No. 14-751

IN THE
Supreme Court of the United States

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

v.

COUNTY OF ALAMEDA; ALAMEDA COUNTY DEPARTMENT OF ENVIRONMENTAL HEALTH,
Respondents.

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

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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Date: January 28, 2015

MOTION OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) and the Allied Educational Foundation (AEF) respectfully move for leave to file the attached brief as *amici curiae* in support of Petitioners. Counsel for Petitioners has consented to the filing of this brief. Counsel for Respondents declined to consent. Accordingly, this motion for leave to file is necessary.

WLF is a public interest law firm and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, a limited and accountable government, and the rule of law. To that end, WLF regularly litigates in opposition to state and local regulatory measures whose purpose or effect is to disrupt the free flow of interstate commerce. *See, e.g., American Beverage Assoc. v. Snyder*, 735 F.3d 362 (6th Cir.), *cert. denied*, 134 S. Ct. 61 (2013). WLF also filed a brief in this matter when it was before the court of appeals.

AEF is a non-profit charitable foundation based in Tenafly, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

Amici are concerned that the decision below, if left undisturbed, 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 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 their citizens will not bear a proportionate share of 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 the fact that they manufactured a product that eventually found its way, via 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.

Amici have no direct interest in the outcome of this litigation, financial or otherwise. Accordingly, they can provide the Court with a perspective not shared by any of the parties.

For the foregoing reasons, WLF and AEF respectfully request that they be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

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QUESTION PRESENTED

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

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BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICI CURIAE*

The interests of the *amici curiae* Washington Legal Foundation and the Allied Educational Foundation are set forth in more detail in the accompanying motion for leave to file.[1]

Amici are concerned that the decision below, if left undisturbed, 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 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

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* 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, made a monetary contribution intended to fund the preparation or submission of this brief. More than 10 days prior to the due date, counsel for *amici* provided counsel for Respondents with notice of their intent to file.

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 their citizens will not bear a proportionate share of 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 the fact that they manufactured a product that eventually found its way, via 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.

This brief focuses particular attention on case law setting Commerce Clause limits on taxation by state and local governments. The court below concluded that such case law—which imposes "nexus" and "fairly apportioned" limitations on state and local taxation—is irrelevant to Alameda County's ordinance. Pet. App. 14a. *Amici* contend, to the contrary, that the taxation case law is directly applicable to the Commerce Clause analysis because the Ordinance possesses many of the attributes of a tax.

STATEMENT OF THE CASE

The facts of the case are set out in detail in the Petition. *Amici* wish to highlight several facts of particular relevance to the issues on which this brief focuses.

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 The Ordinance contemplates that Producers may voluntarily agree to jointly operate a PSP. Ordinance § 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

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[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.

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 Petitioners 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 filed in district court, 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. Pet. App. 64a-65a. Accordingly, *all* prescription drugs sold or distributed in Alameda County were shipped there from sources outside the County, by someone other than

the manufacturer. *Id.* at 23a-24a. 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. *Id.* at 22a. The vast majority of drug companies represented by Petitioners have no physical presence in Alameda County; their only connection with the County is that a small percentage of the drugs they manufacture eventually find their way, via the stream of commerce, into the County.

Included within the Ordinance are legislative findings that improperly disposed prescription drugs pose unnecessary health risks and contaminate drinking water. Ordinance § 6.53.010. For purposes of the cross-motions for summary judgment, Petitioners did not contest the Ordinance's environmental, health, and safety benefits. Pet. App. 26a.[3]

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[3] Despite that stipulation, *amici* note 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 and excrete waste. *See, e.g., id.* at 4.

The district court denied Petitioners' motion for summary judgment and granted Respondents' (collectively, "Alameda") cross-motion for summary judgment. *Id.* at 18a-32a. The court rejected Petitioners' contention that the Ordinance was *per se* unconstitutional under the Commerce Clause, concluding that "the Ordinance here neither purports to regulate interstate commerce nor does so as a practical matter." *Id.* at 29a.

The Ninth Circuit affirmed. Pet. App. 1a-17a. The court concluded that the Ordinance neither "discriminates against [n]or directly regulates interstate commerce" and thus rejected Petitioners' contention that the Ordinance amounted to a *per se* violation of the Commerce Clause. *Id.* at 7a.

