

**No. 13-16833**

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

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**PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, ET AL.,**

*Plaintiffs-Appellants,*

v.

**ALAMEDA COUNTY, ET AL.**

*Defendants-Appellees.*

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*On Appeal from the United States District Court  
for the Northern District of California, Case No. CV -12-6203 RS  
The Honorable Richard Seeborg, United States District Judge, Presiding*

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

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CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA

## **RULE 26.1 CORPORATE DISCLOSURE STATEMENT**

The Chamber of Commerce of the United States of America is a non-profit corporation organized under the laws of the District of Columbia. It has no parent corporation. No publicly held corporation owns ten percent or more of its stock.

**MOTION FOR LEAVE TO FILE AS *AMICUS CURIAE***

In accordance with Federal Rule of Appellate Procedure 29(a) and Ninth Circuit Rule 29-3, the Chamber of Commerce of the United States (“the Chamber”) respectfully moves for leave to file the concurrently submitted brief as *amicus curiae* in support of Plaintiffs/Appellants the Pharmaceutical Research and Manufacturers of America (“Plaintiffs”) in *Pharmaceutical Research and Manufacturers of America, et al. v. Alameda County, et al.*, CA No. 13-16833. While Plaintiffs have consented to the filing of this amicus brief, Defendant Alameda County has refused its consent. (Declaration of Fred A. Rowley, Jr. ¶¶ 2-3.) Good cause exists for filing the brief, for the Chamber has a strong interest in the outcome of this appeal and has a perspective on both the legal and policy matters it raises that will aid the Court.

The Chamber is the world’s largest business federation, representing 300,000 direct members and indirectly representing more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. In this representative capacity, the Chamber advocates for its membership 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 facilitate commerce across state lines and prevent

local governments from imposing coercive conditions on out-of-state parties. The Chamber regularly files amicus briefs in important cases that touch on interstate commerce and the orderly administration of justice in our federal system.

The Chamber believes that this is such a case. The Plaintiffs' appeal 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 federalism concerns raised by laws like Alameda's Ordinance, and the potential implications of both the Ordinance and the decision below for businesses nationwide. The Chamber believes that these arguments will aid the Court in its consideration of the serious constitutional issues raised by this appeal. Indeed, the Chamber recently participated in a case before the Sixth Circuit that, like this one, presented "an unusual extraterritoriality question." *Am. Beverage Ass'n v. Snyder*, \_\_ F.3d \_\_, 2013 WL 5584487, at \*11 (6th Cir. Jan. 7, 2013) (internal quotation marks omitted).

For the foregoing reasons, the Chamber's Motion for Leave to File as *Amicus Curiae* should be granted.

DATED: November 22, 2013

MUNGER, TOLLES & OLSON LLP  
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LITIGATION CENTER, INC

s/ Fred A. Rowley, Jr.

Fred A. Rowley, Jr.

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AMERICA

**DECLARATION OF FRED A. ROWLEY, JR.**

I, Fred A. Rowley, Jr., do hereby declare as follows:

1. I am a member of the law firm of Munger, Tolles & Olson LLP, counsel of record for the Chamber of Commerce of the United States (“the Chamber”), which seeks to file the concurrently submitted brief as *amicus curiae* in support of Plaintiffs/Appellants the Pharmaceutical Research and Manufacturers of America (“Plaintiffs”) in *Pharmaceutical Research and Manufacturers of America, et al. v. Alameda County, et al.*, CA No. 13-16833. I am a member in good standing of the bar of this Court. In accordance with Ninth Circuit Rule 29-3, I submit this declaration in support of the Chamber’s “Motion for Leave to File Brief as *Amicus Curiae* in Support of Appellants.” The matters set forth herein are based upon my own personal knowledge, and if called upon to do so, I could and would testify competently thereto.

2. On November 21, 2013, I exchanged emails with Chris Vergonis, counsel for Plaintiffs. Mr. Vergonis indicated that Plaintiffs consent to the filing of this amicus brief.

3. On November 21, 2013, I exchanged emails with Mary Jo Shartsis, counsel for Defendants/Appellees County of Alameda. Ms. Shartsis indicated that the County would not consent to the filing of the amicus brief.

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

Executed at Los Angeles, California on November 22, 2013.

s/ Fred A. Rowley, Jr.

Fred A. Rowley, Jr.

## CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing 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 November 22, 2013.

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.

DATED: November 22, 2013

MUNGER, TOLLES & OLSON LLP  
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LITIGATION CENTER, INC.

s/ Fred A. Rowley, Jr.

