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United States District Court
For the Northern District of California

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA, et al.,

No. C 12-6203 RS

Plaintiffs,

v.

**ORDER DENYING PLAINTIFFS'
MOTION FOR SUMMARY
JUDGMENT AND GRANTING
DEFENDANTS' CROSS-MOTION**

COUNTY OF ALAMEDA, et al.,

Defendant.

I. INTRODUCTION

The County of Alameda has adopted what has been described as a “first in the nation” approach to addressing concerns arising from the disposal of unused prescription drugs. Its “Safe Drug Disposal Ordinance” (the “Ordinance”), scheduled to go into effect in November of this year, requires producers of prescription drugs to fund or operate “take-back” programs in the county, if any of their drugs are sold there. The ordinance is crafted to place the entire cost of such programs on the producers; retail pharmacies are exempt, and sellers are prohibited from passing the expense directly to Alameda County consumers by adding a fee at the point of sale. Plaintiffs are industry associations whose members produce prescription drugs sold in the county, on whom the costs of complying with the Ordinance will fall. They bring this suit to have the ordinance declared an unconstitutional burden on interstate commerce, under the so-called “dormant Commerce Clause.”

Docket
8/28/13

1 Having stipulated that the material facts are undisputed, the parties now bring cross-motions
2 for summary judgment. Because the Ordinance does not discriminate against out-of-state actors in
3 favor of local persons or entities, and does not otherwise impermissibly burden interstate commerce,
4 plaintiffs' motion will be denied, and defendants' motion granted.

5
6 II. BACKGROUND

7 Demonstrating commendable cooperation and professionalism directed at resolving this
8 litigation in an efficient manner, the parties stipulated to a list of 38 points that are not in dispute for
9 purposes of these cross-motions. In slightly condensed form, the following are the parties'
10 stipulations:

11 1. The Ordinance, Alameda Health and Safety Code Sections 6.53.010, et seq., requires that
12 manufacturers of prescription drugs who sell, offer for sale, or distribute prescription drugs in
13 Alameda County ("Producers," as defined in the Ordinance) operate and finance a product
14 stewardship plan that provides for the collection, transportation, and disposal of certain unwanted
15 prescription drugs.

16 2. The Ordinance declares that in Alameda County, the public — particularly children and
17 the elderly — are at significant and unnecessary risk of poisoning due to improper or careless
18 disposal of prescription drugs and the illegal re-sale of prescription drugs; that the groundwater and
19 drinking water are being contaminated by unwanted, leftover, or expired prescription drugs passing
20 through wastewater and treatment centers; and that there is no mandatory statewide drug
21 stewardship program in California for the safe collection of unwanted drugs, and drug
22 manufacturers and producers have not offered any support for a permanent collection program to
23 date.

24 3. Pursuant to the Ordinance, Producers are required to operate, individually or jointly with
25 other Producers, a Department [of Environmental Health]-approved product stewardship program or
26 enter into an agreement with a stewardship organization to operate, on each Producer's behalf, a
27 Department-approved product stewardship program. In order to ensure that costs are fairly
28 allocated, if more than one Producer is involved in a proposed product stewardship program, the

1 product stewardship plan must include a fair and reasonable manner for allocating the costs of the
2 program among the participants, such that the portion of costs paid by each Producer is reasonably
3 related to the amount of prescription drugs that Producer sells in Alameda County.

4 4. The Ordinance, on its face, does not impose different requirements on Producers within
5 Alameda County and Producers outside of Alameda County.

6 5. The Ordinance, on its face, does not impose different requirements on Producers within
7 California and Producers outside of California.

8 6. The Ordinance, on its face, applies both to interstate Producers and intrastate Producers.

9 7. The Ordinance requires Producers that market and sell in Alameda County the
10 prescription drugs identified in the Ordinance be responsible for the disposal of those products.

11 8. Any person, manufacturer, or distributor that does not sell, offer for sale, or distribute
12 prescription drugs in Alameda County is not required to undertake any action under the Ordinance.

