UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; GENERIC PHARMACEUTICAL ASSOCIATION; BIOTECHNOLOGY INDUSTRY ORGANIZATION; and CONSUMER HEALTHCARE PRODUCTS ASSOCIATION, Plaintiffs, v. KING COUNTY, WASHINGTON; KING COUNTY DEPARTMENT OF PUBLIC HEALTH; and DIRECTOR OF THE KING COUNTY DEPARTMENT OF PUBLIC HEALTH, Defendants.	No. 2:13-cv-2151 COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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

INTRODUCTION

1. This is an action challenging King County's "Secure Medicine Return Rule & Regulation" (the "Regulation"), a measure adopted by the King County Board of Health in June 2013 to establish "a county-wide secure medicine return program

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providing equitable access for all of the county's residents that is financed and operated by drug producers selling medicines in or into King County for residential use."

2. The Regulation seeks to "place the obligation of complying with its requirements upon drug producers." Indeed, the Regulation is explicit that it is "not intended to impose any duty whatsoever upon King County or any of its officers or employees." What is more, the Regulation is accompanied by an express finding that King County seeks "to shift from a system focused on government-funded and ratepayer-financed waste disposal and diversion" toward a system funded by pharmaceutical producers.

3. In obligating all drug manufacturers whose products are sold in the County to establish local drug take-back programs, the Regulation conscripts parties engaged in interstate trade to implement what would otherwise be a local governmental function. It would shift costs of waste disposal from local taxpayers and/or local consumers to consumers located in other regions of the county. Far from fulfilling its responsibility to promote health and welfare within its territorial jurisdiction, King County is attempting to shift governmental responsibilities onto interstate businesses and local costs onto out-of-state consumers.

4. The Regulation represents a per se violation of the Commerce Clause for three principal reasons. First, it impermissibly directly regulates and burdens interstate commerce because it transfers a governmental responsibility onto pharmaceutical producers simply for placing their products in the stream of interstate commerce. Second, the Regulation has the impermissible primary purpose and clear effect of shifting costs of a local regulatory program directly onto interstate commerce and unrepresented out-of-county consumers. Finally, the Regulation has an impermissible extraterritorial effect by regulating entities with no significant ties to King County and by directly controlling conduct across county lines.

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5. The Regulation can also be viewed an unconstitutional tax because, among other reasons, it assigns un-apportioned regulatory duties to entities without an adequate nexus to the County and it exposes drug manufacturers to duplicative liability in multiple jurisdictions.

6. The Regulation is also a per se violation of the Commerce Clause because it discriminates against interstate commerce and favors local interests. Under the Regulation, the entire burden of operating local collection efforts is borne by entities engaged in interstate commerce, while local constituents are deliberately and explicitly shielded from regulatory burdens.

7. Even if the Regulation were not a per se infringement of the Commerce Clause, it would still be unconstitutional. The Regulation imposes an excessive burden on interstate commerce because the County could accomplish all of the purported benefits of a unwanted-drug collection program without any interstate burden—*i.e.*, by conducting such a program through government officials paid by the local taxpayers and consumers served by the program.

8. If the Regulation were permissible, then King County could likewise require interstate news publications to conduct the County's paper recycling program or require interstate food producers to collect and dispose of all spoiled food or similar garbage. Localities would have a green light to get something for nothing, simply by free-riding on interstate commerce and transferring the financial burdens to out-of-state consumers. Because such policies offend the dormant Commerce Clause at least as directly as a tariff, the Court should declare the Regulation unconstitutional and permanently enjoin its implementation.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 2201. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b).

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PARTIES

10. Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") is a non-profit organization representing pharmaceutical research and biotechnology companies that produce brand-name drugs. In bringing this lawsuit, PhRMA seeks to vindicate the interests of its members, who are subject to King County's authority, and are being injured by the Regulation. The individual members themselves are not indispensible to proper resolution of the case.

11. Plaintiff Generic Pharmaceutical Association ("GPhA") is a non-profit organization representing the manufacturers and distributors of finished generic pharmaceutical products. In bringing this lawsuit, GPhA seeks to vindicate the interests of its members, who are subject to King County's authority and are being injured by the Regulation. The individual members themselves are not indispensible to proper resolution of the case.