The appeals court also held that the Ordinance survived Commerce Clause scrutiny under the "balancing test" set forth in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). It concluded that the Ordinance did not "substantially burden interstate commerce" because: (1) there was no "evidence that the Ordinance will affect the interstate flow of goods"; and (2) the cost of running the drug disposal program was "minimal" in comparison to prescription drug sales within the County. Pet. App. 14a-15a. The court concluded that the stipulated safety justifications for the Ordinance outweighed its burdens on interstate commerce and tipped the *Pike* balance in Alameda's favor. *Id.* at 15a.

The Ninth Circuit deemed it irrelevant, for purposes of Commerce Clause analysis, that the Ordinance "imposes an affirmative obligation" on drug

companies to establish a new business in the County—even though most of those companies lack any physical presence in Alameda County and are not ordinarily in the disposal business. *Id.* at 13a. It noted that the Ordinance imposes obligations on drug companies if and only if they permit their prescription drugs to be sold or distributed in the County. *Id.* at 12a-13a.

Nor did the court attach any constitutional significance to the fact that Alameda drafted the Ordinance in a manner intended to ensure that the costs of the drug disposal program could not be passed along to residents of the County but instead would be borne almost exclusively by non-residents. Indeed, for purposes of the *Pike* balancing test, the court concluded that the Ordinance's ability to save money for the County should be tallied as one of its "public benefits." *Id.* at 16a.

The appeals court also rejected Petitioners' efforts to demonstrate, based on Commerce Clause tax case law, that the Ordinance was unconstitutional because their sales activities lacked a sufficient "nexus" with Alameda County and because the burdens imposed by the Ordinance were unfairly apportioned. *Id.* at 14a. The court said it was unaware of case law applying "the nexus and fairly apportioned requirements outside of the tax context," and it declined "to break this new legal ground." *Ibid.*

SUMMARY OF ARGUMENT

Alameda County's unprecedented Ordinance is explicitly designed to ensure that local waste disposal

costs, costs that heretofore have been viewed as a local responsibility, will hereafter be imposed on the nation as a whole. Review is warranted to determine whether such parochialism constitutes a *per se* violation of the dormant Commerce Clause. The Court has repeatedly condemned, as *per se* violations, local regulations that either directly regulate interstate commerce or that intentionally favor in-state economic interests over out-of-state interests. The Ninth Circuit held that the Ordinance did not "discriminate" against out-of-state interests because it "treats all private companies"—both out-of-state companies and those headquartered in the local jurisdiction—"exactly the same." Pet. App. 8a. That holding conflicts with this Court's decisions, which have defined in-state economic interests more broadly, so as to include not only the interests of local businesses but also the economic interests of local citizens and consumers.

Review is also warranted in light of the Ninth Circuit's conclusion that Alameda County is entitled to reach across state lines to direct out-of-state companies to establish and operate a new business within the County. For most of the companies, their only connection with the County is that they manufactured a product that eventually found its way there after traveling in the stream of commerce. Pet. App. 11a. The affirmative obligations that the Ordinance seeks to impose on out-of-state companies possessing such extremely limited contacts with the County are precisely the sort of overly burdensome regulations of interstate commerce that the Court has frequently condemned as *per se* Commerce Clause violations. Although such limited contacts with a locality might be sufficient under some circumstances to permit local courts to exercise

specific personal jurisdiction over a company without running afoul of due process constraints, this Court has repeatedly emphasized that the Due Process and Commerce Clauses are animated by different constitutional concerns and policies.

In evaluating the Commerce Clause challenge, the Ninth Circuit declined Petitioners' request that it take into account the criteria established by this Court for addressing Commerce Clause challenges to local taxes. Pet. App. 14a. But given that the Ordinance possesses many of the attributes of a tax, those tax-based criteria—the four-part *Complete Auto* test—are directly relevant here and strongly suggest that the Ordinance is inconsistent with the principles that animate the Commerce Clause. *See Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274, 279 (1977). In particular, there is serious reason to doubt that costs are fairly apportioned: the Ordinance requires a drug company to assume 100% of drug-collection responsibilities if *any* of the drugs it sells end up in Alameda County. Review is warranted to determine whether the County's failure to satisfy the *Complete Auto* criteria dictates a finding that the Ordinance cannot survive Commerce Clause scrutiny.