13 9. Nothing in the Ordinance requires that Producers implement stewardship plans in any
14 location or jurisdiction outside of Alameda County. If Producers are required to implement
15 stewardship programs in any other jurisdiction, nothing in the Ordinance requires that the
16 stewardship program implemented in other jurisdictions be the same as the program implemented in
17 Alameda County pursuant to the Ordinance. Similarly, nothing in the Ordinance prohibits
18 Producers from proposing and implementing a program in Alameda County that they are already
19 using or contemplating using in any other jurisdiction.

20 10. Plaintiffs are non-profit trade organizations representing the manufacturers and
21 distributors of pharmaceutical products. Plaintiff Pharmaceutical Research and Manufacturers of
22 America ("PhRMA") represents companies that produce brand-name drugs. Plaintiff Generic
23 Pharmaceutical Association ("GPhA") represents companies that produce generic drugs. Plaintiff
24 Biotechnology Industry Organization ("BIO") represents companies that produce biotechnology
25 products.

26 11. Plaintiffs' members include approximately one hundred companies that are subject to the
27 Alameda County take-back ordinance because they manufacture prescription drugs that are sold,
28

1 offered for sale, or distributed in Alameda County. Plaintiffs' members also manufacture
2 prescription drugs that are sold or distributed throughout the United States.

3 12. Three of Plaintiffs' members (Amgen, Impax Laboratories, and XOMA Ltd.) have their
4 corporate headquarters or principal places of business in Alameda County. Two of Plaintiffs'
5 members (Bayer and Impax Laboratories) have facilities in Alameda County that manufacture
6 prescription drugs for commercial distribution. Four other members (Abbott, Baxter, Novartis, and
7 Boehringer Ingelheim) have manufacturing facilities in Alameda County that do not manufacture
8 prescription drugs for commercial distribution.

9

10 17. The drugs manufactured in Alameda County for commercial distribution by Bayer and
11 Impax Laboratories account for less than 1% of total annual U.S. prescription drug sales
12 (approximately \$320 billion in 2011). Thus, approximately 99% of all prescription drugs sold in the
13 United States, by revenue, are manufactured outside Alameda County.

14 18. There is a national system for the distribution of prescription drugs from manufacturers
15 to the retail and mail pharmacies that dispense the drugs to consumers. Prescription drugs typically
16 move from a manufacturer's facilities to either a pharmaceutical wholesaler, a chain warehouse
17 operated by a large retail drugstore chain, or a mail pharmacy.

18 19. Smaller retail pharmacies in Alameda County (and elsewhere) typically rely on
19 pharmaceutical wholesalers for direct delivery of prescription drugs to individual retail locations.
20 Large retail drugstore chains typically rely on delivery by either pharmaceutical wholesalers or their
21 own chain warehouses. Mail pharmacies purchase drugs from both pharmaceutical wholesalers and
22 directly from manufacturers.

23 20. Three pharmaceutical wholesalers — AmeriSource Bergen Corporation, Cardinal
24 Health, Inc. and McKesson Corporation — operate more than eighty distribution centers across the
25 United States. None of these wholesalers have a distribution center in Alameda County.

26 21. The California Board of Pharmacy maintains a list of licensed wholesalers. None of the
27 twenty-one locations in Alameda County with an active wholesale license distributes prescription
28 drugs.

1 22. CVS, Walgreen, and Rite Aid are the three largest national drugstore chains but account
2 for less than half of the retail pharmacies in Alameda County. None of these chains operate a
3 warehouse distribution center in Alameda County.

4 23. The prescription drugs manufactured by Bayer and Impax Laboratories in Alameda
5 County are shipped outside the County before being distributed back into Alameda County.

6 24. Neither the County nor Plaintiffs are aware of any prescription drugs distributed in
7 Alameda County that arrive there via intra-County distribution channels as opposed to arriving there
8 via distribution channels that cross the County's borders, either because the drugs are manufactured
9 outside the County or because, if manufactured within the County, they are shipped to out-of-county
10 packaging or distribution centers before being distributed to in-county pharmacies.

