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13 UNITED STATES DISTRICT COURT
14 NORTHERN DISTRICT OF CALIFORNIA

15 C 12 6203
16 Case No. _____

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17 PHARMACEUTICAL RESEARCH AND
18 MANUFACTURERS OF AMERICA;
19 GENERIC PHARMACEUTICAL
20 ASSOCIATION; and BIOTECHNOLOGY
21 INDUSTRY ORGANIZATION,

22 Plaintiffs,

23 v.

24 ALAMEDA COUNTY, CALIFORNIA, and
25 ALAMEDA COUNTY DEPARTMENT OF
26 ENVIRONMENTAL HEALTH,

27 Defendants.

COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF

28 The Pharmaceutical Research and Manufacturers of America, the Generic Pharmaceutical Association, and the Biotechnology Industry Organization, by and through their undersigned attorneys, allege as follows:

1 INTRODUCTION

2 1. This action is facial challenge to the “Alameda County Safe Drug Disposal
3 Ordinance” (the “Ordinance”), a measure adopted by the Alameda County Board of Supervisors
4 in July 2012 as a “first-in-the-nation ordinance” that “requires drug producers to dispose of
5 unwanted household medications.” The Ordinance provides that “[m]anufacture[r]s and
6 producers of drugs” must “finance and operate the collection of unwanted prescription
7 medications for proper disposal and pay for all costs.”

8 2. Alameda County’s drug take-back ordinance is unprecedented. In obligating all
9 drug manufacturers whose products are sold in the County to establish local drug take-back
10 programs, the Ordinance conscripts parties engaged in interstate trade to implement what would
11 otherwise be a local governmental function paid for by local taxpayers. Far from fulfilling its
12 responsibility to promote health and welfare within its territorial jurisdiction, Alameda County is
13 attempting to shift governmental responsibilities onto interstate businesses.

14 3. The Ordinance represents a per se violation of the Commerce Clause for three
15 distinct reasons. First, it directly regulates and burdens interstate commerce and its primary
16 purpose and clear effect is to shift the costs of a local regulatory program directly onto interstate
17 commerce and out-of-county consumers. Second, the Ordinance discriminates against interstate
18 commerce by targeting interstate commerce and products delivered from outside the County for
19 burdens. Finally, the Ordinance favors local interests by deliberately shifting costs away from
20 local consumers and taxpayers and onto drug manufacturers and pharmaceutical consumers
21 nationwide.

22 4. Even if the Ordinance were not a per se infringement of the Commerce Clause, it
23 would still be unconstitutional. Its burden on interstate commerce is inherently excessive because
24 the County could accomplish all of the purported benefits of a take-back program without any
25 interstate burden—*i. e.*, by developing and conducting the take-back program through government
26 officials paid by the local taxpayers or consumers served by the program. Further, the Ordinance
27 would be unconstitutional even if it were viewed as a tax because it is not fairly apportioned.

28

1 lawsuit, BIO seeks to vindicate the interests of its members, who are subject to Alameda County's
2 authority and are being injured by the Ordinance. The individual members themselves are not
3 indispensable to proper resolution of the case.

4 11. Defendant Alameda County, California, ("Alameda County," "Alameda," or "the
5 County") is the seventh most populous county in California and includes fourteen incorporated
6 cities and unincorporated communities. The County's total population is approximately 1.5
7 million. The Alameda County Board of Supervisors adopted the Ordinance in July 2012.

8 12. Defendant the Alameda County Department of Environmental Health (the
9 "Department") is responsible for implementing and enforcing the Ordinance. The Department
10 has authority to either grant or withhold approval for take-back plans submitted by covered
11 producers. In addition, the Department has authority to impose fines and other sanctions for
12 noncompliance with the Ordinance.