REASONS FOR GRANTING THE PETITION

The Petition raises issues of exceptional importance. The Ordinance is an unprecedented effort to require companies lacking any physical presence in Alameda County to operate a drug collection program there for the benefit of local residents. County officials have been candid in explaining why they adopted the Ordinance: they seek to foist the costs of an existing

waste-collection program onto those living outside the County. If their cost-shifting efforts are upheld by the courts, one can reasonably expect that other local governments will adopt similar cost-shifting mandates. Review is warranted to ensure that the Commerce Clause remains an effective barrier to the persistent efforts by local jurisdictions to garner economic advantage at the expense of the national economy.

It is important to emphasize what is *not* at issue in this case. First, this is not a dispute about whether Alameda County should establish a drug collection program. Indeed, the County for some time has operated a program that adequately addresses its environmental, health, and safety concerns arising from the disposal of unused prescription drugs by county residents. Second, no one contests the County's right to impose taxes to pay the costs of its program. For example, a supplemental sales tax on all prescription drug sales within the County—designed to finance the drug collection program—would raise no Commerce Clause concerns.

Alameda eschewed a tax on drug sales, however, because such a tax would not have accomplished the County's objective: to ensure that the costs of the program are principally borne by those living outside the County. That is, the impact of a sales tax collected by local pharmacies at the point of sale would have fallen on local consumers. Thus, instead of imposing a tax, the Ordinance commandeers drug companies—even those lacking any physical presence in the County—to establish and operate a drug collection program within the County. The express purpose of the Ordinance is to

favor local interests over those of individuals living elsewhere in the nation. Review is warranted to determine whether such parochialism constitutes a *per se* violation of the dormant Commerce Clause.

I. Review Is Warranted to Determine Whether the County's Economic Protectionism Escapes Commerce Clause Challenge Simply Because the Ordinance Treats Local Drug Companies and Out-of-State Drug Companies Alike

Local legislation that provides a commercial advantage to in-state economic interests 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).

The Ninth Circuit concluded that the Ordinance does *not* discriminate against interstate commerce because it "applies to all manufacturers that make their drugs available in Alameda County—without respect to the geographic location of the manufacturer." Pet. App. 8a. The courts below noted that the three drug manufacturers with their principal places of business in the County and the two drug manufacturers that maintain manufacturing facilities in the County are subject to the same responsibilities under the Ordinance as are out-of-state manufacturers. *Id.* at 5a, 22a.

But in determining whether a law improperly discriminates against interstate commerce in favor of local economic interests, this Court has not limited its analysis of "local economic interests" to local *businesses*. The Commerce Clause also restricts local regulations that unduly discriminate in favor of local consumers and taxpayers. Thus, for example, in *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564 (1997), the Court held that a Maine property tax provision violated the Commerce Clause because it discriminated in favor of in-state residents by providing a tax exemption to summer camps only if they catered primarily to in-state residents. The Court explained, "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." *Id.* at 577-78 (quoting *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 580 (1986)).

The Ordinance plainly provides "local consumers an advantage over consumers in other States." First, it transfers to non-resident Producers the costs of collecting and disposing of unused drugs from County residents, costs that heretofore have been borne by County taxpayers. It then bars Producers from imposing fees as a means of recouping their costs—either at the time the drugs are sold to local consumers or at the time the unused drugs are collected from those consumers. Ordinance § 6.53.040.B.3. Moreover, by creating an exemption from the drug collection program for local pharmacies—the only entities that deal directly with local consumers and thus the only entities capable of passing collection costs on to

local consumers through higher prices—the Ordinance ensures that local consumers will never be required to bear more than a small fraction of the program's costs. Ordinance § 6.53.030.14.

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 prevent 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, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 345 (2007).[4] The Court has indicated that in those circumstances, courts should be 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)).

Thus, in *West Lynn Creamery*, the Court struck down, under the dormant Commerce Clause, a

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[4] 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 further attention within Alameda County so long as the costs of programs designed to address disposal issues are not being borne by Alameda County residents.