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## **RULE 29 STATEMENTS**

This brief of *amicus curiae* is submitted under Federal Rule of Appellate Procedure 29(a). Pursuant to Federal Rule of Appellate Procedure 29(c)(5), the Chamber of Commerce of the United States of America (“the Chamber”) states that: (1) no party’s counsel has authored this *amicus curiae* brief in whole or in part; (2) no party or party’s counsel has contributed money intended to fund the preparation or submission of the brief; and (3) no person other than the Chamber, its members, and its counsel has contributed money intended to fund the preparation or submission of this brief.

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### **IDENTITY AND INTEREST OF *AMICUS CURIAE***

The Chamber of Commerce of the United States (the “Chamber”) submits this brief as *amicus curiae* in support of the Appellants—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, representing 300,000 direct members and indirectly representing 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 facilitate commerce across state lines and prevent local governments from imposing coercive conditions on out-of-state parties. The Chamber regularly files amicus briefs in important cases that touch on interstate commerce and the orderly administration of justice in our federal system. In that role, the Chamber recently participated in a case before the Sixth Circuit that, like this one, presented “an unusual extraterritoriality question.” *Am. Beverage Ass’n v. Snyder*, \_\_ F.3d \_\_, No. 11-2097, 2013 WL 5584487, at \*11 (6th Cir. Jan. 7, 2013)



(internal quotation marks omitted). The Chamber welcomes the opportunity to present its views in this case as well.

## **INTRODUCTION**

The Plaintiffs, three pharmaceutical trade associations, have sued the County of Alameda (the “County” or “Alameda County”) on behalf of their member companies that manufacture prescription drugs. Virtually all of these member companies manufacture their drugs outside of Alameda County. Thereafter, they sell these drugs to, among other entities, wholesalers and mail pharmacies, which also are located almost exclusively outside of Alameda County. (Stipulation ¶¶ 14-24; ER 81-88.) At that stage in the chain of commerce, the manufacturers’ involvement ends.

By its new Safe Drug Disposal Ordinance (the “Ordinance” or the “Alameda Ordinance”), Alameda County has arrogated to itself the power to impose direct regulations on these out-of-state manufacturers and their out-of-state commercial transactions, compelling them to establish Alameda-specific programs for disposing of their products. It has asserted this power based solely on the fact that the manufacturers’ products ultimately find their way, through the national chain of commerce, to a local retailer or dispensary. If a drug wholesaler sells a fraction of its stock to a pharmacy in Alameda County, a mail pharmacy fills a prescription for a county resident, or a “Covered Drug” is ultimately “sold or distributed”

within county lines by whatever means, the original manufacturer becomes a “Producer” under the Ordinance. The financial and administrative burdens attached to that label are substantial. Among other duties, a Producer must implement, fund, and operate a “Product Stewardship Program” for disposing of unused prescription drugs in Alameda County; it must secure program approval from county officials at least every three years and file annual reports thereafter; and it must implement an advertising and outreach campaign.

This is a remarkable exercise of municipal power, and one that violates core federalism principles. In the parlance of the dormant Commerce Clause, the Alameda Ordinance regulates “extraterritorially.” *See Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989). By “directly control[ing] commerce occurring wholly outside [its] boundaries,” the County has “exceed[ed] the inherent limits” of its authority. *Id.* That a drug winds up being sold in Alameda County cannot vest local lawmakers with power over every upstream commercial actor, for the Supreme Court has made clear that “whether or not the commerce has effects within the State,” the Constitution “precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders.” *Id.* (quoting

*Edgar v. MITE Corp.*, 457 U.S. 624, 643 (1982) (plurality opinion)) (internal quotation marks omitted).<sup>1</sup>

In upholding the Alameda Ordinance, the decision below contravenes these core federalism principles and reaches a result that cannot be squared with Commerce Clause jurisprudence. Indeed, at least one federal court has struck down a strikingly similar example of municipal overreaching precisely because of its effect on out-of-state commerce:

Because all of plaintiffs' members who are manufacturers of patented prescription drugs are found out of state, and because all of the wholesalers to whom they sell their products are also found out of state, it is impossible to contend that this particular application of the D.C. Act does not effect an impermissible extraterritorial reach.

*Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 70 (D.D.C. 2005) [hereinafter *PhRMA*], *aff'd on other grounds sub nom. Biotech. Ind. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).

