No. 13-16833

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

v.

ALAMEDA COUNTY, CALIFORNIA; ALAMEDA COUNTY DEPARTMENT OF ENVIRONMENTAL HEALTH,
Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of California
Case No. 3:12-CV-06203-RS
Honorable Richard Seeborg, District Judge

BRIEF OF *AMICI CURIAE* THE CALIFORNIA STATE ASSOCIATION OF COUNTIES AND THE LEAGUE OF CALIFORNIA CITIES, IN SUPPORT OF DEFENDANTS-APPELLEES

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amicus curiae* the California State Association of Counties avers that it is a nonprofit mutual benefit corporation, which does not offer stock and which is not a subsidiary or affiliate of any publicly-owned corporation.

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amicus curiae* the League of California Cities avers that it is a nonprofit mutual benefit corporation, which does not offer stock and which is not a subsidiary or affiliate of any publicly-owned corporation.

RULE 29 STATEMENTS

This brief of *amici curiae* is submitted under Federal Rule of Appellate Procedure 29(a).

In accordance with Circuit Rule 29-3 (Circuit Advisory Committee Note), counsel of record received timely notice of the intent of these *amici curiae* to file this brief, and all parties have consented to the filing of this brief.

Pursuant to Federal Rule of Appellate Procedure 29(c)(5), the California State Association of Counties and the League of California Cities state that no party's counsel has authored this *amicus curiae* brief in whole or in part; no party or party's counsel has contributed money intended to fund the preparation or submission of this brief; and no person or entity other than the California State Association of Counties and the League of California Cities, their members, and their counsel has contributed money intended to fund the preparation or submission of this brief.

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IDENTITY AND INTERESTS OF *AMICI CURIAE*

The California State Association of Counties and the League of California Cities (hereinafter collectively referred to as "*amici*") respectfully submit this *amicus curiae* brief in support of Defendants-Appellees County of Alameda and Alameda County Department of Environmental Health (hereinafter "Alameda County" or "Alameda").

The California State Association of Counties ("CSAC") is a non-profit corporation with a membership consisting of 58 California counties. CSAC sponsors a Litigation Coordination Program, which is administered by the County Counsels' Association of California and overseen by the Association's Litigation Overview Committee, comprised of county counsels throughout the state. The Litigation Overview Committee monitors litigation of concern to counties statewide and determined that this is such a case.

The League of California Cities is an association of 470 California cities dedicated to protecting and restoring local control to provide for the public health, safety, and welfare of their residents, and to enhance the quality of life for all Californians. The League is advised by its Legal Advocacy Committee, comprised of 24 city attorneys from all regions of the State. The Committee monitors litigation of concern to municipalities, and identifies those cases that have

statewide or nationwide significance. The Committee has identified this case as having such significance.

I.

INTRODUCTION

In 2012, Alameda County enacted the Safe Drug Disposal Ordinance ("the Ordinance") to protect its residents from the many environmental and health-related harms associated with unsafe disposal of unused prescription medications. The Ordinance requires that producers of prescription drugs ("Producers") sold in Alameda County create and fund programs that facilitate the safe disposal of unused drugs, thereby decreasing their risk to public health and the environment. In so doing, Alameda elected to place the responsibility and costs associated with safe drug disposal on the corporations that manufacture and make hundreds of millions of dollars in profits from drugs sold within the county, rather than placing that burden on the public at large.

Three organizations representing the interests of pharmaceutical manufacturers (collectively "PhRMA") brought a facial challenge to the Ordinance, alleging it violates the dormant Commerce Clause. It is no accident that PhRMA's brief is long on hyperbole and short on discussion of relevant case law. Indeed, PhRMA ignores controlling authority and asks this Court to adopt a rule that would invalidate a wide array of state and local laws, thereby curtailing

the longstanding authority of state and local governments to regulate waste disposal. *Amici* urge this Court to decline Appellants' invitation to depart from long-established Commerce Clause jurisprudence, and affirm the District Court's judgment.

II.

ARGUMENT

A. Under the Dormant Commerce Clause, Local Governments May Enact Non-Discriminatory Laws that Affect But Do Not Substantially Burden Interstate Commerce

The Commerce Clause, which vests Congress with the authority to regulate interstate commerce, implicitly imposes "limitation[s] on the power of the States [and local governments] to enact laws imposing substantial burdens on [interstate] commerce." *Nat'l Ass'n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1147 (9th Cir. 2012) ("*Optometrists*") (citing *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 87 (1984)).

