

CA No. 13-16833

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *et al.*,
Plaintiffs-Appellants,

v.

ALAMEDA COUNTY, *et al.*,
Defendants - Appellees.

**On Appeal from the United States District Court
for the Northern District of California
No. C 12-6203 RS
(Honorable Richard Seeborg)**

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AND CALIFORNIA HEALTHCARE INSTITUTE
AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS,
URGING REVERSAL**

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Washington Legal Foundation (WLF) states that it is a non-profit corporation organized under § 501(c)(3) of the Internal Revenue Code. WLF has no parent corporation, nor has it issued any stock owned by a publicly held company. The California Health Institute (CHI) states that it is a non-profit corporation organized under § 501(c)(6) of the Internal Revenue Code. CHI has no parent corporation, nor has it issued any stock owned by a publicly held company.

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**BRIEF OF WASHINGTON LEGAL FOUNDATION
AND CALIFORNIA HEALTHCARE INSTITUTE
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INTRODUCTION AND INTERESTS OF *AMICI CURIAE*

The interests of the Washington Legal Foundation (WLF) and the California Healthcare Institute (CHI) are set out more fully in the accompanying motion for leave to file.¹ In brief, WLF is a public interest law firm and policy center headquartered in Washington, D.C., with supporters in all 50 States, including many in California. WLF's primary mission is the defense and promotion of free enterprise, and it regularly litigates in opposition to state and local regulatory measures whose purpose or effect is to disrupt the free flow of interstate commerce.

CHI is an independent § 501(c)(6) organization devoted to researching and advocating policy to forward the interests of California's biomedical community. Its mission is to advance biomedical research, investment, and innovation through effective advocacy of policies to improve public health and ensure continued vitality of the life sciences sector.

¹ Pursuant to Fed.R.App.P. 29(c)(5), WLF and CHI state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, contributed monetarily to the preparation and submission of this brief.

Amici are concerned that the decision below, if affirmed by this Court, will usher in a broad array of local ordinances designed to foist onto other jurisdictions costs and responsibilities that traditionally have been borne by local communities. If Alameda County is permitted to adopt legislation designed to ensure that it need not bear the costs of collecting unused pharmaceuticals from county residents, then other jurisdictions can be expected to take similar steps to relieve local residents of all other disposal costs—such as the costs of disposing of old tires or recycling of wine bottles. Or the costs of local fire protection could be foisted onto interstate manufacturers of flammable products.

Amici oppose such Balkanization of the national economy. When local jurisdictions engage in a reciprocal battle to transfer local costs to the interstate market, no one ends up a net winner. Indeed, such cost-shifting efforts cause significant harm to the national economy because they are economically inefficient: local jurisdictions have little incentive to impose costs prudently when they know that none of their citizens will bear those costs.

Amici are also concerned because of the unprecedented nature of Alameda County's ordinance. The ordinance requires pharmaceutical Producers to come to Alameda County to operate a collection program even though many (and perhaps most) of them have never conducted any sales in the county. Their services are

being commandeered based on little more than that they manufactured a product that eventually found its way, through the stream of commerce, into Alameda County. *Amici* do not believe that such commandeering is consistent with the Commerce Clause, particularly when (as here) the County has taken steps to ensure that the Producers are not permitted to pass their compliance costs on to those who benefit from the program.

STATEMENT OF THE CASE

This case presents a Commerce Clause challenge to Alameda County’s “Safe Drug Disposal Ordinance,” Alameda Health and Safety Code §§ 6.53.010 *et seq.*, a 2012 ordinance that requires Producers of prescription drugs to establish programs (“Product Stewardship Programs” or “PSPs”) to collect and safely dispose all unused prescription medicines within the county.² The PSPs must accept all unused drugs proffered for collection. The Ordinance contemplates that Producers may voluntarily agree to jointly operate a PSP. Ordinance

² The Ordinance defines a “Producer” as the manufacturer of any “drug” (within the meaning of federal law) that “is sold, offered for sale, or distributed in Alameda County” under the manufacturer’s own name or brand. Ordinance § 6.53.030.14(i). The Ordinance specifies additional entities that will be deemed the Producer (including, in some instances, the person who brought the drug into the County) in the event that the manufacturer does not fit the definition of a Producer. *Id.* at § 6.53.030.14(ii) & (iii). Local pharmacies that actually sell prescription drugs to Alameda residents are explicitly excluded from the definition.

§ 6.53.040.A.1. It explicitly prohibits Producers from imposing any fee in connection with operation of a PSP, either at the time the drug is sold/distributed in Alameda County or at the time the unused drug is collected from local consumers.