13 **FACTS**

14 **I. Unused Pharmaceuticals and Their Disposal**

15 13. Disposal of unused pharmaceuticals in household trash is safe, convenient, and
16 effective. Promptly throwing away unused pharmaceuticals ensures that unused medicines are
17 inaccessible to children, adolescents, and other unintended users. And double-lined active
18 landfills approved for use by the EPA and equipped with sophisticated leachate collection
19 systems virtually eliminate the possibility that active pharmaceutical ingredients could leach out
20 into the environment if disposed of along with household trash.

21 14. Disposing of unused pharmaceuticals in household trash also minimizes the
22 potential that unused medicines would be stolen, diverted or improperly used. Collection kiosks,
23 bins and other handling facilities used in take-back programs can become a target for thieves and
24 others who might wish to steal unused medicines for improper or illegal purposes. The costs of
25 providing security for collection sites and sorting and processing facilities will be substantial and,
26 regardless of the precautions taken, the potential for theft, diversion and improper use will persist.
27 The disposal of unused medicines in household waste eliminates the problem of
28 "reconcentration" and reduces the likelihood of theft, diversion and improper use.

1 15. For certain medicines that present a heightened risk profile, such as controlled
2 substances or prescription medicines subject to Risk Evaluation and Mitigation Strategies
3 (REMS), federal agencies sometimes require consumers to utilize product-specific disposal
4 options such as product return or mail-back. For these medicines, neither in-home trash disposal
5 nor the program envisioned by the Ordinance is an appropriate disposal option.

6 **II. The Creation of the Ordinance**

7 16. In early 2012, Nathan A. Miley, President of the Alameda County Board of
8 Supervisors, proposed an “Alameda County Safe Drug Disposal Ordinance.” Under the
9 Ordinance, covered pharmaceutical manufacturers must administer drug take-back programs in
10 the County.

11 17. During a Board hearing in February on the proposed ordinance, a representative of
12 the Department of Environmental Health noted that Alameda County had already established a
13 drug take-back system. However, the Department’s representative pointed out that the existing
14 system’s take-back sites “are paid for by taxpayers or ratepayers.” The representative argued that
15 “the cost” of such programs “shouldn’t fall on local government.” A number of other Alameda
16 governmental agencies supported the Ordinance on the same cost-shifting grounds.

17 18. The Board adopted the Ordinance by unanimous vote on July 24, 2012.

18 **III. The Ordinance**

19 19. Alameda County’s Drug Take-Back Ordinance requires each prescription drug
20 manufacturer whose drugs are sold or distributed in Alameda County to develop and submit a
21 plan to take back unused prescription drugs stored in residential homes. Under the Ordinance,
22 every producer of a covered drug whose products reach Alameda County must run, or contribute
23 to, a privately administered drug take-back program.

24 20. The term “Covered Drug” is initially defined to include “all drugs as defined in 21
25 U.S.C. § 321(g)(1) of the Federal Food, Drug and Cosmetic Act,” “including both brand name
26 and Generic Drugs.” § 6.53.030.2. The Ordinance then exempts “nonprescription drugs,” as well
27 as vitamins, supplements, herbal remedies, cosmetics, soap, detergent, “household cleaning
28

1 products,” biological products for which the producer already provides a take-back program, and
2 certain “[p]esticide products.” § 6.53.030.3

3 21. The Ordinance defines “Producer” according to three criteria. First, the measure
4 covers entities that manufacture a covered drug and sell it in Alameda County “under that
5 Person’s own name or brand.” § 6.53.030.14(i). Second, if there is no person who falls within
6 the first criterion, then the Ordinance covers the “owner or licensee of a brand under which the
7 Covered Drug is sold or distributed in Alameda County.” § 6.53.030.14(ii). Third, if there is no
8 person who falls within either of the first two criteria, then the Ordinance covers “the Person who
9 brings the Covered Drug into Alameda County for sale or distribution.” § 6.53.030.14(iii). The
10 definition of “Producer” includes exceptions for retail labelers and pharmacies that compound
11 and/or dispense prescription drugs to patients. § 6.53.030.14.