If upheld, the Ordinance's practical effect would be to visit local encumbrances on commercial and distribution activities that are national in scope. *Cf. Healy*, 491 U.S. at 336, 337 n.14 (deeming a law's practical effects the "critical inquiry" or "critical consideration in determining whether the extraterritorial reach

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<sup>1</sup> Like other Commerce Clause constructs, the ban on extraterritorial laws applies with equal force to both states and political subdivisions, and Alameda County has not argued otherwise. *See, e.g., C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 394 (1994); *BFI Med. Waste Sys. v. Whatcom Cnty.*, 983 F.2d 911, 913 (9th Cir. 1993).

of a statute violates the Commerce Clause”). Even taken alone, the Ordinance forces drug manufacturers to spend millions of dollars establishing a collection and education program. This despite the fact that the manufacturers’ only connection with the County is the eventual sale of a drug, at the end of a national distribution chain, within county lines. Were this Court to affirm the Ordinance’s validity, it could not but encourage other municipalities to adopt similar laws, expanding the regulatory burden faced by drug manufacturers. Prudent drug manufacturers would need to comply with any drug-disposal program adopted by a municipality or trace the distribution channels for every drug that they make in order to ensure municipality-by-municipality compliance. Alternatively, they would need to sell only to distributors that agreed to shun localities with such regulations. In either case, the effect of ordinances like Alameda County’s is to create just the type of “economic Balkanization” that the Commerce Clause is designed to curtail. *See Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979).

The Court should reverse the decision below and strike down the Ordinance.

## ARGUMENT

### I. ALAMEDA COUNTY HAS VIOLATED OUR FEDERAL SYSTEM BY IMPOSING CONDITIONS ON WHOLLY OUT-OF-COUNTY COMMERCIAL TRANSACTIONS

#### A. The Ordinance Regulates Interstate Commercial Sales Between Out-of-County Drug Manufacturers and Out-of-County Drug Wholesalers

Last year, in a professed exercise of its police power, the Alameda County Board of Supervisors enacted the “Alameda County Safe Drug Disposal Ordinance.” *See* Alameda County, Cal., Health & Safety Code § 6.53.010, *et seq.* The Ordinance regulates the disposal of unused prescription drugs—termed “Covered Drugs”—in the County by what amounts to a mandatory take-back program. As its proponents acknowledge, the program is novel; instead of assuming the waste-disposal task itself, the County has charged private drug “Producers” with disposal duties and all costs associated with that task.

Under the Ordinance, any “Producer whose Covered Drug is sold or distributed in Alameda County” must operate and fund what the County terms a “Product Stewardship Program” (“Program”). *Id.* § 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). Each also must offer “educational and other outreach materials,” *id.* § 6.53.070(B), that, for example, “publicize the location and operation of collection locations in Alameda County,” *id.* § 6.53.070(C). These details, and many others, are memorialized in a “product

stewardship Plan” (“Plan”), which Producers must submit to the Alameda County Department of Environment Health for approval, *id.* § 6.53.050(B), and then update and resubmit “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 “describe[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).

By its terms and operation, the Ordinance targets out-of-state manufacturers and commercial activities in the service of purely parochial interests. Among other criteria, a regulated “Producer” encompasses any “owner or licensee of a trademark or brand” under which a Covered Drug is ultimately “sold or distributed in Alameda County.” *Id.* § 6.53.040(14)(ii). This definition sweeps in a wide array of out-of-state commercial actors. Take, for example, an out-of-county, out-of-state, or even international drug manufacturer that sells its product to an out-of-county pharmaceutical wholesaler or mail pharmacy. The wholesaler later sells a fraction of its stock to a retail pharmacy in Alameda County, or the mail pharmacy ships a discrete order to a prescription holder living within the County. With

nothing more, the originating manufacturer becomes a “Producer,” answerable to Alameda County for the foreseeable future. Moreover, the Ordinance has no sunset clause for inactive Producers, and so manufacturers whose products were once sold, by another entity, within the County remain subject to County regulation indefinitely.

The undisputed evidence shows that this extraterritorial reach is more than hypothetical. Alameda County freely admits that *all* prescription drugs within its borders arrive by way of out-of-county distributors, such as wholesalers, mail pharmacies, and chain warehouses. These distributors are, in turn, almost always supplied by manufacturers that are also located outside the County. (Stipulation ¶¶ 14-24; ER 81-88.) Hence, manufacturers labeled “Producers” are ordinarily at least one step, and often two steps, removed from any commercial transaction bridging Alameda County’s lines that involves their products.

