No. _____

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; GENERIC PHARMACEUTICAL ASSOCIATION; BIOTECHNOLOGY INDUSTRY ORGANIZATION,

Petitioners,

v.

COUNTY OF ALAMEDA, CALIFORNIA; ALAMEDA COUNTY DEPARTMENT OF ENVIRONMENTAL HEALTH,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the dormant Commerce Clause permits a local law that directly conscripts out-of-state manufacturers to enter the locality and to assume all costs and responsibility for collecting and disposing of unused medicines from local residents, for the avowed purpose of shifting the costs of this traditional government function from local taxpayers and consumers to foreign producers and consumers?

RULE 29.6 DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Petitioners the Pharmaceutical Research and Manufacturers of America, the Genetic Pharmaceutical Association, and the Biotechnology Industry Organization disclose that they are nonprofit corporations without publicly traded stock or parent corporations.

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OPINIONS BELOW

The opinion of the court of appeals (Pet.App.1a–17a) is reported at 768 F.3d 1037. The opinion of the district court (Pet.App.18a–32a) is reported at 967 F. Supp. 2d 1339.

JURISDICTION

The court of appeals entered its judgment on September 30, 2014. This Court has jurisdiction under 28 U.S.C. § 1254(1). The Ninth Circuit had jurisdiction under 28 U.S.C. §§ 1291 and 1331.

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

The Commerce Clause of the United States Constitution, U.S. Const. art. I, sec. 8, cl. 3, provides:

> The Congress shall have the power *** [t]o regulate Commerce *** among the several States[.]

The Alameda County Safe Drug Disposal Ordinance (codified at Alameda County Health and Safety Code § 6.53.010 *et seq.*) is reproduced in the appendix to this petition. Pet.App.33a-58a.

STATEMENT OF THE CASE

A. Regulatory Background

In July 2012, Alameda County enacted the "Safe Drug Disposal Ordinance." Pet.App.33a-58a. The Ordinance applies to any company located anywhere in the world that owns the brand or trademark of any prescription pharmaceutical that, as the result of normal operation of interstate commerce, is sold or distributed in Alameda County. Companies subject to the ordinance need not have any other presence in or connection to the County. The Ordinance requires

companies to establish, fund, and operate a local "take-back" program to collect and dispose of any and all unused prescription medicines. In addition, the Ordinance expressly prohibits the companies from charging any local fee to recoup the costs. It also exempts local pharmacies from any financial or programmatic responsibilities under the program. Thus, the Ordinance shifts the burden of funding and administering a program solely benefitting local interests onto interstate producers (and, by extension, out-of-state consumers), ensuring that the brunt of the cost falls on outsiders instead of local residents.

1. Before enacting the Ordinance, Alameda operated its own "take-back" program to collect and dispose of pharmaceuticals. The program was funded by local taxpayers and included over two-dozen collection sites. As the costs of the program began to mount, however, the County began exploring ways to limit the cost to locals.

The Ordinance's principal sponsor aptly summarized its purpose: the only thing "wrong" with the preexisting, "publicly-funded [collection] program," he stated, was "that the taxpayers pay for it." Pet.App.97a. Accordingly, almost every comment introduced by the Ordinance's sponsors emphasized that it would shift costs away from local taxpayers. Alameda's Health Care Services Agency stated that "[t]he safe disposal of pharmaceuticals should be considered a societal need for which the cost to provide should not fall to local government." Pet.App.94a-95a. One sanitary district opined that "[t]he burden of cost should not fall on local agencies or the ratepayers." Pet.App.72a. Another stated that

"[l]ocal governments, such as ours, *** should not bear the cost of their collection and proper disposal nor should our ratepayers." Pet.App.76a. And a local environmental group asserted that "the costs of [safe disposal] should not fall on local government." Pet.App.74a.

The same sentiments were echoed in legislative sessions. Alameda's Department of Environmental Health noted that existing collection sites were "paid for by taxpayers' or ratepayers' money," and argued that "the cost shouldn't fall on local government." *See* Recording of Alameda County Board Session of February 28, 2012, at 11:35–12:45, *available at*, http://www.acgov.org/board/broadcast.htm. The local Waste Management Authority concurred, stating "the cost of the safe disposal for pharmaceuticals should not fall on local government." *Id.* at 19:55–20:10.

2. Consistent with its avowed purpose, the Ordinance's practical effect is to ensure that outsiders bear almost all of the costs of disposing of Alameda's unused pharmaceuticals.

The Ordinance requires any "Producer" of "Covered Drugs" to fund and operate programs to "collect, transport, and dispose of" all such drugs within Alameda County. *See* §§6.53.040(A), 6.53.030(15). The term "Producer" is defined in three parts. First, it includes all entities that manufacture and distribute prescription pharmaceuticals in Alameda County "under that Person's own name or brand." *Id.* §6.53.030.14(i); *see also id.* §6.53.030.3 (exempting "nonprescription drugs"). This definition rarely applies because manufacturers typically sell to interstate third-party distributors instead of distributing themselves directly in Alameda. Second,

if no person falls within the first criterion, the term "Producer" includes the "owner or licensee of a trademark or brand under which the [prescription medicine] *is sold or distributed in* Alameda County" by *any* person. Ordinance §6.53.030.14(ii) (emphasis added). Third, if there is no entity who falls within either of the first two criteria, then "Producer" includes "the Person who brings the [prescription medicine] into Alameda County for sale or distribution." *Id.* §6.53.030.14(iii).

The Ordinance forces "Producers" to fund and operate one of two types of local "take-back" program in Alameda. *Id.* §6.53.040A.1. First is a program run by an individual Producer. Second is a "stewardship organization" formed and jointly funded by a group of Producers. *Id.* §6.53.040A.2.

Every Producer's collection program must accept and dispose of all prescription medicines, no matter who manufactured them, unless excused from that obligation by the Alameda Department of Environmental Health. *Id.* §6.53.050.A.1. In addition, kiosks specifically designed to collect controlled substances must be provided if a County law-enforcement agency agrees to provide space. *Id.* §6.53.050.A.11. Although the Ordinance does not require Producers to collect over-the-counter medicines, in practice it leaves them no way to avoid doing so. Indeed, in one recent study of pharmaceutical take-back programs in the San Francisco Bay area, 35 percent of deposits were over-the-counter medicines and nutritional supplements. *See* Telosis Institute, Bay Area Medication Disposal Study 2009, at 22, *available at*

http://www.teleosis.org/wp-content/uploads/2012/02/BAMedicationDisposalReport_PRINT.pdf.

The Ordinance contains two provisions designed to insulate local consumers and businesses from the costs that Producers must incur. First, the Ordinance prohibits any "specific point-of-sale fee to consumers to recoup the costs" of establishing or operating a mandated program. §6.53.040.B.3. And second, the Ordinance exempts local pharmacies from bearing any costs or programmatic responsibilities. *Id.* §6.53.030.14. The Ordinance thus ensures that *local* businesses that sell and profit from prescription medicines are left unburdened.

Producers who refuse to establish a local take-back program are prohibited from having their covered drugs sold within the County, subject to daily penalties of $1,000 per violation. §6.53.110(D). Knowing and willful violations are criminal misdemeanors punishable by additional fines and six months in jail. §6.53.110(M).

Petitioners' members include approximately 100 Producers subject to the Ordinance. Three have their headquarters or principal place of business in Alameda, and another two have facilities that produce drugs in Alameda for commercial distribution. Drugs produced in these facilities are shipped to interstate distributors before being distributed back into the County.

Petitioners do not dispute Alameda's right to operate a take-back program, and indeed the parties have stipulated that having a take-back program provides "health and safety benefits" for the County's residents. Pet.App.69a. Petitioners contend only that Alameda has adopted an impermissible means of

financing and implementing its program: "the County violates the Commerce Clause by requiring interstate drug manufacturers to conduct and pay for such programs," Pet.App.69a, thereby shifting the costs of local regulation onto the interstate market.

B. The Proceedings Below

Petitioners brought the present action in the United States District Court for the Northern District of California pursuant to 28 U.S.C. § 2201 and 42 U.S.C. § 1983 seeking declaratory and other relief. Upon joint factual stipulations, the parties filed cross-motions for summary judgment.

The district court denied Petitioners' motion and granted summary judgment to Alameda County. Petitioners timely appealed, and on September 30, 2014, the Ninth Circuit affirmed. The Court held that the Ordinance is not "per se" invalid because it does not "discriminate[] against or directly regulate[] interstate commerce." Pet.App.7a. The court reasoned that the Ordinance is not discriminatory because it "treats all private companies exactly the same," Pet.App.8a, and because "the cost of running the disposal program has not been *entirely* shifted outside of the county," since a small fraction of the cost *also* falls on local consumers and pharmaceutical companies, Pet.App.10a (emphasis added). The court held that the Ordinance does not "directly regulate" interstate commerce because it only applies to Producers whose products are sold or distributed in Alameda County, and it does not force producers to operate take-back programs "in any location or jurisdiction outside of Alameda County." Pet.App.11a. In the court's view, there is no meaningful "distinction" between regulating products

found within the local jurisdiction and directly imposing "affirmative obligation[s]" on outside producers to establish local operations to benefit local interests. Pet.App.13a.

The court next turned to the "*Pike* balancing test," and asked whether "the burden the Ordinance imposes on interstate commerce is 'clearly excessive in relation to the putative local benefits.'" Pet.App.14a (citation omitted). The court first held that the Ordinance does not "substantially burden[]" interstate commerce because it will not disrupt the "flow of goods" into Alameda since, "assuming the manufacturers comply with the Ordinance, they can continue to sell pharmaceutical drugs in Alameda." Pet.App.15a. The court further held that shifting regulatory costs to out-of-state producers and consumers constitutes a legitimate public benefit, stating that "even if the Ordinance did nothing other than save the county money" by shifting costs onto outsiders, "that is not equivalent to 'no public benefits.'" Pet.App.16a (citation omitted).

REASONS FOR GRANTING THE PETITION

In the decision below, the Ninth Circuit upheld a local ordinance with the avowed purpose and effect of requiring interstate companies to enter the County and perform a traditional function of local government for the exclusive benefit of the local community, precisely in order to shift the costs away from local taxpayers and consumers.

Specifically, Alameda wanted to continue a pharmaceutical take-back program to provide health and environmental benefits for its residents, but it did not want its "taxpayers" to pay for that program through the traditional means of general taxes or

point-of-sale fees. Pet.App.97a. Because Alameda knew that it could not directly use a tariff to shift the tax burden for local programs onto the interstate market, it decided instead to adopt the functional equivalent: Rather than imposing a tariff on foreign companies' products to *fund* its local take-back program, Alameda decided to conscript foreign companies to directly *conduct* its local take-back program for free. To further ensure that local residents do not bear any of the costs, the Ordinance flatly prohibits any "specific point-of-sale fee to consumers to recoup the costs" of the take-back program. §6.53.040.B.3. And to spare local businesses, the Ordinance exempts local pharmacies from any financial or programmatic responsibilities. *Id.* §6.53.030.14. Accordingly, the Ordinance's cost-shifting is actually worse than a tariff because, unlike a tariff, the increased costs are not borne "primarily by local consumers," *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 203 (1994), but by *non-local* consumers, and interstate producers are not only burdened financially, but are forced to engage in a new business in a new location—disposal of unused medicines in Alameda.

Indeed, by opting for the Ordinance's avowed cost-shifting, the County effectively eschewed a constitutionally permissible way of financing its local take-back program. Were the County to impose a point-of-sale fee on the sale of prescription medicines to finance its take-back program, the resulting locally-financed program would neither shift local regulatory costs to outsiders nor conscript outside manufacturers to enter Alameda and operate a take-back program. Obviously the County rejected this constitutionally permissible alternative because it did

not serve its goal of having outsiders pay for its local program.

Nonetheless, the Ninth Circuit upheld the Ordinance because it believed local jurisdictions are free to directly impose "affirmative obligations" on outside companies to perform local government functions for the avowed goal of "shift[ing] [the] costs of [the regulation] away from the county," even though the law does not further any "legitimate interest whatsoever." Pet.App.12a,15a. Consequently, under the Ninth Circuit's specific holding, out-of-state producers of *any* product may be "affirmatively obligated" to enter *every* county where their product is sold to dispose of the product once a consumer elects not to use it. This means that virtually *all* interstate manufacturers can be converted into local collectors of unused products at the whim of local government: Municipalities across the country can conscript non-resident newspaper publishers to operate local paper-recycling centers; require automotive manufacturers to establish local scrap-metal depositories; or force brewers and vintners to establish local glass-recycling facilities.

Indeed, the Ninth Circuit's decision contains no limiting principle and affirmatively authorizes all localities to condition entry of interstate products into the local market on having interstate producers perform *any* task, no matter how unrelated to the products they sell. It is difficult to even hypothesize a rule granting local governments greater license to exploit the interstate market for purely local economic benefit. Under the Ninth Circuit's logic, not only could outside energy companies be dragooned to manage local air-pollution control systems, or

alcoholic-beverage producers be forced to establish local clinics to treat alcoholism—they could be conscripted to perform *any* local service that the local government desires, thus transferring local public-service costs from local taxpayers and consumers to outsiders who derive no benefit from the conscripted service.

The Ninth Circuit's unqualified endorsement of local laws requiring interstate producers to enter the locality, to perform an uncompensated local public service at the expense of the interstate market, sharply conflicts with this Court's precedent. It violates both the specific precedent forbidding laws requiring interstate actors to establish operations in the local jurisdiction, and the general precedent forbidding laws that attach conditions to the sale of products in order to secure a local economic advantage at the expense of outsiders. While the dormant Commerce Clause provides states with broad leeway to regulate interstate *products* to *protect* local residents, it imposes a virtually *per se* prohibition against leveraging the local presence of products to coerce interstate *producers* to *enrich* local residents at the expense of non-local businesses and consumers.

Although no previous case has presented the precise factual situation here, that is only because no local government has ever before engaged in such obvious rent-seeking against the interstate market. And waiting for another Circuit to strike down a take-back program replicating the specific facts here would countenance just the economic Balkanization that the Commerce Clause was designed to forestall. Already, a State Senator in California has sent a

letter to every county in the State informing them of the decision below and urging them to adopt programs comparable to Alameda's.[1] The City of San Francisco is considering legislation to do so,[2] and both Sonoma County and Turlock City have taken preliminary steps in considering the adoption of comparable ordinances. King County, Washington, has already adopted a similar ordinance,[3] and other jurisdictions in California and Washington will undoubtedly follow suit with other such measures, which will be unassailable under the decision below.

Nor will this effort to dragoon out-of-state actors into local jurisdictions to provide services to local residents be confined to pharmaceutical products. The sole mission of the California Product Stewardship Council (CPSC), a group at the heart of the lobbying effort to pass the Alameda Ordinance, is to ensure that "Producers have the primary responsibility to establish, fund, and manage end of life systems for their products with state government setting performance goals."[4] The CPSC hailed the

[1] *See* Sen. Hannah-Beth Jackson, Letter to Contra Costa County Board of Supervisors (Oct. 30, 2014), *available at* http://cchealth.org/hazmat/hmc/pdf/2014-1114-Letter-from-Senator-Jackson.pdf.

[2] CBS News, "San Francisco Looks To Require Pharmaceutical Companies To Fund Drug Take-Back Program," Oct. 21, 2014, *available at* http://sanfrancisco.cbslocal.com/2014/10/21/san-francisco-looks-to-require-pharmaceutical-companies-to-fund-drug-take-back-program-prescription-drugs-david-chiu-9th-circuit-court-of-appeals.

[3] *See* King County, Washington, "Secure Medicine Return Rule & Regulation," *available at* http://www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx.

[4] *See* CPSC, "Vision for Materials Management in California" *available at* http://www.calpsc.org/about-cpsc.

decision below as a "landmark victory" for extended producer responsibility and is pressing for programs comparable to the Alameda pharmaceutical take-back program for medical sharps, paint, and batteries.[5]

There is no reason to think that other jurisdictions in the Nation will not follow suit, as localities have every incentive to favor their own residents by shifting regulatory costs onto the interstate market. The resulting threat of a tit-for-tat trade war makes the Ordinance exactly the type of Balkanizing measure that threatens to "excite those jealousies and retaliatory measures the Constitution was designed to prevent." *C&A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 390 (1994).

Thus, if the decision below is allowed to stand, the proscribed Balkanization will be encouraged and become entrenched before another Circuit invalidates a law precisely replicating the Ordinance. For this reason, this Court has frequently granted certiorari without any circuit split to review laws that conflict with this Court's dormant Commerce Clause precedent. *See, e.g., Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564 (1997); *Fort Gratiot Sanitary Landfill, Inc. v. Mich. Dep't of Natural Res.*, 504 U.S. 353 (1992); *Quill Corp. v. North Dakota*, 504 U.S. 298, 301 (1992).

Review is particularly warranted here because the decision below *does* conflict with other circuits' decisions striking down laws requiring producers to establish a local presence, albeit in somewhat

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[5]*See* California Product Stewardship Council, Newsletter (Nov. 10, 2014), *available at* http://www.calpsc.org/join-cpsc/newsletter-2013.

different factual settings. There is thus a division among the lower courts about whether localities may compel interstate producers to perform a local activity to benefit local interests at the expense of the interstate market. Alameda's Ordinance would be invalidated in all of these other circuits under that binding precedent.

I. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S PRECEDENT AND INFLICTS SERIOUS DAMAGE ON INTERSTATE COMMERCE

The Commerce Clause gives Congress plenary authority to "regulate commerce *** among the several states." U.S. Const. art. I, § 8. It is well settled that this grant of authority contains a "negative" aspect, the dormant Commerce Clause, which "'by its own force prohibits certain state actions that interfere with interstate commerce." *Quill Corp.*, 504 U.S. at 309 (quoting *S.C. State Highway Dep't v. Barnwell Bros., Inc.*, 303 U.S. 177, 185 (1938)).[6]

The fundamental objective of the dormant Commerce Clause is to "preserv[e] a national market for competition undisturbed by preferential advantages conferred by a State upon its residents or resident competitors." *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 299 (1997). Accordingly, "State regulations affecting interstate commerce, whose purpose or effect is to gain for those within the state an advantage at the expense of those without *** impinge upon the constitutional prohibition even

[6] This principle applies equally to local governments like Alameda County. *See Carbone*, 511 U.S. at 394; *Fort Gratiot*, 504 U.S. at 361.

though Congress has not acted." *Barnwell Bros.*, 303 U.S. at 184 n.2.

