No. 14-751

In the Supreme Court of the United States

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

Petitioners,

v.

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

Respondents.

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

MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* AND BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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January 28, 2015

MOTION OF *AMICUS CURIAE* FOR LEAVE TO FILE BRIEF IN SUPPORT OF PETITIONER

The Chamber of Commerce of the United States of America (the "Chamber") respectfully moves for leave to file the accompanying brief as *amicus curiae* under Supreme Court Rule 37.2(b). Petitioners have consented to the filing of this brief. Respondents have withheld consent. The Chamber has a strong interest in the granting of the petition for certiorari and has a perspective on the legal and policy matters it raises that will aid the Court, and therefore requests that its brief be accepted.

The Chamber is the world's largest business federation, directly representing 300,000 members and indirectly representing the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. Because the Chamber's members are frequent participants in interstate commerce, they have an acute interest in the proper application of constitutional principles that prevent local governments from hindering the flow of commerce among the states and in preventing the proliferation of inconsistent regulations across states and municipalities. The Chamber regularly files amicus briefs in important cases implicating these interests.

The Chamber offers a perspective that differs from those of the parties and illuminates the issues before the Court, and would welcome the opportunity to present its views. The petition for certiorari challenges the constitutionality of an Alameda County ordinance that requires pharmaceutical

companies whose products are sold within the County to establish and operate programs for disposing of unused drug products. The concurrently submitted amicus brief addresses the extraterritoriality and federalism concerns raised by laws like Alameda County's, and the potential implications of both the Ordinance and the decision below for businesses nationwide. These issues have not been addressed in depth in the petition, and the Chamber believes that these arguments will aid the Court in its consideration of the serious constitutional issues the petition raises.

For the foregoing reasons, this Motion for Leave to File should be granted, and the attached proposed Brief of *Amicus Curiae* in support of Petitioners should be accepted.

Respectfully submitted,

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INTEREST OF AMICUS CURIAE[1]

The Chamber of Commerce of the United States ("*Amicus*" or the "Chamber") submits this brief as *amicus curiae* in support of the petition for certiorari of the Pharmaceutical Research and Manufacturers of America, the Generic Pharmaceutical Association, and the Biotechnology Industry Organization. The Chamber is the world's largest business federation, directly representing 300,000 members and indirectly representing the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. The Chamber represents its members' interests before Congress, the executive branch, and the courts.

The Chamber's members transact business in interstate commerce every day. For this reason, they have an acute interest in the proper application of constitutional principles that promote the flow of commerce across state lines and prevent local governments from hindering interstate commerce or imposing coercive conditions on out-of-state parties. The Chamber's members also have a strong interest in preventing the proliferation of inconsistent

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[1] No counsel for any party authored this brief in whole or in part, and no person other than *Amicus*, its members, or its counsel made any monetary contribution intended to fund the preparation or submission of this brief. Counsel for all parties received notice of *Amicus*'s intention to file this brief at least 10 days prior to the due date, and Petitioners consented to the filing of this brief. Respondents did not so consent, and *Amicus* accordingly has submitted a Motion for Leave to File.

regulations across states and municipalities, in light of the significant expense and practical difficulty that patchwork regulations visit upon interstate companies. For these reasons, the Chamber regularly files amicus briefs in important cases, like this one, involving potential impediments to the free flow of interstate commerce.

SUMMARY OF ARGUMENT

The Chamber respectfully urges this Court to review the Ninth Circuit's decision below, which endorses municipal laws that further wholly local interests by imposing regulations on commercial actors and transactions up the distribution chain. Alameda County's Safe Drug Disposal Ordinance (the "Ordinance" or the "Alameda Ordinance") reaches across county, state, and even international borders to conscript pharmaceutical companies into funding and overseeing a classic local government service: refuse disposal. Under the Ordinance, a pharmaceutical company must establish a "take-back" program for disposing of unused drugs if *any* of their products are purchased by end-users within the County after flowing through a nationwide distribution network. Alameda County freely admits that *all* of the products made by the manufacturers represented by Petitioners are sold into the County by outside distributors. The County also admits that, with very few exceptions, all of the represented manufacturers are themselves located outside the County. The County insists, however, that it has the authority to reach all the way up national and international commercial chains to impose local

disposal conditions upon those outside manufacturers.

