



## FDA/Environmental ADVISORY ■

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### Ninth Circuit Upholds Alameda County's Drug Take-Back Ordinance

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On September 30, 2014, the U.S. Court of Appeals for the Ninth Circuit upheld Alameda County's Safe Drug Disposal Ordinance—a first-in-the-nation pharmaceutical extended producer responsibility program. There is a growing drumbeat of support for laws that place the primary responsibility for end-of-life management of products on their manufacturers. (See our earlier advisory [here](#).) With this Ninth Circuit opinion, the floodgates are now open for similar pharmaceutical take-back initiatives in California and across the country, as well as additional extended producer responsibility laws for a vast array of consumer products.

Immediately, the pharmaceutical industry must gear up for compliance with the take-back programs in Alameda and King Counties (which has a similar ordinance). While implementation of the Alameda County ordinance commenced in May 2014, implementation of the King County ordinance was delayed by the county pending this Ninth Circuit decision.

Longer term, the pharmaceutical industry may be facing a potential growing patchwork of county and state take-back programs. Further, the Ninth Circuit's analysis could apply to extended producer responsibility laws for any number of consumer products and may encourage other take-back programs.

#### **Why Was the Ordinance Upheld?**

The Ninth Circuit unanimously held that the Safe Drug Disposal Ordinance does not violate the dormant Commerce Clause of the U.S. Constitution. In a pithy conclusion, the court summarized its decision:

The parties agree that the Alameda County Safe Drug Disposal Ordinance constitutes a "first-in-the-nation" ordinance. Opinions vary widely as to whether adoption of the Ordinance was a good idea. We leave that debate to other institutions and the public at large. We needed only to review the Ordinance and determine whether it violates the dormant Commerce Clause of the United States Constitution. We did; it does not.

To reach its conclusion, the court applied the U.S. Supreme Court's two-tiered approach to determining dormant Commerce Clause violations. See *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986). First, when determining whether the ordinance "either discriminates against or directly regulates interstate commerce," the court found that it does neither: it applies to all manufacturers that make their drugs available in Alameda County, without regard to the geographic location of the manufacturers. While the ordinance could cause manufacturers to raise the price of drugs to pay for disposal programs, the court recognized that this will increase costs for people both inside and outside of Alameda County. Further, the court found that the ordinance does not control conduct or transactions outside the county.

Second, the court applied the *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970) balancing test: whether the ordinance's burden on interstate commerce is "clearly excessive in relation to the putative local benefits." This test, as the court noted, turns on the "interstate flow of goods." The court found that the industry plaintiffs did not provide evidence that the ordinance would decrease or interrupt the flow of goods into or out of Alameda County. In other words, industry would not be prevented from selling pharmaceuticals in the county.

### **Immediate Impact**

The Alameda County Safe Drug Disposal Ordinance requires "producers" of "covered drugs" to operate take-back programs, either individually or as part of a group. In amendments issued on October 16, 2013, Alameda County narrowed the definition of "producer" to entities that either cause a prescription drug sold in Alameda County to be manufactured or own a brand under which a prescription drug is sold in Alameda County. This amendment removes wholesale distributors from the ordinance's realm of regulation. Private label distributors, which own the brand, must still comply. Producers were required to submit their stewardship plans by May 1, 2014. Failure to submit a plan by the deadline could trigger a written warning, an administrative citation and a per-day fine of up to \$1,000.

The Ninth Circuit decision also triggers implementation deadlines under the King County Secure Medicine Return Rule & Regulation. This drug take-back law is similar to Alameda County's Safe Drug Disposal Ordinance, as it requires all "producers" that manufacture covered drugs sold in King County to develop or contribute to a privately administered drug take-back program. Notably, it includes over-the-counter drugs (Alameda County's ordinance does not) in addition to prescription drugs.

For King County, producers have until November 14, 2014, to identify its stewardship plan operator and notify all retail pharmacies and law enforcement agencies in King County of its drop-off site and stewardship plan. The stewardship plan and associated fee are due on February 12, 2015.

The Ninth Circuit decision follows the Drug Enforcement Administration's release of its Secure and Responsible Drug Disposal Act regulation, which provides additional options for ultimate users to dispose of controlled substances, including the use of collection receptacles. In the wake of these regulations, the Alameda and King County drug take-back programs are expected to expand to encompass controlled substances, thereby increasing the burden on industry.

## Long-Term Impact

This Ninth Circuit decision opens the floodgates for similar extended producer responsibility initiatives in California and across the country, as well as other state laws and regulations imposing requirements on manufacturers of consumer products. In California, a statewide pharmaceutical take-back program was proposed in February 2014, S.B. 727. A national take-back law, H.R. 2939, was also introduced in the House in 2011. With inaction in Congress, supporters of a national take-back law will continue to pursue friendly state and local jurisdictions where they can continue to build a patchwork across the nation.

The Ninth Circuit decision is likely to put the wind in the sails of efforts to develop other extended producer responsibility laws for many other consumer products such as batteries, carpets, cell phones, electronics, florescent lighting, mercury thermometers, paint, pesticide containers and mattresses.

If you have any questions, please feel free to contact **Maureen Gorsen** at [Maureen.Gorsen@alston.com](mailto:Maureen.Gorsen@alston.com), **Cathy Burgess** at [Cathy.Burgess@alston.com](mailto:Cathy.Burgess@alston.com) or **Elise Paeffgen** at [Elise.Paeffgen@alston.com](mailto:Elise.Paeffgen@alston.com).

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