A. The Ordinance Is a *Per Se* Violation of the Dormant Commerce Clause

This Court has made clear that it is a "virtually *per se*" violation of the dormant Commerce Clause when local laws "directly regulate interstate commerce" or have the "practical effect" of burdening interstate commerce in order to "favor in-state economic interests over out-of-state interests." *Oregon Waste Sys., Inc. v. Dep't of Envtl. Quality of Or.*, 511 U.S. 93, 99 (1994); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986). In contrast, where the local "statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental," it will be analyzed under a far more deferential standard. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). Thus, the critical question in dormant Commerce Clause cases is whether the local regulation constitutes a neutral exercise of legitimate local power to protect local residents against harmful or deceptive interstate practices or products, or whether it is an effort "to gain for those within the [locality] an advantage at the expense of those without." *Barnwell Bros.*, 303 U.S. at 184 n.2.

> This distinction between the power of the State to shelter its people from menaces to their health or safety and from fraud, even when those dangers emanate from interstate commerce, and its lack of power to retard, burden or constrict the flow of such commerce for their economic

> advantage, is one deeply rooted in both our history and our law.

West Lynn Creamery, 512 U.S. at 206 n.21 (1994)(quoting *H. P. Hood & Sons, Inc. v. DuMond*, 336 U.S. 525, 533 (1949)).

States have principal regulatory authority to protect their residents from dangers or difficulties caused by consumer products, notwithstanding any incidental effect on the cost of products brought in through interstate channels. Indeed, such legitimate police-power regulation may even affect the conduct that manufacturers engage in out-of-state, if they need to change their production processes to satisfy local safety or consumer-protection standards. *See, e.g., Kassel v. Consol. Freightways Corp. of Del.*, 450 U.S. 662, 670 (1981) (plurality opinion); *Ass'n des Eleveurs de Canards et D'oies du Quebec v. Harris*, 729 F.3d 937, 941 (9th Cir. 2013), certiorari denied 2014 U.S. LEXIS 6979 (U.S. Oct. 14, 2014) (upholding California's ban on gavage-based foie gras); *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070 (9th Cir. 2013), certiorari denied 134 S. Ct. 2884 (2014) (upholding California's low-carbon fuel standard). This is generally permissible because the Commerce Clause's grant of plenary power to the federal government over interstate commerce did not divest states of their traditional sovereign power to protect local residents against harmful or immoral products, even if those products are delivered from out-of-state. That being so, the Court will, as noted, provide the "States *** great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons." *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid*

Waste Mgmt. Auth., 550 U.S. 330, 342-43 (2007) (citation omitted). Conversely, laws that seek "economic advantage" from interstate producers, rather than protection of local residents against harmful products, "directly" burden and regulate those foreign producers and interstate commerce, and therefore "extend the town's police power beyond its jurisdictional bounds," by regulating in a sphere where the federal government is given "plenary" control. *Carbone,* 511 U.S. at 393; *Oregon Waste*, 511 U.S. at 98.

1. The key question, then, is whether the challenged regulation has the purpose and "practical effect" of regulating a *product* to prevent harmful effects within the jurisdiction. *Carbone*, 511 U.S. at 394. If so, it generally will be tolerated as a legitimate exercise of the police power, even if it has an "incidental" or "indirect" effect on the free flow of commerce. *Pike*, 397 U.S. at 142-43. Conversely, if the local law does not regulate the product to preclude harmful effects, but "*attach[es] restrictions*" to the sale of the product in order to coerce foreign *producers* to take action that *financially* benefits the local jurisdiction, that is *per se* impermissible. *Carbone*, 511 U.S. at 393 (emphasis added); *Brown-Forman*, 476 U.S. at 579 ("[W]hen [a law's] effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry.").

When a local government requires an interstate producer to take action to directly benefit the local community as a condition of entry into the local market, the "practical effect" of the regulation is not to protect local residents, but to exploit the presence

of the product to extract rents from the interstate market. *Maine v. Taylor*, 477 U.S. 131, 138 (1986). As a jurisdictional matter, the burden on interstate commerce is not the "incidental" or "indirect" result of the state's exercise of its traditional authority to ensure safe and non-deceptive products, but is necessarily an impermissibly "direct" and intentional effort to regulate and burden interstate commerce, which falls exclusively within the federal bailiwick. As an economic matter, efforts to secure local advantage by conditioning the local sale of interstate products on having the interstate producer provide money or valuable services to the local community create all of the paradigmatic distortions of the interstate market that the dormant Commerce Clause was designed to prevent.

First, such local regulation distorts the flow of interstate goods by redirecting resources to the local jurisdiction and imposing costs on the interstate market. So "constrict[ing] the flow of [interstate] commerce for [local] economic advantage" is the quintessential problem that the Clause was designed to prevent. *D. H. Holmes Co. v. McNamara*, 486 U.S. 24, 29-30 (1988).

Second, where, as here, conditions are attached to the sale of interstate products in order to reduce the cost of public services that locals would otherwise bear, this plainly constitutes "local legislation that discriminates in favor of local interests." *Carbone*, 511 U.S. at 393. Indeed, requiring interstate actors to shoulder the costs and responsibilities of traditional local regulatory functions—such as unused-product disposal—is particularly pernicious local favoritism because it "shifts the costs of regulation" away from

local taxpayers to producers and consumers in "other States." *United Haulers*, 550 U.S. at 345. This cost-shifting not only has the deleterious economic effect of forcing the interstate market to absorb the costs of regulation that benefits only one locality, but requires especially vigorous scrutiny because, "when the burden of state regulation falls on interests outside the state, it is unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected." *Id.* (citation omitted). *See also* Laurence H. Tribe, American Constitutional Law 105 (3d ed. 2000) (noting "the recognition implicit in the Commerce Clause that state and local lawmakers are especially susceptible to pressures that may lead them to make decisions harmful to the commercial and other interests of those who are not constituents of their political subdivisions").

Third, local policies that coerce interstate actors to assume the costs of local public services are the worst form of local favoritism because they have the same distorting effect as the "paradigmatic Commerce Clause violation"—the "tariff." *West Lynn Creamery*, 512 U.S. at 203. In both cases, the local law shifts the financial burden for local services from local taxpayers to the interstate market. For this reason, the Court's precedent clearly prohibits taxes on interstate products that, "in practical effect," "pass an unfair share of the tax burden onto interstate commerce" by imposing taxes that are not "fair[ly] apportion[ed]" to the interstate actor's connection to the taxing jurisdiction. *Quill*, 504 U.S. at 313; *see also Complete Auto Transit Inc. v. Brady*, 430 U.S. 274, 279 (1977).

2. The most obvious application of these principles has been the Court's consistent condemnation, as "virtually *per se* illegal," of any effort to condition the production or sale of products on having the producer establish "business operations *** in the home State." *Pike*, 397 U.S. at 145. Since such local-presence requirements are forbidden "[e]ven where the State is pursuing a clearly legitimate local interest," *id.*, they are clearly prohibited where the State seeks economic advantage for its residents at the expense of outsiders.

In the paradigmatic local-presence case, a locality imposes a condition on local sales or production, requiring companies either to establish a local operation or to contract with a local company to perform the mandated service. *See, e.g.*, *Carbone*, 511 U.S. at 387-88; *Dean Milk Co. v. City of Madison*, 340 U.S. 349, 350-51 (1951); *Pike*, 397 U.S. at 145. Localities typically try to justify these requirements as a way to reduce regulatory costs, because it is more "convenient [and] economical" to regulate companies located within the jurisdiction. *Dean Milk*, 340 U.S. at 352. But this Court has nonetheless consistently struck down such requirements because they epitomize the jurisdictional and economic harms most directly prohibited by the dormant Commerce Clause. *See, e.g., Carbone*, 511 U.S. 383 (invalidating law requiring waste to be processed at local facility); *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82 (1984) (invalidating regulation requiring timber to be processed in-state prior to export); *Pike*, 397 U.S. 137 (invalidating law requiring Arizona-grown cantaloupes to be packed in Arizona); *Dean Milk*, 340 U.S. 349 (invalidating law requiring all milk sold in Madison to be pasteurized within 5 miles

of city center); *Toomer v. Witsell*, 334 U.S. 385, 403-06 (1948) (invalidating law requiring South Carolina fishing boats to dock, unload, pack, and stamp their catch at a South Carolina port); *Foster-Fountain Packing Co. v. Haydel*, 278 U.S. 1 (1928) (invalidating Louisiana law prohibiting shrimp export unless heads and hulls had first been removed in-state); *Johnson v. Haydel*, 278 U.S. 16 (1928) (invalidating similar Louisiana oyster laws); *Minnesota v. Barber*, 136 U.S. 313 (1890) (invalidating requirement that meat be sold in-state and examined by state inspector).

Local-presence requirements commit the cardinal jurisdictional sin of directly regulating interstate commerce: By conditioning permission for local sales or business activity on agreement to engage in a related local service (or to contract with a local company to perform that service), these laws seek to directly regulate interstate companies' most basic business decisions—where to locate and with whom to contract—that are largely made "wholly outside" the jurisdiction. *Brown-Forman*, 476 U.S. at 582. Even though the local activities that the companies are required to perform serve important environmental and health purposes—such as recycling waste or pasteurizing milk—requiring that companies enter the local market to perform these services for local economic advantage is not a legitimate police-power purpose. It is instead impermissible "discrimination against interstate commerce" that has the "effect" of "favor[ing] in-state economic interests over out-of-state interests." *Id.* at 579. Local-presence requirements also produce the economic harms of Balkanizing the national market by coercing the flow of commerce into the enacting

jurisdiction, increasing the cost of interstate products, and burdening interstate commerce out of all proportion to the interstate companies' interaction with the local jurisdiction. *Complete Auto*, 430 U.S. at 279; *see also Toomer*, 334 U.S. at 403-04 ("[T]he necessary tendency of the statute is to impose an artificial rigidity on the economic pattern of the industry.").

3. Accordingly, it is crystal clear that a local government may not condition sales of milk in its jurisdiction on having the dairy farmer contract with a local milk pasteurizer—or, even more obviously, on having the dairy farmer establish its own local pasteurizing facility. *A fortiori*, a local jurisdiction may not condition milk sales on having the dairy farmer establish a local *recycling* facility to dispose of milk bottles. Yet this is precisely what the Alameda Ordinance does: Any "Producer" whose "Covered Drug" is sold or distributed in Alameda County *by any person* must operate and fund a local take-back program to "collect, transport, and dispose of" unused prescription drugs in the County. *See* Alameda County, Cal., Health & Safety Code §§ 6.53.040(A), 6.53.030(15). It is undisputed that *all* of the drugs triggering the Ordinance's requirements arrive from outside Alameda through interstate channels and virtually all of the covered drugs are distributed to Alameda by independent interstate distributors and wholesalers. Thus, the Ordinance principally regulates Producers whose sole connection with Alameda is that their drug has been brought into and sold in Alameda by others. Indeed, many of the affected Producers have no physical presence in Alameda County, which means they (or their "agent") must establish a physical presence in the County to

conduct and operate the local program. Even the few companies that already have *some* presence in Alameda must establish a different presence and enter the entirely new business of collecting and disposing of unused medicines.

The Ordinance's avowed purpose and effect is to shift costs from Alameda taxpayers and consumers to interstate producers and consumers. The express reason for altering Alameda's extant County-run take-back program, and eschewing the traditional method of financing such a program through local sales taxes or point-of-sale fees paid by Alameda residents, was the County's desire to have interstate producers, rather than "taxpayers," pay for (and conduct) the program. *See supra* 2–5.

To avoid any possibility of locals paying for the take-back program, the Ordinance expressly prohibits any "specific point-of-sale fee to consumers to recoup the costs" of the mandated program. Code § 6.53.040.B.3. In addition, the Ordinance exempts local pharmacies from any financial or programmatic responsibilities, thereby ensuring that none of the program's obligations or costs will fall on local businesses that *sell* medicines, but only on those (mostly non-locals) who *produce* them. § 6.53.030.14.

Conversely, the Ordinance does not even purport to be an effort to regulate products to make them safer or better, which can have the incidental effect of altering out-of-state production or labeling practices. To the contrary, the Ordinance acknowledges that Petitioners' products enable Alameda's citizens to "live longer, healthier, and more productive lives." § 6.53.010(A). Rather, the Ordinance seeks to impose a new affirmative responsibility on Producers, by

transferring to them the traditional government responsibility of ameliorating "improper or careless disposal" by Alameda residents. § 6.63.010(B).

4. To be sure, the particular *form* of local favoritism in the Ordinance differs from that in most of this Court's precedents, which is hardly surprising since it is a "first-in-the-nation" effort to directly conscript interstate manufacturers to dispose of unused products. Pet.App.16a. In a typical case, the local-presence requirement is imposed to aid local *companies* in their profit-making endeavors. Here, the Ordinance conscripts interstate companies to establish a physical presence in Alameda to provide free public services that are normally provided by local government (and which the County currently provides), in order to benefit Alameda's *residents, taxpayers, and budget*. But, contrary to the court below, this difference hardly ameliorates the Commerce Clause violation—laws designed to directly benefit *local taxpayers* at the expense of outsiders are no more defensible than laws favoring local *companies*. The fundamental concern is with "preferential advantages conferred by a State upon its residents *or* resident competitors." *Gen. Motors Corp.*, 519 U.S. at 299 (emphasis added). Conscripting interstate producers to ease the burden of local *taxpayers* plainly "favor[s] in-state economic interests over out-of-state interests," *Brown-Forman*, 476 U.S. at 579, and is an effort "to gain for those within the [locality] an advantage at the expense of those without." *Barnwell Bros.*, 303 U.S. at 184 n.2. Rather than locals paying for a program that benefits them exclusively, the cost is shifted to outside producers and, consequently, outside consumers.

Whatever the specific motive underlying a local-presence requirement, the "practical effect and design," *Carbone,* 511 U.S. at 394, is geographic Balkanization and discrimination: It coerces interstate commercial actors to deploy their resources and/or personnel in the enacting jurisdiction, even though they would otherwise be spent elsewhere in a "national market free from local legislation that discriminates in favor of local interests." *Id.* at 393. The dormant Commerce Clause evil is that the local government is leveraging the presence of an interstate product to compel interstate producers to enter the local jurisdiction, which exceeds the jurisdictional bounds of the police power and distorts the interstate market by coercing outsiders to provide local benefits.

The same evil of cost-shifting exists regardless of whether the interstate market is being exploited for the benefit of local *companies* or local *taxpayers*. If the motive is to benefit local companies, out-of-state producers are harmed because they must contract with local entities instead of potentially less expensive outsiders. If, as here, the motive underlying the compelled local presence is to have the interstate company bear the costs and responsibilities of performing local public services, this harms foreign producers and consumers by shifting the cost of regulation from the local taxpayers (who benefit from the service) to those outside the county (who derive none of the benefit).

Either way, out-of-jurisdiction entities are burdened to benefit local interests. And exploiting the interstate market to reduce the local *tax burden* is just as improper as benefitting local *companies*.

Consequently, a local-presence law's "burden upon interstate commerce is unconstitutional even in the absence of *** a purpose" "to preserve or secure employment for the home State." *Pike*, 397 U.S. at 145. Indeed, in *Carbone*, the "candid" and "admit[ted]" reason for requiring local waste processors to contract with the designated recycling facility was to alleviate local residents' obligation to "subsidize the facility through general taxes or municipal bonds." 511 U.S. at 393-94. Even the dissenters agreed that a law would be impermissible if designed to "transfe[r] [the] cost [of local waste processing] to out-of-state economic interests." *Id.* at 411 (Souter, J., dissenting).

More fundamentally, as noted, regulating the interstate market to enhance the local public fisc is the *worst* kind of local favoritism because the basic problem that the "Framers intended the Commerce Clause as a cure" was precisely the local "taxes and duties which hindered and suppressed interstate commerce" to reduce local tax burdens. *Quill*, 504 U.S. at 312. That is why the *Complete Auto* line of cases prohibits disproportionate taxation of interstate products. *Complete Auto*, 430 U.S. at 279. Since the dormant Commerce Clause prohibits shifting the costs of local public services to interstate producers through disproportionate taxation, it *a fortiori* prohibits cost-shifting through the more direct and draconian means of requiring producers to enter the jurisdiction and *affirmatively conduct* local public services. Indeed, this tax precedent establishes that outside companies cannot be forced to even collect *local sales taxes*, *Quill*, 504 U.S. at 313, much less collect their products after consumers discard them.

B. The Ninth Circuit's Ruling Cannot Be Squared With This Court's Precedents

The clear precedent described above establishes that the virtually dispositive threshold question is whether the challenged law regulates in-state products for the legitimate purpose of protecting local residents or, rather, imposes conditions on the sale of the products to affirmatively oblige producers to provide the locality with an economic advantage, thus impermissibly shifting costs to interstate producers and consumers. The decision below serially violates this precedent by holding that (1) it is irrelevant whether the law serves the legitimate purpose of regulating interstate products within the jurisdiction or any "legitimate interest whatsoever"; (2) there is no difference between legitimate efforts to regulate in-state conduct and imposing "affirmative obligations" to engage in new in-state conduct, and (3) imposing such "affirmative obligations" on interstate producers solely to "shift[] the cost of Alameda's disposal responsibility and local government programs from the county's consumers and taxpayers to the interstate market" is a legitimate, non-discriminatory purpose unless the law facially discriminates in favor of local *companies* and 100% of the costs are shifted to out-of-state consumers. Pet.App.10a,13a. Each of these legal propositions is manifestly incorrect and would affirmatively authorize Balkanizing the interstate market through avowed rent-seeking for local advantage.