The regulatory power that Alameda County claims over interstate commerce is striking. The Ordinance on its face reaches drug manufacturers whose sole connection to Alameda County is that their products are sold in local outlets—almost always by another commercial actor. It provides that if a "Covered Drug" is "sold or distributed" within county lines, the *original manufacturer* of the product ultimately sold in-county is subject to affirmative regulatory obligations. Those obligations apply irrespective of who sold the product or the remoteness of the manufacturer along the chain of distribution. Thus a manufacturer located on the East Coast, or even abroad, that sells its products to a nationwide distribution company is, by the sole fact of that out-of-county sale, subject to regulation by a distant municipal sovereign. The manufacturer incurs the same Alameda County disposal duty if a mail or internet pharmacy fills a single prescription for a county resident.

This regulatory burden is substantial. Under the Ordinance, regulated manufacturers—nearly all of whom have no local operations—must enter Alameda County in order to design, seek approval for, operate, fund, and report on a "Product Stewardship Program" for the disposal of unused prescription drugs. Manufacturers also must advertise the program to Alameda County residents, implement an outreach campaign, and continuously seek re-approval for the program from county officials at least every three years. Compliance with the Ordinance will cost

manufacturers hundreds of thousands of dollars annually. Pet. App. 14a.

By imposing affirmative obligations on out-of-county manufacturers for their out-of-county activity, the County violates the dormant Commerce Clause and threatens core federalism principles. This Court has long held that, under the dormant Commerce Clause, state and local governments have "no power to project [their] legislation" into other jurisdictions, *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 521, 522 (1935), and that they are thus prohibited from regulating "'commerce that takes place wholly outside [their] borders, whether or not the commerce has effects within the State.'" *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion)). Yet the Ninth Circuit upheld the Ordinance without applying, or offering any reasoned analysis of, this extraterritoriality bar. In a single sentence, the Court dismissed *Healy* on the basis of *Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644, 669 (2003). Pet. App. 11a n.2. But *Walsh* had no occasion to address whether a local government could impose regulations—backed by substantial noncompliance penalties—on out-of-state entities that are connected to the municipality only by an interstate commercial chain where another commercial actor is the final link. Rather, *Walsh* held only that a state law that altered an existing *subsidy* program "to achieve additional cost savings on Medicaid purchases" did not constitute extraterritorial regulation of out-of-state drug manufacturers. *Walsh*, 538 U.S. at 649.

This Court should grant certiorari to clarify the continuing force of the longstanding principle that municipalities may not impose regulations on activities occurring outside their borders. By allowing municipalities to regulate out-of-state companies whenever those companies "choose[] to engage the state or county *through interstate commerce*" (Pet. App. 12a (emphasis added)), the Opinion below departs from this Court's precedents and destabilizes federalism's balance of national and state power in favor of parochial interests. Because the market for pharmaceuticals is national in scope, a manufacturer has little "choice" but to avail itself of the distribution network that makes its drugs available to local pharmacies and consumers. The extraterritoriality prohibition supports and safeguards such channels of interstate commerce, protecting its participants from overlapping and inconsistent regulation. It also reinforces local government accountability by aligning the regulated population with the voting population. These concerns go to the heart of constitutional federalism: The Framers sought to eliminate the "serious interruptions of the public tranquillity" that could flow from local efforts to burden the free flow of trade among the states. The Federalist No. 42, at 283 (James Madison) (Jacob E. Cooke ed., 1961).

The Opinion below also carries serious consequences for drug makers and other national manufacturers. If allowed to stand, the decision below would force drug manufacturers to establish local waste disposal operations in Alameda County. Any manufacturer seeking to avoid this duty would be forced to take steps to ensure that its products do

not cross County lines. Worse still, other jurisdictions have already begun to promulgate similar drug take-back laws and may extend the Ninth Circuit's reasoning to other products in other industries. The result may be a new network of local laws ensnaring distant manufacturers in a web of locality-specific obligations.

Although this Court properly reserves its resources for cases of exceptional importance, the Chamber submits that this is such a case, and that the time for this Court to resolve the issue is now. Further percolation of this issue will only worsen the jurisdiction-by-jurisdiction inconsistencies that the dormant Commerce Clause was meant to prevent. The petition for certiorari should be granted.