"Modern dormant Commerce Clause jurisprudence primarily is driven by concern about economic protectionism . . . The principal objects of dormant Commerce Clause scrutiny are statutes that discriminate against interstate commerce. . . Most regulations that run afoul of the dormant Commerce Clause do so because of discrimination." *Id.* at 1148 (quoting *Dep't of Revenue v. Davis*, 553

U.S. 328, 337-38 (2008) and *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 87 (1987)).

But "in a small number of dormant Commerce Clause cases courts also have invalidated statutes that imposed other significant burdens on interstate commerce" even though they are non-discriminatory. *Id.* In these cases, "[a] critical requirement for proving a violation of the dormant Commerce Clause is that there must be a *substantial burden* on *interstate commerce.*" *Id.* (emphasis in original).

Indeed, "[t]he limitation imposed by the Commerce Clause on state regulatory power is by no means absolute, and the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor*, 477 U.S. 131, 138 (1986) (internal quotation marks omitted). "[T]he Supreme Court has recognized that 'under our constitutional scheme the States [and local governments] retain broad power to legislate protection for their citizens in matters of local concern such as public health' and has held that 'not every exercise of local power is invalid merely because it affects in some way the flow of commerce between the States.'" *Optometrists*, 682 F.3d at 1148 (quoting *Great Atl. & Pac. Tea Co., Inc. v. Cottrell,* 424 U.S. 366, 371 (1976)). Thus, a law that is non-discriminatory and only incidentally burdens interstate commerce will be upheld "unless the burden

imposed upon [interstate] commerce is clearly excessive in relation to the putative local benefits." *Kleenwell Biohazard Waste & Gen. Ecology Consultants, Inc. v. Nelson*, 48 F.3d 391, 399 (9th Cir. 1995) (quoting *Pike v. Bruce Church, Inc*., 397 U.S. 137, 142 (1970)).

B. As Part of Their Traditional Authority to Regulate Waste Disposal, Local Governments Have Long Had the Power to Place the Responsibility of Waste Disposal on Private Entities

"Waste disposal is both typically and traditionally a local government function." *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 344 (2007). For more than a century "it has been settled law that garbage collection and disposal is a core function of local government in the United States." *USA Recycling, Inc. v. Babylon*, 66 F.3d 1272, 1275 (2d Cir. 1995). Furthermore, a municipality "has legitimate—indeed, compelling—interests that are served by its waste management program. In our multi-tiered federal system, local governments have historically borne primary responsibility for ensuring the safe and reliable disposal of waste generated within their borders—a role that Congress has expressly recognized." *Id.* at 1288.

State and local "power to regulate commerce is at its zenith in areas traditionally of local concern," such as waste disposal. *Kleenwell*, 48 F.3d at 398. Furthermore, regulations that protect public safety, including those governing safe waste disposal, enjoy a "strong presumption of validity." *Id.* at 400 n.11.

Despite this, PhRMA argues that the Ordinance violates the Commerce Clause because Alameda County is not *exercising* its authority over waste disposal, but is instead "*transferring* its traditional police power responsibility of waste disposal to [private] interstate actors[.]" PhRMA Br. at 24. In advancing this argument, PhRMA evinces a fundamental misunderstanding of the core power of local governments to regulate waste disposal. Indeed, local governments have traditionally *regulated* waste disposal by, among other things, relying "on a closely regulated private market to provide those services." *USA Recycling*, 66 F.3d at 1275; *see also United Haulers*, 550 U.S. at 344 ("It is not the office of the Commerce Clause to control the decision of the voters on whether government or the private sector should provide waste management services."). Thus, PhRMA's suggestion that there is something unusual—much less unconstitutional—about a regulatory scheme under which private entities undertake waste disposal is baseless.