1. The court below first asserted that whether a law serves a legitimate local purpose need not be resolved to answer the threshold question of whether

the law is "virtually *per se* unlawful" or instead subject to deferential review, but is *only* examined during the "second tier, *Pike* balancing test, which asks whether the 'State's interest is legitimate.'" Pet.App.11a-12a. That is precisely backwards. In fact, *Pike*'s deferential test applies *only* "[w]here the statute *** effectuate[s] a legitimate local public interest." *Pike*, 397 U.S. at 142. If not, then "*per se*" heightened scrutiny must apply. The (il)legitimacy of the local purpose therefore *must* be resolved to determine the level of scrutiny. The lower court's contrary analysis is like refusing to resolve whether a speech restriction is content-based, because whether the law serves a "legitimate" content-neutral purpose is relevant only when applying the deferential scrutiny given to such neutral laws. *Cf. Ward v. Rock Against Racism*, 491 U.S. 781, 798 (1989).

2. The court also held that states are free to impose "affirmative obligation[s]" on out-of-state producers to *enter* the state and *engage* in "in-state conduct" benefitting local interests, because the state may "*regulat[e]* the in-state conduct of an out-of-state entity" that voluntarily enters the state. Pet.App.12a (emphasis added). This, of course, obliterates the distinction between intrastate and interstate regulation. More specifically, it obliterates the clear distinction between the police power to regulate *products* sold within the state, to ensure "safety" and "protect consumers," *Pike*, 397 U.S. at 143, and the power to *condition* the local *sale* of interstate products on having the producer enter the locality to perform certain activities. If the court below is correct that there is no such distinction, then Madison, Wisconsin, could require interstate actors to pasteurize milk locally because it can require that

only pasteurized milk be sold; Arizona could require that cantaloupes be packaged in Arizona because it can require that only properly packaged cantaloupes be sold there; and Clarkstown, New York, could require that garbage be recycled in a local facility because it may require trash recycling. But this Court's precedent holds otherwise, because there is a fundamental difference between ensuring that interstate *products* are safe and non-misleading, and affirmatively obligating an interstate *producer* to become (or contract with) an in-state entity to perform local functions.

3. The court further held that "shifting costs to counties and states outside Alameda" for no reason "other than saving the county money" is perfectly permissible so long as there is no facial "discriminat[ion]" between local and non-local *companies.* Pet.App.9a,16a. Thus, the Ordinance's avowed cost-shifting is perfectly legitimate because it does not facially discriminate among companies, since it "applies across-the-board" without making distinctions based on the "geographic location of the manufacturer[s]" subject to the Ordinance. Pet.App.8a-9a. But the notion that cost-shifting constitutes proscribed local favoritism only if it discriminates in favor of local *companies* is directly contrary to the facts and reasoning of this Court's precedents. As this Court has consistently recognized, a jurisdiction can obviously shift costs and "discriminat[e] in favor of local interests," *Carbone*, 511 U.S. at 393, without discriminating in favor of local *companies*. The Clause prohibits favoritism for local "residents," as well as for "resident competitors." *Gen. Motors*, 519 U.S. at 299. In both cases, the discriminatory local favoritism is

the favoring of the local *jurisdiction* at the expense of the interstate market, by requiring all interstate actors, local and non-local, to do the mandated operation in that locality, rather than deploying their resources in the most economically efficient manner.

Specifically, this Court has repeatedly rejected the proposition that impermissible cost-shifting ordinances can be salvaged by making requirements equally applicable to local and non-local companies: a local-presence ordinance "is no less discriminatory because in-state or in-town [companies] are also covered by the prohibition." *Carbone*, 511 U.S. at 391. *See also Fort Gratiot*, 504 U.S. at 362 (The "burden imposed by a State upon interstate commerce is not to be sustained simply because the statute imposing it applies alike to the people of all the States, including the people of all the States enacting such a statute."). Laws requiring *all* companies to contract locally or perform local services obviously "treat[] all private companies" burdened by the regulation "exactly the same," Pet.App.8a, without regard to whether they are local or foreign. In *Dean Milk*, 340 U.S. at 350, all dairy farmers, inside or outside of Madison, were required to contract with a Madison pasteurizer (or directly pasteurize the milk themselves in Madison). Indeed, in a large majority of the compelled local-presence cases, the challenged law principally burdened local companies, and the challenges were brought by local companies, so they could not possibly have discriminated in favor of such companies. [7] Despite this equal treatment of local and

[7] In *Pike*, the challenged law affected *only* Arizona companies whose cantaloupes were "grown in Arizona" by requiring that such Arizona cantaloupes be packaged in the State (and the plaintiff itself was a local company). 397 U.S. at 138. Likewise

foreign companies, these laws nonetheless constituted invalid "exploit[ation]" of the interstate market because they forced "persons or operations in other States" to "bear the brunt of [the] regulations imposed by" the locality to benefit local interests. *South-Central Timber*, 467 U.S. at 92.

To be sure, local-presence regulations often seek to help local companies by "divert[ing] to [the locality] employment and business which might otherwise go" elsewhere, *Toomer*, 334 U.S. at 403-04. Favoring local companies is certainly *one way* to burden interstate commerce by cost-shifting. But it is not the *only* way.

When local governments relieve the local tax burden by conscripting outsiders to perform uncompensated public services or imposing disproportionate taxation, an "unfair share of the tax [or regulatory] burden" is "passed onto interstate commerce," thus *directly* producing the Commerce Clause evil that *indirectly results* from discriminating in favor of local companies. *Quill*, 504 U.S. at 313. There is therefore "discrimination in favor of local interests," because local consumers are favored over outsiders by having the latter pay for the costs of regulation benefitting only the former. Thus, there is "[d]iscrimination against *interstate*

(continued…)

in *Carbone*, the challenged ordinance imposed identical burdens on "all competitors, be they local or nonlocal," and the plaintiffs themselves were "*local* recyclers, physically located *in* [the local town]." 511 U.S. at 404 (O'Connor, J., concurring in judgment). The same was true in *Foster-Fountain Packing Co.*, 278 U.S. at 7-8 (plaintiff "Louisiana corporation") and *South-Central Timber*, 467 U.S. at 85 (plaintiff "Alaska corporation").

commerce" *Carbone*, 511 U.S. at 392 (emphasis added), even without facial discrimination against *out-of-state companies*. The court below reached a contrary conclusion only by ignoring the precedent invalidating local-presence requirements and by artificially limiting *Complete Auto's* condemnation of disproportionate taxation to "the tax context." Pet.App.14a. In fact, *Complete Auto* was broadly aimed at "structural concerns about the effects of state *regulation* on the national economy," and local laws requiring interstate companies to directly aid local taxpayers through compelled provision of public services has the same cost-shifting effect as excessive taxation, and is even more burdensome on producers. *Quill*, 504 U.S. at 312 (emphasis added).[8]

4. In addition to holding that cost-shifting is permissible unless 100% of the burdened companies are non-local, the court below also stated that such cost-shifting is authorized unless non-local *consumers* absorb 100% of the shifted costs. The court ruled that cost-shifting to "everyone outside of

[8] It is particularly baffling that the court below relied on *United Haulers* for its contrary rule, since that case emphasized that "the citizens and businesses of the Counties b[ore] the costs of the ordinances" because the local government there *itself* undertook the "traditional[] *** local government function" of waste disposal. 550 U.S. at 344. Accordingly, the laws in *United Haulers* were upheld because their "most palpable harm" was "likely to fall upon the very people who voted for [them]." *Id.* Here, the opposite is true because Alameda opted for the exact solution *criticized* in *United Haulers*—i.e., "shift[ing] the costs of regulation" to outsiders by *eschewing* the "traditional" method of waste disposal—"*public*" collection financed by general taxes or special disposal fees paid by *local* citizens. *Id.* at 345, 347. *United Haulers* obviously would have come out differently if, as here, the law required all producers of products that become waste to enter the locality to dispose of waste for free.

Alameda" is somehow permissible because it "also result[s] in higher prices for residents of Alameda." Pet.App.10a. But again, the dormant Commerce Clause prohibits local "economic advantage" legislation that purposely increases the *costs* of interstate goods nationwide. Such increased nationwide costs are in no way justified simply because Alameda consumers bear a small fraction of the costs borne by consumers nationally to finance a program benefitting only Alameda residents. Most obviously, costs imposed on interstate producers by *tariffs* are not somehow justified simply because those costs are borne "*primarily* by local consumers." *West Lynn Creamery*, 512 U.S. at 203 (emphasis added). Nor will minor costs on local consumers (or the miniscule presence of Producers in Alameda) alleviate the political desirability of cost-shifting because normal "political restraints" obviously do not obtain "when the regulation is of such a character that its burden falls *principally* upon those without the state." *South-Central Timber,* 467 U.S. at 92 (quoting *Barnwell Brothers,* 303 U. S. at 185, n.2) (emphasis added); *see also Camps Newfound*, 520 U.S. at 579-80 ("Given the burden *** falls by design in a predictably *disproportionate* way on out-of-staters, the effect on interstate commerce is the same as in our cases involving taxes targeting out-of-staters alone"); *Kasell*, 450 U.S. at 675-676 (plurality opinion) ("Less deference to the legislative judgment is due *** where the local regulation bears *disproportionately* on out-of-state residents and businesses.") (emphasis added).

5. Even assuming arguendo that the Ordinance is not "virtually *per se* illegal," it nonetheless violates *Pike's* balancing test. As noted above, because the

environmental benefits of a take-back program could be fully achieved were it conducted and financed by the local government, the Ordinance produces no "local benefit," apart from impermissible cost shifting, to balance against its burden on interstate commerce. The Ordinance's burden on interstate commerce is, at a minimum, hundreds of thousands of dollars annually. Pet.App.14a. Thus, the Ordinance's burden is necessarily "clearly excessive," *Pike*, 397 U.S. at 142, in light of its lack of legitimate local benefits. Because Alameda "has imposed this burden without any significant countervailing safety interest, its [Ordinance] violates the Commerce Clause." *Kassel*, 450 U.S. at 678-79 (plurality opinion).

The court below rejected this conclusion because conscripting interstate producers solely to "save the county money" was purportedly a legitimate benefit. Pet.App.16a. This endorsement of naked cost-shifting not only conflicts with the precedent described above, but also with *Pike's* holding that burdens will not usually be "tolerated" if the local interest "could be promoted as well with a lesser impact on interstate activities." *Pike*, 397 U.S. at 142. Here, the "benefits" of a take-back program can be fully realized without any such "impact," by the traditional route of locally financed and operated disposal programs.

The court below also held that the Ordinance does not impose *any* substantial burden on interstate commerce because, "assuming the manufacturers comply with the Ordinance, they can continue to sell pharmaceutical drugs in Alameda." Pet.App.15a. But the burden on interstate commerce is properly measured by how much the Ordinance *costs*, not

whether the costs are unbearable. Indeed, tariffs and other direct burdens on interstate commerce violate the Constitution even though companies *pay* the costs in order to conduct interstate business. In *Carbone*, for example, the unconstitutional burden was merely a "tipping fee" of $81 per ton, 511 U.S. at 387, which many companies were willing to bear.

II. THE NINTH CIRCUIT'S RULING CONFLICTS WITH THE DECISIONS OF OTHER CIRCUITS

In upholding the Ordinance, the Ninth Circuit put itself at odds with multiple other circuits that have invalidated local-presence requirements that benefit local interests by imposing costs on outsiders.

1. In *Tri-M Group, LLC v. Sharp*, 638 F.3d 406, 413 (3d Cir. 2011), the Third Circuit struck down a Delaware law requiring contractors to establish "a permanent place of business" within the state in order to become eligible to pay reduced apprentice wages. The Court held the law invalid under the dormant Commerce Clause because it contained an "express in-state presence requirement" that "burden[ed]" out-of-state companies by requiring them to undertake "expenditures [to establish] a new local operation." *Id.* at 427-28. The *Tri-M* decision built on a prior Third Circuit case involving a law that "direct[ed] district consumers of [waste-disposal] services to utilize a favored service provider who *** operates a local facility." *Atl. Coast Demolition & Recycling, Inc. v. Bd. of Chosen Freeholders of Atl. Cnty.*, 48 F.3d 701, 713 (3d Cir. 1995). The court imposed heightened scrutiny and ultimately struck down the law because it favored companies "that [we]re willing to construct a facility within[] the state" to dispose of local waste. *Id.* at 708. *See also*

Atl. Coast Demolition & Recycling, Inc. v. Bd. of Chosen Freeholders of Atl. Cnty., 112 F.3d 652, 667 (3d Cir. 1997). That ruling conflicts with the decision below because the Alameda County Ordinance forces interstate companies to establish and operate "local facilities" to dispose of unused medicines.

2. The decision below also conflicts with decisions of the Sixth and Eighth Circuits that have invalidated schemes that have implemented local favoritism through local-waste-disposal requirements. In *Waste Management, Inc. of Tennessee v. Metropolitan Government of Nashville & Davidson County*, 130 F.3d 731, 736 (6th Cir. 1997), the Sixth Circuit struck down a local law "requir[ing] that all *residential* waste be sent to" a local disposal facility. *See also Huish Detergents, Inc. v. Warren Cnty., Ky.*, 214 F.3d 707 (6th Cir. 2000) (same). The Eighth Circuit reached an identical result in *Waste Systems Corp. v. County of Martin*, 985 F.2d 1381, 1385-89 (8th Cir. 1993), striking down an ordinance requiring local entities to deliver their waste to a local disposal facility. The ruling below contradicts these decisions by upholding a law that not only forces companies to *use* or *contract with* local disposal facilities, but to affirmatively *fund and operate* such facilities for the benefit of local residents.

3. The decision below also conflicts with the Eleventh Circuit's decision in *Florida Transportation Services, Inc. v. Miami-Dade County*, 703 F.3d 1230 (11th Cir. 2012), which struck down a scheme that effectively required out-of-state companies to use local stevedores to unload goods at a local port. The court reaffirmed the principle that "a state or local

law" is invalid when it "condition[s] participation in an interstate market on the in-state or local processing of goods," and that "a state or local government may not require diversion of resources of an interstate market into the local market to serve local interests." *Id.* at 1244. That principle is flatly contrary to the decision below here, which undisputedly requires producers to "diver[t]" their resources "into the local market to serve local interests" by "process[ing]" Alameda's unused medicines. *Id.*

4. The D.C. Circuit has similarly recognized that a local law would be invalid under the dormant Commerce Clause if it "require[d] *** wholesalers to acquire and maintain" their storage warehouses within the District of Columbia, thereby "requir[ing] business operations [to] be performed in the District[.]" *Milton S. Kronheim & Co. v. Dist. of Columbia*, 91 F.3d 193, 201 (D.C. Cir. 1996). Again, the Ordinance *does* require producers to conduct "business operations" locally by funding and operating local take-back programs.

CONCLUSION

For these reasons, the petition for certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; GENERIC PHARMACEUTICAL ASSOCIATION; BIOTECHNOLOGY INDUSTRY ORGANIZATION, *Plaintiffs-Appellants*, v. COUNTY OF ALAMEDA; ALAMEDA COUNTY DEPARTMENT OF ENVIRONMENTAL HEALTH, *Defendants-Appellees*.	No. 13-16833 D.C. No. 3:12-cv-06203-RS OPINION

Appeal from the United States District Court
for the Northern District of California
Richard Seeborg, District Judge, Presiding
Argued and Submitted
July 11, 2014—San Francisco, California
Filed September 30, 2014
Before: N. Randy Smith and Morgan Christen, Circuit
Judges, and Lawrence L. Piersol, Senior District Judge.*
Opinion by Judge N.R. Smith

PRMA V. COUNTY OF ALAMEDA

SUMMARY**

Civil Rights/Commerce Clause

The panel affirmed the district court's summary judgment and held that Alameda County's Safe Drug Disposal Ordinance was constitutional under the Commerce Clause.

The Safe Drug Disposal Ordinance requires any prescription drug producer who either sells, offers for sale, or distributes brand name and generic drugs in Alameda County, to collect and safely dispose of the

* The Honorable Lawrence L. Piersol, Senior District Judge for the U.S. District Court for the District of South Dakota, sitting by designation.

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

County's unwanted prescription drugs, no matter which manufacturer made the drug in question.

Plaintiffs, non-profit trade organizations representing the manufacturers and distributors of pharmaceutical products, alleged that the Ordinance violates the dormant Commerce Clause by requiring interstate drug manufacturers to conduct and pay for Alameda County's drug disposal program.

The panel first held that the Ordinance neither discriminates against nor directly regulates interstate commerce. The panel determined that the Ordinance does not discriminate on its face and in effect because it applies to all manufacturers that make their drugs available in Alameda County—without respect to the geographic location of the manufacturer. The panel further determined that the Ordinance does not directly regulate interstate commerce because it does not control conduct beyond the boundaries of the County.

Applying the balancing test set forth in *See Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), the panel could not say that the Ordinance substantially burdens interstate commerce, given that plaintiffs provided no evidence that the Ordinance will affect the interstate flow of goods. The panel then noted that the Ordinance's environmental, health, and safety benefits were not contested for purposes of the cross-motions for summary judgment and that the Supreme Court is reluctant to invalidate regulations that touch upon safety.

OPINION

N.R. SMITH, Circuit Judge:

The Supreme Court "has adopted what amounts to a two-tiered approach to analyzing state economic regulation under the Commerce Clause." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 578–79 (1986).

> [1] When a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, [the Court has] generally struck down the statute without further inquiry.
>
> [2] When, however, a statute has only indirect effects on interstate commerce and regulates evenhandedly, [the Court has] examined whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.

Id. at 579 (citations omitted). Because the Alameda County Safe Drug Disposal Ordinance (the "Ordinance") passes constitutional muster under this two-tiered approach, we affirm the district court.

FACTS

The facts are not in dispute. Alameda County ("Alameda") passed the Ordinance in July of 2012. The Ordinance requires that prescription drug manufacturers, who either sell, offer for sale, or distribute "Covered Drugs" in Alameda, operate and finance a "Product Stewardship Program." The term "Covered Drug" includes "all drugs in 21 U.S.C. § 321(g)(1) of the Federal Food, Drug and Cosmetic Act . . . including both brand name and Generic Drugs." To operate and finance a Product Stewardship Program, the manufacturers must provide for the collection, transportation, and

disposal of any unwanted Covered Drug—no matter which manufacturer made the drug in question.