Massachusetts dairy regulation that even-handedly taxed both in-state and out-of-state milk producers but also included a subsidy for in-state producers. The Court explained that "the existence of major in-state interests adversely affected" by regulations that burden interstate commerce "is a powerful safeguard against legislative abuse." *West Lynn Creamery*, 512 U.S. at 200. But when, as here and in *West Lynn Creamery*, the government adopts measures to ensure that those "major in-state interests" will no longer be adversely affected by the regulation, "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." *Id.*

The Ninth Circuit rejected Petitioners' absence-of-political-constraints argument, asserting that "the cost of running the disposal program has not been *entirely* shifted outside the county." (Emphasis added.) Noting that the costs of the drug disposal program would likely be incorporated into nationwide prices for prescription drugs, the appeals court concluded that Alameda County residents would experience the very same price increases experienced by consumers throughout the country and thus that they could be expected to exert normal "political restraints" on Alameda County to control unwarranted programs. Pet. App. 10a.

The appeals courts' assessment of political constraints likely to be exerted by Alameda County voters is ludicrous. The parties stipulated that total prescription drug sales in the United States were $309

billion in 2010 and have been increasing by approximately $10 billion each year. Pet. App. 68a. They further stipulated that approximately $965 million of those 2010 sales (or about 0.3% of total sales) took place in Alameda County. *Ibid.* In other words, assuming that costs are incorporated into nationwide drug prices, for every $10.00 spent to collect and dispose of unused drugs in Alameda County, $.03 will be paid by consumers living in Alameda County and $9.97 will be paid by consumers living elsewhere in the country. Those numbers belie the Ninth Circuit's political accountability theory. Alameda's voters would likely conclude that they are getting their money's worth from the drug disposal program even if they think that the program is worth only a tiny fraction of its overall costs. Accordingly, it is utterly unrealistic to conclude that the minute percentage of overall program costs Alameda County voters bear provides any meaningful check on burdens being imposed on interstate commerce. When the burden of regulation falls on interests outside the jurisdiction, "it is not likely to be alleviated by those political restraints which are normally exerted on legislation where it affects adversely interests within" the jurisdiction. *McGoldrick v. Berwind-White Coal Mining Co.*, 309 U.S. 33, 45 n.2 (1940).

The parties have stipulated that the drug disposal program provides some health and safety benefits for Alameda County. But the same could be said for any waste disposal program, yet *amici* are aware of no other such program that incorporates the cost-shifting features of the Ordinance. The mere fact that Alameda County may have some perceptible justification for exercising its police powers to address drug disposal

concerns does not authorize the County to do so by establishing a program whose highly unusual procedures impose a significant burden on interstate commerce and were adopted for the express purpose of foisting local waste disposal costs on those living outside the County. As Justice Holmes wrote for the Court more than a century ago, "[A] State cannot avoid the operation of [the Commerce Clause] by simply invoking the convenient apologetics of the police power." *Kansas City Southern R. Co. v. Kaw Valley Drainage Dist.*, 233 U.S. 75, 79 (1914).

II. Review Is Warranted to Determine Whether the Affirmative Obligations the Ordinance Imposes on Drug Manufacturers Are *Per Se* Violations of the Commerce Clause

Review is also warranted in light of the Ninth Circuit's conclusion that Alameda County is entitled to reach across state lines to direct out-of-state companies to operate a new business within the County. The appeals court's conclusion is at odds with this Court's many decisions holding that it is a *per se* violation of the Commerce Clause to condition the right to sell products in a jurisdiction on the performance of burdensome tasks within the jurisdiction.

Importantly, the Ordinance does not merely regulate the terms under which drug manufacturers are permitted to sell their product in Alameda County. Rather, if a manufacturer seeks the privilege of having its drugs dispensed in the County, the Ordinance imposes on the manufacturer an affirmative obligation to establish a presence in Alameda for the purpose of

entering into an entirely new line of business: the collection and disposal of unused prescription drugs from any and all residents of Alameda County. The Court has repeatedly held that such local-presence requirements impose undue burdens on interstate commerce.

