

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

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

**SUMMARY\*\***

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**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 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

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

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.

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## COUNSEL

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## 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 Env’tl. 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).



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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).<sup>1</sup>

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

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<sup>1</sup> 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)).

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.”<sup>2</sup> *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*’ effect on interstate commerce, but is necessarily an effort to directly regulate and burden [interstate commerce].” The problem

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<sup>2</sup> 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 ‘[i]e 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.

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.<sup>3</sup> *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 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.

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<sup>3</sup> 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.*

## 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.<sup>4</sup> 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 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.

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<sup>4</sup> 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.*