Id. at § 6.53.040.B.3.

A drug collection and disposal program of the sort mandated by the Ordinance already exists in Alameda County; it is operated by the County itself. The County has not suggested that the existing program is ineffective or that the Producers could run a more effective program. Proponents of the Ordinance explained that it was being adopted as a replacement for the existing program because, they believed, the costs of drug collection and disposal ought to be borne by the Producers of those drugs, rather than by the County government or by Alameda County consumers who seek to dispose of previously purchased drugs.

The three Appellants (plaintiffs below) are trade organizations that represent all major manufacturers and distributors of pharmaceutical products, including about 100 companies that are subject to the Ordinance because their products are sold in Alameda County. They contend that the Ordinance violates the “dormant” aspect of the Commerce Clause of the U.S. Constitution, Art. I, § 8, cl. 3, which has long been understood to impose implicit restraints on the power of state and local governments to regulate interstate commerce.

In connection with cross-motions for summary judgment, the parties stipulated that the material facts are undisputed. Among the principal stipulated facts: (1) drug manufacturers do not supply their products directly to retail pharmacies or engage in any retail sales of their own; rather, they distribute the great bulk of their products to wholesalers or to chain warehouses operated by large retail drugstore chains; and (2) none of the large pharmaceutical wholesalers or retail drugstore chains operates a distribution center in Alameda County. District Court Opinion (“Op.”) at 4-5, ER 4-5. Accordingly, *all* prescription drugs sold or distributed in Alameda County were shipped there from sources outside the County, by someone other than the manufacturer. Op. at 5, ER 5. Two companies maintain facilities within Alameda County for the manufacture of prescription drugs for commercial distribution. The drugs manufactured at those facilities are not kept within Alameda County for retail sale; rather, they are shipped to wholesalers outside the county and account for less than 1% of total annual U.S. prescription drug sales. Op. at 4, ER 4.

Included within the Ordinance are legislative findings that improperly disposed prescription drugs pose unnecessary health risk and cause the contamination of drinking water. Ordinance § 6.53.010. For purposes of the cross-motions for summary judgment, Appellants did not contest the Ordinance’s

environmental, health, and safety benefits. Op. at 6, ER 6.³

On August 28, 2013, the district court issued an order denying Appellants' motion for summary judgment and granting Appellees' (collectively, "Alameda") cross-motion for summary judgment. ER 1-11. The court explained that a local regulation will be found to constitute a *per se* violation of the dormant Commerce 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." Op. at 8, ER 8 (quoting *National Collegiate Athletic Ass'n v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993) ("*NCAA*"). Appellants contended that the Ordinance was *per se* unconstitutional under all three prongs of that test; the court rejected each of those contentions. *Id.* at 8-10.

The district court observed that both the second and third prongs "contain an element of discrimination—*i.e.*, that a challenged regulation favors local commerce

³ Despite that stipulation, it is worth noting that the scientific community has remained quite skeptical of claims that disposal of unused drugs is a cause for significant environmental, health, or safety concerns. Numerous empirical studies have found—and no credible study has disputed—that the minuscule amounts of active pharmaceutical ingredients ("APIs") found in the environment have no adverse effect on human health. *See, e.g.*, World Health Organization, PHARMACEUTICALS IN DRINKING WATER xi (2012). Moreover, there is no evidence that the trace levels of APIs detected are the result of improper disposal, as opposed to the normal bodily functions of patients who ingest medicines. *See, e.g., id.* at 4.

over interstate commerce, or in-state entities over out-of-state entities.” *Id.* at 8.

The court held that “the kind of discrimination potentially prohibited by [the second and third prongs of] the dormant Commerce Clause” requires proof of “differential treatment favoring local entities over substantially similar out-of-state interests,” and that Appellants had supplied no such evidence. *Id.* The court did not discuss whether retail pharmacies located in Alameda County—who are explicitly excepted from the Ordinance—are “substantially similar” to the Producers who are required by the Ordinance to establish drug collection and disposal programs.

The court also rejected Appellants’ contention that the Ordinance was *per se* unconstitutional under the first prong, concluding that “the Ordinance here neither purports to regulate interstate commerce nor does so as a practical matter.” *Op.* at 9, ER 9. It explained:

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. . . . [W]hile 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.

Op. at 9-10, ER 9-10.