12 22. The Ordinance prohibits covered producers or other persons from charging a
13 “specific point-of-sale fee to consumers to recoup the costs” of establishing or operating a take-
14 back program mandated under the Ordinance. § 6.53.040.B.3.

15 23. The Ordinance obligates each covered drug producer to operate a comprehensive
16 drug take-back program. § 6.53.040A.1. A group of covered producers can comply with this
17 mandate by establishing a “product stewardship organization” that, in turn, will run a single take-
18 back program. If the program is jointly funded, the funding must involve a “fair and reasonable
19 manner for allocating the costs” such that each “producer” is charged a portion of the costs
20 related to that manufacturer’s contribution to covered drugs sold in the County. § 6.53.050.A.13.
21 The Ordinance does not specify how the “amount” of covered drugs in Alameda County is to be
22 measured (for example, by dose, weight, cost, etc.). *Id.* All programs must provide collection
23 options that are “convenient and adequate to serve the needs of Alameda County residents.”
24 § 6.53.050.A.3.

25 24. Each producer’s take-back program must accept and dispose of all covered
26 medicines received, no matter who manufactured the drugs, unless excused from that
27 comprehensive obligation by the Alameda Department of Environmental Health. § 6.53.050.A.1.
28 Controlled substances must be collected if a law enforcement agency within the County agrees to

1 provide a collection kiosk for controlled substances and other unused items. § 6.53.050.A.11.
2 The manufacturer or manufacturers are required to provide funding for and technical support to
3 the law enforcement agency or agencies, including education for the staff, education materials for
4 consumers, and collection and sorting of the collected items. *Id.* Finally, each producer must
5 compensate Alameda County for the costs of administering the Ordinance by paying fees under a
6 schedule determined by the Department. § 6.53.100.

7 25. The Ordinance mandates that disposal must occur by incineration at a medical
8 waste or hazardous waste facility. § 6.53.060.B. There are several additional requirements for
9 monitoring the emissions from the waste destruction that are set out in the Ordinance.

10 § 6.53.060.B.

11 26. Covered producers must provide materials to be reproduced and distributed to
12 consumers by retailers when consumers purchase products that might be disposed of at a take-
13 back site. The sponsor must also provide signage, advertising, and other promotional materials,
14 establish and maintain a website, and operate a toll-free call system for consumers to locate
15 collection sites and learn how the program operates. § 6.53.070.

16 27. The Ordinance provides that covered entities must submit plans to the Alameda
17 Department of Environmental Health on July 1, 2013. Within 180 days, the Department will
18 conduct a hearing to review each covered entity's plan submission. § 6.53.050.B.2-3. The
19 Ordinance contains no specific criteria for approving or disapproving a plan. A rejected plan
20 must be revised within sixty days, at which time Alameda may give approval, direct additional
21 revisions, or "impose" its own plan. § 6.53.050.B.3. Every three years, each covered producer
22 must submit to the County for approval an update to its product stewardship plan.

23 § 6.53.050.B.4.

24 28. The Department may charge a civil penalty of up to \$1,000 per day for any
25 violation of the Ordinance, but a producer shall have thirty days after receipt of a notice of non-
26 compliance to come into compliance with the Ordinance before the Department can impose a
27 penalty. § 6.53.110.E. A producer can appeal the Department's citation at a formal hearing
28 before a Department hearing officer. Covered producers also have the right to appeal to the

1 Board of Supervisors. The County is authorized to go to court to compel a covered producer to
2 comply with the Ordinance's requirements. § 6.53.110.1.

3 29. Over 99% of the Covered Drugs triggering the take-back obligations arrive from
4 outside of Alameda County.