Facially, the Ordinance applies equally to both manufacturers located within Alameda and manufacturers located outside the county. While some manufacturers have their corporate offices or principal places of business in Alameda, all prescription drugs currently sold arrive in Alameda via inter-county or interstate commerce; even drugs manufactured in Alameda are shipped to other counties for packaging and then shipped back into Alameda. Alameda estimates that its total 2010 prescription drug retail sales were approximately $965 million and neither party asserts that sales have declined since then.

Pursuant to the Ordinance, manufacturers must set up disposal kiosk sites throughout Alameda. The kiosks will consist of disposal bins located in areas "convenient and adequate to serve the [disposal] needs of Alameda County residents." Manufacturers must also promote the stewardship program to the public via "educational and outreach materials." After collection, the prescription drugs must be destroyed at medical waste facilities.

The manufacturers are free to individually operate separate product stewardship programs or to jointly operate a program with one or more other manufacturers. If manufacturers choose to operate a program jointly, the Ordinance requires that the program's costs be spread fairly and reasonably among the manufacturers. The manufacturers may run the stewardship program themselves, or they may pay a third-party to operate the stewardship program on their behalf. Assuming the

manufacturers jointly operated a stewardship program, the start-up costs would approximate $1,100,000. Around $200,000 of the start-up costs consists of reimbursement to Alameda for the county's costs to administer the Ordinance. While Plaintiffs estimate the subsequent annual costs to maintain the stewardship program to be around $1,200,000, Alameda estimates annual maintenance costs of only $330,000. However, both parties agreed this difference in estimates was immaterial for summary judgment purposes. Alameda estimates an annual cost of $200,000 per year to oversee the stewardship program and the Ordinance requires the manufacturers to reimburse Alameda for this cost. Using these numbers, Alameda estimates a total annual cost to each manufacturer between $5,300 and $12,000. Under the Ordinance, manufacturers may not implement a point-of-sale "tax" or fee to recoup the stewardship program's administrative costs.

Plaintiffs, non-profit trade organizations representing the manufacturers and distributors of pharmaceutical products, claim that the Ordinance violates the dormant Commerce Clause by requiring interstate drug manufacturers to conduct and pay for Alameda County's drug disposal program. The district court disagreed and granted Defendants' motion for summary judgment.

STANDARD OF REVIEW

"We review de novo the district court's grant of summary judgment." *Smith v. Clark Cnty. Sch. Dist.*, 727 F.3d 950, 954 (9th Cir. 2013).

DISCUSSION

The Commerce Clause dictates that "Congress shall have Power . . . [t]o regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl 3. "Though phrased as a grant of regulatory power to Congress, the Clause has long been understood to have a 'negative' aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce." *Or. Waste Sys., Inc. v. Dep't of Envtl. Quality of State of Or.*, 511 U.S. 93, 98 (1994). "The modern law of what has come to be called the dormant Commerce Clause is driven by concern about economic protectionism that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 337–38 (2008) (internal quotation marks omitted). We analyze dormant Commerce Clause claims using the Supreme Court's two-tiered approach. *See Brown-Forman*, 476 U.S. at 578–79.

I.

The first tier asks whether the Ordinance "either discriminates against or directly regulates interstate commerce." *Greater L.A. Agency on Deafness, Inc. v. Cable News Network, Inc.*, 742 F.3d 414, 432 (9th Cir. 2014). If the Ordinance does either of these things, "it violates the Commerce Clause per se, and we must strike it down without further inquiry." *NCAA v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993). The Ordinance does neither.

A. Discrimination

A statute is discriminatory if it "impose[s] commercial barriers or discriminates against an article of commerce by reason of its origin or

destination out of State." *C & A Carbone, Inc. v. Town of Clarkstown, N.Y.*, 511 U.S. 383, 390 (1994). "Conversely, a statute that treats all private companies exactly the same does not discriminate against interstate commerce. This is so even when only out-of-state businesses are burdened because there are no comparable in-state businesses." *Assoc. des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 948 (9th Cir. 2013) (internal quotation marks, alteration, and citation omitted).

The Ordinance, both on its face and in effect, applies to all manufacturers that make their drugs available in Alameda County—without respect to the geographic location of the manufacturer. Even if one of the manufacturers represented by Plaintiffs were to close all of its production facilities, open a single production facility in Alameda County, and limit the sale of its products to intra-county commerce, the Ordinance would still apply to that manufacturer. In other words, the Ordinance does not discriminate, because it "treat[s] all private companies exactly the same." *See United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 342 (2007).[1]

Plaintiffs argue that the Ordinance is discriminatory, because "the real world effect of the Ordinance is indistinguishable from a tariff." The

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[1] The fact that the Ordinance exempts local pharmacies does not change the outcome, because no "actual or prospective competition" exists between the pharmacies and the manufacturers. *See Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 298, 299–300 (1997) ("Conceptually, of course, any notion of discrimination assumes comparison of substantially similar entities." (footnote omitted)).

Commerce Clause forbids the use of tariffs "[b]ecause of their distorting effects on the geography of production." *W. Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 193 (1994). The evil of a tariff is that it "artificially encourag[es] in-state production even when the same goods could be produced at lower cost in other States." *Id.* Tariff-like statutes similarly provide distinct advantages to in-state entities over out-of-state entities, so courts routinely strike them down. "[C]ases of this kind are legion." *Id.* at 194 (collecting cases).

However, unlike any of these statutes, an ordinance that applies across-the-board provides no geographic advantages. This holds true even where the ordinance only affects interstate commerce due to an absence of intrastate businesses. *See Assoc. des Eleveurs*, 729 F.3d at 948. Given that the Ordinance applies across the board, it does not discriminate at all, let alone in the same way as a tariff.

Plaintiffs also argue that the Ordinance discriminates against interstate commerce by shifting costs to counties and states outside of Alameda. As the Supreme Court has observed,

> [o]ur dormant Commerce Clause cases often find discrimination when a State shifts costs of regulation to other States, because when "the burden of state regulation falls on the interests outside of the state, it is unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected."

United Haulers, 550 U.S. at 345 (quoting *S. Pac. Co. v. Ariz. ex rel. Sullivan*, 325 U.S. 761, 767 n.2 (1945)). In *United Haulers*, the Supreme Court upheld a

statute and noted that it "bears mentioning" that the cost of the ordinances "is likely to fall upon the very people who voted for the laws." *Id.* It concluded that "[t]here [was] no reason to step in and hand local businesses a victory they could not obtain through the political process." *Id.*

Plaintiffs' political-restraints argument fails because, like in *United Haulers*, the Ordinance affects "interests within the [county]." *Id.* Even though all of the pharmaceutical drugs travel in interstate commerce before being sold in Alameda, three of Plaintiffs' members have their corporate headquarters or principal place of business in Alameda and two of Plaintiffs' members have facilities in Alameda that manufacture prescription drugs for commercial distribution.

Moreover, the cost of running the disposal program has not been entirely shifted outside of the county. Plaintiffs assert that the manufacturers will cover the cost of the Ordinance by raising the price of their drugs. This will result in higher prices for everyone outside of Alameda, but it will also result in higher prices for residents of Alameda. Given these facts, we are satisfied that the burden imposed by the Ordinance was sufficiently subjected to "those political restraints normally exerted when interests within the state are affected." *Id.*

B. The Ordinance does not directly regulate interstate commerce.

"[A] statute violates the dormant Commerce Clause per se when it *directly* regulates interstate commerce." *Assoc. des Eleveurs*, 729 F.3d at 949 (internal quotation marks omitted). "Direct regulation occurs when a state law directly affects

transactions that take place across state lines or entirely outside of the state's borders." *S.D. Myers, Inc. v. City and Cnty. of S.F.*, 253 F.3d 461, 467 (9th Cir. 2001) (internal quotation marks omitted). "The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State."[2] *Healy v. Beer Institute, Inc.*, 491 U.S. 324, 336 (1989).

Two stipulations of the parties reveal that the Ordinance does not "control conduct beyond the boundaries of the [county]," *see id.*:

> 8. Any person, manufacturer, or distributor that does not sell, offer for sale, or distribute prescription drugs in Alameda County is not required to undertake any action under the Ordinance.
>
> 9. Nothing in the Ordinance requires that [manufacturers] implement stewardship plans in any location or jurisdiction outside of Alameda County.

Unable to quarrel with these facts, Plaintiffs essentially assert four arguments as to how the Ordinance directly regulates interstate commerce.

First, Plaintiffs argue that the Ordinance "cannot be an exercise of the police power with an '*incidental*'

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[2] Under *Assoc. des Eleveurs*, the test articulated in Healy may not apply to the Ordinance at all. *See Assoc. des Eleveurs*, 729 F.3d at 951 ("Healy [does not apply] to a statute that does not dictate the price of a product and does not 't[ie] the price of its in-state products to out-of-state prices.'" (quoting *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003)). Assuming *Healy* does apply, the Ordinance withstands its scrutiny.

effect on interstate commerce, but is necessarily an effort to directly regulate and burden [interstate commerce]." The problem with Plaintiffs' argument—aside from the fact that Plaintiffs cite not a single case to support this theory—is that it conflates the "direct regulation" doctrine and the second-tier, *Pike* balancing test, which asks whether the "State's interest is legitimate," *Brown-Forman*, 476 U.S. at 578–79. Moreover, direct regulation of interstate commerce is more than the absence of a legitimate statutory purpose. Even assuming the State has no legitimate interest whatsoever in passing the Ordinance, it does not automatically follow that the Ordinance directly regulates interstate commerce.

Second, Plaintiffs argue that the Ordinance directly regulates interstate commerce, because "it regulates [manufacturers] whose only connection to Alameda is such interstate commerce." 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. *Cf. Assoc. des Eleveurs*, 729 F.3d at 948–49 ("A statute is not invalid merely because it affects in some way the flow of commerce between the States." (internal quotation marks omitted)). For example, in *Assoc. des Eleveurs*, this court upheld a California statute that prohibited the sale of products that were the result of force feeding birds. *Id.* at 941–42. It did not matter that the practical effect of the statute was to regulate the conduct of farmers and producers that were "non-California entities" who chose to engage California through interstate commerce. *Id.* at 942, 950–51.

Plaintiffs suggest that the Ordinance is different, because it imposes an affirmative obligation. However, neither the Supreme Court nor this court has drawn such a distinction. *See Pharm. Research*, 538 U.S. at 668–69 (rejecting a dormant commerce clause challenge to a Maine regulation that required drug manufacturers to enter into a rebate agreement with the state in order to compensate pharmacists for selling cheaper drugs); *Greater L.A. Agency*, 742 F.3d at 419, 432–33 (rejecting a dormant commerce clause challenge to a statute that "compell[ed] [CNN] to caption videos posted on its web site").

Third, Plaintiffs argue that the Ordinance directly regulates interstate commerce, because it "shift[s] the costs of Alameda's disposal responsibility and local government program from the County's consumers and taxpayers to the interstate market." This rationale applies when determining whether a statute discriminates against, rather than directly regulates, interstate commerce.[3] *United Haulers*, 550 U.S. at 345. Accordingly, we addressed this argument above.

Fourth, Plaintiffs invite the panel to apply dormant Commerce Clause tax cases to the

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[3] Plaintiffs try to make this an argument about direct regulation by asserting that "this Court has squarely stated that a law has an impermissible 'direct burden' on interstate commerce if, under the law, the locality 'would be able to shift the tax burden to out-of-state . . . producers.'" *See Nat'l Meat Ass'n v. Deukmejian*, 743 F.2d 656, 661 (9th Cir. 1984). But that statement did not come from the court. The court was quoting the state's economic expert, who made the statement in support of *upholding* a state statute. 743 F.2d at 661. The only thing "this Court . . . squarely stated" concerning that quotation is that it "is not controlling." *Id.*

Ordinance. Specifically, Plaintiffs ask the panel to apply the "nexus" and "fairly apportioned" requirements. Plaintiffs cite no case, and we can find none, in which a court has applied the nexus and fairly apportioned requirements outside of the tax context. We decline the invitation to break this new legal ground.

II.

The second tier of a dormant commerce clause analysis has come to be known as the *Pike* balancing test. *See Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). Under *Pike*, we ask whether "the burden [the Ordinance] imposes on interstate commerce is 'clearly excessive in relation to the putative local benefits.'" *See S.D. Myers, Inc.*, 253 F.3d at 471 (quoting *Pike*, 397 U.S. at 142). "We have explained that under *Pike*, a plaintiff must first show that the statute imposes a substantial burden before the court will determine whether the benefits of the challenged laws are illusory." *Assoc. des Eleveurs*, 729 F.3d at 951–52 (internal quotation marks omitted). The analysis "turn[s] on the interstate *flow of goods*." *See Nat. Ass'n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1153 (9th Cir. 2012).

A. Substantial Burden

The parties' briefs provide minimal discussion as to the burden imposed by the Ordinance. The county compares the cost of running the disposal program ($530,000–$1,200,000 per year) to the manufacturers' revenue-stream in Alameda County (approximately $950 million per year) to conclude that the burden is minimal. Plaintiffs' merely state that "the County cannot dispute that the Ordinance imposes some

burdens on [manufacturers] engaged in interstate commerce."

Significantly, Plaintiffs provide no evidence that the Ordinance will interrupt, or even decrease, the "*flow of goods*" into or out of Alameda. *See id.* Further, assuming the manufacturers comply with the Ordinance, they can continue to sell pharmaceutical drugs in *Alameda*. *Cf. Assoc. des Eleveurs*, 729 F.3d at 952 (finding Plaintiffs failed to raise serious questions about whether a statute imposed a substantial burden even though it would "*preclude* Plaintiffs' 'more profitable' method of producing foie gras" (emphasis added)). Without any evidence that the Ordinance will affect the interstate flow of goods, we cannot say that the Ordinance substantially burdens interstate commerce.

B. Local Benefits

According to the joint-stipulation, "Plaintiffs agree that the Ordinance's environmental, health, and safety benefits are not contested for purposes of the cross-motions for summary judgment." And "regulations that touch upon safety . . . are those that the [Supreme] Court has been most reluctant to invalidate. Indeed, if safety justifications are not illusory, the Court will not second-guess legislative judgment about their importance in comparison with related burdens on interstate commerce." *Kassel v. Consol. Freightways Corp. of Del.*, 450 U.S. 662, 670 (1981) (internal quotation marks and citations omitted).

In an attempt to avoid this "strong presumption of validity" *see id.* (internal quotation marks omitted), Plaintiffs contend that the purpose of the Ordinance is merely to shift costs away from the county and

onto the manufacturers. Plaintiffs reason that, because Alameda County could run a drug disposal program that "would achieve precisely the same effects" as the program mandated by the Ordinance, the Ordinance "yields no public benefits." We reject this logic.

The fact that the county could run a similar program does not nullify the program's benefits.[4] For example, in *Walsh*, the Supreme Court rejected a dormant Commerce Clause challenge, despite the fact that Maine could have simply compensated the pharmacists itself rather than force drug manufacturers to do so. 538 U.S. at 654. Moreover, even if the Ordinance did nothing other than save the county money, that is not equivalent to "no public benefits." *Cf. United Haulers*, 550 U.S. at 346 ("While revenue generation is not a local interest that can justify *discrimination* against interstate commerce, we think it is a cognizable benefit for purposes of the *Pike* test." (internal quotation marks and citation omitted)).

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

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[4] To the extent that Plaintiffs argue that the panel must consider less burdensome alternatives, "case law requir[es] the consideration of less restrictive alternatives only when heightened scrutiny is required." *Nat. Ass'n of Optometrists*, 682 F.3d at 1157. Because the Ordinance is not discriminatory and does not directly regulate interstate commerce, heightened scrutiny is not required. *See id.*

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.

AFFIRMED.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, et al.,
Plaintiffs,
v.
COUNTY OF ALAMEDA, et al.,
Defendant.

No. C 12-6203 RS

ORDER DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND GRANTING DEFENDANTS' CROSS-MOTION

I. INTRODUCTION

The County of Alameda has adopted what has been described as a "first in the nation" approach to addressing concerns arising from the disposal of unused prescription drugs. Its "Safe Drug Disposal Ordinance" (the "Ordinance"), scheduled to go into effect in November of this year, requires producers of prescription drugs to fund or operate "take-back" programs in the county, if any of their drugs are sold there. The ordinance is crafted to place the entire cost of such programs on the producers; retail

pharmacies are exempt, and sellers are prohibited from passing the expense directly to Alameda County consumers by adding a fee at the point of sale. Plaintiffs are industry associations whose members produce prescription drugs sold in the county, on whom the costs of complying with the Ordinance will fall. They bring this suit to have the ordinance declared an unconstitutional burden on interstate commerce, under the so-called "dormant Commerce Clause."

Having stipulated that the material facts are undisputed, the parties now bring cross-motions for summary judgment. Because 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, plaintiffs' motion will be denied, and defendants' motion granted.

II. BACKGROUND

Demonstrating commendable cooperation and professionalism directed at resolving this litigation in an efficient manner, the parties stipulated to a list of 38 points that are not in dispute for purposes of these cross-motions. In slightly condensed form, the following are the parties' stipulations:

1. The Ordinance, Alameda Health and Safety Code Sections 6.53.010, et seq., requires that manufacturers of prescription drugs who sell, offer for sale, or distribute prescription drugs in Alameda County ("Producers," as defined in the Ordinance) operate and finance a product stewardship plan that provides for the collection, transportation, and disposal of certain unwanted prescription drugs.

2. The Ordinance declares that in Alameda County, 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; that the groundwater and drinking water are being contaminated by unwanted, leftover, or expired prescription drugs passing through wastewater and treatment centers; and that there is no mandatory statewide drug stewardship program in California for the safe collection of unwanted drugs, and drug manufacturers and producers have not offered any support for a permanent collection program to date.