Having determined that Appellants had failed to demonstrate that the Ordinance was a *per se* violation of the Commerce Clause, the district court evaluated it under the far-less-exacting “balancing test” articulated in *Pike v. Bruce Church Inc.*, 397 U.S. 137 (1970). The court held that the Ordinance survived that test, concluding that the public health and safety interests served by the Ordinance outweighed “the relatively modest compliance costs producers will incur should they choose to sell their products in the county.” Op. at 10, ER 10.

SUMMARY OF ARGUMENT

Alameda County already has established a program that adequately addresses its environmental, health, and safety concerns arising from the disposal of unused prescription drugs by county residents. Accordingly, the dispute between the parties boils down to the question of who, going forward, is to pay for the costs of continuing to operate an identical or equivalent program. The Ordinance is designed for the express purpose of ensuring that *none* of those costs are borne by Alameda County, its taxpayers, or residents of Alameda County who use prescription drugs. It is designed so that those costs are borne instead by drug manufacturers and distributors with few or no connections to Alameda County and,

ultimately, by consumers living in other parts of the country. It ensures the accomplishment of that objective by: (1) explicitly prohibiting Producers from imposing any fee in connection with operation of a PSP, either at the time the drug is sold/distributed in Alameda County or at the time it is collected from local consumers; and (2) exempting local retail pharmacies—entities that, if included under the Ordinance, would likely have passed along any increased operating expenses to their local customers in Alameda County.

Under those circumstances, the Ordinance constitutes a *per se* violation of the Commerce Clause under all three prongs of the test articulated by this Court in *NCAA*; the Ordinance: (1) directly regulates interstate commerce; (2) discriminates against interstate commerce; and (3) favors in-state economic interests over out-of-state interests. *NCAA*, 10 F.3d at 638. Appellants’ brief explains at length why the Ordinance constitutes an unconstitutional “direct” regulation of interstate commerce. Accordingly, *amici* focus exclusively on the second and third prongs.

First, the Ordinance explicitly discriminates against interstate commerce. It does so principally by exempting local retail pharmacies from the Ordinance while applying it to all drug manufacturers, many of whom have no contacts whatsoever with Alameda County other than that some of the products they manufacture eventually find their way into the county after passing through the stream of

commerce. Discrimination against interstate commerce is deemed to exist when, *inter alia*, a local jurisdiction imposes dissimilar regulations on “substantially similar” entities, one of which is local and the other is based outside the jurisdiction. *General Motors Corp. v. Tracy*, 519 U.S. 278, 298-300 (1997).

Retail pharmacies, drug manufacturers, and drug wholesalers are “substantially similar” with respect to all of the factors relevant to this case. All play a major role in the product distribution system that leads ultimately to the sale of prescription drugs within Alameda County. Indeed, retail pharmacies would seem to have the greatest role in that sales process because they are the ones most directly responsible for bringing the drugs into County and delivering them into the hands of local consumers. Yet, the Ordinance exempts retail pharmacies from any drug collection/disposal responsibilities while imposing those responsibilities on others involved in the sales/distribution process—the great majority of whom have little or no connection with Alameda County.

The discrimination in favor of local retail pharmacies facilitates the overriding objective of the Ordinance: ensuring that costs associated with the collection and disposal program are borne by those living outside of Alameda County. If retail pharmacies were made subject to the Ordinance and thereby faced higher operating costs, one could reasonably expect them to charge increased

prices to their Alameda-based customers as a means of recouping those costs. As Appellants' account of the Ordinance's legislative history conclusively demonstrates, Alameda County adopted the Ordinance for the purpose of transferring to those living outside the County the costs of collecting and disposing unused prescription drugs. The discriminatory preference afforded to retail pharmacies, in contrast to others who play a role in the sale of prescription drugs within the County, is essential to effectuating the County's purpose. Accordingly, not only does the Ordinance have the effect of discriminating against interstate commerce, but that is its intended effect.

The Supreme Court's dormant Commerce Clause cases have been more likely to find improper discrimination when, as here, the burden imposed by the challenged regulation falls on those living outside the local jurisdiction. In such circumstances, the regulatory burdens are "unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected," *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 345 (2007), thereby increasing the need for judicial intervention. No interest group within Alameda County has any economic incentive to oppose a scheme designed to ensure that the benefits conferred on county residents are paid for by burdens imposed on out-of-state companies. The

dormant Commerce Clause’s *per se* ban on discrimination against interstate commerce is aimed at precisely the sort of politically-unaccountable cost-shifting being attempted by Alameda County.

