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2008 MAY -1 PM 4:41

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May 1, 2008

RULES AND LEGISLATION COMMITTEE
Oakland, Ca.

Chairperson De La Fuente and Members of the Rules and Legislation Committee:

SUBJECT: RESOLUTION IN SUPPORT OF ASSEMBLY BILL (AB) 501 (SWANSON AND HANCOCK) – "PHARMACEUTICAL DEVICES" WHICH WOULD REQUIRE PHARMACEUTICAL MANUFACTURERS TO PROVIDE SAFE DISPOSAL OPTIONS FOR HOME-GENERATED PEN NEEDLES, PRE-FILLED SYRINGES, AND OTHER INJECTION DEVICES (SHARPS) BY PROVIDING A PREPAID MAIL-BACK CONTAINER TO CONSUMERS.

I am submitting the attached resolution in support of AB 501 for your review and support. If passed by the State legislature, AB 501 would require pharmaceutical manufacturers to provide safe disposal options for home-generated pen needles, pre-filled syringes, and other injection devices (sharps) by providing a prepaid mail-back container to consumers.

I have asked our Environmental Services staff to prepare a detailed analysis of AB 501 for your supplemental packet.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Jean Quan".

JEAN QUAN
Councilmember, District Four

AMENDED IN SENATE MARCH 13, 2008
AMENDED IN ASSEMBLY JANUARY 29, 2008
AMENDED IN ASSEMBLY JANUARY 9, 2008
AMENDED IN ASSEMBLY JANUARY 7, 2008
AMENDED IN ASSEMBLY JUNE 21, 2007
AMENDED IN ASSEMBLY APRIL 30, 2007
CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 501

**Introduced by Assembly Members Swanson and Hancock
(Coauthor: Assembly Member Dymally)**

February 20, 2007

An act to add Section 118288 to the Health and Safety Code, relating to pharmaceutical devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 501, as amended, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act prohibits, on or after September 1, 2008, a person from knowingly placing home-generated sharps waste in certain types of containers, provides that home-generated sharps waste is to be transported only in a sharps container, as defined, or other container approved by the department

or local enforcement agency, and requires this waste to only be managed at specified locations consistent with existing law.

This bill would require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to arrange to provide, upon request from a consumer, a postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the department or a sharps container for the safe storage and transport of sharps to a sharps consolidation location approved by the department or a clinic, physician, or pharmacy that accepts home-generated sharps waste, along with concise information on ~~specified disposal~~ *safe disposal alternatives and options for sharps*.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

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

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) An estimated 1 million Californians must self-inject
- 4 prescription medications annually to treat a broad range of serious
- 5 health problems.
- 6 (b) *The use of prefilled syringes, prefilled pens, and other*
- 7 *prefilled devices with needles is an effective method of prescription*
- 8 *drug delivery and is expected to increase significantly in the future.*
- 9 *Prefilled syringes, prefilled pens, and other prefilled devices with*
- 10 *needles are clearly identified and linked to specific pharmaceutical*
- 11 *manufacturers for the provision of their product to California*
- 12 *residents.*
- 13 (c) The increased use of prefilled syringes, prefilled pens, and
- 14 other prefilled devices with needles will generate millions of
- 15 home-generated sharps each year. Prefilled pen devices are being
- 16 used for the treatment of some of the most serious health conditions
- 17 such as HIV/AIDS, hepatitis C, and many other diseases. If
- 18 improperly disposed in solid waste and recycling containers these
- 19 needles will result in significant public health risks.
- 20 (d) The Legislature has found that sharps mail-back programs
- 21 utilizing containers and packaging approved by the United States
- 22 Postal Service offer one of the most convenient means for
- 23 collecting and destroying home-generated sharps and that the

1 cooperative efforts of the pharmaceutical industry are needed to
2 develop a safe needle disposal system for California.

3 SEC. 2. Section 118288 is added to the Health and Safety Code,
4 to read:

5 118288. (a) Upon request of a consumer of a prefilled syringe,
6 prefilled pen, or other prefilled injection device administered at
7 home, a pharmaceutical manufacturer shall arrange to provide the
8 consumer with either of the following:

9 (1) A postage prepaid, mail-back sharps container that has been
10 approved by the United States Postal Service and the State
11 Department of Public Health.

12 (2) A sharps container for the safe storage of, and transport to,
13 a sharps consolidation location that is approved by the State
14 Department of Public Health or to a clinic, physician, or pharmacy
15 that accepts home-generated sharps waste. This sharps container
16 shall be provided with concise information on ~~the closest available~~
17 ~~safe sharps disposal sites~~ *safe disposal alternatives and options*
18 *for sharps.*

19 (b) For purposes of this section, “sharps container” has the same
20 meaning as in Section 117750.

