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The Alameda County Safe Drug Disposal Ordinance – Opening the Floodgates?

The first pharmaceutical extended producer responsibility law in the United States, the Alameda County Safe Drug Disposal Ordinance (the "Ordinance"), was upheld by the U.S. District Court for the Northern District of California. In ***Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda***, No. 3:12-cv-06203 (N.D. Cal., Aug. 28, 2013), the three leading pharmaceutical industry associations brought a dormant Commerce Clause challenge to the Ordinance. Judge Richard Seeborg held that the pharmaceutical take-back program required under the Ordinance is not an impermissible burden on interstate commerce. The trade associations representing drug manufacturers filed an appeal on September 12, 2013, but it is not clear whether the Ordinance will be stayed pending the appeal. If the Ordinance is upheld, it is likely to open the floodgates 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.

This litigation does not raise or resolve issues of ambiguity in the Ordinance's applicability. Thus, whether the Ordinance will be extended beyond drug manufacturers to others in the supply chain, such as importers of record and repackagers, is still an open question. Further, it is unclear when a distributor may be required to comply. Barring a stay of the Ordinance, these entities, if covered, must act quickly—either by submitting a petition for extension by September 27, or submitting a product stewardship plan by November 1.

What drugs are covered by the Ordinance?

The Ordinance applies to prescription drugs sold in Alameda County (the "County"). The Ordinance applies to "Covered Drugs," a term that is defined broadly in the Ordinance to include "all drugs as defined in 21 U.S.C. § 321(g)(l) of the Federal Food, Drug and Cosmetic Act," "including both brand name and Generic Drugs." Alameda Health and Safety Code § 6.53.030.3. However, there are multiple exemptions, including "nonprescription drugs," vitamins, supplements, soap, cosmetics and certain "[p]et pesticide products." *Id*.

Who must comply with the Ordinance?

The Ordinance requires "Producers"—entities that distribute, offer for sale or sell Covered Drugs in Alameda County—to fund and operate a product stewardship program. The primary responsible entity—i.e., the "Producer"—is a manufacturer who sells the Covered Drug in Alameda County "under that Person's own name or brand." § 6.53.030.14(i). If no entity meets that criterion, responsibility shifts to the "owner or licensee of a trademark or brand under which Covered Drug is sold or distributed in Alameda County." § 6.53.030.14(ii). Lastly, if no entity falls within the first two categories, "the Person who brings Covered Drug into Alameda County for sale or distribution" must create and maintain the drug take-back program. § 6.53.030.14(iii). A "Producer" does not include retail labelers or pharmacies. § 6.53.030.14.

This ambiguous scheme to determine whether an entity qualifies as a "Producer" may catch many companies—who assumed the ordinance applied only to pharmaceutical manufacturers—off guard. For example, it is unclear when, and if, the Ordinance will apply to distributors, importers of record and repackagers. In § 6.53.030.14(iii), quoted above, the ambiguity relates to the term "brings." What does it mean to bring the product into the county? Does this apply to the person who physically transports the product? The person who owns the product? What if drugs change hands within the secondary wholesale market before the products are sold to a pharmacy? The Ordinance triggers a duty on importers of record, distributors and repackers to understand and apply the county's qualification system to its supply chain, a task that draws heavily on legal interpretation.

How does a Producer of a Covered Drug comply with the Ordinance?

Producers must provide for the collection, transportation and disposal of unwanted Covered Drugs. Producers may fund a product stewardship program individually or by paying a stewardship organization, which may operate a program for multiple Producers. Each program must provide for the collection of drugs from Alameda County residents (for example, by providing a collection bin at a pharmacy). Programs must have promotional materials informing consumers about how to dispose of drugs at a take-back site, as well as maintain a website and toll-free call system to help consumers learn about the program and locate a take-back site. The program must accept and dispose of all drugs received, regardless of who manufactured the drugs. The drugs must be incinerated at a medical waste or hazardous waste facility, and the emissions from this destruction must be monitored. Producers are also required to reimburse Alameda County for the costs of administering the Ordinance.

