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Drugmakers seek to block disposal rule

By Fiona Smith

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The pharmaceutical industry, hoping to stop a novel drug take-back program in Alameda County, is pinning its hopes on a decision by the 9th U.S. Circuit Court of Appeals. Drug and biotechnology companies have balked at an ordinance requiring them to manage and pay for the safe disposal of unused prescription drugs in the county. Their trade groups sued, arguing the move violates the Commerce Clause.

The stakes are potentially high in the case. It could not only affect whether states and local governments around the country can push similar measures, but a loss for the county could undermine a growing number of programs that require businesses to bear the costs of disposing of products they make, such as paint, mercury thermostats and mattresses.

The U.S. Chamber of Commerce and nonprofit California Healthcare Institute have filed briefs in support of the drug companies while Attorney General Kamala Harris, the League of California Cities and the Natural Resources Defense Council have weighed in on Alameda County's side. *Pharmaceutical Research and Manufacturers of America v. Alameda County*, 16833 (9th Cir. filed Sept. 12, 2013).

"This is the most egregious violation of the free flow of commerce that is at the heart of the Commerce Clause," said Michael A. Carvin, a Washington, D.C.-based partner with Jones Day who is leading the case for the pharmaceutical industry.

"And it will have a severe economic effect when other counties across the country inevitably decide, like Alameda, that they'll exploit out-of-state companies and interstate commerce" by shifting the costs and responsibilities of col-

lecting local waste, Carvin added.

The county could simply add a small fee onto the waste collection charges to fund drug disposal rather than force the companies to bear the cost, he said.

The ordinance, passed by the county's board of supervisors in 2012, was the first drug take-back program in the nation to require the drug makers to operate and fund it. The move comes amid an increase in prescription drug poisonings and concern that drugs are contaminating waterways and threatening human health and wildlife.

The ordinance bars companies from directly charging pharmacies or consumers for the program, but they may raise the prices of drugs sold in the county. Companies are required to submit their program plans May 1.

The industry is hoping the appeals court will reverse U.S. District Judge Richard G. Seeborg, who dismissed their suit and ruled that the ordinance is not discriminatory because it treats local and out-of-state drug companies the same.

He further found that the program served a legitimate health and safety purpose and those benefits outweighed the relatively modest compliance costs.

The overall price tag to run the disposal program will be roughly



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Arthur J. Shartsis of Shartsis Friese LLP represents Alameda County in a case currently before the 9th Circuit. Alameda passed an ordinance requiring drugmakers to pay for the safe disposal of unused drugs, prompting an industry suit.

\$1.5 million a year, according to industry estimates.

The cost is a drop in the bucket for the industry, which sold \$320 billion worth of prescription drugs in 2011 and, in 2010, sold an estimated \$965 million worth of such drugs in Alameda County alone, according to the county's court filing.

"There's been 200 years of cases saying the courts must give some deference to local governments to innovate," said Arthur J. Shartsis, name partner with Shartsis Friese LLP who is representing Alameda County in the case. "The heart of the Commerce Clause is economic protectionism and there's nothing protectionist about this provision."

Calvin R. Massey, an emeritus professor of Constitutional law at UC Hastings College of the Law, said the county has a strong case because the ordinance applies even handedly to companies regardless of their location.

The industry's other argument, that the ordinance unfairly burdens

interstate commerce by shifting all the costs from the public onto drug makers, was rejected by the Supreme Court in 2007, *Massey v. United Haulers Association v. Oneida-Herkimer Solid Waste Management Authority*, 550 U.S. 330 (2007).

The legal fight comes as State Sen. Hannah-Beth Jackson, D-Santa Barbara, has introduced legislation to create a state-wide version of Alameda County's program.

The bill, SB104, passed out of the Senate Environmental Quality Committee last week and is supported by a long list of cities, public health and environmental groups. The pharmaceutical industry, California Chamber of Commerce and other business groups oppose the bill. The fight has also spread to Washington, where the drug industry has sued Seattle's King County over a similar drug disposal ordinance it passed last year.

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