The Ordinance is a *per se* violation of the dormant Commerce Clause for the additional reason that it favors local economic interests over out-of-state and out-of-county interests. The district court rejected Appellants’ assertion that the Ordinance flunked this third prong of the *NCAA* test, concluding that the only relevant “in state economic interests” are “in state producers.” Op. at 8, ER 8. But as the Supreme Court has explained, “Economic protectionism is not limited to attempts to convey advantages over local merchants; it may include attempts to give local consumers an advantage over consumers in other States.” *Camps Newfound/ Owatonna, Inc. v. Township of Harrison*, 520 U.S. 564, 577-78 (1997). By transferring to non-resident Producers the costs of collecting and disposing unused drugs— and then adding provisions barring Producers from seeking to recoup those costs and exempting from the Ordinance the one entity (retail pharmacies) capable of passing those costs on to local residents through higher prices—Alameda County can only be understood to have given “local consumers an advantage over consumers in other States.”

If Alameda is permitted to transfer local costs to the interstate market, other

local jurisdictions can be expected to reciprocate. There ultimately can be no net winners in such inter-jurisdictional battles. Indeed, such cost-shifting efforts cause significant harm to the national economy because they are economically inefficient: local jurisdictions have little incentive to impose costs prudently when they know that none of their citizens will bear those costs.

ARGUMENT

I. THE ORDINANCE VIOLATES THE COMMERCE CLAUSE BECAUSE IT DISCRIMINATES AGAINST INTERSTATE COMMERCE

Local legislation that provides a commercial advantage to in-state business has long been deemed to constitute a *per se* violation of the dormant Commerce Clause. “[S]tate statutes that clearly discriminate against interstate commerce are routinely struck down . . . unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism.” *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 192 (1994).

In rejecting Appellants’ Commerce Clause claim, the district overlooked a glaring discriminatory feature of the Ordinance: the great majority of local merchants involved in the sale and distribution of prescription drugs within the county (*i.e.*, local retail pharmacies) are not subject to drug collection and disposal requirements, while there is no similar exemption for those outside Alameda

county who play a role in the sale and distribution process. The district court stated, without elaboration, that the Ordinance did not entail any “differential treatment favoring local entities over substantially similar out-of-state interests.” Op. at 8, ER 8. That erroneous finding can only be attributed to a misunderstanding of what constitutes “substantially similar” entities.

A. Producers and Local Pharmacies Are “Substantially Similar” Entities for Purposes of Commerce Clause Analysis

As the Supreme Court has explained, “Any notion of discrimination [against interstate commerce] assumes a comparison of substantially similar entities.” *Tracy*, 519 U.S. at 298. “There is a threshold question whether the companies are indeed similarly situated for constitutional purposes” when the entities being compared do not provide precisely the same product. *Id.* The Court explained that when different products are provided, the operations of the two entities might remain unchanged even if the “the supposedly discriminatory burden were removed,” and thus “eliminating the tax or other regulatory differential would not serve the dormant Commerce Clause’s fundamental objective of preserving a national market for competition undisturbed by preferential advantages conferred by a State upon its residents or resident competitors.” *Id.*

Alameda County’s retail pharmacies and Producers should be deemed

“substantially similar” for Commerce Clause purposes, as that term was explained by *Tracy*. Their products are identical—each sells the same drug product, they simply do so at different levels of the distribution chain (Producers at the wholesale level, and local pharmacies at the retail level).⁴ Nonetheless, Producers and pharmacies have directly competing interests with respect to pricing and profit maximization. By exempting local retail pharmacies from the Ordinance (and prohibiting Producers from imposing any fees to recoup their compliance costs), Alameda County ensures that the Ordinance will not create pressure on local pharmacies to increase their prices – and thus that costs of the drug collection and disposal can be foisted entirely on those outside the county. If “the discriminatory burden were removed,” *id.*, retail pharmacies would almost surely respond by seeking to raise the prices they charge to Alameda County residents—and the “Commerce Clause’s fundamental objective of preserving a national market for competition undisturbed by preferential advantages conferred by a State upon its residents or resident competitors” would thereby be served. *Id.* Under the analytic framework established by *Tracy*, Alameda County’s retail pharmacies and the

⁴ Other similarities: both businesses profit from the sale of prescription medicines and both have significant technical expertise relevant to the collection of unwanted drugs. Indeed, retail pharmacies are arguably even more adept than Producers at transporting the medicines.

Producers are “substantially similar” entities.

