

**CSAC Agriculture, Environment & Natural Resources
Policy Committee Meeting**

Alameda County Safe Drug Disposal Ordinance

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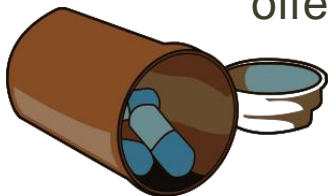
Need for An Ordinance

- Residents brought the issue of how to dispose of unused and expired drugs to Nate Miley, their local member of the Board of Supervisors.
- After community meetings and grassroots efforts to address the problems they proposed an extended producer responsibility ordinance.
- There were numerous public meetings and solicitations for input from industry and the community.



Need for An Ordinance

- Community members articulated the needs for the Ordinance including:
 - The public, particularly children and the elderly, are at significant and unnecessary risk of poisoning due to improper or careless disposal of prescription drugs and the illegal re-sale of prescription drugs.
 - Our groundwater and drinking water are being contaminated by unwanted, leftover or expired prescription drugs passing through our wastewater and treatment centers.
 - There is no mandatory statewide drug stewardship program for unwanted drugs in California, and drug manufacturers and producers have not voluntarily offered any support for a permanent collection program.




Ordinance Requirements

The Alameda County Board of Supervisors passed the Safe Drug Disposal Ordinance in July 2012, with an original compliance date of July 1, 2013.

- Producers of drugs that are sold or distributed in Alameda County must participate in a plan for the safe and legal collection and disposal of their drugs from residents when those drugs are no longer needed or wanted.
- The Product Stewardship Plan must be approved by the County Department of Environmental Health.
- Producers are required to pay all costs, without a specific point of sale fee to consumers or a point of collection fee. Drug producers are not prohibited from recouping their costs through the price for their medications.



Ordinance Requirements: Product Stewardship Plans

- Product Stewardship Plans are required to:
 - Accept all Unwanted Drugs. 
 - Provide collection services in all areas of Alameda County in a manner that is convenient to the public and adequate to meet the needs of the population.
 - Submit annual reports.
 - Pay County costs for program administration.

Ordinance Requirements: Education and Outreach

- Provide education and outreach activities in languages serving the needs of County residents. The education is to include information on:
 - The importance of promptly and properly disposing of Unwanted Drugs.
 - How to find and use Collection Points.
 - How to properly dispose of Unwanted Drugs.
 - Privacy issues, such as removing Unwanted Drugs from labeled prescription containers, which may disclose private information.



Federal Lawsuit

In December 2012 a lawsuit was filed in Federal Court claiming the Ordinance violated the dormant commerce clause of the US Constitution, by placing an unfair burden on interstate commerce.

*Pharmaceutical Research And Manufacturers Of America;
Generic Pharmaceutical Association; Biotechnology Industry Organization
v. County Of Alameda*

The plaintiffs bringing the lawsuit were trade groups:



- Pharmaceutical Research and Manufactures of America (PhRMA);
- Generic Pharmaceutical Association; and
- Biotechnology Industry Organization.

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Federal Lawsuit

- Complaint allegations included:
 - The ordinance violates the dormant commerce clause by discriminating against or burdening interstate commerce.
 - The ordinance is an attempt to shift governmental responsibilities onto interstate commerce
 - Plaintiff's members have and will incur substantial compliance costs
 - Complaint's statement of facts included: "Disposal of unused pharmaceutical in household trash is safe, convenient and effective."



Federal Trial Court Ruling

- The parties agreed to stipulate facts, and motions for Summary Judgment were filed by both sides. The case proceeded on oral argument in the Northern District in San Francisco.
- The Court issued its decision in favor of the County in August 2013, holding that the ordinance did not violate the dormant commerce clause and serves a legitimate public health and safety interest.
- The trade organizations promptly filed an appeal with the 9th Circuit Court of Appeals.



Federal Trial Court Ruling

“The Ordinance does not discriminate against out of state actors in favor of local persons or entities and does not otherwise impermissibly burden interstate commerce...”

[The County has]“adequately shown that that the ordinance serves a legitimate public health and safety interest and that the relatively modest compliance costs producers will incur should they chose to sell their products in the County do not unduly burden interstate commerce.”

Pharma v. County Of Alameda (2013)
967 F.Supp.2d 1339, 1346



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9th Circuit Court of Appeals



- The trade organizations promptly filed an appeal with the 9th Circuit Court of Appeals.
- The parties stipulated and the court agreed to an expedited briefing schedule.
- Two Amicus Curiae Briefs were filed supporting the trade associations and opposing the Ordinance:
 - Washington Legal Foundation with the California Healthcare Institute.
 - Chamber of Commerce of the United States.
- Three Amicus Curiae Briefs were filed supporting the Ordinance and the County's position:
 - California State Association of Counties with the League of California Cities (drafted by Santa Clara County Counsel's Office).
 - Natural Resource Defense Counsel.
 - The California Attorney General, Kamala D. Harris.

9th Circuit Court of Appeals

In September 2014, the 9th Circuit Court of Appeals affirmed the District Court, holding the Ordinance:

- Does not discriminate against interstate commerce as it applies to all manufacturers that make their drugs available in Alameda County, without respect to the geographical location of the manufacturer.
- Does not directly regulate commerce as it does not control conduct beyond the boundaries of the County.
- Does not indirectly regulate interstate commerce as there was no evidence presented that the Ordinance will interrupt or even decrease the flow of goods into or out of Alameda.



9th Circuit Court of Appeals

“However, there is nothing unusual or unconstitutional per se about a state or county regulating the in-state conduct of an out-of-state entity when the out-of-state entity chooses to engage the state or county through interstate commerce.”

Pharma, et al v. County Of Alameda (2014) 768 F.3d 1037, 1043.

The Court specifically explained “the fact that the county could run a similar program does not nullify the program’s benefits ... Moreover, even if the Ordinance did nothing other than save the county money, that is not equivalent to “no public benefits.”

768 F.3d 1037, 1045

The court’s decision included the following conclusion:

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.

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768 F.3d 1037, 1046





US Supreme Court

December 2014: Plaintiff's file Petition for Writ of Certiorari with US Supreme Court.

January 2015: Amicus Curiae Brief filed in support of the petition by:

- Washington Legal Foundation with the California Healthcare Institute
- Chamber of Commerce of the United States

February 2015: Court requests response from the County.

May 25, 2015: **US Supreme Court Denies Petition for Cert**
filed by trade organizations.



Implementation

- The County did not agree to stay the ordinance during litigation.
- County did agree to extend compliance date to allow time to meet and work cooperatively with pharmaceutical companies.
- Initially, over 50 pharmaceutical companies joined to create the Pharmaceutical Product Stewardship Work Group, which requested an extension to submit a plan.
- The group found a third party vendor to create and operate a Product Stewardship Plan, which by 2014 had grown to over 180 companies.
- Two plans were approved after public hearings in February 2015. One plan for an individual company and the other, the Alameda MED-Project, a large group plan that by then had over 250 producers participating.
- In response to the County sending Notice to Comply letters, the group plan has increased to over 320 companies.

Challenges

- Coordination with other legislation and legal requirements.
- Diversity and locations of producers.
- Time.
- Product expertise.
- Company education.
- Public education.



Safe Drug Disposal Ordinance

Alameda County Safe Drug Disposal
page:

<http://www.acgov.org/aceh/safedisposal/>



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