3. Pursuant to the Ordinance, Producers are required to operate, individually or jointly with other Producers, a Department [of Environmental Health]-approved product stewardship program or enter into an agreement with a stewardship organization to operate, on each Producer's behalf, a Department-approved product stewardship program. In order to ensure that costs are fairly allocated, if more than one Producer is involved in a proposed product stewardship program, the product stewardship plan must include a fair and reasonable manner for allocating the costs of the program among the participants, such that the portion of costs paid by each Producer is reasonably related to the amount of prescription drugs that Producer sells in Alameda County.

4. The Ordinance, on its face, does not impose different requirements on Producers within Alameda County and Producers outside of Alameda County.

5. The Ordinance, on its face, does not impose different requirements on Producers within California and Producers outside of California.

6. The Ordinance, on its face, applies both to interstate Producers and intrastate Producers.

7. The Ordinance requires Producers that market and sell in Alameda County the prescription drugs identified in the Ordinance be responsible for the disposal of those products.

8. Any person, manufacturer, or distributor that does not sell, offer for sale, or distribute prescription drugs in Alameda County is not required to undertake any action under the Ordinance.

9. Nothing in the Ordinance requires that Producers implement stewardship plans in any location or jurisdiction outside of Alameda County. If Producers are required to implement stewardship programs in any other jurisdiction, nothing in the Ordinance requires that the stewardship program implemented in other jurisdictions be the same as the program implemented in Alameda County pursuant to the Ordinance. Similarly, nothing in the Ordinance prohibits Producers from proposing and implementing a program in Alameda County that they are already using or contemplating using in any other jurisdiction.

10. Plaintiffs are non-profit trade organizations representing the manufacturers and distributors of pharmaceutical products. Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") represents companies that produce brand-name drugs. Plaintiff Generic Pharmaceutical Association ("GPhA") represents companies that produce generic drugs. Plaintiff Biotechnology Industry Organization

("BIO") represents companies that produce biotechnology products.

11. Plaintiffs' members include approximately one hundred companies that are subject to the Alameda County take-back ordinance because they manufacture prescription drugs that are sold, offered for sale, or distributed in Alameda County. Plaintiffs' members also manufacture prescription drugs that are sold or distributed throughout the United States.

12. Three of Plaintiffs' members (Amgen, Impax Laboratories, and XOMA Ltd.) have their corporate headquarters or principal places of business in Alameda County. Two of Plaintiffs' members (Bayer and Impax Laboratories) have facilities in Alameda County that manufacture prescription drugs for commercial distribution. Four other members (Abbott, Baxter, Novartis, and Boehringer Ingelheim) have manufacturing facilities in Alameda County that do not manufacture prescription drugs for commercial distribution.

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17. The drugs manufactured in Alameda County for commercial distribution by Bayer and Impax Laboratories account for less than 1% of total annual U.S. prescription drug sales (approximately $320 billion in 2011). Thus, approximately 99% of all prescription drugs sold in the United States, by revenue, are manufactured outside Alameda County.

18. There is a national system for the distribution of prescription drugs from manufacturers to the retail and mail pharmacies that dispense the drugs to consumers. Prescription drugs typically move from a manufacturer's facilities to either a pharmaceutical

wholesaler, a chain warehouse operated by a large retail drugstore chain, or a mail pharmacy.

19. Smaller retail pharmacies in Alameda County (and elsewhere) typically rely on pharmaceutical wholesalers for direct delivery of prescription drugs to individual retail locations. Large retail drugstore chains typically rely on delivery by either pharmaceutical wholesalers or their own chain warehouses. Mail pharmacies purchase drugs from both pharmaceutical wholesalers and directly from manufacturers.

20. Three pharmaceutical wholesalers — AmeriSource Bergen Corporation, Cardinal Health, Inc. and McKesson Corporation — operate more than eighty distribution centers across the United States. None of these wholesalers have a distribution center in Alameda County.

21. The California Board of Pharmacy maintains a list of licensed wholesalers. None of the twenty-one locations in Alameda County with an active wholesale license distributes prescription drugs.

22. CVS, Walgreen, and Rite Aid are the three largest national drugstore chains but account for less than half of the retail pharmacies in Alameda County. None of these chains operate a warehouse distribution center in Alameda County.

23. The prescription drugs manufactured by Bayer and Impax Laboratories in Alameda County are shipped outside the County before being distributed back into Alameda County.

24. Neither the County nor Plaintiffs are aware of any prescription drugs distributed in Alameda County that arrive there via intra-County

distribution channels as opposed to arriving there via distribution channels that cross the County's borders, either because the drugs are manufactured outside the County or because, if manufactured within the County, they are shipped to out-of-county packaging or distribution centers before being distributed to in-county pharmacies.

25. Producers will incur start-up costs to establish a product stewardship program that complies with the Ordinance. These costs include the incorporation and governance of an entity to operate the required collection program on behalf of the Producers, initial one-time investments in equipment and facilities, and the preparation and dissemination of education and outreach materials publicizing the program.

26. Assuming that all Producers jointly operate a single collection program — an assumption that results in lower overall costs than if multiple programs were operated separately — Plaintiffs estimate that overall start-up costs will be approximately $1,100,000.

27. Plaintiffs estimate that Producers will incur annual costs to operate a program that complies with the Ordinance, including costs for labor, insurance, education and outreach, and transportation and disposal of collected unwanted prescription drugs. Assuming that all Producers jointly operate a single program, overall annual compliance costs (including reimbursement of County administrative expenses) are estimated by Plaintiffs to be approximately $1,200,000, provided that local pharmacies are willing to provide free space for the location of collection kiosks. If local pharmacies either demand rent or refuse altogether to provide space for

collection kiosks, then Plaintiffs believe the recurring annual costs may be higher.

28. The Ordinance requires Producers to reimburse Alameda County for actual costs incurred by the County in administering the Ordinance. Alameda County has estimated those annual administrative costs to be roughly $200,000.

29. Plaintiffs' estimated costs for its members to comply with the Ordinance assume that the costs would not be paid by any single Producer or financed solely by the approximately 100 members of Plaintiffs that are Producers. Rather, the estimated costs are assumed to be spread amongst all Producers that sell, offer for sale, or distribute prescription drugs in Alameda County.

30. Defendants estimate that the annual cost for compliance with the Ordinance is lower than Plaintiffs' estimates, totaling less than $330,000 per year. For purposes of the cross-motions for summary judgment contemplated by the parties, however, the parties believe that the difference between their estimates is not material to the outcome of the parties' motions.

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32. According to IMS Health, a pharmaceutical information and consulting company, total prescription drug sales in the U.S. [in] 2010 were $308.6 billion.

33. Plaintiffs at this time lack specific data about the annual revenue generated by their members that is attributable to selling, offering for sale, or distributing prescription drugs in Alameda County. Similarly, at this time Plaintiffs do not know the

annual revenue generated by all Producers that is attributable to selling, offering to sell, or distributing prescription drugs in Alameda County.

34. Defendants estimate the total retail pharmaceutical sales in Alameda County in 2010 [were] approximately $965 million.

. . .

37. Plaintiffs agree that the Ordinance's environmental, health and safety benefits are not contested for purpose of the cross-motions for summary judgment.

38. Plaintiffs' legal position is that, even assuming that take-back programs further important interests, the County violates the Commerce Clause by requiring interstate drug manufacturers to conduct and pay for such programs.

III. LEGAL STANDARD

Summary judgment is proper "if the pleadings and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The purpose of summary judgment "is to isolate and dispose of factually unsupported claims or defenses." *Celotex v. Catrett*, 477 U.S. 317, 323-24 (1986). The moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings and admissions on file, together with the affidavits, if any which it believes demonstrate the absence of a genuine issue of material fact." *Id.* at 323 (citations and internal quotation marks omitted). If it meets this burden, the moving party is then

entitled to judgment as a matter of law when the non-moving party fails to make a sufficient showing on an essential element of the case with respect to which he bears the burden of proof at trial. *Id.* at 322-23.

In this instance, the parties are in agreement that no material facts are in dispute, for purposes of these cross-motions. The question is only which side is entitled to judgment as a matter of law given those undisputed facts.

IV. DISCUSSION

The Commerce Clause of the Constitution assigns to Congress authority to "regulate commerce . . . among the several states. U.S. Const., art. I, § 8. The so-called "dormant" Commerce Clause is the implied converse proposition—state and local governments may not enact regulations that unduly interfere with interstate commerce. *See Quill Corp. v. North Dakota*, 504 U.S. 298, 309 (1992) ("the Commerce Clause is more than an affirmative grant of power; it has a negative sweep as well. The Clause . . . by its own force prohibits certain state actions that interfere with interstate commerce.") (citation omitted).

The Supreme Court has outlined a two-tiered approach to analyzing whether a state or local economic regulation violates the dormant Commerce Clause:

> When a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry. When, however, a statute has only

> indirect effects on interstate commerce and regulates evenhandedly, we have examined whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.

Healy v. Beer Institute, 491 U.S. 324, 337 n. 14 (1989) (quoting *Brown–Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579 (1986) (citations omitted in original)).

The Ninth Circuit has explained that under this two-tiered approach, a local regulation will be found to be a *per se* violation of the clause if it, "1) directly regulates interstate commerce; 2) discriminates against interstate commerce; or 3) favors in-state economic interests over out-of-state interests." *National Collegiate Athletic Ass'n v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993) ("NCAA").

Here, plaintiffs contend that the Ordinance is a *per se* violation of the clause under any and all of the three prongs. As opposed to the first prong, the second and third prongs both contain an element of discrimination—i.e., that a challenged regulation favors local commerce over interstate commerce, or in-state entities over out-of-state entities. Plaintiffs argue there is such a discriminatory effect here because costs that would ordinarily be borne primarily by Alameda County—and hence its own taxpayers—are being shifted on to the community of producers as a whole, most of whom are based elsewhere. Plaintiffs presume that the producers likely will pass those costs on to their customer base at large, with the result that consumers nationwide will bear expenses that otherwise would be solely the responsibility of Alameda taxpayers, or perhaps of

Alameda prescription drug buyers, under a different regulatory scheme.

The "discrimination" on which plaintiffs would rely, is indisputably not being visited on out-of-state producers as a means of favoring in-state producers. As the Supreme Court has several times observed, "any notion of discrimination assumes a comparison of substantially similar entities." *Department of Revenue of Ky. v. Davis*, 553 U.S. 328, 343 (2008), quoting *United Haulers Assn., Inc. v. Oneida–Herkimer Solid Waste Management Authority*, 550 U.S. 330, 342 (2007), in turn quoting *General Motors Corp. v. Tracy*, 519 U.S. 278, 298 (1997). In the absence of "differential treatment favoring local entities over substantially similar out-of-state interests," the kind of discrimination potentially prohibited by the dormant Commerce Clause is not implicated. *Davis*, 553 U.S. at 343. Accordingly, the Ordinance cannot be invalidated as *per se* improper under either the second or third prongs.

As the Ninth Circuit has cautioned, however, "discrimination and economic protectionism are not the sole tests." *NCAA*, 10 F.3d at 638. A regulation may still be *per se* invalid under the first prong if it "directly regulates interstate commerce." *Id.* Nevertheless, and notwithstanding plaintiffs' protestations to the contrary, the Ordinance here neither purports to regulate interstate commerce nor does so as a practical matter.

The Ordinance applies to producers who elect to sell their products within Alameda County, regardless of where the producers are based or the product originates. Nothing in the structure of the Ordinance targets producers on the basis of their

location—they are being required to participate in providing take-back programs because they sell prescription drugs in the county, not because they are out-of-state actors. Nothing in the Ordinance will require, as a practical matter, any producer to alter its manner of doing business in any jurisdiction outside Alameda County, although producers will be free to use programs that they may already be using elsewhere, provided they meet the standards of the Ordinance. (See Stipulated Fact No. 9.)

In *NCAA*, by way of contrast, the statute in dispute regulated *only* interstate organizations, specifically "national collegiate athletic associations," which were defined as any "group of institutions in 40 or more states who are governed by the rules of the association relating to athletic competition." 10 F.3d at 637 n.3. (In practice, this definition encompassed only one entity—the plaintiff NCAA.) The effect of the challenged law, which purported to govern how the NCAA conducted its own enforcement proceedings, was that the organization would have to "use the Statute in enforcement proceedings in every state in the union." *Id.* at 639. As such it violated the Commerce Clause because "the practical effect of the regulation [was] to control conduct beyond the boundaries of the State" and because of the potential conflict with similar laws in other states. *Id.* ("Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State."). The Ordinance plaintiffs challenge here is not specifically directed at regulating interstate organizations and has no remotely similar consequence to any conduct occurring outside county borders.

Plaintiffs repeatedly urge that the Ordinance directly regulates interstate commerce in a manner not meaningfully distinguishable from a tariff. A tariff, however, "taxes goods imported from other States, but does not tax similar products produced in State." *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 193 (1994). As the Supreme Court explained, "[a] tariff is an attractive measure because it simultaneously raises revenue and benefits local producers by burdening their out-of-state competitors." *Id.* Plaintiffs' characterization of the Ordinance as equivalent to a tariff is unpersuasive, given that it shares none of these salient features.

Finally, while plaintiffs are correct that the effect on interstate commerce must be evaluated by looking to the effect of a regulation and not merely its face, the happenstance that most producers of prescription drugs are located outside Alameda County is insufficient to transform what is fundamentally a local measure into one that could be found to burden interstate commerce impermissibly. *See Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 126 (1978) ("[t]he fact that the burden of a state regulation falls on some interstate companies does not, by itself, establish a claim of discrimination against interstate commerce."); *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 88 (1987)(following *Exxon* and rejecting argument that regulation was impermissible merely because it in most cases would apply to out-of-state entities). Accordingly, the Ordinance is not *per se* invalid under any of the analytical prongs.

Plaintiffs suggest almost in passing that the Ordinance could be found invalid even under the balancing test that applies where the challenged

regulation has only indirect, and nondiscriminatory, effects on interstate commerce. Plaintiffs do not question, for purposes of these motions, that the interests Alameda County had in enacting the ordinance were legitimate. Plaintiffs merely contend that those interests could be equally well served through take-back programs funded in another manner. Arguing that an alternative regime would have *no* burden on interstate commerce does not establish that the minimal burden this Ordinance arguably imposes on interstate commerce "clearly exceeds the local benefits." Defendants have adequately shown that the Ordinance serves a legitimate public health and safety interest, and that the relatively modest compliance costs producers will incur should they choose to sell their products in the county do not unduly burden interstate commerce.

V. CONCLUSION

Plaintiffs' motion for summary judgment is denied, and defendants' cross-motion is granted. A separate judgment will enter.

IT IS SO ORDERED.

Dated: 8/28/13

/s/
RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

APPENDIX C

ORDINANCE NO. O-2012-27

ORDINANCE AMENDING THE ALAMEDA COUNTY ORDINANCE CODE BY ADDING CHAPTER 6.53, SECTIONS 6.53.010 THROUGH 6.53.120 TO: REQUIRE ANY PERSON WHO PRODUCES A DRUG OFFERED FOR SALE IN ALAMEDA COUNTY TO PARTICIPATE IN AN APPROVED DRUG STEWARDSHIP PROGRAM FOR THE COLLECTION AND DISPOSAL OF UNWANTED DRUGS FROM RESIDENTIAL SOURCES; PROVIDE FOR IMPLEMENTATION, ENFORCEMENT, FEES, AND PENALTIES; AND MAKING ENVIRONMENTAL FINDINGS.

WHEREAS, the County of Alameda has a substantial interest in, and a substantial need for, a drug stewardship program; and

WHEREAS, the health and welfare of the residents of the County of Alameda, particularly children and the elderly, would be improved and advanced by the proper disposal of unwanted, expired or unneeded prescription drugs;

NOW THEREFORE, the Board of Supervisors of the County of Alameda ordains as follows:

Title 6 of the Alameda County Health and Safety Code is hereby amended by adding Chapter 6.53, Sections 6.53.010 through 6.53.120, to read as follows:

6.53.010 - Declaration of findings.

The Board of Supervisors hereby finds and declares the following:

A. Prescription Drugs are a necessary medical technology that successfully allows us to live longer, healthier, and more productive lives;

B. 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;

C. Our groundwater and drinking water are being contaminated by unwanted, leftover or expired prescription drugs passing through our wastewater and treatment centers;

D. There is no mandatory statewide drug stewardship program for unwanted drugs in California, and drug manufacturers and producers have not offered any support for a permanent collection program to date.

Section 6.53.020 - Title

This Chapter may be cited as the "Alameda County Safe Drug Disposal Ordinance."

Section 6.53.030 - Definitions.

For the purposes of this Chapter, the following terms have the meanings given.

1. "Controlled Substance" for purposes of this Section shall mean any substance listed under California Health and Safety Code Sections 11053 through 11058 or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.

2. "Cosmetics" means (i) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, (ii) articles intended for use as a component of any such articles, and (iii) cosmetics as defined above with expiration dates.

3. "Covered Drug" means all drugs as defined in 21 U.S.C. § 321(g)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) covered under 21 U.S.C. § 353(b)(1) of the FFDCA, including both brand name and Generic Drugs.

"Covered Drug" does not include: (i) Vitamins or supplements; (ii) Herbal-based remedies and homeopathic drugs, products, or remedies; (iii) Cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and Nonprescription Drugs under the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. Sec. 301 et seq. (2002)); (iv) Drugs for which Producers provide a take-back program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1); (v) Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this Section if the Producer already provides a take-back program; (vi) Pet

pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems; and (vii) nonprescription drugs.

4. "Department" means the Alameda County Department of Environmental Health.

5. "Drug Wholesaler" means a business that sells or distributes drugs and Covered Drugs for resale to an Entity other than a consumer.

6. "Drugs" means: (i) articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias; (ii) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (iii) substances, other than food, intended to affect the structure or any function of the body of humans or other animals.

"Drugs" does not mean medical devices, their component parts or accessories, or a Covered Drug contained in or on medical devices or their component parts or accessories.

7. "Entity" means a person other than an individual.

8. "Generic Drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality,

performance characteristics, and intended use, though inactive ingredients may vary.

9. "Mail-Back Program" means a system whereby Residential Generators of Unwanted Products obtain prepaid and preaddressed mailing envelopes in which to place Unwanted Products for shipment to an Entity that will dispose of them safely and legally.