C. "Shifting" Costs of Waste Disposal from Alameda County to Private Actors Is Well Within the County's Authority

PhRMA argues that Alameda County's decision to "shift" the costs of drug disposal to Producers violates the dormant Commerce Clause by favoring local interests and by directly burdening interstate commerce. PhRMA Br. at 29-31, 39-43. PhRMA asserts that "local laws that transfer regulatory costs *away from* local interests to whom the enacting governments are accountable and *toward*

unrepresented external entities give rise to the recognized danger that . . . the burden falls on economic interests" with little or no influence in the local political process, thereby violating the Commerce Clause. PhRMA Br. at 30 (emphasis in original). But as Alameda County notes, nothing in the Ordinance precludes Producers from passing along the costs of compliance to the Alameda County electorate.[1] Alameda Br. at 48-51. If the electorate believes the costs of the Ordinance outweigh its benefits, the electorate will demand its repeal. As such, the "danger" that Producers must bear costs imposed by political actors they have no ability to influence is illusory.

PhRMA's assertion that, as a practical matter, Producers will not pass along these costs is of no moment. Even if Producers will likely *choose* not to pass along these costs because of the complexity of the supply chain or because the costs to be recouped would amount to a fraction of a penny per prescription, this has no

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[1] PhRMA argues that the Ordinance "expressly exempts local consumers from any point-of-sale fee related to collection and disposal costs" and thereby ensures that these costs "will be exclusively paid for by consumers outside of Alameda." PhRMA Br. at 43. Section 6.53.040(B)(3) of the Ordinance, upon which PhRMA bases this argument, states that "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." ER 124 (emphasis added). As Alameda argues, the Ordinance only precludes the addition of a specific point-of-sale *fee* on drug purchases; it does not preclude a price increase on drugs sold in Alameda County for purposes of recouping compliance costs. Alameda Br. at 48-51. Indeed, PhRMA conceded this point before the District Court. *See* Plaintiffs' Reply in Supp. of Summ. J. at 22-24, Docket Entry 33 at 27-29.

bearing on the Commerce Clause inquiry. *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 110-11 (2d Cir. 2001) (holding that a manufacturer's unwillingness or practical inability to modify its production and distribution processes to recoup costs does not give rise to a Commerce Clause violation).

Furthermore, even if the Ordinance prohibited Producers from passing along the costs, it would still pass constitutional muster. The Supreme Court has held that imposing financial burdens on private actors in order to protect the public fisc is a legitimate objective for purposes of the Commerce Clause. *United Haulers*, 550 U.S. at 346; *see also Pharm. Research & Mfrs. Ass'n of Am. v. Walsh*, 538 U.S. 644, 669-70 (2003). Furthermore, federal courts have consistently rejected the notion that the Commerce Clause protects businesses against regulations that may reduce their profit margin. *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127 (1978); *Optometrists*, 682 F.3d at 1152 n.11, 1154-55; *Sorrel*, 272 F.3d at 111. Thus, even if Producers were precluded from passing their compliance costs on to Alameda County residents, the Ordinance would not violate the Commerce Clause.

D. The Ordinance Is Not An "Extraterritorial" or Direct Regulation of Interstate Commerce

PhRMA and *amicus curiae* the U.S. Chamber of Commerce argue that Alameda County's Ordinance impermissibly regulates commerce extraterritorially because it imposes burdens on pharmaceutical companies with "no connection" to the county. PhRMA Br. at 25-26; Chamber Br. at 5. Specifically, PhRMA

suggests that because the Ordinance imposes duties and costs on Producers whose products arrive in Alameda County "through a complex chain of wholesalers and intermediaries" operating outside the county, any regulation of those Producers impermissibly regulates and burdens interstate commerce. PhRMA Br. at 3-4, 13, 28-29; ER 85 (¶ 20).

Alameda County and *amicus curiae* Natural Resources Defense Council (NRDC) identify the controlling authority definitively rejecting such arguments and we will not repeat those legal arguments. We note, however, that PhRMA and the Chamber's position defies credulity. Producers spend millions of dollars marketing their products in Alameda County each year, and reaped a staggering $965 million in revenue based on sales of pharmaceuticals in Alameda County *in 2010 alone*. ER 87 (¶ 34). This is more than a sufficient "connection" to justify the Ordinance.

Moreover, taken to its logical conclusion, the rule advocated by PhRMA and the Chamber would allow a manufacturer to exempt itself from any state or local regulation by using an intermediary outside the jurisdiction to put its product into the stream of commerce.

In any event, state and local laws imposing costs on manufacturers to protect local residents from harms associated with products that arrive through a national

chain of commerce involving multiple intermediaries are commonplace.[2] As this Court recently held, "[t]he Commerce Clause does not protect Plaintiffs' ability to make others pay for the hidden harms of their products merely because those products are shipped across state lines." *Rocky Mountain Farmers Union*, 730 F.3d at 1106. To hold that state or local governments are precluded from regulating products sold through out-of-state middlemen would substantially curtail their ability to protect public health and safety and would improperly limit the scope of their core regulatory powers.