More than 100 pharmaceutical companies sell prescription drugs in Alameda County. Although Producers may incur significant costs, the Ordinance prohibits Producers from charging point-of-sale or point-of-collection fees to recoup these costs. Therefore, the costs to comply with this one-county Ordinance will be passed on to pharmaceutical consumers in every jurisdiction. Although three pharmaceutical companies are headquartered or have their principal place of business in the county, and two other companies manufacture prescription drugs in the county for commercial distribution, most of the industry bearing the costs is outside of Alameda County. In short, the Ordinance's impact is far-reaching, imposing a burden across the entire pharmaceutical industry.

When must Producers comply?

Producers subject to the Ordinance must submit their product stewardship plans to Alameda County by November 1, 2013. If needed, Producers may submit a petition for an extension by September 27, 2013. Failure to submit a plan will subject Producers to enforcement, including penalties up to $1,000 per day.

Why was the Ordinance upheld?

Ruling on the parties' cross-motions for summary judgment, Judge Seeborg held that "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." In determining that the Ordinance is not a per se violation of the dormant Commerce Clause, Judge Seeborg looked to whether the Ordinance "1) directly regulates interstate commerce; 2) discriminates against interstate commerce; or 3) favors in-state economic interests over out-of-state interests," as outlined by the Ninth Circuit in ***National Collegiate Athletic Ass'n v. Miller***, 10 F.3d 633 (9th Cir. 1993). Starting with the second two "discriminatory prongs," the court assessed the plaintiffs' allegation that the Ordinance has a discriminatory effect because it deliberately shifts the costs of the compliance to Producers located outside Alameda County and their customer base nationwide. Rejecting this allegation, the court found that there was no differential treatment favoring local entities over similar out-of-state Producers.

Turning to the first prong, Judge Seeborg found that the Ordinance does not directly regulate interstate commerce. In the decision, he noted that the Ordinance applies to Producers who "elect" to sell prescription drugs in Alameda County; it does not target out-of-state Producers, or require them to alter their business practices because their products are manufactured out-of-state. Even though the effects of the Ordinance fall predominantly on out-of-state manufacturers, Judge Seeborg found it merely "happenstance" that most manufacturers are located outside of Alameda County. In sum, the Ordinance was upheld because Judge Seeborg did not find it to be an impermissible burden on interstate commerce.

The impact

The Northern District of California decision, upholding an extended producer responsibility law, may give traction to similar extended producer responsibility initiatives in California and across the country, as well as other state laws and regulations imposing requirements in consumer products. King County, Washington, is also enacting a pharmaceutical take-back program, and similar legislation could appear in counties across the country. In California, a statewide pharmaceutical take-back program was proposed in February in S.B. 727. Although it failed to advance, a pharmaceutical take-back law may now gain support in the California legislature.

California, along with Maine and Vermont, lead the country in the highest number of extended producer responsibility laws. The rapidly growing "patchwork quilt" of state extended producer responsibility laws target consumer products such as batteries, carpets, cell phones, electronics, florescent lighting, mercury thermometers, paint, pesticide containers and mattresses. These laws place the primary responsibility for end-of-life management of products on the manufacturers of the products. Complying with and managing

the patchwork quilt of varying state laws is challenging for consumer product manufacturers that sell their products nationwide. The pharmaceutical and consumer product industries must be aware of the increase in extended producer responsibility laws, track legislation carefully and develop a robust legislative strategy.

The pharmaceutical industry should work to educate municipal governments, such as Alameda County, as well as state and federal legislators, about the unintended consequence of industry-funded product take-back programs. Such programs could result in higher drug costs for patients, decreasing access for lower income patients. Further, pharmaceutical take-back programs will do little to reduce pharmaceuticals in municipal water supplies. Compelling evidence is available, from sources such as the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), that most pharmaceuticals enter water systems through municipal sewer systems when patients naturally excrete drug products. Rather than relying on consumers to "take-back" unwanted medications, efforts may be better spent improving waste water treatment systems. Such efforts could be funded by taxes or local fees paid for by the community that would benefit from improved water quality.

Finally, it is not clear whether the Ordinance applies to other entities in the pharmaceutical supply chain, such as prescription drug distributors, importers of record or repackagers. Open questions about applicability warrant further analysis.

Alston & Bird can assist entities in determining the "Producers" of Covered Drugs in their supply chains by seeking clarity from Alameda County and filing petitions for extension. Companies that are potentially affected by the Ordinance must act quickly to determine questions of applicability, and whether they must create, or band together with industry to create, product stewardship programs.

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