10. "Nonprescription Drug" means any drug that may be lawfully sold without a prescription.

11. "Person" means an individual, firm, sole proprietorship, corporation, limited liability corporation, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal Entity, however organized.

12. "Plan" or "Product Stewardship Plan" means a product stewardship plan required under this Chapter that describes the manner in which a Product Stewardship Program will be provided.

13. "Prescription Drug" means any drug that by federal or state law may be dispensed lawfully only on prescription.

14. "Producer" shall be determined, with regard to a Covered Drug that is sold, offered for sale, or distributed in Alameda County as meaning one of the following:

(i) The Person who manufactures a Covered Drug and who sells, offers for sale, or distributes that a Covered Drug

in Alameda County under that Person's own name or brand.

(ii) If there is no Person who sells, offers for sale, or distributes the Covered Drug in Alameda County under the Person's own name or brand, the producer of the Covered Drug is the owner or licensee of a trademark or brand under which the Covered Drug is sold or distributed in Alameda County, whether or not the trademark is registered.

(iii) If there is no Person who is a producer of the Covered Drug for purposes of paragraphs (i) and (ii), the producer of that Covered Drug is the Person who brings the Covered Drug into Alameda County for sale or distribution.

"Producer" does not include (i) a retailer that puts its store label on a Covered Drug or (ii) a pharmacist who dispenses Prescription Drugs to, or compounds a prescribed individual drug product for a consumer.

15. "Product Stewardship Program" or "Program" means a program financed and operated by Producers to collect, transport, and dispose of Unwanted Products.

16. "Residential Generators" means single and multiple family residences and locations where household drugs are unused, unwanted, disposed of, or abandoned. "Residential Generators" do not include airport security,

drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a nonresidential source.

17. "Stewardship Organization" means an organization designated by a group of Producers to act as an agent on behalf of each Producer to operate a Product Stewardship Program.

18. "Unwanted Product" means any Covered Drug no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

Section 6.53.040. - Product Stewardship Program.

A. Requirement for sale. This Chapter shall apply only to a Producer whose Covered Drug is sold or distributed in Alameda County. This Chapter shall apply to all of Alameda County including unincorporated and incorporated areas, except for those incorporated areas (cities) where the governing body of that incorporated area (city) has authorized its own local health officer or environmental health director to administer and enforce the provisions of California Health and Safety Code section 117800. This Chapter shall be administered and implemented by the Alameda County Department of Environmental Health. Each Producer must:

1. Operate, individually or jointly with other Producers, a Product Stewardship Program approved by the Department; or

2. Enter into an agreement with a Stewardship Organization to operate, on the

Producer's behalf, a Product stewardship Program approved by the Department.

B. Product Stewardship Program costs.

1. A Producer, group of Producers, or Stewardship Organization must pay all administrative and operational fees associated with their Product Stewardship Program, including the cost of collecting, transporting, and disposing of Unwanted Products collected from Residential Generators and the recycling or disposal, or both, of packaging collected with the Unwanted Product.

2. A Producer, group of Producers, or Stewardship Organization must pay for all fees associated with obtaining compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.), if required, for a specific Product Stewardship Program and product stewardship Plan.

3. No Person or Producer may charge a specific point-of-sale fee to consumers to recoup the costs of their Product Stewardship Program, nor may they charge a specific point-of-collection fee at the time the Unwanted Products are collected from Residential Generators or delivered for disposal.

4. A Producer, group of Producers, or Stewardship Organization must pay all costs incurred by the County of Alameda, including but not limited to the Department, in the administration and enforcement of their Product Stewardship Program. Exclusive of fines and penalties, the County of Alameda shall only recover its actual costs of

administration and enforcement under this Ordinance and shall not charge any amounts under this Ordinance in excess of its actual administrative and enforcement costs.

6.53.050 - Product stewardship plan.

A. Plan content. Each Product Stewardship Program shall have a product stewardship Plan that contains each of the following:

1. Certification that the Product Stewardship Program will accept all Unwanted Products regardless of who produced them, unless excused from this requirement by the Department as part of the approval of the Plan;

2. Contact information for the individual and the Entity submitting the Plan and for each of the Producers participating in the Product Stewardship Program;

3. A description of the methods by which Unwanted Products from Residential Generators will be collected in Alameda County and an explanation of how the collection system will be convenient and adequate to serve the needs of Alameda County residents;

4. A description of how the product stewardship Plan will provide collection services for Unwanted Products in all areas of Alameda County that are convenient to the public and adequate to meet the needs of the population in the area being served.

5. The location of each collection site and locations where envelopes for a Mail-Back Program are available (if applicable);

6. A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each Person that will be involved in transporting Unwanted Products and each medical waste or hazardous disposal facility proposed to participate in the Product Stewardship Program;

7 A description of how the Unwanted Products will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security;

8. A description of the public education and outreach activities required under this Chapter and how their effectiveness will be evaluated;

9. A description of how the scope and extent of the Product Stewardship Program are reasonably related to the amount of Covered Drugs that are sold in the County of Alameda, by the Producer or group of Producers;

10. A starting date when collection of Unwanted Products will begin;

11. A description of how support will be provided to any law enforcement agencies within Alameda County that have, or later agree to have, a collection program for Controlled substances, including: (i) the

provision of a collection kiosk with appropriate accessories and signage, (ii) an ability to accept Controlled Substances and other Covered Drugs, (iii) technical support up to and including an appropriate Person to provide on-site assistance with the sorting and separation of Controlled Substances at no cost to a participating law enforcement agency. Otherwise, Controlled Substances are expressly excluded from this Chapter notwithstanding any other provision contained herein;

12. A description of how collection sites for Unwanted Products may be placed at appropriate retail stores in Alameda County including a description of the involvement of the retail store. Retailers are not required or mandated to host collection sites and nothing in this Ordinance shall be interpreted as requiring such participation; and

13. If more than one Producer will be involved in a proposed Product Stewardship Program, then the product stewardship Plan for that Program must include a fair and reasonable manner for allocating the costs of the Program among the participants in that Program, such that the portion of costs paid by each Producer is reasonably related to the amount of Covered Drugs that Producer sells in the County of Alameda.

B. Department review and approval; updates.

1. No Producer, group of Producers, or Stewardship Organization may begin collecting Unwanted Products to comply with

this Ordinance until it has received written approval of its product stewardship Plan from the Department.

2. Product stewardship Plans must be submitted to the Department for approval. The initial Plans must be submitted by July 1, 2013, or at a later date as approved in writing by the Department.

3. Within 180 days after receipt and review of a product stewardship Plan, the Department shall conduct a noticed public hearing and determine whether the Plan complies with the requirements of this Chapter and of any regulations adopted pursuant to this Chapter.

a) As part of its approval, the Department may set reasonable performance goals for the Program.

b) If the Department approves a Plan, it shall notify the applicant of its approval in writing.

c) If the Department rejects a Plan, it shall notify the applicant in writing of its reasons for rejecting the Plan. The Department may reject a Plan without conducting a public hearing.

d) An applicant whose Plan has been rejected by the Department must submit a revised Plan to the Department within 60 days after receiving notice of the rejection. The Department may require the submission of a further revised Plan or, in its sole discretion, the Department may develop, approve and impose its

own product stewardship Plan or an approved Plan submitted by other Producer(s) pursuant to this Ordinance. The imposed Plan will be presented at the public hearing. The Department is not required, and nothing in this Ordinance shall be interpreted as requiring, the Department to create or impose a product stewardship Plan.

e) If the Department rejects a revised Product Stewardship Plan or any other subsequently revised Plan, the Producer(s) at issue shall be out of compliance with this Chapter and are subject to the enforcement provisions contained in this Chapter. If the Department imposes its own or another Plan the Producer(s) at issue shall not be considered out of compliance with this Chapter if they comply with that Plan. However, the Producers shall be subject to the enforcement provisions contained in this Chapter as they relate to compliance with an approved Plan.

4. At least every three years, a Producer, group of Producers or Stewardship Organization operating a Product Stewardship Program shall update its product stewardship Plan and submit the updated Plan to the Department for review and approval.

5. A Producer who begins to offer a Covered Drug for sale in the County of Alameda after July 1, 2013, must submit a product stewardship Plan to the Department

or provide evidence of having joined an existing approved Product Stewardship Program within 180 days following the Producer's initial offer for sale of a Covered Drug.

6. Any proposed changes to a product stewardship Plan must be submitted in writing to the Department and approved by the Department in writing prior to implementation of any change.

6.53.060 - Disposal of Unwanted Products.

A. Compliance with applicable law. Each Product Stewardship Program must comply with all local, state, and federal laws and regulations applicable to its operations, including laws and regulations governing the disposal of medical waste and Controlled Substances.

B. Disposal at medical waste or hazardous waste facility. Each Product Stewardship Program must dispose of all Unwanted Products by incineration at a medical waste or hazardous waste facility. The medical waste or hazardous waste facility must be in possession of all required regulatory permits and licenses.

C. Producers with Product Stewardship Programs may petition the Department for approval to use final disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current medical waste disposal technologies for Covered Drugs if and when those technologies are proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of the following areas:

1. Monitoring of any emissions or waste;

2. Worker health and safety;

3. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and,

4. Overall impact on the environment and human health.

D. Packaging separation. Each Product Stewardship Program shall encourage Residential Generators to separate Unwanted Products from their original containers, when appropriate, prior to collection or disposal.

6.53.070 - Product Stewardship Program promotion and outreach.

A. A Product Stewardship Program must promote the Product Stewardship Program to Residential Generators, pharmacists, retailers of Covered Drugs, and health care practitioners as to the proper and safe method to dispose of Unwanted Products.

B. A Product Stewardship Program shall include, but is not limited to, developing, and updating as necessary, educational and other outreach materials aimed at retailers of Covered Drugs. These materials may include, but are not limited to, one or more of the following:

1. Signage that is prominently displayed and easily visible to the consumer.

2. Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both.

3. Advertising and/or other promotional materials related to the Product Stewardship Program.

C. A Product Stewardship Program must prepare education and outreach materials that publicize the location and operation of collection locations in Alameda County and disseminate the materials to health care facilities, pharmacies, and other interested parties. The Program also must establish a website publicizing collection locations and Program operations and a toll-free telephone number that Residential Generators can call to find nearby collection locations and understand how the Program works.

6.53.080 - Report.

A. On or before July 1, 2014 (or at a later date as approved in writing by the Department) and in each subsequent year, every Producer, group of Producers, or Stewardship Organization operating a Product Stewardship Program must prepare and submit to the Department an annual written report describing the Program's activities during the previous reporting period. The report must include the following:

1. A list of Producers participating in the Product Stewardship Program;

2. The amount, by weight, of Unwanted Products collected from Residential Generators collected at each drop-off site and in the entire County of Alameda and, if applicable, the total amount by weight collected by a Mail-Back Program;

3. A description of the collection system, including the location of each collection site and, if applicable, locations where envelopes for a Mail-Back Program are provided;

4. The name and location of disposal facilities at which Unwanted Products were disposed of and the weight of Unwanted Products collected from Residential Generators disposed of at each facility;

5. Whether policies and procedures for collecting, transporting, and disposing of Unwanted Products, as established in the Plan, were followed during the reporting period and a description of any noncompliance;

6. Whether any safety or security problems occurred during collection, transportation, or disposal of Unwanted Products during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security;

7. A description of public education and outreach activities implemented during the reporting period, including the methodology used to evaluate the outreach and Program activities;

8. How the Product Stewardship Program complied with all other elements in the product stewardship Plan approved by the Department, including its degree of success in meeting any performance goals set by the Department as part of its approval of the Program; and

9. Any other information that the Department may reasonably require.

B. For the purposes of this section, "reporting period" means the period beginning January 1 and ending December 31 of the same calendar year.

6.53.090. — List of Producers. The Department shall provide on its website a list of all Producers participating in Product Stewardship Programs approved by the Department and a list of all Producers the Department has identified as noncompliant with this Chapter or any regulations adopted pursuant to this Chapter.

6.53.100. - Regulations and fees.

A. The Director of the Department of Environmental Health may, after a noticed public hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this Chapter.

B. As soon as practicable, the Department shall submit to the Board of Supervisors a proposed schedule of fees to be charged to the Producers to cover Alameda County's costs of administering and enforcing this Ordinance.

6.53.110. - Enforcement.

A. The Department of Environmental Health shall administer the penalty provisions of this Chapter.

B. The Department of Environmental Health may issue an administrative citation to a Producer for violation of this Chapter or any regulation adopted pursuant to this Chapter. The Department shall first send a written warning to the Producer as well as a copy of this Chapter and any regulations adopted

pursuant to this Chapter. The Producer shall have 30 days after receipt of the warning to comply and correct any violations.

C. If the Producer fails to comply and correct any violations, the Department may impose administrative fines for violations of this Chapter or of any regulations adopted pursuant to this Chapter. Each day shall constitute a separate violation for these purposes.

D. Any Person in violation of this Chapter or any regulation adopted pursuant to this Chapter shall be liable to the County of Alameda for a civil penalty in an amount not to exceed one thousand dollars ($1,000) per day per violation. Each day in which the violation continues shall constitute a separate and distinct violation.

E. In determining the appropriate penalties, the Department of Environmental Health shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.

F. Any Producer receiving an administrative citation under this Chapter or any regulation adopted pursuant to this Chapter may appeal it within 21 calendar days from the date the administrative citation was issued. The administrative citation is deemed issued on the day it is sent by first class mail or personal service. The administrative citation shall state the date of issuance. If the deadline falls on a weekend or County of Alameda holiday, then the deadline shall be extended until the next regular business day.

The request to appeal must:

1. Be in writing;
2. Be accompanied by a deposit of the total fine and any fees noted on the administrative citation;
3. Specify the basis for the appeal in detail;
4. Be postmarked within 21 days from the date the administrative citation was issued; and
5. Be sent to the address as set forth on the administrative citation.

G. The written request to appeal will be reviewed and, if found to be complete, a date, time and place shall be set for a hearing before a hearing officer designated by the Director of the Department of Environmental Health. Written notice of the time and place for the hearing will be served by first class mail or personal service at least 21 days prior to the date of the hearing to the Producer appealing the citation. Service by first class mail, postage prepaid shall be effective on the date of mailing.

H. Failure of any Producer to file an appeal in accordance with the provisions of this section shall constitute waiver of that Producer's rights to administrative determination of the merits of the administrative citation and the amount of the fine and any fees and shall constitute a failure by that Producer to exhaust administrative remedies.

I. The Producer requesting the appeal may request the Director of the Department of Environmental Health to recuse a hearing officer for reasons of actual prejudice against the party's cause. The hearing officer shall conduct an orderly, fair hearing and accept evidence as follows:

1. A valid administrative citation shall be prima facie evidence of the violation;

2. Testimony shall be by declaration under penalty of perjury except to the extent the hearing officer permits or requires live testimony concerning the violation.

3. The hearing officer may reduce, waive or conditionally reduce the fines and any fees stated in the administrative citation. The hearing officer may impose deadlines or a schedule for payment of the fine and any fees due in excess of the deposit.

4. The hearing officer shall make findings based on the record of the hearing and make a written decision based on the findings ("Hearing Officer Decision"). The Hearing Officer Decision shall be served by first class mail on the Producer appealing and the Department. The Hearing Officer Decision affirming or dismissing the administrative citation is final, unless a timely notice of appeal is filed for hearing by the Board of Supervisors of the County of Alameda.

J. A second appeal may be filed with the Board of Supervisors within ten calendar days after the date of service of the Hearing Officer Decision.

1. The appeal may be taken by any Producer or the Department within said ten-day period, by filing with the clerk of the Board of Supervisors a notice of appeal specifying the grounds for such appeal. The \Board of Supervisors shall

not hear any appeal that is untimely filed.

2. Upon receiving an appeal, the Clerk of the Board of Supervisors shall indicate upon every notice of appeal received the date upon which it was filed. The Department shall immediately arrange for an administrative record to be made available to the Board of Supervisors of all of the documents constituting the record upon which the action appealed was taken.

3. The Board of Supervisors shall give written notice of the time and place for a public hearing on any appeal filed pursuant to this section to the appellant and the Department.

4. The Board of Supervisors may hear additional evidence in its sole discretion and may sustain, modify or overrule any order brought before it on appeal.

5. The Board of Supervisors may make such findings and decisions as are consistent with state law and the County of Alameda Ordinances. If no motion relative to the Hearing Officer Decision appealed attains a majority vote of the Board of Supervisors within thirty (30) days from the date of the hearing by said board thereon, the Hearing Officer Decision shall stand sustained and be final.

K. The Department of Environmental Health may establish appropriate administrative rules for

implementing this Chapter, conducting hearings, and rendering decisions pursuant to this section.

L. Upon the failure of any Producer to comply with any requirement of this Chapter and any rule or regulation adopted pursuant to this Chapter, the Alameda County Counsel's Office may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including restraining such Person from continuing any prohibited activity and compelling compliance with lawful requirements. However, this subsection does not permit the County of Alameda or any court of competent jurisdiction to restrain the sale of any Covered Drug in Alameda County.

M. Any Person who knowingly and willfully violates the requirements of this Chapter or any rule or regulation adopted pursuant to this Chapter is guilty of a misdemeanor and may be prosecuted by the Alameda County District Attorney's Office. A conviction for a misdemeanor violation under this Chapter is punishable by a fine of not less than fifty dollars ($50) and not more than five hundred ($500) for each day per violation, or by imprisonment in the Alameda County Jail for a period not to exceed six (6) months, or by both such fine and imprisonment.

6.53.120 - Additional provisions.

A. Disclaimer. In adopting and implementing this Chapter, the County of Alameda is assuming an undertaking only to promote the general welfare. Alameda County is not assuming or imposing on its officers and employees an obligation by which they could be liable in money damages to any Person or Entity who claims that a breach proximately caused injury.

B. Conflict with State or Federal Law. This Chapter shall be construed so as not to conflict with applicable federal or state laws, rules or regulations. Nothing in this Chapter shall authorize any Alameda County agency or department to impose any duties or obligations in conflict with limitations on municipal authority established by state or federal law at the time such agency or department action is taken. Alameda County shall suspend enforcement of this Ordinance to the extent that said enforcement would conflict with any preemptive state or federal legislation subsequently adopted.