**B. Alameda County Exceeds its Municipal Authority By Regulating Out-of-County Commercial Actors**

**1. The Dormant Commerce Clause Reflects Core Federalism Principles**

Alameda County’s expansive exercise of municipal power is at odds with our federal system and violates the Commerce Clause. It is well settled that, “while a literal reading evinces a grant of power to Congress, the Commerce Clause also directly limits the power of the States.” *Wyoming v. Oklahoma*, 502

U.S. 437, 454 (1992). This negative, or dormant, aspect of the Commerce Clause prohibits extraterritorial regulation; a state may not “directly control[] commerce occurring wholly outside [its] boundaries.” *Healy*, 491 U.S. at 336. Since the Supreme Court first linked the extraterritoriality doctrine to the Commerce Clause, *see Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 522 (1935), courts have applied it to a range of laws, including: price-affirmation statutes, *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573 (1986); laws restricting corporate takeovers, *Edgar*, 457 U.S. at 641-42 (plurality opinion); rules governing athletic-association hearings, *NCAA v. Miller*, 10 F.3d 633, 637 (9th Cir. 1993); and waste-disposal regulations, *Nat’l Solid Wastes Mgmt. Ass’n v. Meyer*, 165 F.3d 1151, 1152-53 (7th Cir. 1999) (per curiam).

Though sometimes framed in terms of the dormant Commerce Clause, the extraterritoriality doctrine is at base “one of those foundational principles of our federalism,” drawn “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). “Laws have no force 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); *see also N.Y. Life Ins. Co. v. Head*, 234 U.S. 149, 160-61 (1914); *BMW of N. Am. v.*



*Gore*, 517 U.S. 559, 571 (1996). The prohibition on extraterritorial regulation is the natural corollary of the principle that, as against one another, the states are “upon an equal footing, in all respects whatever.” *Pollard v. Hagan*, 44 U.S. 212, 224 (1845). “The several States are of equal dignity and authority, and the independence of one implies the exclusion of power from all others.” *Pennoyer v. Neff*, 95 U.S. 714, 722 (1877), *overruled in part on other grounds by Shaffer v. Heitner*, 433 U.S. 186 (1977).

These principles have special purchase when it comes to commerce between the states. The whole point of forming the Union was to create a separate government that, though limited in power, would have the singular authority to regulate on a national scale. Many of the Framers saw, for example, a critical need for a unified system regulating truly interstate commerce. *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” so long as local laws could infringe on 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); 1 Laurence H. Tribe, *American Constitutional Law* § 6-12, at

1098 (3d ed. 2000) (discussing “the *per se* principle against extraterritorial state regulation”).

## **2. The Ordinance Violates the Dormant Commerce Clause’s Ban on Extraterritorial Regulation**

By regulating manufacturers that conduct wholly out-of-state transactions, Alameda County exceeds its authority and regulates extraterritorially. The Plaintiffs’ member companies generally produce prescription drugs outside of Alameda County and deal with distributors that are also located outside county lines. (Stipulation ¶ 24; ER 85.) Yet if any drug ends up in Alameda County, the County looks far up the supply chain and visits locality-specific burdens on the original manufacturer. In other words, the Ordinance imposes conditions on out-of-county commerce between out-of-county manufacturers and out-of-county buyers and threatens significant penalties for violation. *See* Alameda County, Cal., Health & Safety Code §§ 6.53.110(D) (providing for a fine of up to \$1,000 per day per violation), 6.53.110(M) (designating knowing and willful violations as misdemeanors).

This is quintessential extraterritorial regulation. “A statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State’s authority.” *Healy*, 491 U.S. at 336. By regulating wholly out-of-county actors and activities, Alameda County extends its police power “beyond its jurisdictional bounds.” *C & A Carbone, Inc. v. Town of*

*Clarkstown*, 511 U.S. 383, 393 (1994). A manufacturer whose out-of-county transactions trigger the Ordinance must submit stewardship Plans for county approval, revise and re-revise the Plans until county administrators are satisfied, report back annually, and formally seek re-approval every three years. Consequently, the Ordinance impermissibly “force[s] ... out-of-state merchant[s] to seek regulatory approval” from Alameda County as a condition of “undertaking ... transaction[s]” elsewhere. *Healy*, 491 U.S. at 337 (citing *Brown-Forman*, 476 U.S. at 582). It makes no difference that the Ordinance regulates only manufacturers whose drugs eventually cross county lines. 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. *Id.* at 336.<sup>2</sup>