12. Plaintiff Biotechnology Industry Organization ("BIO") is a non-profit organization representing the manufacturers and distributors of biotechnology products. In bringing this lawsuit, BIO seeks to vindicate the interests of its members, who are subject to King County's authority and are being injured by the Regulation. The individual members themselves are not indispensible to proper resolution of the case.

13. Plaintiff Consumer Healthcare Products Association ("CHPA") is a non-profit organization representing leading manufacturers and marketers of over-the-counter medicines and dietary supplements. In bringing this lawsuit, CHPA seeks to vindicate the interests of its members, who are subject to King County's authority and are being injured by the Regulation. The individual members themselves are not indispensible to proper resolution of the case.

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14. Defendant King County, Washington ("King County," or the "County") is a county in Washington with a population of approximately two million, including Seattle. The King County Board of Health adopted the Regulation in June 2013.

15. Defendant Seattle-King County Department of Public Health (the "Department") is the King County department responsible for implementing and enforcing the Regulation.

16. Defendant Director of the Department of Public Health (the "Director") is the head of the Department and the King County official responsible for implementing and enforcing the Regulation. The Director has authority to either grant or withhold approval for take-back plans submitted by covered producers and to impose fines and other sanctions for noncompliance with the Regulation. The Director is sued in his official capacity.

FACTS

I. Unwanted Pharmaceuticals and Their Disposal

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

18. Disposing of unwanted pharmaceuticals in household trash also minimizes the potential that unwanted medicines would be stolen, diverted or improperly used. Collection kiosks, bins and other handling facilities used in take-back programs can become a target for thieves and others who might wish to steal unwanted medicines for improper or illegal purposes. The costs of providing around-the-clock security for

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collection sites and sorting and processing facilities will be significant and, regardless of the precautions taken, some level of theft, diversion and improper use will inevitably occur. The disposal of unwanted medicines in household waste eliminates the problem of "reconcentration" and reduces the likelihood of theft, diversion and improper use.

II. The Regulation

19. The King County Board of Health enacted the Regulation on June 20, 2013.

20. The Regulation requires each covered drug manufacturer whose drugs are sold or distributed in King County to develop and submit a plan to take back unwanted drugs stored in residential homes. Under the Regulation, every covered drug manufacturer whose products reach King County must run, or contribute to, a privately administered drug take-back program.

21. The term "Covered drug" is defined to include any "drug sold in any form and used by" King County residents, "including prescription, nonprescription, brand name and generic drugs." Regulation § 5(B)(1). The Regulation then excludes a number of items from the definition of "Covered drug." The list of exclusions includes: all vitamins, herbal remedies, cosmetics, soap, detergent, drugs "for which producers provide a pharmaceutical product stewardship or take-back program as part of a federal food and drug administration managed risk evaluation and mitigation strategy," drugs "that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this rule if the producer already provides a pharmaceutical product stewardship or take-back program," and "[m]edical devices, their component parts or accessories, or a covered drug contained in or on medical devices or their component parts or accessories. Regulation § 5(B)(2).

22. The Regulation defines "Producer" as "a manufacturer that is engaged in the manufacture of a covered drug sold in or into King County, including a brand-name or

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generic drug." Regulation § 5(P). The Regulation then lists three exclusions from the definition of Producer. These exclusions apply to certain "retailer[s] whose store label appears on a covered drug or the drug's packaging," "pharmacist[s] who compounds a prescribed individual drug product for a consumer," and any "wholesaler who is not also a manufacturer." *Id*.

23. The Regulation provides that no Producer or other persons may "charge a specific point-of-sale fee to consumers to recoup the costs of their stewardship plan, nor may they charge a specific point-of-collection fee at the time the covered drugs are collected from covered entities." Regulation § 11(C).

24. The Regulation obligates each Producer to operate either a "standard" comprehensive drug collection program, or an "independent" program approved by the Director. *See* Regulation § 6 ("Each producer shall participate in the standard stewardship plan approved by the director, except that a producer may individually, or with a group of producers, form and participate in an independent stewardship plan if approved by the director."). Producers must inform the Director of their intent to establish a collection program within six months of either the Regulation's adoption or "by six months after a producer initiates sale of a covered drug in or into King County." Regulation § 6(C). At that point, Producers have three additional months to identify a "plan operator" and six months to propose a plan for the Director to approve. *See* Regulation § 6(D).