ARGUMENT

I. BY UPHOLDING A LOCAL LAW THAT OPERATES ACROSS STATE LINES, THE OPINION BELOW CONTRAVENES THIS COURT'S DORMANT COMMERCE CLAUSE PRECEDENTS, FLOUTS CORE FEDERALISM PRINCIPLES, AND DISRUPTS INTERSTATE COMMERCE

a. The Ordinance Imposes Conditions on Out-of-County Commercial Transactions for Purely Local Ends

The Alameda Ordinance places regulatory requirements and conditions on commercial actors based on out-of-state transactions as though they were wholly local activities. Under the Ordinance, an

out-of-state drug manufacturer whose products pass through the national chain of commerce and find their way to Alameda County is conscripted into designing and managing an Alameda-specific program to retrieve pharmaceutical waste that may or may not include waste from the manufacturer's own products. By reaching far up the national distribution chain and hailing interstate drug manufacturers into Alameda County, the Ordinance—in the parlance of the Dormant Commerce Clause—regulates "extraterritorially."

The Ordinance's parochial objectives, and national scope, are evident from its face. It compels any "Producer" whose "Covered Drug" is sold or distributed in Alameda County to operate and fund a "Product Stewardship Program" ("Program"). Alameda County, Cal., Health & Safety Code § 6.53.040(A). By definition, each Program must "collect, transport, and dispose of" Alameda County's unused prescription drugs. *Id.* § 6.53.030(15). Regulated Producers also must offer "educational and other outreach materials," *id.* § 6.53.070(B), that "publicize the location and operation of collection locations in Alameda County," *id.* § 6.53.070(C), among other things.

The Ordinance sweeps out-of-state pharmaceutical manufacturers within its reach. Any "owner or licensee of a trademark or brand" under which a Covered Drug is ultimately "sold or distributed in Alameda County" is subject to affirmative refuse collection duties as a "Producer" under the Ordinance. *Id.* § 6.53.030(14)(ii). For this reason, under the Ordinance, an out-of-county or

international drug manufacturer that sells its product to a national distributor located outside the County will be regulated if any fraction of the manufacturer's product is ultimately sold in Alameda County. If, for example, a Massachusetts drug manufacturer sells its product to a Tennessee distributor with a national distribution base, that out-of-county transaction, without more, compels the Massachusetts manufacturer to operate a drug take-back program in a far-away county in California. Because drug distribution—at least until now—has moved freely across state and municipal lines, the Ordinance would make all drug manufacturers Alameda County refuse collectors.

The burdens created by the Ordinance on pharmaceutical companies are substantial, and produce benefits only for Alameda County citizens. Drug companies must submit a "product stewardship Plan" ("Plan") for County approval, *id.* § 6.53.050(B), and then resubmit it "at least every three years," *id.* § 6.53.050(B)(4). Those Producers whose Plans the County approves must also prepare and submit an annual written report that exhaustively "describ[es] the Program's activities." *Id.* § 6.53.080(A). All costs associated with these Programs must be borne by the Producers, either individually or collectively through a jointly-operated Program. *Id.* § 6.53.040(B). And on top of their own expenses, Producers must also pay Alameda County itself for the cost of implementing and enforcing the Ordinance. *Id.* § 6.53.040(B)(4).

b. The Ninth Circuit's Endorsement of Extraterritorial Municipal Regulation Contravenes this Court's Dormant Commerce Clause Precedents

By reaching outside its territorial boundaries to impose conditions upon transactions occurring outside Alameda County, the Ordinance violates the Commerce Clause. The negative or "dormant" aspect of the Commerce Clause "limits the power of the States," *Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992), including by prohibiting them from "directly control[ling] commerce occurring wholly outside [their] boundaries," *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989). This extraterritoriality doctrine has been a core constitutional principle since the 19th century, *see Bonaparte v. Tax Court*, 104 U.S. 592, 594 (1881), and was first linked to the Commerce Clause in *Baldwin*, 294 U.S. 511. In *Baldwin*, this Court invalidated a New York statute setting minimum prices for milk purchases. New York purported to regulate not only milk purchased within the state, but also milk purchased in Vermont for resale in New York. *Baldwin*, 294 U.S. at 522. But New York, the Court held, had "no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there." *Id.* at 521.