Indeed, a similar municipal ordinance attempting to regulate out-of-state pharmaceutical companies was recently invalidated based on its extraterritorial

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<sup>2</sup> The County cannot avoid this problem by pointing out that “[a]ny person, manufacturer, or distributor that does not sell, offer for sale, or distribute prescription drugs in Alameda County is not required to undertake any action under the Ordinance.” (ER 3 at ¶ 8.) Under the dormant Commerce Clause, the “practical effect” of the regulation has always been the touchstone for determining its extraterritorial reach. *S.D. Myers*, 253 F.3d at 467 (citing *Healy*, 491 U.S. at 336; *Valley Bank v. Plus System, Inc.*, 914 F.2d 1186, 1189-90 (9th Cir. 1990); *NCAA*, 10 F.3d at 639-40). As explained in further detail in part II, below, the practical effect of the Ordinance is not meaningfully limited by the hypothetical possibility that covered manufacturers could refrain from selling drugs in Alameda County.

reach. Under the District of Columbia's now-defunct "Prescription Drug Excessive Pricing Act," D.C. Code § 28-4551 *et seq.*, it was "unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale ... a patented prescription drug that results in the prescription drug being sold in the District for an excessive price." *Id.* § 28-4553. In other words, for a prescription drug sold at an "excessive price" in D.C., the law exposed only the original manufacturer to liability.

The D.C. law was invalidated for the same reasons the Plaintiffs press here. The court found that "the D.C. Act, as applied to sales between out-of-state manufacturers ... and other out-of-state entities has a *per se* invalid extraterritorial reach in violation of the Commerce Clause." *PhRMA*, 406 F. Supp. 2d 56, 71. Like the Plaintiffs here, the manufacturers in *PhRMA* sold the overwhelming bulk of their prescription drugs "in out-of-state transactions to wholesalers or large retail chains that maintain their own warehousing and retail distribution system[s]," which were also located out-of-state. *Id.* at 68. Since the D.C. law targeted the manufacturers based on those sales, the court reasoned, "the Act effectively [sought] to regulate transactions that occur[red] wholly out of state." *Id.*

There is no principled distinction between the D.C. law and the Alameda County Ordinance. While the Alameda Ordinance is formally triggered by an in-county sale, the County exploits that in-county "hook" to regulate out-of-county

conduct. *See id.* at 69 (citing *Baldwin*, 294 U.S. at 518-21); *see also id.* (“[A]s soon as [a] drug is sold in the District, the manufacturer’s out-of-state sale becomes the Act’s primary target.”). Because the Plaintiffs’ members are found outside of Alameda County, and “because all of the wholesalers to whom they sell their products are also found” outside of the County, the Ordinance “effect[s] an impermissible extraterritorial reach.” *Id.* at 70. As far as Alameda County is concerned, the manufacturers’ commercial transactions are wholly “‘interstate business,’” which the county may not directly burden “‘in any form or under any guise.’” *Baldwin*, 294 U.S. at 522 (quoting *Int’l Textbook Co. v. Pigg*, 217 U.S. 91, 112 (1910)). By doing so, Alameda County oversteps its jurisdiction and violates the dormant Commerce Clause. *See Healy*, 491 U.S. at 336.

## **II. THE ORDINANCE PROMISES SERIOUS ILL EFFECTS BEYOND COUNTY LINES.**

In upholding the Ordinance, the decision below threatens to impose serious financial and administrative burdens on nationwide commercial activity by pharmaceutical companies. It also encourages other municipal governments—at least one of which has already adopted a similar drug take-back law—to adopt similar laws for products in other industries. The result would be a new class of regulations that attempts to reach back across national channels of commerce to impose local rents. The burden on out-of-state commercial activity, potential for

abuse and mischief, and likelihood of harm to competition are manifest, and underscore the need for reversal.

“Because of the potential liability they will face in” Alameda County, the Plaintiffs’ members are decidedly not “free to conduct commerce on their own terms elsewhere.” *PhRMA*, 406 F. Supp. 2d at 70 (citations and internal quotation marks omitted). Every drug manufacturer that deals with national distributors may find itself subject to the Ordinance. Thus, if the Ordinance is upheld, the prudent manufacturer will need to bear millions of dollars in costs establishing the collection and education operations required for a valid “Product Stewardship Program.” Alameda County, Cal., Health & Safety Code § 6.53.050. It would also need to spend time and resources, on an ongoing basis, obtaining and maintaining certification by the County. *Id.* § 6.53.050(B). A manufacturer that wishes to avoid these expenditures and regulatory burdens would need to ensure it sells only to buyers that agree not to do business in Alameda County, an effort that would involve substantial monitoring costs. Regardless of how the manufacturers respond, the Ordinance will effect precisely the type of “economic Balkanization” the Commerce Clause is designed to curtail. *Pac. Nw. Venison Producers v. Smith*, 20 F.3d 1008, 1015 (9th Cir. 1994).