25. Producers must "pay all administrative and operational costs related to" the collection programs they must establish. Regulation § 11(A). These costs include: "[c]ollection and transportation supplies for each drop-off site, "[p]urchase of all secure drop boxes for drop-off sites in any independent stewardship plan," "[o]ngoing maintenance or replacement of secure drop boxes, as requested by collectors," "[p]repaid, preaddressed mailers provided to differentially-abled and home bound residents, and to specific areas of the county if utilized," "[o]perating periodic collection events if utilized,

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including costs of law enforcement staff time if necessary," "[t]ransportation of all collected pharmaceuticals to final disposal, including costs of law enforcement escort if necessary," "[e]nvironmentally sound disposal of all collected pharmaceuticals," and "program promotion." *Id*.

26. Producers "shall ensure the provision of up to four hundred secure drop boxes for retail pharmacies and law enforcement agencies willing to participate as drop-off sites for the standard stewardship plan." *See* Regulation § 11(C).

27. When a retail pharmacy or law enforcement agency requests to serve as a collection site, Producers have three months to include those entities as collection locations. Regulation § 8(D)(2).

28. Producers "shall provide in every city, town, or unincorporated community service area with a pharmacy or law enforcement facility, one drop-off site and a minimum of at least one additional drop-off site for every thirty thousand residents, geographically distributed to provide reasonably convenient and equitable access." Regulation § 8(D)(3). Other areas "shall be served through periodic collection events or mail-back services, or a combination of these collection methods." *Id*. § 8(D)(4). "Mail-back services shall be free of charge." *Id*. § 8(F).

29. Producers must "[p]romote the use of their stewardship plan so that collection options for covered drugs are widely understood by residents," including by establishing "a toll-free telephone number and web site." Regulation § 9(A).

30. Collected medicines "must be disposed of at a permitted hazardous waste disposal facility" in compliance with federal regulations, unless the Director grants special permission pursuant to specified procedures.

31. Collection plans approved by the Director must include a "list of all collection methods and participating collectors, a list of drop-off locations, a description of how periodic collection events will be scheduled and located if applicable, a description

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of how mail-back services will be provided and an example of the prepaid, preaddressed mailers to be utilized." Regulation § 7(B). Plans must also include a "description of the handling and disposal system, including identification of and contact information for collectors, transporters and waste disposal facilities to be used." *Id*. § 7(C).

32. Plans are due one year after the Regulation's adoption. Regulation § 14(A). In reviewing plan submissions, the Director will allow for public comment. *Id*. § 14(B). Within ninty days of receiving a plan submission, the Director will either approve or reject the submission. *Id*. § 14(C). If the plan is rejected, then the Producers will have sixty days to submit a revised plan. *Id*. § 14(D). If the revised plan is also rejected, then the Producers are considered out of compliance. *Id*. § 14(E). The Regulation contains no specific criteria for approving or disapproving a plan.

33. "A producer not participating in the standard stewardship plan or an independent stewardship plan and whose covered drug continues to be sold in or into the county sixty days after receiving a written warning from the director may be assessed a penalty." Regulation § 14(C). If the Director finds a Producer to be out of compliance, the Director may transmit a written warning, at which point the Producer has thirty days to achieve compliance. *Id.* § 16(C).

34. The Director may charge a civil penalty of up to $2,000 for any violation. Regulation § 16(D). "Each day upon which a violation occurs or is permitted to continue constitutes a separate violation." *Id*.

III. Plaintiffs' Efforts to Comply With the Regulation

35. Plaintiffs and their respective members have incurred, and will continue to incur, substantial compliance costs. The Regulation requires Plaintiffs' members to enter into a new form of business—a combination of municipal waste disposal and local law enforcement. Plaintiffs, their members, and their employees are expending considerable resources and time to develop and submit a plan that complies with the Regulation, and

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will continue to expend considerable resources and time to operate the required take-back programs. In addition, operation of the required collection programs will subject Plaintiffs, their members, and their employees to substantial liability risk.