Supreme Court decisions that two entities are not “substantially similar” for Commerce Clause purposes have often involved government-operated entities. When one of the competing entities is government-operated, the Court on several occasions has concluded that such an entity is not “substantially similar” to private-sector firms operating in the same field, because the entities have fundamentally different purposes. *See, e.g., United Haulers Ass’n*, 550 U.S. at 342 (government-run trash-collection business held not “substantially similar” to private trash collection companies; they are “far” different because “[u]nlike private enterprise, government is vested with the responsibility of protecting the health, safety, and welfare of its citizens.”); *Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 343-45 (2008) (States that issue bonds are not substantially similar to other bond issuers).

On the other hand, the Court has not hesitated to apply Commerce Clause restrictions to local regulations that choose a favorite between two private-sector competitors, even when the products they offer are quite different. For example, in *Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263 (1984), the Court invoked the dormant Commerce Clause to strike down a Hawaii law that exempted producers of okolehao (a drink made from indigenous Hawaiian plants) and pineapple wine

from an excise tax on wholesale liquor sales. The Court deemed the makers of those products to be substantially similar to other liquor wholesalers for purposes of Commerce Clause analysis, even though okolehao and pineapple wine were produced only in Hawaii and only in small quantities, and even though the plaintiffs had no interest in selling those products. The Court simply assumed that those products might compete for market share with other alcoholic beverages, and that eliminating the tax exemption might cause some okolehao and pineapple wine drinkers to increase their consumption of other types of alcoholic beverages. *Id.* at 268-69.

B. Alameda County Drafted the Ordinance with the Specific Intent of Ensuring That the Costs of Its Program Would Be Borne By Those Outside the County

The discriminatory burden that the Ordinance imposes on interstate commerce is not accidental. This is not an instance in which a policy pursued for some other regulatory purpose had, as one of its unintended consequences, an indirect impact on commerce. Rather, as Appellants' brief explains in great detail, Alameda County officials adopted the Ordinance's discriminatory provisions precisely because they realized that those provisions—the exemption for local retail pharmacies and the ban on Producer fees designed to recoup costs incurred in complying with the Ordinance— were necessary to ensure that costs associated

with the collection and disposal program would be borne by those living outside of Alameda County. There can be no defense of discriminatory regulation when its very purpose was to provide an economic advantage to the favored local entity.

In particular, it is simply untrue to suggest that the Ordinance was adopted to address previously unaddressed environmental, health, and safety issues. Those issues were already being addressed by Alameda County's previously adopted collection and disposal program. By the time that the Ordinance was up for consideration, the sole issue was: who should pay for the program? The answer from county officials was loud and clear: the cost of the program should be borne by drug manufacturers, not by the local government or its citizens. *See Appellants' Br. 4-6.* As stated by Board of Supervisors President Nathan A. Miley, the Ordinance's chief sponsor, the only thing "wrong" with the preexisting, "publicly-funded [drug collection and disposal] program" was "that the taxpayers pay for it." *See KQED Radio Interview, "Alameda County Poised to Require Companies to Take Back Unused Drugs" (July 23, 2012), Ex. D, ER 190.*

A local jurisdiction's discriminatory treatment of interstate commerce is particularly pernicious where, as here, the economic burdens imposed by the discrimination are not borne by those living within the jurisdiction. The democratic process tends to provide restraints against excessively discriminatory

regulation where some of the burdens created by the regulation fall on at least a portion of the jurisdiction's voting population. But in the absence of locally-felt burdens, measures that discriminate against interstate commerce are "unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected." *United Haulers Ass'n*, 550 U.S. at 345.⁵

The Supreme Court has indicated that in those circumstances, courts are more willing to step in to provide relief under the dormant Commerce Clause. *Id.* (citing *Southern Pacific Co. v. Arizona ex rel. Sullivan*, 325 U.S. 761, 767-68 (1945)). As the Court explained in striking down a facially nondiscriminatory tax because it was combined with a subsidy to in-state groups:

Nondiscriminatory measures, like the evenhanded tax at issue here, are generally upheld, in spite of any adverse effect on interstate commerce, in part because "[t]he existence of major in-state interests adversely affected . . . is a powerful safeguard against legislative abuse." However, when a nondiscriminatory tax is coupled with a subsidy to one of the groups hurt by the tax, a State's political processes can no longer be relied upon to prevent legislative abuse, because one of the in-state interests which would otherwise lobby against the tax has been mollified by the subsidy.

⁵ As noted *supra* at 6 n.3, there is considerable skepticism within the scientific community that disposal of unused drugs is a cause for significant environmental, health, or safety concerns. But the merits of that scientific debate are unlikely to attract attention within Alameda County so long as the costs of programs designed to address disposal issues are not being borne by Alameda County residents.