The Court has since drawn on this aspect of the Commerce Clause to invalidate a statute empowering a state regulator to prevent interstate stock transactions taking place outside state lines. *See Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion). And it has invoked

extraterritoriality principles in striking down state "price-affirmation laws," which effectively regulated the liquor price sold in other states by requiring liquor distributors to post those prices and affirm they would not sell liquor at a lower price in any neighboring state. *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 578, 583 (1986); *Healy v. Beer Inst.*, 491 U.S. 324, 336-37 (1989). Taken together, these cases establish that the "'Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State.'" *Healy*, 491 U.S. at 336 (quoting *Edgar*, 457 U.S. at 642-43). The doctrine reflects not only the federal government's primary power over interstate commerce, but also the need for states "to respect the interests of other States." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 571 (1996).

In this case, as in *Healy*, *Edgar*, and *Brown-Forman*, Alameda County reaches beyond its borders to place burdens and conditions on transactions occurring outside the County. With just a few exceptions, the Plaintiffs' member companies design and manufacture pharmaceutical products outside of Alameda County and distribute their products through companies that are also located outside County lines. Pet. 5. Yet, transactions among these out-of-county manufacturers and out-of-county distributors subject the manufacturers to the onerous requirements of the Ordinance. These burdens include submitting a stewardship Plan, revising the Plan regularly according to County specifications, funding the Plan and Program, and preparing annual

reporting. By imposing these requirements, the County has taken local waste and refuse responsibilities and shifted that burden to commercial actors in other states. The Court's precedents squarely foreclose regulations that operate in such territorial fashion. *See Healy*, 491 U.S. at 336 ("The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State.").

The Ninth Circuit all but ignored these principles, stating in a footnote that "the test articulated in *Healy* may not apply to the Ordinance at all." Pet. App. 11a n.2. The court rested this determination on a Ninth Circuit case[2] applying *Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644, 669 (2003). But *Walsh* provides no basis to ignore the extraterritorial obligations imposed by Alameda County. *Walsh* did not involve a statute that directly imposed conditions on out-of-state commercial activity; the Maine statute at issue amended the state's prescription *subsidy* program, allowing drug manufacturers to enter into "rebate agreements" with the state "to achieve additional cost savings on Medicaid purchases." *Id.* at 649. Manufacturers were not compelled to enter into the rebate agreements, although prescriptions for drugs manufactured by companies without rebate agreements were subject to a "prior authorization program" for Medicaid payments. *Id.* at 654.

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[2] *Association des Éleveurs de Canards et d'Oies du Québec v. Harris*, 729 F.3d 937 (9th Cir. 2013), *cert. denied*, 135 S. Ct. 398 (2014).

The Maine statute challenged in *Walsh* thus directed the flow of the state's existing subsidies for prescription drug purchases, giving manufacturers a choice between a reduced subsidy amount (under a rebate agreement) or state gatekeeping of fully-subsidized purchases (via a prior authorization program). *Id.* at 654. The statute did not "control conduct beyond [state] boundaries." *Healy*, 491 U.S. at 336. A manufacturer making an out-of-state sale to a national distributor reselling in Maine faced no penalties for not participating in the state's rebate program. And any effect on the manufacturer's sales was indirect, flowing from "additional procedural burdens" that prior authorization places "on physicians prescribing the manufacturer's drug and retail pharmacies dispensing it." *Walsh*, 538 U.S. at 656 (internal quotation marks and citation omitted).

Walsh therefore correctly rejected the challenge to the Maine statute in the absence of any "direct[] control[] [of] commerce occurring wholly outside" Maine's boundaries. *Healy*, 491 U.S. at 336. The reasoning of *Walsh* does not govern here, where the Alameda Ordinance attaches affirmative obligations—backed by substantial noncompliance penalties—to out-of-county transactions. A manufacturer's out-of-state transaction with a national distributor reselling in Alameda County means the manufacturer must comply or pay fines, subjecting the manufacturer to affirmative obligations with a clear extraterritorial reach.

The Ninth Circuit also placed weight on the fact that the Ordinance regulates only those manufacturers whose products ultimately cross the

County line after flowing through interstate commerce. Pet. App. 11a. But this supposed limitation does not cure the Ordinance's constitutional defect. The Constitution precludes the application of a local law to commerce that takes place wholly outside jurisdictional boundaries "whether or not the commerce has effects within" the jurisdiction. *Healy*, 491 U.S. at 336. In this case, the in-county transactions that trigger the Ordinance may be the last link in the interstate distribution chain, but the Ordinance undisputedly reaches back *up* that chain, across county and state lines, to regulate out-of-county actors for those out-of-county transactions. The Ninth Circuit ought to have struck down a local law with this extraterritorial reach under this Court's precedents. The petition should be granted to clarify those precedents' continuing force.