C. Severability. If any of the provisions of this Chapter or the application thereof to any Person or circumstance is held invalid, the remainder of those provisions, including the application of such part or provisions to Persons or circumstances other than those to which it is held invalid shall not be affected thereby and shall continue in full force and effect. To this end, the provisions of this Chapter are severable.

D. Environmental Findings. The County of Alameda has determined that the actions contemplated in this Ordinance are in compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.).

E. Nothing in this Ordinance, or the Program of stewardship in which manufacturers of pharmaceutical products who sell Prescription Drugs in Alameda County are required to participate, is intended to protect anticompetitive or collusive conduct nor shall this Ordinance be construed to modify, impair, or supersede the operation of any of the antitrust laws or unfair competition laws of the State of California or of the United States.

F. This Ordinance shall be construed in accordance with California state law, including but not limited to the Medical Waste Management Act set forth at California Health and Safety Code sections 117600, et seq., and shall not be construed in a way that would result in conflict with, or preemption by, any such state law.

G. This Ordinance is entitled to a categorical exemption of the California Environmental Quality Act ("CEQA") pursuant to 14 California Code of Regulations section 15307, which exempts "actions taken by regulatory agencies, as authorized by state or local ordinance, to assure the maintenance, restoration, enhancement, or protection of the environment where the regulatory process involves procedures for protection."

H. This Chapter shall be in effect for a period of ten (10) years following enactment.

Adopted by the Board of Supervisors of the County of Alameda, State of California, on July 24, 2012, by the following called vote:

AYES: Supervisors Carson, Chan, Haggerty, Valle and President Miley—5.

NOES: None

EXCUSED: None

/s/ Nate Miley

NATE MILEY,
President
Board of Superviors
County of Alameda,
State

ATTESTED TO:

Clerk Board of Supervisors, County of Alameda
By: _____

APPROVED AS TO FORM:

DONNA R. ZIEGLER
County Counsel
By: /s/ Robert D. Reiter
ROBERT D. REITER
Deputy County Counsel

APPENDIX D

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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PHARMACEUTICAL RESEARCH AND	Case No. 3:12-cv-06203-

MANUFACTURERS OF AMERICA; GENERIC PHARMACEUTICAL ASSOCIATION; and BIOTECHNOLOGY INDUSTRY ORGANIZATION, Plaintiffs, v. ALAMEDA COUNTY, CALIFORNIA, and ALAMEDA COUNTY DEPARTMENT OF ENVIRONMENTAL HEALTH, Defendants.	RS **STIPULATION AS TO UNDISPUTED FACTS FOR CROSS-MOTIONS FOR SUMMARY JUDGMENT** Date: June 27, 2013 Time: 10:00 a.m. Judge: The Honorable Richard Seeborg Place: Courtroom 3, 17th Floor

Plaintiffs Pharmaceutical Research and Manufacturers of America ("PhRMA"); Generic Pharmaceutical Association ("GPhA); and Biotechnology Industry Organization ("BIO") and Defendants Alameda County, California, and Alameda County Department of Environmental Health (collectively "Alameda County") hereby stipulate that the following facts are undisputed for purposes of the parties' cross-motions for summary judgment. This Stipulation governs only those cross-motions and does not preclude the parties from challenging the facts set forth herein if this case is

not resolved by the motions and this action moves into formal discovery.

1. The Alameda County Safe Drug Disposal Ordinance, Alameda Health and Safety Code Sections 6.53.010, *et seq.* (the "Ordinance"), requires that manufacturers of prescription drugs who sell, offer for sale, or distribute prescription drugs in Alameda County ("Producers," as defined in the Ordinance) operate and finance a product stewardship plan that provides for the collection, transportation, and disposal of certain unwanted prescription drugs.

2. The Ordinance declares that in Alameda County, 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; that the groundwater and drinking water are being contaminated by unwanted, leftover, or expired prescription drugs passing through wastewater and treatment centers; and that there is no mandatory statewide drug stewardship program in California for the safe collection of unwanted drugs, and drug manufacturers and producers have not offered any support for a permanent collection program to date.

3. Pursuant to the Ordinance, Producers are required to operate, individually or jointly with other Producers, a Department-approved product stewardship program or enter into an agreement with a stewardship organization to operate, on each Producer's behalf, a Department-approved product stewardship program. In order to ensure that costs are fairly allocated, if more than one Producer is

involved in a proposed product stewardship program, the product stewardship plan must include a fair and reasonable manner for allocating the costs of the program among the participants, such that the portion of costs paid by each Producer is reasonably related to the amount of prescription drugs that Producer sells in Alameda County.

4. The Ordinance, on its face, does not impose different requirements on Producers within Alameda County and Producers outside of Alameda County.

5. The Ordinance, on its face, does not impose different requirements on Producers within California and Producers outside of California.

6. The Ordinance, on its face, applies both to interstate Producers and intrastate Producers.

7. The Ordinance requires Producers that market and sell in Alameda County the prescription drugs identified in the Ordinance be responsible for the disposal of those products.

8. Any person, manufacturer, or distributor that does not sell, offer for sale, or distribute prescription drugs in Alameda County is not required to undertake any action under the Ordinance.

9. Nothing in the Ordinance requires that Producers implement stewardship plans in any location or jurisdiction outside of Alameda County. If Producers are required to implement stewardship programs in any other jurisdiction, nothing in the Ordinance requires that the stewardship program implemented in other jurisdictions be the same as the program implemented in Alameda County pursuant to the Ordinance. Similarly, nothing in the Ordinance prohibits Producers from proposing and

implementing a program in Alameda County that they are already using or contemplating using in any other jurisdiction.

10. Plaintiffs are non-profit trade organizations representing the manufacturers and distributors of pharmaceutical products. Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") represents companies that produce brand-name drugs. Plaintiff Generic Pharmaceutical Association ("GPhA") represents companies that produce generic drugs. Plaintiff Biotechnology Industry Organization ("BIO") represents companies that produce biotechnology products.

11. Plaintiffs' members include approximately one hundred companies that are subject to the Alameda County take-back ordinance because they manufacture prescription drugs that are sold, offered for sale, or distributed in Alameda County. *See* Ex. A (lists of members). Plaintiffs' members also manufacture prescription drugs that are sold or distributed throughout the United States. *Id.*

12. Three of Plaintiffs' members (Amgen, Impax Laboratories, and XOMA Ltd.) have their corporate headquarters or principal places of business in Alameda County. Ex. A.

13. Two of Plaintiffs' members (Bayer and Impax Laboratories) have facilities in Alameda County that manufacture prescription drugs for commercial distribution. Four other members (Abbott, Baxter, Novartis, and Boehringer Ingelheim) have manufacturing facilities in Alameda County that do not manufacture prescription drugs for commercial distribution.

14. According to a database maintained by the Federal Drug Administration, twenty-four facilities that are registered to manufacture, prepare, propagate, compound, or process prescription and non-prescription drugs for commercial distribution in the United States are located in Alameda County. Ex. B (list of companies).

15. Nineteen of these facilities do not manufacture prescription drugs, but either manufacture products such as medical gases, cosmetics, vitamins, and supplements, or engage in non-manufacturing activities such as compounding or repackaging.

16. Of the remaining five facilities, one facility (operated by Boehringer Ingelheim) manufactures products that are not commercially distributed in the United States. The other four are the facilities mentioned above that are operated by Plaintiffs' members Bayer and Impax Laboratories.

17. The drugs manufactured in Alameda County for commercial distribution by Bayer and Impax Laboratories account for less than 1% of total annual U.S. prescription drug sales (approximately $320 billion in 2011). Thus, approximately 99% of all prescription drugs sold in the United States, by revenue, are manufactured outside Alameda County.

18. There is a national system for the distribution of prescription drugs from manufacturers to the retail and mail pharmacies that dispense the drugs to consumers. Prescription drugs typically move from a manufacturer's facilities to either a pharmaceutical wholesaler, a chain warehouse operated by a large retail drugstore chain, or a mail pharmacy.

19. Smaller retail pharmacies in Alameda County (and elsewhere) typically rely on pharmaceutical

wholesalers for direct delivery of prescription drugs to individual retail locations. Large retail drugstore chains typically rely on delivery by either pharmaceutical wholesalers or their own chain warehouses. Mail pharmacies purchase drugs from both pharmaceutical wholesalers and directly from manufacturers.

20. Three pharmaceutical wholesalers — AmeriSource Bergen Corporation, Cardinal Health, Inc. and McKesson Corporation — operate more than eighty distribution centers across the United States. None of these wholesalers have a distribution center in Alameda County.

21. The California Board of Pharmacy maintains a list of licensed wholesalers. None of the twenty-one locations in Alameda County with an active wholesale license distributes prescription drugs.

22. CVS, Walgreen, and Rite Aid are the three largest national drugstore chains but account for less than half of the retail pharmacies in Alameda County. None of these chains operate a warehouse distribution center in Alameda County.

23. The prescription drugs manufactured by Bayer and Impax Laboratories in Alameda County are shipped outside the County before being distributed back into Alameda County.

24. Neither the County nor Plaintiffs are aware of any prescription drugs distributed in Alameda County that arrive there via intra-County distribution channels as opposed to arriving there via distribution channels that cross the County's borders, either because the drugs are manufactured outside the County or because, if manufactured within the County, they are shipped to out-of-county packaging

or distribution centers before being distributed to in-county pharmacies.

25. Producers will incur start-up costs to establish a product stewardship program that complies with the Ordinance. These costs include the incorporation and governance of an entity to operate the required collection program on behalf of the Producers, initial one-time investments in equipment and facilities, and the preparation and dissemination of education and outreach materials publicizing the program.

26. Assuming that all Producers jointly operate a single collection program — an assumption that results in lower overall costs than if multiple programs were operated separately — Plaintiffs estimate that overall start-up costs will be approximately $1,100,000.

27. Plaintiffs estimate that Producers will incur annual costs to operate a program that complies with the Ordinance, including costs for labor, insurance, education and outreach, and transportation and disposal of collected unwanted prescription drugs. Assuming that all Producers jointly operate a single program, overall annual compliance costs (including reimbursement of County administrative expenses) are estimated by Plaintiffs to be approximately $1,200,000, provided that local pharmacies are willing to provide free space for the location of collection kiosks. If local pharmacies either demand rent or refuse altogether to provide space for collection kiosks, then Plaintiffs believe the recurring annual costs may be higher.

28. The Ordinance requires Producers to reimburse Alameda County for actual costs incurred by the County in administering the Ordinance.

Alameda County has estimated those annual administrative costs to be roughly $200,000. Ex. C (Alameda estimates)

29. Plaintiffs' estimated costs for its members to comply with the Ordinance assume that the costs would not be paid by any single Producer or financed solely by the approximately 100 members of Plaintiffs that are Producers. Rather, the estimated costs are assumed to be spread amongst all Producers that sell, offer for sale, or distribute prescription drugs in Alameda County.

30. Defendants estimate that the annual cost for compliance with the Ordinance is lower than Plaintiffs' estimates, totaling less than $330,000 per year. For purposes of the cross-motions for summary judgment contemplated by the parties, however, the parties believe that the difference between their estimates is not material to the outcome of the parties' motions.

31. The Form 10-Ks required under federal law to be filed by some of Plaintiffs' members on an annual basis are required to be signed under penalty of perjury by each company's chief executive officer, chief financial officer, chief accounting officer, and a majority of the Board of Directors and filed with the Securities and Exchange Commission ("SEC") and represent to the SEC and to the public that the financial information and data provided in the filing accurately reflect the financial condition of the company. For purposes of the cross-motions for summary judgment, Plaintiffs do not dispute the information in these and similar regulatory filings.

32. According to IMS Health, a pharmaceutical information and consulting company, total

prescription drug sales in the U.S. since 2005 are as follows:

Year	Total U.S. Prescription Drug Market
2005	$247.3 billion
2006	$270.3 billion
2007	$280.5 billion
2008	$285.7 billion
2009	$300.7 billion
2010	$308.6 billion
2011	$319.9 billion

33. Plaintiffs at this time lack specific data about the annual revenue generated by their members that is attributable to selling, offering for sale, or distributing prescription drugs in Alameda County. Similarly, at this time Plaintiffs do not know the annual revenue generated by all Producers that is attributable to selling, offering to sell, or distributing prescription drugs in Alameda County.

34. Defendants estimate the total retail pharmaceutical sales in Alameda County in 2010 was approximately $965 million. The parties have no reason to believe that the total retail pharmaceutical sales in Alameda County have materially decreased since 2010.

35. According to IMS Health, pharmaceutical promotional spending in the U.S. since 2007 is as follows:

Year	Total U.S. Promotional Spending
2007	$11.812 billion
2008	$11.267 billion
2009	$10.973 billion
2010	$10.185 billion
2011	$10.737 billion

36. Plaintiffs do not know the amount of spending by their members or by all Producers attributable to promotional activities in Alameda County.

37. Plaintiffs agree that the Ordinance's environmental, health and safety benefits are not contested for purpose of the cross-motions for summary judgment.

38. Plaintiffs' legal position is that, even assuming that take-back programs further important interests, the County violates the Commerce Clause by requiring interstate drug manufacturers to conduct and pay for such programs.

DATED: April 4, 2013 JONES DAY

By: /s/ Craig E. Stewart
CRAIG E. STEWART

Attorneys for Plaintiffs PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; GENERIC PHARMACEUTICAL ASSOCIATION; and BIOTECHNOLOGY INDUSTRY ORGANIZATION

DATED: April 4, 2013 SHARTSIS FRIESE LLP

By: /s/ Mary Jo Shartsis
MARY JO SHARTSIS

Attorneys for Defendants
ALAMEDA COUNTY,
CALIFORNIA and
ALAMEDA COUNTY
DEPARTMENT OF
ENVIRONMENTAL
HEALTH

APPENDIX E

February 10, 2012

County of Alameda CA Board of Supervisors
Nathan A. Miley
Supervisor District 4
Oakland Office
1221 Oak Street, Suite 536
Oakland CA 94612

Subject: Support of the Alameda County Medication Disposal Ordinance

Dear Supervisor Miley:

Union Sanitary District enthusiastically supports the Alameda County Medication Disposal Ordinance. USD's primary focus is to collect, treat and dispose of wastewater from residents in Fremont, Newark and Union City. USD also developed and coordinates a pharmaceutical collection program for Tri-City residents that is entirely funded by USD. This program has grown in the volume of medications received each year, since its inception in 2009. Last year USD responsibly collected and properly disposed of 2,400 pounds of unused pharmaceuticals.

We support the concept of requiring pharmaceutical companies to design and fund a program for the disposal of these unused medications. Keeping these medications out of the wastestream and receiving waters is the main objective for these programs, and is in line with USD's mission to protect human health and the environment.

We support the product stewardship concept in this ordinance, which aligns with other product stewardship programs recently passed by the California Legislature for carpet and paints. USD believes that Pharmaceutical companies should share in the responsibility of collection and disposal of medications they produce. The burden of cost should not fall on local agencies or the ratepayers.

Union Sanitary District thanks you for your leadership on this very important issue and strongly supports the Alameda County Medication Disposal Ordinance.

Sincerely,

/s/ Richard Currie

Richard Currie
General Manager

5072 Benson Road, Union City, CA 94587-2508
P.O. Box 5050, Union City, CA 94587-8550
(510) 477-7500 FAX: (510) 477-7501
www.unionsanitary.com

February 21, 2012

The Alameda County Board of Supervisors
1221 Oak Street, Suite 536
Oakland, CA 94612

RE: Alameda County Safe Disposal Ordinance

Dear Alameda County Board of Supervisors:

On behalf of thousands of supporters in Alameda County and 25,000 members throughout the Bay Area, we strongly urge your support for the Alameda County Safe Disposal Ordinance.

Mounting evidence of dramatic increases in accidental poisonings, diversion for abuse and harmful environmental effects demonstrate the need for safe and secure options for disposal which are as convenient as are opportunities to purchase pharmaceuticals. Medications improperly disposed of in the trash are a stormwater runoff and groundwater contamination concern. Sewage treatment plants are unable to filter pharmaceuticals out of our waste water, which means that

medications flushed down the toilet end up in the Bay.

Safe disposal of pharmaceuticals is a shared societal burden, the costs of which should not fall on local government which does not profit from the sale of pharmaceuticals. Like other products such as auto batteries, paint and carpets whose manufacturers have taken responsibility for end of life and residual product management, we believe pharmaceutical manufacturers should be responsible for designing and funding programs for the disposal of their unused products.

Sincerely,

/s/ David Lewis

David Lewis
Executive Director

1330 Broadway,
Suite 1800
Oakland, CA 94612
510-463-6850

SaveSFbay.org

FAX: (925) 372-7635

JAMES M. KELLY
General Manager

KENTON L. ALM
Counsel for the District
(510) 808-2000

ELAINE R. BOEHME
Secretary of the District

January 18, 2012

Supervisor Miley in partnership with the
Senior Alcohol and Other Drug (AOD)
Prevention Workgroup
1221 Oak Street, #536
Oakland, CA 94612

Dear Supervisor Miley and AOD Prevention Workgroup:

Support of the Alameda County Safe Drug Disposal Ordinance

Central Contra Costa Sanitary District (CCCSD) supports the Alameda County Safe Drug Disposal ordinance. CCCSD provides wastewater treatment and collects household hazardous waste from residents in central Contra Costa County. CCCSD also operates a pharmaceutical collection program that continues to increase in waste volume and expense of which all of our ratepayers must bear the cost.

We support the concept of requiring pharmaceutical companies to design and fund a program for the disposal of their unused products. Local governments, such as ours, do not profit from the sale of pharmaceuticals. Therefore, we should not bear the cost of their collection and proper disposal nor should our ratepayers.

CCCSD supports the extended producer responsibility (EPR) concept in this ordinance which aligns with other EPR programs which recently passed the California legislature for carpet and paint. CCCSD believes that pharmaceutical companies should share in the responsibility for proper management of the pharmaceuticals they produce.