West Lynn Creamery, 512 U.S. at 200 (quoting *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 473 n.17 (1981)).

In sum, where (as here) the Ordinance was adopted precisely because the local jurisdiction desired its anticipated discriminatory effect, *per se* invalidation under the dormant Commerce Clause is well warranted.

C. The Burden Imposed by the Ordinance Is Not Fairly Apportioned

The Ordinance violates the Commerce Clause for the additional reason that it is not fairly apportioned. If even a single pill from a prescription drug manufacturer finds its way through the stream of commerce and into Alameda County, the manufacturer is responsible for setting up a multi-million dollar drug collection and disposal program and for accepting all unused pills proffered by Alameda County residents. Such disproportionate imposition of burdens on interstate commerce is not permissible under the dormant Commerce Clause.

The Supreme Court has long held that a tax or other financial burden imposed by a state or local government cannot survive a dormant Commerce Clause challenge unless it is “fairly apportioned.” *Quill Corp. v. North Dakota*, 504 U.S. 298, 311 (1992); *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274, 279 (1977). Among the requirements of a “fairly apportioned” tax is that it be “internally consistent,” which the Supreme Court has explained as follows:

Internal consistency is preserved when the imposition of a tax identical to the one in question by every other State would add no burden to interstate commerce that intrastate commerce would not also bear. This test asks nothing about the degree of economic reality reflected by the tax, but simply looks to the structure of the tax at issue to see whether its identical application by every State in the Union would place interstate commerce at a disadvantage as compared with commerce intrastate.

Oklahoma Tax Comm'n v. Jefferson Lines, Inc., 514 U.S. 175, 185 (1995). See also *Goldberg v. Sweet*, 488 U.S. 252, 261 (1989).⁶

The Ordinance plainly does not pass the internal consistency test. The Ordinance requires that if even a single prescription pill manufactured by a Producer is sold or distributed in Alameda County, the Producer must establish an unused drug collection and disposal program for all drugs sold in the county. If every jurisdiction in the country adopted an identical ordinance, a manufacturer that distributes a small number of pills in each jurisdiction would face ruinous costs—it would be required to take responsibility for collection and disposal of all unused drugs nationwide. Those costs would be vastly greater than costs incurred

⁶ The Court has applied this approach not only to challenges to tax assessments but also to all Commerce Clause challenges to economic regulation imposed by state or local governments. When considering such challenges, courts are to evaluate the “practical effect” of the challenged economic regulation and to consider “how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation.” *Healy v. Beer Institute*, 491 U.S. 324, 336 (1989).

by a drug manufacturer who sells an equal number of drugs but does not engage in interstate commerce (*i.e.*, it sells all of its prescription drugs within a single jurisdiction). The multi-million dollar obligation potentially imposed on each Producer by the Ordinance cannot be deemed “fairly apportioned.”⁷

Alameda will no doubt respond that the Ordinance permits Producers to reduce their financial obligations considerably by agreeing to operate a collection and disposal program in conjunction with other Producers. Perhaps so, although we can easily envision drug companies having considerable difficulty arriving at a mutually agreeable cost allocation agreement.⁸ Moreover, the Ordinance as drafted highlights the economic inefficiency that will arise if jurisdictions are granted unchecked power to impose costs on those outside the jurisdictions. Because

⁷ Moreover, a significant number of prescription drug manufacturers lack even a “substantial nexus” with Alameda County and thus the county government may not constitutionally seek to commandeer those manufacturers’ services. *Quill*, 504 U.S. at 313. The mere act of shipping prescription drugs into Alameda County is insufficient to create such a “substantial nexus.” *Id.*

⁸ For example, the negotiating parties will have no way to measure how many of each Producer’s products enter Alameda County. And it will not be possible to identify the manufacturer of many of the collected products—meaning that the most visible companies, assuming that they can reach any sort of deal, will be forced to bear a disproportionate share of costs. Moreover, “hold out” problems are sure to arise; some smaller companies will simply refuse to contribute any funds and/or will decline to sign on to a joint program until threatened with litigation.

Alameda County will bear none of the costs that will arise if prescription drug manufacturers cannot successfully negotiate joint collection/disposal agreements and end up having to operate multiple duplicative programs, county officials have no incentives to write their ordinances in a manner that minimizes the burdens they impose on interstate commerce.