c. The Opinion Below Ignores Core Federalism Principles

In upholding the Ordinance, the Ninth Circuit reached a result that is at odds with federalism principles repeatedly recognized by this Court. The bar on extraterritorial state regulation is not only an aspect of the Commerce Clause, but is also "one of those foundational principles of our federalism," evident "from the structure of the Constitution as a whole." Donald H. Regan, *Siamese Essays: (I)* CTS Corp. v. Dynamics Corp. of America *and Dormant Commerce Clause Doctrine; (II) Extraterritorial State Legislation*, 85 Mich. L. Rev. 1865, 1885 (1987). For well over a century, this Court has repeatedly made clear that "[n]o State can legislate except with reference to its own jurisdiction." *Gore*, 517 U.S. at

571 (quoting *Bonaparte*, 104 U.S. at 594). "[T]he extraterritoriality principle is our central principle of state legislative jurisdiction." Regan, *Siamese Essays*, at 1894. For this reason, state laws "have no force of themselves beyond the jurisdiction of the state which enacts them, and can have extraterritorial effect only by the comity of other states." *Huntington v. Attrill*, 146 U.S. 657, 669 (1892).

The Opinion below nowhere mentions, much less does it grapple with, the federalism concerns raised by local laws that operate extraterritorially. These concerns, however, go to the heart of our constitutional structure. The extraterritoriality bar promotes political accountability by aligning the voting populace with the regulated population. *Cf. Printz v. United States*, 521 U.S. 898, 920 (1997) ("The Constitution [] contemplates that a State's government will represent and remain accountable to its own citizens."). And it protects those transacting in the interstate market from the mischief created by inconsistent regulation. A central purpose driving the formation of the Union was to create a separate government with the singular authority to regulate on a national scale. *See Gibbons v. Ogden*, 22 U.S. 1, 100 (1824). As Alexander Hamilton warned during the 1787 ratification debates, commercial relations between the states would continue to be "fettered, interrupted, and narrowed by a multiplicity of causes" if local laws were allowed to interfere with commerce among the states. The Federalist No. 11, at 63 (Alexander Hamilton) (Hallowell ed., 1826); *see also* James Madison, *Preface to Debates in the Convention of 1787*, *in* 3 Records of the Federal

Convention of 1787, 547 (Max Farrand ed., 1911) ("The . . . want of a general power over Commerce led to an exercise of this power separately, by the States, which not only proved abortive, but engendered rival, conflicting and angry regulations."). The Framers thus shared "the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.'" *Okla. Tax Comm'n v. Jefferson Lines*, 514 U.S. 175, 180 (1995) (quoting *Wardair Canada, Inc. v. Fla. Dep't of Rev.*, 477 U.S. 1, 7 (1986)).

By ignoring the Ordinance's extraterritorial reach, the Court elevated form over substance and paved the way for more cross-state regulatory incursions. *Healy* and its progeny make clear that a state's regulation of commercial activities in another state raises deep federalism, and thus constitutional, problems. Regardless of whether a state *intended* to target out-of-state commercial activity or *effectively* shifted regulatory burdens across state lines, federalism principles bar one state from interfering with commerce beyond its borders. Because the Opinion below places a local law that creates local duties based upon out-of-state activities as beneath constitutional concerns, it threatens to inject further confusion into dormant Commerce Clause jurisprudence. This Court should intervene to clarify the scope of the extraterritoriality doctrine and confirm its continuing vitality.

d. By Allowing Municipalities to Impose Regulatory Obligations Outside Their Borders, the Ninth Circuit's Ruling Threatens Significant Disruption to Interstate Commerce

The Ninth Circuit's decision threatens to impose serious and immediate burdens on interstate pharmaceutical companies. These companies will, as a practical matter, be forced to choose between expending money and resources establishing a waste disposal program for Alameda County or implementing measures to ensure none of their products are sold there. Under cover of the Ninth Circuit's decision, other municipalities may adopt similar drug take-back laws or extend the Ninth Circuit's reasoning to other products in other industries, creating a whole new class of local laws reaching up interstate commercial chains to impose locality-specific obligations on far-flung manufacturers.