Central Contra Costa Sanitary District thanks you for your leadership on this important issue and strongly supports the Alameda County Safe Drug Disposal ordinance.

Sincerely,

/s/ David Wyatt

David Wyatt
Supervisor, HHW Program

DW/mvp

cc: Kamika Dunlap, kamika.dunlap@acgov.org

February 10, 2012

Nate Miley, Alameda County Supervisor, District 4
Eden Area District Office
20993 Redwood Road
Castro Valley, CA 94546

Subject: Letter of Support for Countywide Safe Drug Disposal Ordinance

On behalf of the Castro Valley Sanitary District (CVSan) Board and staff, I would like to express our support for the Draft Countywide Safe Drug Disposal Ordinance.

The safe management and disposal of pharmaceutical (medicine) waste is important to CVSan and our community. As Castro Valley Community Action Network (CVCan) has found: "Improper disposal (of pharmaceuticals) can lead to pharm abuse, accidental poisonings and groundwater/bay pollution."

We believe the Draft Ordinance, which proposes a product stewardship program wherein all producers of covered products sold in Alameda County shall collect and dispose of unwanted products from residential generators, is the right direction for Alameda County.

Again, we thank you for your efforts to provide safe management and disposal of pharmaceutical (medicine) waste in Castro Valley and Alameda

County and support the Countywide Safe Drug Disposal Ordinance.

Yours Truly,

/s/ Roland P. Williams Jr.

Roland P. Williams Jr.
General Manager

cc: Board, N. Lue, J. Figueiredo, Pharmaceuticals File

S:\Solid Waste\Pharmaceutical Waste\2012\Letter of Support to Nate Miley_2012-2-10.docx

21040 MARSHALL STREET, CASTRO VALLEY, CA 94546-6020 | (510) 537-0757 | FAX (510) 537-1312 | www.cvsan.org

Municipal Services Agency

Department of Waste Management & Recycling
Paul Philleo, Director

Bradley J. Hudson, County Executive

Robert B. Leonard, Chief Deputy County Executive

February 16, 2012

The Alameda County Board of Supervisors
1221 Oak Street
Suite 536
Oakland, California 94612

Honorable Chairperson, Alameda County Board of Supervisors,

The Sacramento County Waste Management and Recycling Department supports the Alameda County Safe Disposal Ordinance for consideration by your board, and strongly encourages adoption of the ordinance.

The Sacramento County Board of Supervisors adopted Resolution 2008-0593 supporting Extended Producer Responsibility policies and legislation to shift universal waste management costs, for products such as pharmaceuticals, from local government and local waste management service ratepayers to the producers of the product.

Mounting evidence of dramatic increases in accidental poisonings, diversion for abuse, and the harmful environmental effects demonstrate the need

for safe and secure options for disposal which are as convenient as are opportunities to purchase pharmaceuticals.

Safe disposal of pharmaceuticals is a shared societal burden, the costs of which should not fall on local government which does not profit from the sale of pharmaceuticals. Like other products such as auto batteries, paint and carpets whose manufacturers have taken responsibility for end of life and residual product management, we believe pharmaceutical manufacturers should be responsible for designing and funding programs for the disposal of their unused products.

Therefore, this Department supports Alameda County's Safe Disposal Ordinance and strongly encourages the Board's adoption of the ordinance.

Sincerely,

/s/ Paul Philleo

Paul Philleo
Director

9850 Goethe Road • Sacramento, California 95827•

phone (916) 875-6789 • fax (916) 875-6767

www.saccounty.net • www.sacgreenteam.com

Wednesday, February 15, 2012

The Alameda County Board of Supervisors
1221 Oak Street
Suite 536
Oakland, California 94612
Fax: (510) 465-7628
Staff Contact: kamika.dunlap@acgov.org

RE: Alameda County Safe Disposal Ordinance

Dear Alameda County Board of Supervisors:

The Teleosis Institute supports the Alameda County Safe Disposal Ordinance for consideration by your board, and strongly encourages adoption of the ordinance.

Mounting evidence of dramatic increases in accidental poisonings, diversion for abuse and harmful environmental effects demonstrate the need for safe and secure options for disposal which are as convenient as are opportunities to purchase pharmaceuticals.

Safe disposal of pharmaceuticals is a shared societal burden, the costs of which should not fall on local government which does not profit from the sale of pharmaceuticals. Like other products such as auto batteries, paint and carpets whose manufacturers have taken responsibility for end of life and residual product management, we believe pharmaceutical manufacturers should be responsible for designing and funding programs for the disposal of their unused products.

Sincerely:

/s/ Evin Guy

Evin Guy
Teleosis Institute
863 Arlington Ave.
Berkeley, CA 94707
Phone: 510.558.7285
www.teleosis.org

EAST BAY MUNICIPAL UTILITY DISTRICT

DAVID R. WILLIAMS
DIRECTOR OF
WASTEWATER

February 6, 2012

Supervisor Nate Miley in partnership with the
Senior Alcohol and Other Drug (AOD) Prevention
Workgroup
1221 Oak Street, #536
Oakland, CA 94612

Dear Supervisor Miley:

Re: Support for the proposed Alameda County Safe Drug Disposal Ordinance

The East Bay Municipal Utility District (the District) supports the Alameda County Safe Drug Disposal Ordinance and the implementation of a sustainable collection and disposal program for unwanted medication funded by pharmaceutical companies.

Currently the District provides wastewater treatment for approximately 650,000 customers in Alameda and Contra Costa Counties. The District has implemented a limited pharmaceutical collection program which increases in waste volume year after year. Following District sponsored collection events and due to our proper disposal outreach campaign we receive many calls from residents and businesses requesting medicine disposal alternatives. The District sponsored take-back locations are limited due to the challenges associated with establishing sites with third parties and costs of a broader program.

The District supports the idea of product stewardship, specifically extended producer responsibility, and the

concept of requiring the pharmaceutical companies to design, implement and fund programs for the disposal of their unused products. The District believes that the pharmaceutical companies should be properly managing the products they produce.

The East Bay Municipal Utility District appreciates your attention to this critical issue and supports approval and implementation of the Alameda County Safe Drug Disposal Ordinance.

Sincerely,

/s/ David R. Williams

David R. Williams
Director of Wastewater

DRW:CRJ

cc: Kamika Dunlap, kamika.dunlap@acgov.org
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PO. BOX 24055 . OAKLAND . CA 94623-1055 . (510) 287-1405

LIVERMORE
CALIFORNIA

January 31, 2012

Supervisor Miley in parternship with the
Senior Alcohol and Other Drug (AOD)
Prevention Workgroup
1221 Oak Street, #536
Oakland, CA 94612

RE: Support of the Alameda County Safe Drug Disposal Ordinance

Dear Supervisor Miley and AOD Prevention Workgroup:

The City of Livermore Water Resources Division provides wastewater collection and treatment for approximately 83,604 residents, businesses and industries; and delivers drinking water to nearly 29,000 customers, recycled water for irrigation to more than 60 customers, and recycled water for fire protection to 22 commercial and industrial buildings. In addition, the Water Resource Division operates the annual Livermore Drug Take-Back Event at the Livermore Police Department.

In 2008, the Livermore Drug Take-Back Event was developed to educate Tri-Valley (Livermore, Pleasanton and Dublin) residents about the threat of potential misuse or abuse of unwanted drugs at home among children, teens and older adults, and the environmental impacts of pouring or flushing unwanted drugs down the sink and toilet on the San Francisco Bay and irrigation water. From 2008 to 2011, the number of annual event participants

increased from 201 participants to 428 participants, the quantity of pharmaceutical waste collected increased from 305 pounds to 1,073 pounds, and the cost of pharmaceutical waste disposal increased from $941.00 to $1,650.00. Surveyed participants thanked Water Resources Division for the opportunity to safely and properly dispose of their unwanted drugs, and voiced the need for more events and/or a permanent drop-box. Unfortunately, the Livermore Drug Take-Back Event cannot be duplicated or sustained over the long-term due to increasing waste volumes and rising pharmaceutical waste disposal costs on rate payers.

We support the Safe Drug Disposal Ordinance's product stewardship strategy that requires pharmaceutical companies to design and fund a program for the disposal of their unused products with a minimum of one take back location in every city. We and our rate payers do not profit from the sale of pharmaceuticals; therefore, we should not bear the cost and responsibility of their collection and proper disposal. We also support the Ordinance's recommendations for implementation, reporting, regulations and fees, and enforcement.

Water Resources Division	101 W. Jack London Boulevard . Livermore, CA 94551	www.ci.livermore.ca.us

The City of Livermore Water Resources Division thanks you for your leadership on this issue and strongly supports the Alameda County Safe Drug Disposal Ordinance.

Sincerely,

/s/ Darren Greenwood

Darren Greenwood
Assistant Public Works Director
Water Resources Division, Public Works Department
Phone (925) 960-8120
Fax (925) 960-8105

Cc: Kamika Dunlap, Kamika.dunlap@acgov.org

February 10, 2012

Dear Supervisor Miley,

The ***ADULT DAY SERVICES NETWORK OF ALAMEDA COUNTY*** would like to express our support for the proposed County-wide Safe Drug Disposal Ordinance. This ordinance will hold producers responsible for creating a program to dispose of unwanted and expired drugs and thereby reduce the incidents of illnesses and deaths caused by accidental poisonings among older adults.

Establishing a program that will make drug disposal easy and accessible will encourage older adults to remove unneeded over-the-counter medications and prescription drugs from their homes. Removing these drugs will help eliminate occurrences of taking the wrong medication, mixing medications, and taking expired medications.

The safe and proper disposal of unnecessary medications will decrease access and availability of drugs to younger members of the family and insure that excess drugs don't end up in our landfills and ground water.

We absolutely support the Safe Drug Disposal Ordinance and encourage the Board of Supervisors to support this ordinance which will protect Alameda County residents and our environment.

Sincerely,

/s/ Cait McWhir

Cait McWhir
SIPP Member,
Program & Outreach Coordinator

510 17th Street, Suite 200, Oakland, CA 94612 | (510) 883-0874 | fax (510) 344-6356 | www.adsnac.org

CREEKSIDE MIDDLE SCHOOL
"A California Distinguished School"
19722 CENTER STREET
$ CASTRO VALLEY,
CALIFORNIA 94546
CASTRO VALLEY UNIFIED
SCHOOL DISTRICT
(510) 247-0665

Mary Ann DeGrazia, Principal
Susan Goldman, Assistant Principal

February 15, 2012

Attn: Clerk of the Board
Alameda County Board of Supervisors
1221 Oak Street, Suite 536
Oakland, CA 94612

Dear Honorable Supervisors:

On behalf of Creekside Middle School, I would like to express our support for the proposed County-wide Safe Drug Disposal Ordinance. This ordinance will hold producers responsible for creating a program to dispose of unwanted and expired drugs and thereby reduce the incidents of illnesses and deaths caused by accidental poisonings among older adults and youth.

Establishing a program that will make drug disposal easy and accessible will encourage citizens to remove unneeded over-the-counter medications and prescription drugs from their homes. Removing these drugs will help eliminate occurrences of taking the wrong medication, mixing medications, and taking expired medications.

The safe and proper disposal of unnecessary medications will decrease access and availability of drugs to younger members of the family and insure that excess drugs don't end up in our landfills and ground water.

We support the Safe Drug Disposal Ordinance and encourage the Board of Supervisors to support this ordinance which will protect Alameda County residents, youth, and our environment.

Sincerely,

/s/ Mary Ann DeGrazia

Mary Ann DeGrazia
Principal

CV CAN
4400 Alma Avenue
Castro Valley, CA 94546
510.537.3335 x1936
www.cvcan.net

A coalition committed to reducing substance use among youth in Castro Valley

February 10, 2012

Attn: Clerk of the Board
Alameda County Board of Supervisors
1221 Oak Street, Suite 536
Oakland, CA 94612

Dear Honorable Supervisors,

Castro Valley Community Action Network (CV CAN) would like to express our support for the proposed County-wide Safe Drug Disposal Ordinance. This ordinance will hold producers responsible for creating a program to dispose of unwanted and expired drugs and thereby reduce the incidents of illnesses and deaths caused by accidental poisonings among older adults and youth.

Establishing a program that will make drug disposal easy and accessible will encourage citizens to remove unneeded over-the-counter medications and prescription drugs from their homes. Removing these drugs will help eliminate occurrences of taking the wrong medication, mixing medications, and taking expired medications.

The safe and proper disposal of unnecessary medications will decrease access and availability of drugs to younger members of the family and insure that excess drugs don't end up in our landfills and ground water.

We support the Safe Drug Disposal Ordinance and encourage the Board of Supervisors to support this ordinance which will protect Alameda County residents, youth and our environment.

Sincerely,

/s/ Traci Cross

Traci Cross
Executive Director of CV CAN

ALAMEDA COUNTY
HEALTH CARE SERVICES
AGENCY
ALEX BRISCOE, Director

AGENCY ADMIN. & FINANCE
1000 San Leandro Blvd.,
Suite 300
San Leandro, CA 94577
Tel: (510) 618-3452
Fax: (510) 351-1367

Wednesday, February 22, 2012

Alameda County Board of Supervisors
1221 Oak Street
Suite 536
Oakland, California 94612

Dear Board Members:

Health Care Services Agency supports the Alameda County Safe Disposal Draft Ordinance that will be considered by your Board for adoption.

Evidence shows that accidental poisonings and the diversion of drugs from medicinal to abusive use are increasing. Studies also show that improper disposal of unwanted pharmaceuticals is resulting is unintended yet harmful consequences to the environment. The need for safe and secure mechanisms to dispose of pharmaceuticals which encourages widespread use through convenient access is desirable.

The safe disposal of pharmaceuticals should be considered a societal need for which the cost to

provide should not fall to local government. After all, local government does not produce or profit from the sale of medications, it is the pharmaceutical companies that do. The manufacturers of many other products such as auto batteries paint and carpets have taken responsibility for end of life and residual product management. Health Care Services Agency considers it the pharmaceutical manufacturer's role to be a positive member of the community by shouldering this responsibility by designing and funding the disposal program as described in the draft ordinance.

In considering the adoption of the proposed ordinance, it is recommended the Board also be prepared to accept a mid-year budget adjustment from the Agency for Environmental Health. As part of this consideration it is recommended that General Fund allocation be considered to allow the program adequate time and resources to develop the infrastructure necessary to implement an effective program.

Sincerely,

/s/ Alex Briscoe	/s/ Muntu Davis
Alex Briscoe, Agency Director	Muntu Davis, M.D., MD, MPH Health Officer

Ariu Levi
Director, Environmental Health Services

APPENDIX F

KQED
BAY AREA

Alameda County Poised to Required Companies to Take Back Unused Drugs

by KQED News Staff and Wires | July 23, 2012 — 5:47 PM

Enlarge

Getty Images

Drug companies could soon have to pay for a program to dispose of unused medication in Alameda County. Supervisors are expected to pass a first-in-the-nation "Safe Drug Disposal Measure" on Tuesday.

Alameda County may be the first to pass a law requiring drug companies to dispose of unused medications.

The bill is designed to keep the medications from poisoning kids, being abused by teenagers, or polluting waterways.

Nate Miley is president of the Board of Supervisors and he sponsored the measure.

Cyrus Musiker: Supervisor, explain how you imagine the drug company stewardship program will work.

Nate Miley: Well, basically we're asking the pharmaceutical industry to set up take-back programs or permanent disposal locations so that people could take their unwanted or unused medications and properly dispose of them at a convenient location. We're not telling the pharmaceutical industry what type of program they need to put in place. It could be mail-back, it could be holding more frequent take-back events like the DEA holds, or it could be setting up permanent locations, for instance at all the law enforcement facilities in Alameda County.

Musiker: And law enforcement agencies because controlled substances like Ritalin or OxyContin need to be handled by law enforcement only?

Miley: Exactly.

Musiker: There is a publicly funded program right now where people can discard pills at 28 drop-off locations. What's wrong with that one?

Miley: Well, what's wrong with it is that the taxpayers pay for it. Everybody's got medications in their household and we feel that stewardship is extremely important, so that the pharmaceutical manufacturers of these medications deal with the end-of-life-cyle of these products just like there is with batteries or paint or oil or tires. It basically comes under the title of extended product responsibility. And we just think it's a responsibility on their part to do this and not something that the taxpayers should have to pay for.

Musiker: Drug companies say people could still resell their drugs on the black market, and teenagers could still harvest these drugs from their parent's medicine cabinets to abuse. So would this measure really make a difference on the illegal market?

Miley: I think this measure would make a difference. There's no panacea. In our society there's nothing that can't be abused, but right now we don't have enough in place to try and address the problem of the hoarding of medications. The more we can do to eliminate or reduce that problem, as opposed to allowing someone to just say, "the heck with it," and just toss them in the trash or toss them in the toilet, I think is an important step forward in terms of public safety and public health, as well as environmental health.

Musiker: Here's another argument from the drug companies-- that drugs end up in waterways not after people pour the pills down the toilet, but after people have legally taken the drugs and then excreted them.

Miley: Yeah, they do say that. And I think the data shows that's the case. And so far, I don't think the data has actually shown how that would actually affect and harm both wildlife and humans over time. But clearly there's an impact there. And clearly even the pharmaceutical companies agree that the less we can put in our waterways the better off we all are.

Musiker: And are you expecting a lawsuit from drug companies hoping to block the measure?

Miley: Yes, we've met with the pharmaceutical companies I'd say about half a dozen times, probably more, and they just continue to put up obstacles and reasons why we shouldn't do this. They're saying that the intentions that I'm trying to push here are good,

but the approach is wrong. But they're not offering anything to help. And so, we really anticipate that they're going to file a lawsuit against us on any number of grounds from preemption to antitrust to say that we shouldn't be doing this. I really do think the pharmaceutical companies could be doing themselves a favor by just moving ahead, coming up with a program, a program that the environmental health department would sign off on, as opposed to trying to fight this.

Musiker: Thanks so much. Nate Miley is president of the Alameda County Board of Supervisors. The Board is expected to vote on Tuesday on a Miley's pharmaceutical disposal law.
