

**Senate Bill No. 600**

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Passed the Senate August 29, 2014

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*Secretary of the Senate*

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Passed the Assembly August 26, 2014

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*Chief Clerk of the Assembly*

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This bill was received by the Governor this \_\_\_\_\_ day  
of \_\_\_\_\_, 2014, at \_\_\_\_\_ o'clock \_\_\_\_M.

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*Private Secretary of the Governor*

## CHAPTER \_\_\_\_\_

An act to amend Sections 4033 and 4045 of, to repeal Sections 4034, 4034.1, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5 of, and to repeal and add Section 4163 of, the Business and Professions Code, and to amend Section 111825 of, and to add Section 111397 to, the Health and Safety Code, relating to pharmacy.

## LEGISLATIVE COUNSEL'S DIGEST

SB 600, Lieu. Drugs.

(1) Existing federal law, the Federal Food, Drug, and Cosmetic Act, regulates, among other matters, the manufacture, distribution, and sale of prescription drugs in interstate commerce and is administered by the United States Food and Drug Administration.

Existing law, the federal Drug Supply Chain Security Act, provides for the development of a system that will require, among other things, manufacturers, wholesale drug distributors, repackagers, and dispensers in the drug supply chain to provide specified transaction information about a drug product, and prohibits a state or political subdivision of a state from continuing in effect any requirements for tracing products through the distribution system, including any requirements with respect to electronic pedigree systems, that are inconsistent with, more stringent than, or in addition to, any requirements of federal law.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy. Existing law, commencing July 1, 2016, prohibits a wholesaler or repackager from selling, trading, or transferring a dangerous drug at wholesale without providing a pedigree, as defined, and from acquiring a dangerous drug without receiving a pedigree. Existing law imposes parallel requirements with respect to pharmacies commencing July 1, 2017. Existing law makes these pedigree requirements inoperative upon the effective date of federal law addressing pedigree or serialization measures for dangerous drugs, or as otherwise specified in the event of a conflict with federal law.

This bill would repeal the pedigree requirements and make related conforming changes.

(2) Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of drugs and devices and is administered by the State Department of Public Health. Existing law makes it unlawful to manufacture, sell, deliver, hold, or offer for sale, any drug that is misbranded, and provides that a drug or device is misbranded if its labeling is false or misleading in any particular. A violation of this law is a misdemeanor.

This bill would provide that any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded, except as specified. Because a violation of this provision would be a crime, the bill would impose a state-mandated local program.

The bill would provide that any person, except as specified, who purchases or sells a foreign dangerous drug or medical device, or an illegitimate product or suspect product, as those terms are defined pursuant to federal law, that is not approved or otherwise authorized by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is guilty of a misdemeanor and subject to imprisonment for not more than one year in a county jail, a fine of not more than \$10,000 per occurrence, or both the imprisonment and fine. By creating new crimes, the bill would impose a state-mandated local program.

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

*The people of the State of California do enact as follows:*

SECTION 1. Section 4033 of the Business and Professions Code is amended to read:

4033. (a) (1) “Manufacturer” means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), “manufacturer” shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

(3) Notwithstanding paragraph (1), “manufacturer” shall not mean a pharmacy that, at a patient’s request, repackages a drug previously dispensed to the patient, or to the patient’s agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), “manufacturer” also means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a private label distributor (including colicensed partners) for whom the private label distributor’s prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer’s affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

SEC. 2. Section 4034 of the Business and Professions Code is repealed.

SEC. 3. Section 4034.1 of the Business and Professions Code is repealed.

SEC. 4. Section 4045 of the Business and Professions Code is amended to read:

4045. “Third-party logistics provider” or “reverse third-party logistic provider” means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs.

SEC. 5. Section 4163 of the Business and Professions Code is repealed.

SEC. 6. Section 4163 is added to the Business and Professions Code, to read:

4163. (a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. If the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

SEC. 7. Section 4163.1 of the Business and Professions Code, as added by Section 68 of Chapter 658 of the Statutes of 2006, is repealed.

SEC. 8. Section 4163.1 of the Business and Professions Code, as added by Section 9 of Chapter 713 of the Statutes of 2008, is repealed.

SEC. 9. Section 4163.2 of the Business and Professions Code is repealed.

SEC. 10. Section 4163.3 of the Business and Professions Code is repealed.

SEC. 11. Section 4163.4 of the Business and Professions Code is repealed.

SEC. 12. Section 4163.5 of the Business and Professions Code is repealed.

SEC. 13. Section 111397 is added to the Health and Safety Code, to read:

111397. (a) Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State

Board of Pharmacy, or State Department of Public Health is misbranded.

(b) Any foreign dangerous drug that is imported lawfully under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or pursuant to an announcement by the United States Food and Drug Administration of the exercise of enforcement discretion for instances including, but not limited to, clinical research purposes, drug shortages, development of countermeasures against chemical, biological, radiological, and nuclear terrorism agents, or pandemic influenza preparedness and response is not misbranded.

SEC. 14. Section 111825 of the Health and Safety Code is amended to read:

111825. (a) Any person who violates any provision of this part or any regulation adopted pursuant to this part shall, if convicted, be subject to imprisonment for not more than one year in a county jail or a fine of not more than one thousand dollars (\$1,000), or both the imprisonment and fine.

(b) Notwithstanding subdivision (a), any person who violates Section 111865 by removing, selling, or disposing of an embargoed food, drug, device, or cosmetic without the permission of an authorized agent of the department or court shall, if convicted, be subject to imprisonment for not more than one year in a county jail or a fine of not more than ten thousand dollars (\$10,000), or both the fine and imprisonment.

(c) (1) Notwithstanding subdivision (a), any person who purchases or sells a foreign dangerous drug or medical device, an illegitimate product, as defined in Section 360eee(8) of Title 21 of the United States Code, or suspect product, as defined in Section 360eee(21) of Title 21 of the United States Code, that is not approved or otherwise authorized by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is guilty of a misdemeanor and subject to imprisonment for not more than one year in a county jail, a fine of not more than ten thousand dollars (\$10,000) per occurrence, or both the imprisonment and fine.

(2) This subdivision does not apply to those individuals determined by the United States Food and Drug Administration

to have acted in compliance with the requirements under Part H (commencing with Section 360eee) of Subchapter V of Chapter 9 of Title 21 of the United States Code with regard to the illegitimate or suspect products.

(d) If the violation is committed after a previous conviction under this section that has become final, or if the violation is committed with intent to defraud or mislead, or if the person committed a violation of Section 110625 or 111300 that was intentional or that was intended to cause injury, the person shall be subject to imprisonment for not more than one year in a county jail, imprisonment in the state prison, or a fine of not more than ten thousand dollars (\$10,000), or both the imprisonment and fine.

(e) This section does not preclude punishment under any other law that provides for a greater punishment.

SEC. 15. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Approved \_\_\_\_\_, 2014

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*Governor*