11 25. Producers will incur start-up costs to establish a product stewardship program that
12 complies with the Ordinance. These costs include the incorporation and governance of an entity to
13 operate the required collection program on behalf of the Producers, initial one-time investments in
14 equipment and facilities, and the preparation and dissemination of education and outreach materials
15 publicizing the program.

16 26. Assuming that all Producers jointly operate a single collection program — an assumption
17 that results in lower overall costs than if multiple programs were operated separately — Plaintiffs
18 estimate that overall start-up costs will be approximately \$1,100,000.

19 27. Plaintiffs estimate that Producers will incur annual costs to operate a program that
20 complies with the Ordinance, including costs for labor, insurance, education and outreach, and
21 transportation and disposal of collected unwanted prescription drugs. Assuming that all Producers
22 jointly operate a single program, overall annual compliance costs (including reimbursement of
23 County administrative expenses) are estimated by Plaintiffs to be approximately \$1,200,000,
24 provided that local pharmacies are willing to provide free space for the location of collection kiosks.
25 If local pharmacies either demand rent or refuse altogether to provide space for collection kiosks,
26 then Plaintiffs believe the recurring annual costs may be higher.

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1 28. The Ordinance requires Producers to reimburse Alameda County for actual costs
2 incurred by the County in administering the Ordinance. Alameda County has estimated those
3 annual administrative costs to be roughly \$200,000.

4 29. Plaintiffs' estimated costs for its members to comply with the Ordinance assume that the
5 costs would not be paid by any single Producer or financed solely by the approximately 100
6 members of Plaintiffs that are Producers. Rather, the estimated costs are assumed to be spread
7 amongst all Producers that sell, offer for sale, or distribute prescription drugs in Alameda County.

8 30. Defendants estimate that the annual cost for compliance with the Ordinance is lower than
9 Plaintiffs' estimates, totaling less than \$330,000 per year. For purposes of the cross-motions for
10 summary judgment contemplated by the parties, however, the parties believe that the difference
11 between their estimates is not material to the outcome of the parties' motions.

12 ...

13 32. According to IMS Health, a pharmaceutical information and consulting company, total
14 prescription drug sales in the U.S. [in] 2010 were \$308.6 billion.

15 33. Plaintiffs at this time lack specific data about the annual revenue generated by their
16 members that is attributable to selling, offering for sale, or distributing prescription drugs in
17 Alameda County. Similarly, at this time Plaintiffs do not know the annual revenue generated by all
18 Producers that is attributable to selling, offering to sell, or distributing prescription drugs in
19 Alameda County.

20 34. Defendants estimate the total retail pharmaceutical sales in Alameda County in 2010
21 [were] approximately \$965 million.

22 ...

23 37. Plaintiffs agree that the Ordinance's environmental, health and safety benefits are not
24 contested for purpose of the cross-motions for summary judgment.

25 38. Plaintiffs' legal position is that, even assuming that take-back programs further important
26 interests, the County violates the Commerce Clause by requiring interstate drug manufacturers to
27 conduct and pay for such programs.

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III. LEGAL STANDARD

Summary judgment is proper “if the pleadings and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The purpose of summary judgment “is to isolate and dispose of factually unsupported claims or defenses.” *Celotex v. Catrett*, 477 U.S. 317, 323-24 (1986). The moving party “always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings and admissions on file, together with the affidavits, if any which it believes demonstrate the absence of a genuine issue of material fact.” *Id.* at 323 (citations and internal quotation marks omitted). If it meets this burden, the moving party is then entitled to judgment as a matter of law when the non-moving party fails to make a sufficient showing on an essential element of the case with respect to which he bears the burden of proof at trial. *Id.* at 322-23.

In this instance, the parties are in agreement that no material facts are in dispute, for purposes of these cross-motions. The question is only which side is entitled to judgment as a matter of law given those undisputed facts.