For example, the Court struck down a Madison, Wisconsin ordinance conditioning the right to sell milk in the city on the seller's agreement to arrange for the pasteurization and bottling of its milk within five miles of the city. *Dean Milk Co. v. City of Madison*, 340 U.S. 349 (1951). Madison sought to justify its ordinance as a health and safety measure that facilitated inspection of bottling facilities. The Court nonetheless concluded that the ordinance unduly burdened interstate commerce by denying the privilege of selling milk in Madison to dairies unwilling to move their bottling operations to the city. *Id.* at 352-53. If anything, the local-presence requirement imposed on drug manufacturers by Alameda County is even more onerous than the one imposed on milk producers by Madison—Alameda does not even pretend that the drug-disposal obligations it imposes on out-of-state manufacturers bear any direct relationship to the safety of the prescription drugs that manufacturers seek the privilege of selling. Indeed, an effective drug disposal program was in place in the County for several years before adoption of the Ordinance, and the County's only rationale for adopting it was to transfer disposal costs to the manufacturers.

The Ninth Circuit discounted the importance of the affirmative burden that the Ordinance imposes on

Producers to enter into a new business. Pet. App. 13a. It contended that this Court's Commerce Clause decisions do not distinguish between laws that impose "affirmative obligations" and laws that merely regulate the manner in which businesses must operate. *Id.* But the appeals court failed to address any of this Court's decisions that discuss local-presence requirements. The sole decision cited by the appeals court, *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003), is inapposite. It involved a Maine statute that imposed no affirmative obligations whatsoever on drug manufacturers to conduct business within the State. Rather, the statute was merely an effort by Maine to induce manufacturers to reduce their prices for some lower-income individuals. The only consequence of declining requested price reductions was the application of more onerous rules governing Medicaid reimbursement, not denial of the privilege of doing business in the State. *Id.* at 654.

The Ninth Circuit's rejection of Petitioners' claims was premised on its conclusion that there are virtually no Commerce Clause limitations on a jurisdiction's authority to impose local regulations on out-of-state firms that wish to sell products within the jurisdiction. Pet. App. 11a. That contention is belied by the numerous Commerce Clause decisions that have struck down non-discriminatory regulations deemed by the Court to impose unwarranted burdens on interstate commerce. *See, e.g., Quill Corp. v. North Dakota*, 504 U.S. 298, 315 n.8 (rejecting assertion that a corporation's "slightest presence" in a jurisdiction constitutes a connection between the corporation and the jurisdiction sufficient to overcome Commerce Clause

objections to regulation). Review is warranted to resolve the conflict between the decision below and this Court's decisions regarding Commerce Clause limitations on physical-presence requirements.

III. The Ninth Circuit Erred in Refusing to Consider Whether the Ordinance Runs Afoul of the Four-Part Test That Determines Whether State Taxes Violate the Commerce Clause, Given That the Ordinance Possesses Many Attributes of a Tax

The Court has developed a four-part test—the *Complete Auto* test—to assist in determining whether a state tax violates the Commerce Clause. *See Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977). That test has greatly assisted courts when seeking to weigh the competing claims of taxpayers and state taxing authorities. Yet, although the Ninth Circuit's opinion included an analysis of the relative strength of Petitioners' and Alameda's claims, it explicitly declined Petitioners' request that it incorporate the four *Complete Auto* factors into its analysis. Pet. App. 14a. In particular, it declined to consider whether burdens imposed by the Ordinance are "fairly apportioned" and whether there is a sufficient "nexus" between the activities of Petitioners' members and the County. *Ibid.*

The Ninth Circuit erred in failing to do so. The Constitution contains only one Commerce Clause, and the factors that would lead a court to conclude that a state tax violates the Commerce Clause would often correctly lead to a similar result in a Commerce Clause

challenge to another form of state regulation. The *Complete Auto* test is particularly relevant here, given that the Ordinance possesses many of the attributes of a tax. Moreover, application of the *Complete Auto* factors strongly suggest that the Ordinance is inconsistent with the principles that animate the Commerce Clause. Review is warranted to resolve the conflict between the decision below and the Commerce Clause analysis that the Court has applied in tax cases.

Complete Auto explained that a state tax should be sustained against a Commerce Clause challenge when it meets each of the following four requirements:

> [T]he tax is applied to an activity with a substantial nexus with the taxing State, is fairly apportioned, does not discriminate against interstate commerce, and is fairly related to the services provided by the State.

Complete Auto, 430 U.S. at 279.