5 **IV. Plaintiffs' Efforts to Comply With the Ordinance**

6 30. Plaintiffs and their respective members have incurred, and will continue to incur,
7 substantial compliance costs, including the costs of establishing a Stewardship Organization
8 and/or a Product Stewardship Program, and securing the equipment and facilities needed to
9 collect, transport, store, and process unwanted medicines. The Ordinance requires Plaintiffs'
10 members to enter into a new form of business—a combination of municipal waste disposal and
11 local law enforcement. Plaintiffs, their members, and their employees are expending considerable
12 resources and time to develop and submit a plan that complies with the Ordinance, and will
13 continue to expend considerable resources and time to operate the required take-back programs.
14 In addition, operation of the required take-back programs will subject Plaintiffs, their members,
15 and their employees to substantial liability risks, not only for their own products, but also for
16 products sold by other producers and, predictably, controlled substances or non-covered products
17 that are deposited at collection sites erroneously by consumers.

18 **COUNT I**

19 **(Violation of the Commerce Clause)**

20 31. Plaintiffs reallege and incorporate by reference the allegations contained in all of
21 the preceding paragraphs as though set forth fully herein.

22 32. The Constitution affords the federal government authority to "regulate commerce
23 . . . among the several states." U.S. Const. art. I, § 8. The constitutional framers adopted this
24 provision in order to prevent local governments from imposing self-serving regulations that
25 burden interstate trade for parochial purposes.

26 33. In its "negative" or "dormant" aspect, the Commerce Clause by its own force
27 prohibits certain local regulations that discriminate against or burden interstate commerce. Local
28 laws violate the Commerce Clause on a per se basis when they directly burden or regulate

1 interstate commerce, discriminate against interstate commerce, or favor local interests. Local
2 measures also violate the Commerce Clause when they levy unfairly apportioned taxes on
3 interstate trade or impose excessive burdens on interstate commerce.

4 34. The Ordinance shifts Alameda County's public health responsibilities for waste
5 disposal to private parties engaged in interstate commerce. This cost shifting does not improve or
6 promote public health relative to a government-run take-back program, financed through normal
7 or special public revenues. Thus, the only purpose and effect of this measure is to shift costs
8 away from local government, local consumers, and local taxpayers.

9 35. The Ordinance represents a per se violation of the Commerce Clause for three
10 distinct reasons. First, it directly regulates or burdens interstate trade. It conscripts interstate
11 producers to perform a local public duty, and its primary purpose and effect is to shift the costs of
12 a local regulatory program directly onto interstate products and businesses. As a result, the
13 Ordinance reaches private entities across the United States, even if they have no connection to
14 Alameda other than the fact that one of their products is distributed in the County. Second, the
15 Ordinance discriminates against interstate commerce, both in practical effect and on its face. The
16 Ordinance discriminates against articles of interstate commerce because over 99% of Covered
17 Drugs arrive from outside the County, and it facially discriminates against interstate producers
18 and consumers by barring local recoupment of Alameda's take-back costs. Finally, the Ordinance
19 favors local interests by deliberately shifting costs away from local taxpayers, businesses and
20 consumers and onto businesses and consumers nationwide. In addition to inherently favoring
21 local interests by transferring take-back responsibilities from County government to interstate
22 producers, the Ordinance facially favors local businesses by exempting local pharmacies from
23 take-back responsibilities and favors local consumers by outlawing fees to recoup Alameda's
24 take-back costs.

25 36. Even if the Ordinance were viewed as a tax, it would still violate the Commerce
26 Clause. The Ordinance discriminates against interstate trade, applies extraterritorially, and lacks
27 any meaningful relation to regulated entities' connection to the County. In addition, the
28 Ordinance imposes burdens that are not fairly apportioned.

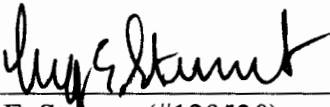
PRAYER FOR RELIEF

Wherefore, Plaintiffs pray for the following relief:

1. A declaration, order and judgment that the Ordinance violates the Commerce Clause of the U.S. Constitution;
2. An injunction prohibiting Alameda County and the Department from implementing the Ordinance or seeking enforcement of its requirements;
3. All costs and attorneys' fees pursuant to any applicable statute or authority;
4. Any other relief that this Court deems just and proper.

Dated: December 7, 2012

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