IV. DISCUSSION

The Commerce Clause of the Constitution assigns to Congress authority to “regulate commerce . . . among the several states. U.S. Const., art. I, § 8. The so-called “dormant” Commerce Clause is the implied converse proposition—state and local governments may not enact regulations that unduly interfere with interstate commerce. *See Quill Corp. v. North Dakota*, 504 U.S. 298, 309 (1992) (“the Commerce Clause is more than an affirmative grant of power; it has a negative sweep as well. The Clause . . . by its own force prohibits certain state actions that interfere with interstate commerce.”) (citation omitted).

The Supreme Court has outlined a two-tiered approach to analyzing whether a state or local economic regulation violates the dormant Commerce Clause:

When a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests,

1 we have generally struck down the statute without further inquiry. When, however, a
2 statute has only indirect effects on interstate commerce and regulates evenhandedly,
3 we have examined whether the State's interest is legitimate and whether the burden
4 on interstate commerce clearly exceeds the local benefits.

5 *Healy v. Beer Institute*, 491 U.S. 324, 337 n. 14 (1989) (quoting *Brown-Forman Distillers*
6 *Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579 (1986) (citations omitted in original)).

7 The Ninth Circuit has explained that under this two-tiered approach, a local regulation will be found
8 to be a *per se* violation of the clause if it, "1) directly regulates interstate commerce; 2) discriminates
9 against interstate commerce; or 3) favors in-state economic interests over out-of-state interests."

10 *National Collegiate Athletic Ass'n v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993) ("*NCAA*").

11 Here, plaintiffs contend that the Ordinance is a *per se* violation of the clause under any and
12 all of the three prongs. As opposed to the first prong, the second and third prongs both contain an
13 element of discrimination—i.e., that a challenged regulation favors local commerce over interstate
14 commerce, or in-state entities over out-of-state entities. Plaintiffs argue there is such a
15 discriminatory effect here because costs that would ordinarily be borne primarily by Alameda
16 County—and hence its own taxpayers—are being shifted on to the community of producers as a
17 whole, most of whom are based elsewhere. Plaintiffs presume that the producers likely will pass
18 those costs on to their customer base at large, with the result that consumers nationwide will bear
19 expenses that otherwise would be solely the responsibility of Alameda taxpayers, or perhaps of
20 Alameda prescription drug buyers, under a different regulatory scheme.

21 The "discrimination" on which plaintiffs would rely, is indisputably not being visited on out-
22 of-state producers as a means of favoring in-state producers. As the Supreme Court has several
23 times observed, "any notion of discrimination assumes a comparison of substantially similar
24 entities." *Department of Revenue of Ky. v. Davis*, 553 U.S. 328, 343 (2008), quoting *United*
25 *Haulers Assn., Inc. v. Oneida-Herkimer Solid Waste Management Authority*, 550 U.S. 330, 342
26 (2007), in turn quoting *General Motors Corp. v. Tracy*, 519 U.S. 278, 298 (1997). In the absence of
27 "differential treatment favoring local entities over substantially similar out-of-state interests," the
28 kind of discrimination potentially prohibited by the dormant Commerce Clause is not implicated.

1 *Davis*, 553 U.S. at 343. Accordingly, the Ordinance cannot be invalidated as *per se* improper under
2 either the second or third prongs.

3 As the Ninth Circuit has cautioned, however, “discrimination and economic protectionism
4 are not the sole tests.” *NCAA*, 10 F.3d at 638. A regulation may still be *per se* invalid under the
5 first prong if it “directly regulates interstate commerce.” *Id.* Nevertheless, and notwithstanding
6 plaintiffs’ protestations to the contrary, the Ordinance here neither purports to regulate interstate
7 commerce nor does so as a practical matter.