COUNT I

(Violation of the Commerce Clause)

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

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

38. In its "negative" or "dormant" aspect, the Commerce Clause by its own force prohibits certain local regulations that discriminate against or burden interstate commerce. Local laws violate the Commerce Clause on a per se basis when they directly burden or regulate interstate commerce, discriminate against interstate commerce, or favor local interests. Local measures also violate the Commerce Clause when they levy unfairly apportioned taxes on interstate trade or impose excessive burdens on interstate commerce.

39. The Regulation does not improve or promote public health, but merely shifts King County's public health responsibilities for waste disposal to private parties engaged in interstate commerce. The only purpose and effect of this measure is to shift costs away from local government, local consumers, and local taxpayers.

40. The Regulation represents a per se violation of the Commerce Clause for three principal reasons. First, the Regulation impermissibly directly regulates and burdens interstate commerce by transferring the County's traditional police power responsibility of waste disposal to interstate actors solely on the basis that one of their products is sold in King County after being delivered there through an interstate distribution chain. Second,

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the Regulation has the impermissible primary purpose and effect of burdening interstate commerce for local advantage by shifting costs and responsibilities of a local regulatory program away from local consumers and taxpayers and directly onto entities identified by their participation in interstate commerce. Because the Regulation prohibits charging fees to recoup the costs of the take-back program, out-of-county consumers will necessarily have to pay for a program that serves only King County residents. Finally, the Regulation has impermissible extraterritorial effect by reaching entities with no significant connection to King County and by compelling conduct across county lines.

41. The Regulation can also be viewed as an unconstitutional tax that violates the Commerce Clause. As noted above, the Regulation directly regulates and burdens interstate trade, applies extraterritorially, lacks any meaningful relation to regulated entities' connection to the County, and favors local interests. In addition, the Regulation imposes burdens that are not fairly apportioned and so creates a risk of duplicative regulatory burdens.

42. The Regulation further represents a per se violation of the Commerce Clause because it discriminates against interstate commerce and favors local interests. Under the Regulation, the entire burden of operating local collection efforts is borne by entities engaged in interstate commerce, while local constituents are deliberately and explicitly shielded from regulatory burdens.

43. The Regulation also violates the Commerce Clause because it imposes excessive burdens on interstate trade, despite the availability of less burdensome alternatives. King County could plainly achieve its environmental and health objectives by levying a conventional sales tax and implementing its own take-back program. Furthermore, disposal of unwanted pharmaceuticals in home garbage offers a safe, environmentally sound, and convenient alternative solution that does not burden significant and additional burdens on interstate commerce.

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COUNT II

(Violation of 42 U.S.C. § 1983)

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

45. 42 U.S.C. § 1983 provides a civil cause of action to any person who is deprived of rights guaranteed by the U.S. Constitution or federal laws by another under color of State law.

46. Defendants, acting under color of state and local law, and through their enactment, threatened enforcement, and enforcement of the Regulation as alleged herein, have deprived Plaintiffs and their members of their rights under the Commerce Clause of the U.S. Constitution.

47. Pursuant to 28 U.S.C. § 2201 and 42 U.S.C. § 1983, Plaintiffs and their members are therefore entitled to a declaration that Defendants, by their enactment, threatened enforcement, and enforcement of the Regulation, have violated the rights of Plaintiffs and their members under the Commerce Clause of the U.S. Constitution.

48. Pursuant to 42 U.S.C. § 1983, Plaintiffs and their members are further entitled to preliminary and or permanent injunctive relief, prohibiting Defendants or any other King County officers, employees, or agents from enforcing or threatening to enforce the Regulation against Plaintiffs and their members.

49. As a further result of Defendants' violation of the rights of Plaintiffs and their members as alleged herein, Plaintiffs are entitled to an award of their attorneys' fees pursuant to 42 U.S.C. § 1988.

PRAYER FOR RELIEF

Wherefore, Plaintiffs pray for the following relief:

1. A declaration, order and judgment that the Regulation violates the Commerce Clause of the U.S. Constitution;

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2. An injunction prohibiting King County, the Department, the Director, and any other King County officer, employee, or agent from implementing the Regulation 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 this 27th day of November, 2013.

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