The burden on drug manufacturers would increase exponentially if “not one, but many or every” jurisdiction adopted similar legislation. *Healy*, 491 U.S. at

336. Tracing individual products and monitoring their entry into these localities would be impracticable. And a manufacturer would almost certainly be subject to fines and penalties if a retail store or pharmacy with no direct connection to the manufacturer sold its products within the state. Many manufacturers would therefore choose to undertake stewardship programs *whenever* a new state, county, or town institutes such a scheme.

Alameda County has discounted the burdens that will follow from this patchwork quilt of disposal regimes, optimistically citing “economies of scale.” (Def.’s Cross-Mot. Summ. J. at 23, Dkt. No. 31.) But it is highly unlikely that disposal rules, outreach obligations, and reporting laws will be consistent across jurisdictional lines. *Cf.* King Cnty., Wash., Proposed Rule and Regulation No. 13-03 § 9(A)(3) (June 5, 2013) (requiring “explanatory images” in outreach materials for “individuals with limited English proficiency”). Forced to comply with state- or locality-specific “stewardship” obligations, manufacturers would face “just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude.” *Healy*, 491 U.S. at 337.

Worse yet, the potential for schemes like Alameda County’s to create a nationwide system of overlapping and conflicting product-management obligations extends not just across jurisdictions, but across industries. The district court’s analysis, if upheld, could be invoked in defense of “extended producer

responsibility” (EPR) laws for a wide range of products, empowering municipalities to regulate national industries. Ignoring this Court’s consistent focus on a law’s effects on extraterritorial *activity*, the district court deemed the Ordinance constitutional because it “applies to producers who elect to sell their products within Alameda County, regardless of where the producers are based or the product originates.” (ER 9.) Under this line of reasoning, an ordinance that directly regulates out-of-state manufacturers whose products eventually flow into national commerce is permitted so long as it does not “target[] producers on the basis of their location.” (*Id.*) That flawed analysis could be applied to virtually any take-back scheme for widely available products. Nor is the risk of encouraging such laws merely academic, for as the County told the district court, (ER 49-50), California alone has instituted numerous EPR laws for products as diverse as batteries, paint, thermostats, and carpets. *See, e.g.*, 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); *see generally* Product Stewardship Inst., *Extended Producer Responsibility State Laws*, <http://productstewardship.us/displaycommon.cfm?an=1&subarticlenbr=280> (last visited Nov. 22, 2013) (identifying EPR laws that govern, among other items, cell phones, fluorescent lighting, and mattresses). Whatever the merits of EPR laws,



*see* Appellants’ Opening Br. at 2 n.1, these programs cannot constitutionally govern commerce taking place outside the enforcing jurisdiction.

Finally, the Ordinance—and the many others that will follow in its wake if states and localities are given the green light to transfer the costs of waste disposal to out-of-jurisdiction producers—cannot be defended on the basis that adversely affected manufacturers are free to stop selling their products in Alameda County. As explained, manufacturers attempting to do so would have to make substantial outlays to ensure that their products never enter the County, meaning that, as practical matter, *no* national manufacturer can avoid the Ordinance’s broad reach. Moreover, even if it were practical for national manufacturers to carve Alameda County from their distribution networks, such a result would still violate the core Commerce Clause prohibition against the creation of isolated economic fiefdoms through onerous local regulation. “The very purpose of the Commerce Clause was to create an area of free trade among the several States.” *McLeod v. J.E. Dilworth Co.*, 322 U.S. 327, 330 (1944). The Ordinance turns that foundational principle on its head.

## CONCLUSION

For these reasons, the Chamber respectfully urges this Court to reverse the judgment of the district court.

DATED: November 22, 2013

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**CERTIFICATE OF COMPLIANCE**

I hereby certify that this amicus brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B). It contains 4,113 words.

DATED: November 22, 2013

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### CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing 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 November 22, 2013.

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DATED: November 22, 2013

s/ Fred A. Rowley, Jr.

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