Most importantly, the constitutionality of the Ordinance cannot rest on the mere possibility that some Producers *may* be able to negotiate jointly-operated programs. As written, the Ordinance is not fairly apportioned and thus does not pass muster under the dormant Commerce Clause.

II. THE ORDINANCE VIOLATES THE COMMERCE CLAUSE BECAUSE IT FAVORS LOCAL ECONOMIC INTERESTS OVER OUT-OF-STATE AND OUT-OF-COUNTY INTERESTS

The Ordinance violates the dormant Commerce Clause for the separate reason that it favors local interests over out-of-county and out-of-state interests. *Healy v. Beer Inst.*, 491 U.S. at 337 n.14 (stating that when a law's effect is to favor local economic interests over outside interests, the law is *per se* invalid).

It is stipulated that all covered drugs under the Ordinance are delivered from *outside* Alameda County, while none are distributed wholly *within* the County. *See* Stipulations ¶¶ 23, 24. Prior to enacting the Ordinance, Alameda County considered imposing the cost of local collection efforts directly on pharmaceutical

retailers, but ultimately abandoned that approach in the face of opposition from local pharmacies. Consequently, the Ordinance expressly exempts Alameda County pharmacies from any drug collection duties or costs. *See* § 6.53.030.14.

At the same time, pharmaceutical manufacturers “are prohibited from passing the expense [of the Alameda program] directly to Alameda County consumers by adding a fee at the point of sale.” § 6.53.040.B.3. As detailed earlier, the Ordinance’s legislative history further confirms the naked desire to shift the regulatory costs of the Ordinance entirely to those outside of Alameda County. On its face, then, the Ordinance impermissibly shifts all costs of the Alameda collection program to those outside of Alameda County by protecting local retailers and consumers.

The county’s claimed rationale for imposing collection costs solely on interstate manufacturers is that those who “benefit” from pharmaceutical sales should pay for pharmaceutical disposal and collection. But not only do Alameda pharmacies and consumers clearly benefit from the sale of pharmaceuticals, they are largely responsible for creating any purported disposal “problem” to begin with. Yet despite the fact that Alameda County pharmacies economically benefit from local pharmaceutical sales, they incur none of the disposal and collection costs borne by interstate sellers. Likewise, while local consumers medically

benefit from pharmaceutical sales (and presumably benefit from the Ordinance's disposal and collection mandate itself), they are completely exempted from any fees to help pay for the program. The Ordinance thus treats entities outside of Alameda County (i.e., those who are the most removed from Alameda County's pharmaceutical distribution and disposal) *far worse* than local consumers and pharmacies (i.e., those who are directly responsible for creating the need for a collection and disposal program and who stand to benefit the most from the Ordinance).

Under the Supreme Court's Commerce Clause jurisprudence, Alameda County may not shift costs to outside interests merely because that is more politically attractive than addressing directly the practices of local consumers and retailers whom the County prefers to insulate from the costs of its collection and disposal program. By refusing to countenance local favoritism, the Commerce Clause checks the very natural tendency toward parochialism among State and local policymakers and leaves it to Congress to determine when (if ever) cost-shifting regulations are appropriate. Because "the evil of protectionism can reside in legislative means as well as legislative ends," the Supreme Court "has consistently found parochial legislation of this kind to be constitutionally invalid," no matter how "legitimate" the ultimate aim of the legislation may be.

Philadelphia v. New Jersey, 437 U.S. 617, 626-27 (1978) (holding that even “a presumably legitimate goal” cannot be “achieved by the illegitimate means of isolating the [locality] from the national economy.”).

Alameda County’s scheme blatantly “attempts to give local consumers an advantage over consumers in other States.” *Brown-Forman Distillers Corp. v. N.Y. State Liq. Auth.*, 476 U.S. 573, 580 (1986). Because the Ordinance strictly prohibits interstate manufacturers from recouping or even sharing the expense of the collection program from Alameda County consumers, those costs will necessarily be absorbed by interstate manufacturers and consequently passed on to pharmaceutical consumers throughout the United States and the rest of California. Indeed, the central purpose of the Ordinance is to impose collection duties and related costs on interstate, out-of-county interests in order to benefit local, Alameda County interests. As such, the Ordinance is an impermissible attempt to favor local interests through “shifting the costs of regulation” to the interstate market. *See United Haulers Ass’n*, 550 U.S. at 345.