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[2] *See, e.g., Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1078 (9th Cir. 2013) (noting that "[s]ince 1957, California has acted at the state level to regulate air pollution from motor vehicles" while rejecting a Commerce Clause challenge to recent state regulations regarding fuel production and greenhouse gas emissions); *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937 (9th Cir. 2013) (rejecting a dormant Commerce Clause Challenge to a California law requiring foie gras producers to adopt certain production processes in order for their products to be sold in California); *Committee of Dental Amalgam Mfrs. & Distributors v. Stratton*, 92 F.3d 807 (9th Cir. 1996) (rejecting a preemption challenge to a California law requiring manufactures to include additional labels on hazardous products); *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby*, 958 F.2d 941 (9th Cir. 1992) (same); *Sorrell*, 272 F.3d 104 (2d Cir. 2001) (rejecting a dormant Commerce Clause challenge to a Vermont law requiring manufacturers of mercury-containing products to include specific labels on any such products sold within Vermont); *Toy Mfrs. of America, Inc. v. Blumenthal*, 986 F.2d 615 (2d Cir. 1993) (rejecting a preemption challenge to a Connecticut law requiring toy manufactures to include additional labels on products sold in Connecticut).

E. The Fact that Other Jurisdictions May Impose Similar Requirements on Producers Does Not Render the Ordinance Unconstitutional

PhRMA and its *amici* argue that the Ordinance violates the dormant commerce clause because "[w]idespread adoption of Ordinance-like laws would 'stifle' the interstate market by making interstate businesses liable for the full costs of running waste-disposal programs in every county where their products are sold." PhRMA Br. at 44. This argument likewise is meritless.

First, for the Ordinance to be invalidated on this basis, PhRMA must "either present evidence that conflicting, legitimate legislation is already in place or that the threat of such legislation is both actual and imminent." *S.D. Myers, Inc. v. City & County of San Francisco*, 253 F.3d 461, 469-70 (9th Cir. 2001). It does neither. Instead, PhRMA points only to a nearly identical ordinance enacted by King County, Washington, and a similar law pending before the California legislature. PhRMA Br. at 45. Those pieces of legislation do not "conflict" with the Ordinance, and do not suggest that the threat of *conflicting* laws is actual, much less imminent.

Second, any interference with interstate commerce resulting from widespread enactment of laws like the Ordinance would be minimal. As the facts to which PhRMA stipulated make clear, the costs to Producers of compliance with the Ordinance are trivial relative to the revenues generated through pharmaceutical sales in Alameda County, and the same would likely be true of similar laws in

other jurisdictions. *See* ER 86-87 (¶¶ 28, 30, 34). Thus, there is no basis for suggesting that Producers' ability to market and distribute their products would be "stifled" by the widespread enactment of similar legislation. And even if widespread adoption of laws like the Ordinance do reduce Producers' profits, such a consequence would not give rise to a Commerce Clause violation. *Exxon Corp.*, 437 U.S. at 127; *Optometrists*, 682 F.3d at 1152 n.11, 1154-55; *Sorrel*, 272 F.3d at 111.

Finally, and most importantly, if this Court were to accept PhRMA's position that the Ordinance should be invalidated based on the prospect that other jurisdictions may adopt similar laws, legislative innovation would be stifled:

> If [courts] were to invalidate [a] regulation every time another state considered a complementary statute, we would destroy the states' ability to experiment with regulation. Successful experiments inspire imitation both vertically, as when the federal government followed California's lead on air pollution, and horizontally, as shown by the federal Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501–23, adopted after twenty-two states, starting with Oregon, enacted organic food labeling standards. *See* Or.Rev.Stat. § 632.925 (1973); S.Rep. No. 357, *reprinted in* 1990 U.S.C.C.A.N. 4656, 4943. After nearly half of the states acted, Congress provided a uniform standard. As it did there, Congress may decide that uniformity [in drug disposal legislation] is warranted . . . If it does so after several states [or municipalities] have acted, it will have the benefit of their experiments. But when or if such uniformity is desirable is not a question for courts. The proliferation of organic labeling standards did not threaten our economic union, and the possibility that many [jurisdictions] might [require drug manufactures to dispose of products] sold within their borders does not risk the "competing and interlocking local economic regulation that the Commerce Clause was meant to preclude."

