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New Stewardship Responsibilities, Costs Proposed for Drug, Needle Manufacturers

by George Lauer, California Healthline Features Editor

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The question of what to do with toxic waste from the health care industry -- medications, used needles and other detritus -- is generating proposals for new county and state regulations in California, some of which place the burden on drug makers and needle manufacturers.

Two bills in the California Legislature seek statewide regulations on the proper disposal of unused drugs and disposable needles, syringes and lancets -- collectively known as "medical sharps."

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SB 727, by Sen. Hannah-Beth Jackson (D-Santa Barbara), proposes a statewide program to collect and dispose of unused prescription drugs.

AB 403, by Assembly members Mark Stone (D-Monterey Bay), and Susan Eggman (D-Stockton) proposes regulations building on the 2008 state law banning improper disposal of medical sharps.

Both introduced last year, the bills are in legislative limbo and might not survive in their current form. Sponsors of both bills plan to reintroduce legislation if these bills die.

Jackson, author of the drug "take-back" bill, said the next version of her bill would require that pharmaceutical companies cover the cost of the program, following the lead of a new ordinance in Alameda County.

"We decided the best thing to do if this version doesn't survive is to include the ordinance that Alameda County has passed," Jackson said. "The frustration is that we can't get the pharmaceutical companies to come to the table and talk to us.

"At this point, our thinking is that the bill will require manufacturers to be responsible for the cost of collecting and disposing of unused pharmaceuticals. If they want to talk about another approach, we welcome that."

In response to requests for comment for this story the Pharmaceutical Research and Manufacturers Association of America referred to an April 2013 letter to Jackson opposing her bill and a July 2012 letter to the Alameda County supervisors opposing their ordinance.

In the letter to Jackson, PhRMA Vice President Merrill Jacobs wrote:


"Placing new, considerable cost pressures onto the industry is inconsistent with the Legislature's and the manufacturers shared goal to keep the cost of medicine affordable. ... If Californians truly support a take back program for the small amount of unused medicine in residents' homes, PhRMA urges California to consider the efficiencies of administering a program as part of the local waste management system, funded by the resources provided by the people who are eligible to use the program."

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In the letter to Alameda supervisors, Ritchard Engelhardt -- vice president of BayBio, a Bay Area trade group representing biotechnology, pharmaceutical and medical device companies -- wrote:

"While your goals of preventing the abuse of prescription medicine and diversion of pharmaceutical waste into the environment are laudable, this ordinance places an onerous burden on life sciences companies, is difficult to administer, and will not achieve your goals."

Alameda's Take-Back Program at Forefront

A new drug take-back ordinance in Alameda County -- thought to be the first of its kind in the country -- survived a court challenge by the pharmaceutical industry and is now at the vanguard of a trend spreading to other cities and states around the country.

"This movement is catching on," Jackson said. "Los Angeles is likely to be introducing something similar and I've heard that New York, Chicago and Seattle are also looking into it."

The Alameda County safe drug disposal ordinance requires pharmaceutical manufacturers to fund and operate a county-wide take-back program for unused prescription drugs.

A federal court judge ruled in favor of Alameda County last summer, rejecting a lawsuit by PhRMA, the Generic Pharmaceutical Association, and the Biotechnology Industry Organization that challenged the new ordinance.

Jackson said her bill targeting drugs is part of a "larger movement to hold producers responsible for the products they produce."

"That goes for everything -- from mattresses and tires to prescription drugs," Jackson said. "There is a movement afoot to get manufacturers -- those who produce the products and make enormous profits off them -- to take some responsibility for the entire lifespan of the product."

"We've got to figure out better ways of disposing of things, better ways to end the life cycles of things," Jackson said.

Environmental, Health Hazards

The disposal of unused drugs and used medical sharps pose environmental as well as health hazards.

More than 3 billion disposable needles, syringes and lancets are disposed every year in the United States, according to the Product Stewardship Institute, a national not-for-profit coalition based in Boston.

People treating their own diabetes represent the largest block of users of disposable needles and that population is expected to increase as the disease spreads.

Every 14 minutes, someone in the U.S. dies from an unintentional drug overdose, according to the Product Stewardship Institute. Emergency department visits by children for accidental drug poisonings are twice as common as poisonings from other household products, according to the institute.

Unused medications also pose environmental risks if they make their way into water systems or landfills, where they can contaminate drinking water and harm aquatic life.

"There are costs that are hard to quantify," said Heidi Sanborn, executive director of the California Product Stewardship Council. "We're not sure about the long-term effects of pharmaceuticals getting into the water supply but that's definitely something we should be concerned about."

Stewardship Slow Coming to U.S.

"This is the last country in the industrialized world to deal with this," Sanborn said. "Most countries in Europe, Japan, Canada, Korea are already doing it and now Brazil is taking on pharmaceuticals."

"I ask these companies -- a lot of them based in California -- why it's common practice for their products to be part of stewardship programs in other parts of the world but not here. They say the American side of the house operates completely differently," Sanborn said.

Ultimately, getting pharmaceutical and medical sharp manufacturers to be financially tied to their wares for the entire lifespan of the product may lead to improvements on several levels, according to stewardship proponents.

"We're just beginning to realize that we can't continue to burden the planet with waste," Jackson said. "With new efforts like these regulations represent, I think we'll see manufacturers figure out better, more efficient, greener ways of doing things. We have to deal with these things."

Three Answers to Important Question: Who Pays?

Tom Erickson -- a member of the California Product Stewardship Council and CEO of UltiMed, a manufacturer of insulin syringes and pen needles sold in the U.S. and Canada -- is confident the way drugs and medical sharps are disposed of in this country will change. But he's not sure who will pay for it.

"The next few years will be interesting as political pressure and EPA guidelines move the 50 states to enact home use sharps collection legislation," Erickson wrote in a guest editorial for Pharmacy Times. "It's easy to predict what the most controversial issue with this new legislation will be -- who is going to pay the bill?"

Erickson said there are three working models so far:

- Pharmacies pay, as they do in Canada;
- Local governments pay as they do in a couple of cities with sharps collection programs (San Luis Obispo and Sioux Falls, S.D.); or
- Manufacturers pay.