drug or device is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with provisions of federal law governing FDA approval of an IND application.

4) Regulates the collection, preparation, testing, processing, and storage of human whole blood, human whole blood derives, and other biologics, and prohibits a person from engaging in the production of human whole blood or human whole blood derivatives, unless that person is licensed by DPH and the human whole blood or human whole blood derivatives are collected, prepared, labeled or stored according to specified requirements.

5) Prohibits any person from engaging in the production of biologics other than human whole blood and human whole blood derivatives unless in a federally licensed laboratory, as specified, or licensed by DPH.

6) Requires every tissue bank operating in California to be licensed by DPH, unless subject to one of a number of specified exemptions, including if the collection, processing storage, or distribution of tissue is for autopsy, biopsy, training, education, or for other medical or scientific research or investigation, when transplantation of the tissue is not intended or reasonably foreseeable.

FISCAL EFFECT: According to the Senate Appropriations Committee: 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 of 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.

COMMENTS:

1) **PURPOSE OF THIS BILL**. According to the author, this bill will align the licensing requirements for non-biologic and biologic drugs used solely for investigational purposes. Existing law already exempts drugs and devices regulated under the Sherman Law from state licensing requirements when these drugs are the subject of an approved IND clinical investigation. However, a separate body of state law governs biologics, and while they are not supposed to be in conflict, the biologic-specific portion of law only exempts biologics produced in a federally licensed facility, and makes no mention of an exemption for uses of biologics in investigational studies. This bill conforms the biologic sections of law to the exemption that already exists in the Sherman Law for clinical investigations.

2) **BACKGROUND**. Biologics" are a type of drug. Drugs are generally defined to be articles used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and which are not devices. The key difference between biologics and non-biologic drugs is that biologics are 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, which means that it is

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 IND application prior to their use in humans. This approval mechanism, and the continuing oversight of FDA during the conduct of these investigational drugs, enables facilities that manufacture and use these investigational drugs to be exempt from California licensure requirements. However, under California law, facilities manufacturing and receiving investigational biologic drugs for use in a clinical investigation approved by the FDA remain subject to licensure requirements.

3) **FDA regulation of INDs.** Before a drug can be administered to humans, the use of the drug must be approved by the FDA pursuant to an IND application. 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. Under the Federal Policy for the Protection of Human Subjects, referred to as the Common Rule, any studies involving the use of investigational drugs in activities constituting human subjects research is subject to institutional review board and informed consent requirements. The FDA also retains the right to inspect clinical sites and related documents.

4) **SUPPORT**. This bill is sponsored by the University of California (UC), which states that clinical trials are one of the most important ways that potential new treatments are developed, and are a cornerstone of UC's unparalleled clinical research enterprise. UC states that their researchers are currently running more than 4,600 clinical trials investigating treatments for more than 2,400 conditions. Recently, however, UC was made aware of an inconsistency in state law that threatened to delay an imminent trial of a new biologic. According to UC, DPH partnered with them and processed the required paperwork in time, but upon further review, UC believes the current licensing requirement is redundant. UC states that there are two sets of laws in the Health and Safety Code that apply to biologic drugs, and that while the law states that the two sections are not supposed to conflict, the biologic-specific portion of the code makes no mention of any exemption for uses of biologics in investigational studies, in contradiction to the exemption under the Sherman Law for non-biologics. UC believes this misalignment is largely a technical oversight in existing law, and this bill will streamline unnecessary administrative burdens for clinical trials while in no way jeopardizing patient safety.

REGISTERED SUPPORT / OPPOSITION:

Support

University of California

Opposition

None on file.

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