Rocky Mountain Farmers Union, 730 F.3d at 1105.

F. The Existence of Alternative Means to Achieve the Ordinance's Purpose is Irrelevant

Where, as here, a non-discriminatory law is "directed to legitimate local concerns" and its "effects upon interstate commerce are only incidental," courts apply the balancing test set forth in *Pike*, and will reject a challenge under the Commerce Clause "unless the burden imposed on interstate commerce is clearly excessive in relation to the putative local benefits." *United Haulers*, 550 U.S. at 346 (internal quotation marks and citations omitted). "As the party challenging the regulation, [PhRMA] must establish that the burdens that the regulation imposes on interstate commerce clearly outweigh the local benefits arising from it." *Kleenwell*, 48 F.3d at 399.

PhRMA argues that the Ordinance cannot satisfy even the deferential *Pike* standard because it "yields no public benefits while imposing burdens on interstate commerce" as "pharmaceutical-collection efforts would achieve precisely the same effects if performed by the County and financed by a local waste-disposal fee, rather than conducted and paid for by Appellants." PhRMA Br. at 59. This argument is also baseless.

First, contrary to its assertion that the Ordinance "yields no public benefits," PhRMA *stipulated* that the "environmental, health and safety benefits [of the Ordinance] are not contested[.]" ER 87; *see also* Alameda Br. at 8-10 (identifying

numerous scientific studies establishing the substantial harms associated with improper drug disposal).

Second, PhRMA offers no support whatsoever for its assertion that the Ordinance is *merely* a cost shifting measure that does not significantly expand upon current drug disposal programs operated by Alameda County. Because it bears the burden of proof, PhRMA's failure to cite any evidence in support of its arguments is fatal.

Third, as noted above, the Supreme Court held in *United Haulers* that revenue generation or cost avoidance by a governmental entity is a legitimate interest. *United Haulers*, 550 U.S. at 346.

Finally, PhRMA's argument that the Ordinance must be struck down because a drug disposal program paid for by Alameda would be equally effective and impose a lesser burden on interstate commerce was rejected in *Optometrists*. *Optometrists*, 682 F.3d at 1157. There, this Court held that an examination of alternatives is only required under the Commerce Clause where a law is discriminatory, thereby triggering a heightened standard of review. *Id*. By declining to challenge the District Court's finding that the Ordinance is non-discriminatory, PhRMA essentially concedes this point. Furthermore, the Ordinance does not impose a significant burden on interstate commerce. As such,

this Court need "not consider any evidence regarding alternative means for the [county] to achieve its goals." *Optometrists*, 682 F.3d at 1157.

III.

CONCLUSION

For the reasons set forth above, and those in the briefs of Defendant Alameda County and *amicus* Natural Resources Defense Council, the District Court's order denying Plaintiff's motion for summary judgment and granting Alameda County's cross-motion should be affirmed.

Dated: January 22, 2014

Respectfully submitted,

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STATEMENT OF RELATED CASES

Attorneys for *amici* are not aware of any related cases pending in this Court, as defined in Ninth Circuit Rule 28-2.6.

Dated: January 22, 2014

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that, pursuant to Federal Rule of Appellate Procedure 32(a)(7)(c) and Ninth Circuit Rule 32-1, the attached *amicus curiae* brief is proportionately spaced, has a typeface of 14 points or more, and contains approximately 3,389 words.

Dated: January 22, 2014

Respectfully submitted,

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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

CERTIFICATE OF ELECTRONIC SERVICE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; GENERIC PHARMACEUTICAL ASSOCIATION; BIOTECHNOLOGY INDUSTRY ORGANIZATION, v. ALAMEDA COUNTY, CALIFORNIA; ALAMEDA COUNTY DEPARTMENT OF ENVIRONMENTAL HEALTH

Case No. 13-16833

I hereby certify that I electronically filed the foregoing

BRIEF OF *AMICI CURIAE* THE CALIFORNIA STATE ASSOCIATION OF COUNTIES AND THE LEAGUE OF CALIFORNIA CITIES, IN SUPPORT OF DEFENDANTS-APPELLEES

with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on January 22, 2014.

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/ .
Alexandra K. Weight