By design, the Ordinance guarantees that the burden of the County’s mandated collection efforts will be felt almost entirely by nationwide pharmaceutical sellers and consumers who reside outside of Alameda County. The Supreme Court has repeatedly condemned laws that have the effect of increasing

interstate producers' prices outside the enacting jurisdiction. *See, e.g., Camps Newfound/ Owatonna*, 520 U.S. at 577-78 (“Economic protectionism is not limited to attempts to convey advantages on local merchants; it may include attempts to give local consumers an advantage over consumers in other States.”). Alameda County’s regulatory scheme is similar to the Maine law invalidated in *Camps Newfound*, which denied a charitable tax deduction to nonprofit camps that predominantly served out-of-state interests. The Supreme Court overturned that exemption as discriminatory, reasoning that “[i]nsofar as Maine’s discriminatory tax has increased tuition, that burden is felt almost entirely by out-of-staters, deterring them from enjoying the benefits of camping in Maine.” 520 U.S. at 581; *see also Kassel v. Consol. Freightways Corp. of Del.*, 450 U.S. 662, 671 n.12 (1981) (plurality opinion) (invalidating an Iowa highway regulation and finding it “highly relevant” that the measure contained “several exemptions that secure Iowans many of the benefits of large trucks while shunting to neighboring states many of the costs associated with their use”).

By shifting the costs of local pharmaceutical collection from local consumers and pharmacies to consumers and sellers located elsewhere, Alameda County escapes any political accountability for forcing consumers and patients from jurisdictions *outside* the County to subsidize the County’s “take-back”

program. But where the burden of regulation falls on interests outside the jurisdiction, “it is unlikely to be alleviated by the operation of those political restraints normally averted when interests within the [jurisdiction] are affected.” *Southern Pacific*, 325 U.S. at 767-68 n.2 (1945); *see also McGoldrick v. Berwind-White Coal Mining Co.*, 309 U.S. 33, 45 n.2 (1940) (acknowledging the “recognized danger that, to the extent that the burden falls on economic interests without the state, it is not likely to be alleviated by those political restraints which are normally exerted on legislation where it affects adversely interests within the state”). *See also supra*, at 19 n.5 (explaining that residents of Alameda County are unlikely to focus on the scientific debate regarding whether the disposal of unused drugs is a cause for significant environmental, health, or safety concerns, because the costs of programs designed to address disposal issues are not being borne by those residents). Since out-of-county consumers and patients are unrepresented within the Alameda County government, the Ordinance “undermine[s] the assumption that the [County’s] own political processes will act as a check on local regulations that unduly burden interstate commerce.” *Conservation Force, Inc. v. Manning*, 301 F.3d 985, 998 (9th Cir. 2002). Under the dormant Commerce Clause, however, a broader array of the interests at stake must be taken into account. That task now falls to this Court.

The district court’s rejection of Appellants’ challenge to the Ordinance invites chaos and inefficiency. The blatant local favoritism sanctioned below is likely to lead to adoption of similar measures elsewhere. Other jurisdictions, including King County in Washington state, have already attempted similar measures, and the California legislature is considering requiring similar “producer responsibility” programs for other industries. *See* Appellants’ Br. at 45.

This case is a clear reminder of the principle that our constitutional system was “framed upon the theory that the peoples of the several states must sink or swim together, and that in the long run prosperity and salvation are in union and not in division.” *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 523 (1935).

Alameda County in this case, or another jurisdiction in another case, may believe that to protect the interests of its residents it is appropriate to impose “take back” programs whose costs fall entirely on entities outside the jurisdiction. But one county’s protection of its residents’ interests does not take into account the interests of other counties, other states, or of the nation as a whole. While it is only natural that any given locality will behave in a protectionist, rent-seeking manner, it is the triumph of this type of parochialism in arenas where single jurisdiction’s interests should govern what the Commerce Clause proscribes.

CONCLUSION

Amici respectfully request that the Court reverse the decision of the district court.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation. Pursuant to Fed.R.App.P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, I hereby certify:

1. This brief complies with the type-volume limitation of Fed.R.App.P. 32(a)(7)(B) because: this brief contains 6,335 words, excluding the parts of the brief exempted by Fed.R.App.P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed.R.App.P. 32(a)(5) and the type style requirements of Fed.R.App.P. 32(a)(6) because: this brief has been prepared in a proportionately spaced typeface using WordPerfect X5 Times New Roman.

/s/ Richard A. Samp
Richard A. Samp

Attorney for Washington Legal
Foundation

Dated: November 22, 2013

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 22nd day of November, 2013, I electronically filed the foregoing brief of *amici curiae* Washington Legal Foundation, *et al.*, with the Clerk of the Court for the U.S. Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp
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