Left standing, the Ninth Circuit's decision would require *every* prudent pharmaceutical manufacturer dealing with national distributors to bear the substantial costs of establishing the collection and education operations required for a valid "Product Stewardship Program." Alameda County, Cal., Health & Safety Code § 6.53.050. The fact that manufacturers that "do[] not sell, offer for sale, or distribute prescription drugs in Alameda County" may avoid creating such a Program (Pet. App. 11a) does not ameliorate this burden. Manufacturers attempting to stop delivery of their products to Alameda County would face financial and logistical

hurdles that may make it more expensive to avoid the Alameda County market than to comply with the Ordinance. And even if national manufacturers succeeded in diverting distributions away from Alameda County, that result would frustrate the Framers' purpose of preventing states "'from retreating into economic isolation'" by imposing onerous regulations on interstate commerce. *Fulton Corp. v. Faulkner*, 516 U.S. 325, 330 (1996) (quoting *Okla. Tax Comm'n*, 514 U.S. at 180).

Nor are the Opinion's effects limited to the Ordinance or the pharmaceutical industry. The Opinion invites other jurisdictions to adopt local take-back laws across a wide range of product categories. Under the Ninth Circuit's decision, a locality may impose affirmative obligations on out-of-state manufacturers whose products are sold into national commerce so long as the manufacturer's products ultimately arrive in the regulating jurisdiction at the end of the commercial chain. Pet. App. 12a. This flawed analysis may be applied to virtually *any* take-back scheme for an array of widely available products. Indeed, Alameda County has stated publicly that it hopes its Ordinance "will set a national precedent as a new policy tool for local governments," Ed Silverman, Wall Street Journal Pharmalot Blog, Oct. 1, 2014,[3] and commentators believe that the County will get its wish. *See* Alston & Bird LLP, Ninth Circuit Upholds Alameda

[3] Available at http://blogs.wsj.com/pharmalot/2014/10/01/that-flushing-sound-pharma-must-pay-for-a-drug-take-back-program/.

County's Drug Take-Back Ordinance, Oct. 6, 2014 ("With this Ninth Circuit opinion, the floodgates are now open for similar pharmaceutical take-back initiatives in California and across the country, as well as additional extended producer responsibility laws for a vast array of consumer products.").[4]

The proliferation of far-reaching local take-back laws has already begun. In 2014, for example, the California State Assembly considered a bill that would have created a statewide pharmaceutical take-back program. *See* California Legislative Information, SB-727 Medical Waste: Pharmaceutical Product Stewardship Program.[5] King County, Washington has also enacted a drug take-back ordinance similar to Alameda's, *see* King Cnty., Wash. Secure Medicine Return Rule & Regulation;[6] the implementation of the King County ordinance was suspended pending the Ninth Circuit's ruling but is now going forward.[7] In addition, the state of

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[4] Available at http://www.alston.com/advisories/ninth-circuit-upholds-alameda/.

[5] http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140SB727, last visited Jan. 27, 2015.

[6] http://www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx, last visited Jan. 27, 2015.

[7] Beveridge & Diamond, *Ninth Circuit Upholds Alameda Safe Drug Disposal Ordinance, Triggering Implementation of King County Secure Medicine Return Rule*, Oct. 3, 2014 ("The *Alameda* decision triggers the implementation timeline for the Secure Medicine Return Rule & Regulation … in King County, Washington."), http://www.bdlaw.com/news-1649.html, last visited Jan. 27, 2015.

California has already instituted numerous other "extended producer responsibility" laws for a wide array of products, including batteries, paint, thermostats, and carpets. *See* Cal. Pub. Res. Code §§ 42451 *et seq.* (batteries), 48700 *et seq.* (paint), 42970 *et seq.* (carpets); Cal. Health & Safety Code § 25214.8.10 *et seq.* (thermostats). The Product Stewardship Institute, which collects information about such statutes, shows that 34 states have at least one state or local extended-producer law. *See* Prod. Stewardship Inst., Map of State and Local EPR Laws.[8]

Even as these extended producer laws stretch the traditional understanding of a state's constitutional authority, their local benefits are far from clear. Extended producer responsibility schemes have been criticized on the ground that their transaction costs may outweigh their environmental benefits. *See* Noah Sachs, *Planning the Funeral at the Birth: Extended Producer Responsibility in the European Union and the United States*, 30 Harv. Envtl. L.R. 51, 51 (2006) ("*Planning the Funeral*"). The use of such schemes raise special concerns in the context of unused pharmaceuticals. When aggregated for collection, unused drugs present serious risks of theft and abuse that government entities, not manufacturers, are best positioned to address. In addition, drug take-back laws are unlikely to spur manufacturers to reorient production towards sustainability, given that the volume of unused drugs