8 The Ordinance applies to producers who elect to sell their products within Alameda County,
9 regardless of where the producers are based or the product originates. Nothing in the structure of
10 the Ordinance targets producers on the basis of their location—they are being required to participate
11 in providing take-back programs because they sell prescription drugs in the county, not because they
12 are out-of-state actors. Nothing in the Ordinance will require, as a practical matter, any producer to
13 alter its manner of doing business in any jurisdiction outside Alameda County, although producers
14 will be free to use programs that they may already be using elsewhere, provided they meet the
15 standards of the Ordinance. (See Stipulated Fact No. 9.)

16 In *NCAA*, by way of contrast, the statute in dispute regulated *only* interstate organizations,
17 specifically “national collegiate athletic associations,” which were defined as any “group of
18 institutions in 40 or more states who are governed by the rules of the association relating to athletic
19 competition.” 10 F.3d at 637 n.3. (In practice, this definition encompassed only one entity—the
20 plaintiff NCAA.) The effect of the challenged law, which purported to govern how the NCAA
21 conducted its own enforcement proceedings, was that the organization would have to “use the
22 Statute in enforcement proceedings in every state in the union.” *Id.* at 639. As such it violated the
23 Commerce Clause because “the practical effect of the regulation [was] to control conduct beyond
24 the boundaries of the State” and because of the potential conflict with similar laws in other states.
25 *Id.* (“Generally speaking, the Commerce Clause protects against inconsistent legislation arising from
26 the projection of one state regulatory regime into the jurisdiction of another State.”). The Ordinance
27 plaintiffs challenge here is not specifically directed at regulating interstate organizations and has no
28 remotely similar consequence to any conduct occurring outside county borders.

1 Plaintiffs repeatedly urge that the Ordinance directly regulates interstate commerce in a
2 manner not meaningfully distinguishable from a tariff. A tariff, however, “taxes goods imported
3 from other States, but does not tax similar products produced in State.” *West Lynn Creamery, Inc.*
4 *v. Healy*, 512 U.S. 186, 193 (1994). As the Supreme Court explained, “[a] tariff is an attractive
5 measure because it simultaneously raises revenue and benefits local producers by burdening their
6 out-of-state competitors.” *Id.* Plaintiffs’ characterization of the Ordinance as equivalent to a tariff
7 is unpersuasive, given that it shares none of these salient features.

8 Finally, while plaintiffs are correct that the effect on interstate commerce must be evaluated
9 by looking to the effect of a regulation and not merely its face, the happenstance that most producers
10 of prescription drugs are located outside Alameda County is insufficient to transform what is
11 fundamentally a local measure into one that could be found to burden interstate commerce
12 impermissibly. *See Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 126 (1978) (“[t]he fact
13 that the burden of a state regulation falls on some interstate companies does not, by itself, establish a
14 claim of discrimination against interstate commerce.”); *CTS Corp. v. Dynamics Corp. of Am.*, 481
15 U.S. 69, 88 (1987)(following *Exxon* and rejecting argument that regulation was impermissible
16 merely because it in most cases would apply to out-of-state entities). Accordingly, the Ordinance is
17 not *per se* invalid under any of the analytical prongs.

18 Plaintiffs suggest almost in passing that the Ordinance could be found invalid even under the
19 balancing test that applies where the challenged regulation has only indirect, and non-
20 discriminatory, effects on interstate commerce. Plaintiffs do not question, for purposes of these
21 motions, that the interests Alameda County had in enacting the ordinance were legitimate. Plaintiffs
22 merely contend that those interests could be equally well served through take-back programs funded
23 in another manner. Arguing that an alternative regime would have *no* burden on interstate
24 commerce does not establish that the minimal burden this Ordinance arguably imposes on interstate
25 commerce “clearly exceeds the local benefits.” Defendants have adequately shown that the
26 Ordinance serves a legitimate public health and safety interest, and that the relatively modest
27 compliance costs producers will incur should they choose to sell their products in the county do not
28 unduly burden interstate commerce.

V. CONCLUSION

Plaintiffs' motion for summary judgment is denied, and defendants' cross-motion is granted. A separate judgment will enter.

IT IS SO ORDERED.

Dated: 8/28/13


RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

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Sterios, Susan

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8/28/2013