(Without Reference to File)

ASSEMBLY THIRD READING
 AB 501 (Swanson)
 As Amended January 29, 2008
 Majority vote

HEALTH 9-6

Ayes:	Dymally, Bass, Berg, De Leon, Hancock, Hernandez, Jones, Lieber, Salas
Nays:	Nakanishi, Emmerson, Gaines, Huff, Ma, Strickland

SUMMARY : Requires pharmaceutical manufacturers, at the request of a consumer of specified injection devices, to provide a prepaid mail-back sharps container or a sharps container for the safe storage and transport to a sharps consolidation location or other specified locations. Specifically, this bill :

- 1) Requires pharmaceutical manufacturers, at the request of a consumer of a prefilled syringe, prefilled pen, or other refilled injection device administered at home to provide either of the following:
 - a) A prepaid mail-back sharps container that has been approved by the United States Postal Service (USPS) and the state Department of Public Health (DPH); or,
 - b) A sharps container for the safe storage of, and transport to, a sharps consolidation location that is approved by DPH or to a clinic, physician, or pharmacy that accepts home-generated sharps waste. Requires that this sharps container be provided with concise information on the closest available safe sharps disposal sites.
- 2) Defines "sharps container" to mean a rigid puncture-resistant container that, when sealed, is leak resistant and cannot be reopened without great difficulty.

□

AB 501

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- 3) Makes findings and declarations relevant to the use of injection devices and disposal means.

EXISTING LAW :

- 1) Prohibits a person from knowingly placing home-generated sharps waste in commercial and residential solid waste collection containers after September 1, 2008. Defines "home-generated sharps" as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household.
- 2) Regulates, under the Medical Waste Management Act (Act), administered by DPH, the generation, handling, storage, treatment, and disposal of medical waste.
- 3) Allows hospitals and other health facilities, pharmacies, fire stations, and existing city and county household hazardous waste programs to accept home-generated sharps for disposal.

FISCAL EFFECT : None

COMMENTS : According to the author, this bill responds to the urgent need to keep more than three billion used medical sharps out of the nation's municipal waste stream each year. Most of these used needles end up in household trash and pose a significant risk of injury and/or infection to children, sanitation workers, and solid waste employees. The author states that the Legislature has already found that sharps mail-back programs utilizing containers and packaging approved by the USPS offer one of the most convenient means for collecting and destroying home-generated sharps. Additionally, the author reports that the Legislature has declared that the pharmaceutical industry should cooperate in the development of a safe needle disposal system for California.

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

FN: 0003946

OFFICE OF THE CITY CLERK
OAKLAND

OAKLAND CITY COUNCIL

DRAFT
City Attorney

DRAFT RESOLUTION No. _____ C.M.S.
2008 MAY -1 PM 4:41

RESOLUTION IN SUPPORT OF ASSEMBLY BILL (AB) 501 (SWANSON AND HANCOCK) – “PHARMACEUTICAL DEVICES” WHICH WOULD REQUIRE PHARMACEUTICAL MANUFACTURERS TO PROVIDE SAFE DISPOSAL OPTIONS FOR HOME-GENERATED PEN NEEDLES, PRE-FILLED SYRINGES, AND OTHER INJECTION DEVICES (SHARPS) BY PROVIDING A PREPAID MAIL-BACK CONTAINER TO CONSUMER.

WHEREAS, improper management of used sharps poses a health risk to the public and solid waste workers through needle stick and injuries; and

WHEREAS, regulations governing the disposal of sharps protect solid waste and other utility workers and the general public from needle sticks and illness; and

WHEREAS, Senate Bill (SB) 372 of 1995 amended the Medical Waste Management Act to define “home-generated sharps” and to allow hospitals and other healthcare facilities to accept them from their patients; and

WHEREAS, SB 1362 of 2004 established the Safe Needle Disposal Act and allowed existing city and county household hazardous waste programs to accept sharps waste generated from homes; and

WHEREAS, SB 1305 of January 2008 amended the Medical Waste Management Act and made it unlawful for home-generated sharps to be disposed into either the municipal solid waste stream or any container used for recyclable materials; and

WHEREAS, the current available disposal option for Oakland residents to dispose of spent sharps is drop off at the Alameda County Household Hazardous Waste facility; and

WHEREAS, AB 501 would require a pharmaceutical manufacturer whose product is administered for home use through a pre-filled syringe or pen needle to provide each person who uses the product with container for the safe disposal of the used sharps; and

WHEREAS, the City of Oakland is charged with protecting the public health and welfare of its residents and workers and assumes the authority and responsibility to comply with the California Health and Safety Code Chapter 6.95 and the Oakland Municipal Code Chapter 8.12; and

WHEREAS, the City Council adopted Resolution #80390 C.M.S in 2007, to support state and local legislation that would hold manufacturers responsible for the management of post consumer waste products; and enacting AB 501 will ensure the cooperation of the pharmaceutical industry in the development of a safe needle disposal system in California; therefore be it

RESOLVED: that the City of Oakland declares its support for AB 501 (Swanson and Hancock); and be it

FURTHER RESOLVED: that the City Council hereby directs the City Administrator to advocate for enacting AB 501 with the California State Legislature.

IN COUNCIL, OAKLAND, CALIFORNIA, _____, 20____

PASSED BY THE FOLLOWING VOTE:

AYES - BROOKS, BRUNNER, CHANG, KERNIGHAN, NADEL, QUAN, REID, and
 PRESIDENT DE LA FUENTE

NOES -

ABSENT -

ABSTENTION -

ATTEST: _____
 LaTonda Simmons
 City Clerk and Clerk of the Council
 of the City of Oakland, California