Although the Ordinance is not a tax, it operates on drug manufacturers like a tax. The Ordinance requires Producers of prescription drugs to establish programs ("PSPs") to collect and safely dispose of all unused prescription medicines within the County. The sale within Alameda County of even a single drug manufactured by a Producer is sufficient to trigger the Producer's obligation to accept from local residents unused prescription drugs of all descriptions. However, the Ordinance contemplates that Producers may voluntarily agree to jointly operate a single PSP and to share its costs. Were that to happen, the payments

made by a single manufacturer for its share of operating the PSP would be economically equivalent to a tax payment made by the manufacturer to a local taxing jurisdiction—and thus, whether the obligation to make such payments is consistent with Commerce Clause limitations could and should be evaluated in light of the *Complete Auto* test.

Any such evaluation strongly suggests that application of the Ordinance to drug manufacturers is, in most instances, inconsistent with the Commerce Clause. *Amici* have explained above why the Ordinance flunks the third *Complete Auto* factor (does the tax discriminate against interstate commerce?). The Ordinance also fails to satisfy the first factor (substantial nexus) and the second factor (fairly apportioned).

The nexus between the activities of drug manufacturers and Alameda County varies considerably from manufacturer to manufacturer. The three manufacturers with principal places of business within the County and the two manufacturers who maintain manufacturing facilities within the County obviously have a substantial nexus with the County. Accordingly, the Ordinance meets the "substantial nexus" test with respect to those five manufacturers.

It is questionable whether the ordinance meets the "substantial nexus" test with respect to the other manufacturers (numbering in the hundreds) who are subject to the Ordinance. The great majority of them maintain no sales offices within the County. They maintain no sales relationship with Alameda County

consumers, who obtain prescriptions from their doctors and purchase drugs (in most instances) from local pharmacies. The manufacturers do not ship drugs into Alameda County; rather, they generally sell their products to pharmaceutical wholesalers, none of whom operate distribution centers in Alameda County. Pet. App. 65a. The only "nexus" between the activities of those manufacturers and Alameda County is that a substantial number of prescription drugs that they place into the stream of commerce eventually make their way downstream to Alameda County pharmacies and are sold to County residents.

This Court's case law suggests that a nexus of that nature does not qualify as "substantial." For example, the Court determined in *Nat'l Bellas Hess, Inc. v. Dep't of Revenue*, 386 U.S. 753, 758 (1967), that a "seller whose only connection with customers in the State is by common carrier or the United States mail" and has no other connections with the State lacks a sufficient nexus with the State to authorize the State, consistently with the Commerce Clause, to compel the seller to collect and pay a use tax on goods purchased for use within the State. The Court re-affirmed *Bellas Hess*'s Commerce Clause holding 25 years later, in *Quill*, 504 U.S. at 317-318. *Quill* added that a "substantial nexus" between the State of North Dakota and the sales activities of a Delaware corporation could not be established by evidence that the seller "licensed software to some of its North Dakota customers." *Id.* at 315 n.8. The Court explained that prior case law had "expressly rejected a 'slightest presence' standard of constitutional nexus." *Ibid.* If the sellers in *Bellas Hess* and *Quill* lacked a "substantial nexus" with the States

in question despite regularly shipping goods directly to customers living within those States, it is highly questionable whether the vast majority of drug manufacturers—who do not ship any drugs into Alameda County and do not have any direct relationship with any customers in the County—could be found to have a "substantial nexus" with the County.

It is also highly questionable whether costs imposed by the Ordinance could be deemed "fairly apportioned." Indeed, costs are not apportioned at all among the hundreds of drug companies subject to the Ordinance; rather, the Ordinance makes each of the companies fully responsible for ensuring that the drug disposal program collects and disposes of all unused drugs proffered by County residents.

Among the requirements of a "fairly apportioned" tax is that it be "internally consistent," which the 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).[5]

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 by a drug manufacturer who sells an equal number of pills but does not engage in interstate commerce (*i.e.*, it sells all of its prescription drugs within a single jurisdiction). And as the Petition explains, the possibility of similar cost-shifting ordinances being adopted elsewhere is not merely hypothetical: in the wake of the Ninth Circuit's decision, numerous localities are considering adopting expensive drug-waste disposal ordinances—but only if all costs can be foisted onto other jurisdictions.

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[5] 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).

In sum, review is also warranted to resolve the conflict between the decision below and the Commerce Clause analysis that the Court has applied in tax cases.

CONCLUSION

Amici curiae respectfully request that the Court grant the Petition.

Respectfully submitted,

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