[8] http://www.productstewardship.us/?State_EPR_Laws_Map, last visited Jan 27, 2015.

is most directly controlled by those who prescribe and consume them, not by manufacturers. Drug take-back laws are thus particularly ill-suited to fulfilling the purported goal of extended producer responsibility, which seeks to "provide market incentives for bringing environmental considerations into the design process" for consumer products. Sachs, *Planning the Funeral*, 30 Harv. Envtl. L.R. 51, 53. In any event, whatever their merits, extended producer responsibility laws cannot constitutionally govern commerce taking place outside the jurisdiction that imposes them. Because the Alameda Ordinance does just that, this Court should grant certiorari to avoid the cascade of ill effects that may result from the Ordinance and its likely progeny.

II. THE TIME FOR REVIEW IS NOW

Certiorari is warranted to limit the ill effects of the Ninth Circuit's decision sanctioning the imposition of municipal regulatory obligations on out-of-county transactions. As explained, the consequences of the Ninth Circuit's ruling are already growing; withholding review while additional municipalities adopt, and courts rule on, similar laws will only worsen the regulatory inconsistencies visited on interstate companies. The Chamber respectfully submits that the time for the Court's review of this issue is now.

This case also presents an appropriate vehicle for the Court to correct the Ninth Circuit's refusal to apply its extraterritoriality precedents. The Chamber recognizes that this Court last Term denied certiorari in *Association des Éleveurs de Canards et*

d'Oies du Québec v. Harris, 729 F.3d 937 (9th Cir. 2013), *cert. denied*, 135 S. Ct. 398 (2014), a case involving the allegedly extraterritorial application of California's foie gras ban to out-of-state poultry farmers. But the California statute challenged in that case prohibited the sale of a certain sort of product within the state. *See* Cal. Health & Safety Code § 25982 (prohibiting sale of products resulting from "force feeding a bird"). In this case, by contrast, the Alameda Ordinance, instead of simply regulating the sale of certain products within the jurisdiction, reaches up the national commercial chain to impose affirmative, county-specific obligations on the out-of-state manufacturers who create the products. Because Alameda County's actions operate more directly on commercial transactions taking place in other states, its Ordinance carries far more serious consequences for interstate companies.

CONCLUSION

For these reasons, the Chamber respectfully urges this Court to grant the petition for certiorari.

Respectfully submitted,

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WORD COUNT CERTIFICATION

Pursuant to Supreme Court Rule 33.1(h), I certify that the foregoing proposed Brief of the Chamber of Commerce of the United States of America as *Amicus Curiae* in Support of Petitioners contains 4,713 words, including footnotes but excluding the caption, table of contents, table of cited authorities, and counsel listing. This word count was prepared using the word count feature of Microsoft Word, the word-processing system used to prepare the document.

Respectfully submitted,

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AFFIDAVIT OF SERVICE

SUPREME COURT OF THE UNITED STATES

No. 14-751

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

Petitioners,

v.

COOUNTY OF ALAMEDA, CALIFORNIA COUNTY DEPARTMENT OF ENVIRONMENTAL HEALTH,

Respondents.

----------X

STATE OF NEW YORK)

COUNTY OF NEW YORK)

I, Mariana Braylovskiy, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

I am retained by Counsel of Record for *Amicus Curiae.*

That on the 28th day of January, 2015, I served the within *Motion for Leave to File Brief as Amicus Curiae and Brief of the Chamber of Commerce of the United States of America as Amicus Curiae in Support of Petitioners* in the above-captioned matter upon:

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by depositing three copies of same, addressed to each individual respectively, and enclosed in a post-paid, properly addressed wrapper, in an official depository maintained by the United States Postal Service, via Regular Mail.

That on the same date as above, I sent to this Court forty copies of the within *Motion for Leave to File Brief as Amicus Curiae and Brief of the Chamber of Commerce of the United States of America as Amicus Curiae in Support of Petitioners* through the United States Postal Service by Express Mail, postage prepaid.

All parties required to be served have been served.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 28th day of January, 2015.

Mariana Braylovskiy

Sworn to and subscribed before me this 28th day of January, 2015.

Elias Melendez
Notary Public, State of New York
Qualified in [illegible]
Commission Expires [illegible] 17

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WORD COUNT CERTIFICATION

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