

# Mandatory Drug Take-Back Programs: Will They Survive the Dormant Commerce Clause Challenge?

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## I. INTRODUCTION

Prozac-ridden fish and intersex frogs—these animals sound like they belong in a science fiction movie, yet exist all around us.<sup>1</sup> Why? Because drugs manufactured for human use enter our waterways from multiple sources. For decades, scientists have documented the presence of pharmaceuticals in waterways and the effects of low drug concentrations on aquatic animals.<sup>2</sup>

This Comment will explore one way United States' local governments are responding to this ever-growing problem: mandatory, manufacturer-sponsored, drug take-back programs. Two counties—Alameda in California and King in Washington—recently passed ordinances requiring drug manufacturers to dispose of drugs that consumers no longer need. Both ordinances are the subject of ongoing litigation; trade associations representing manufacturers are challenging the ordinances, claiming that the ordinances violate the dormant Commerce Clause. This Comment argues that ultimately the ordinances will survive a dormant Commerce Clause challenge because they do not discriminate against or regulate interstate commerce, nor do they excessively burden interstate commerce. These ordinances are rather an appropriate expansion of the Extended Producer Responsibility (EPR) framework. They are subject to legal attack, where dozens of other EPR laws have not been, not because they violate the dormant Commerce Clause but because they affect politically powerful businesses.

## II. DRUG DISPOSAL BACKGROUND

### A. *An Environmental Issue*

Nationally, “an estimated 40 percent of drugs prescribed outside of hospitals go unused.”<sup>3</sup> One can imagine numerous scenarios that would lead to leftover drugs needing disposal. To name a few: a patient after

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1. See P.P. Fong & N. Molnar, *Norfluoxetine Induces Spawning and Parturition in Estuarine and Freshwater Bivalves*, 81 BULL. ENVTL. CONTAMINATION & TOXICOLOGY 535, 535 (2008); Wynne Parry, *Water Pollution Caused by Birth Control Poses Dilemma*, LIVE SCI. (May 23, 2012, 2:00 PM), <http://www.livescience.com/20532-birth-control-water-pollution.html>.

2. See John M. Brausch et al., *Human Pharmaceuticals in the Aquatic Environment: A Review of Recent Toxicological Studies and Considerations for Toxicity Testing*, 218 REV. ENVTL. CONTAMINATION & TOXICOLOGY 1, 2 (2012); Naomi Lubick, *Drugs in the Environment: Do Pharmaceutical Take-Back Programs Make a Difference?*, 118 ENVTL. HEALTH PERSP. A211, A212 (2010) (“[A]n increasing number of reports from across the world have tracked active pharmaceutical ingredients (APIs) in surface waters and even tap water . . .”).

3. Colin Woodard, *New Rules Could Hurt Maine Drug Takeback Programs*, PORTLAND PRESS HERALD (Jan. 27, 2013), [http://www.pressherald.com/news/new-rules-could-hurt-take-back-programs\\_2013-01-27.html](http://www.pressherald.com/news/new-rules-could-hurt-take-back-programs_2013-01-27.html).

surgery feels well enough to stop taking a pain reliever, a woman decides to try to get pregnant so she discontinues birth control, or a pet dog is weaned off steroids. These pills, drops, patches, and injectables present a pressing waste-disposal problem.

Patients and consumers typically throw away leftover drugs in the trash or flush them down the toilet. However they are discarded, they are likely to find a local waterway. Drugs that make their way to landfills can escape, leaching from the landfill and into nearby groundwater.<sup>4</sup> Maine's Department of Environmental Protection tested groundwater near landfills and the results alarmed them; landfill leachate could amount to hundreds of pounds of active pharmaceutical ingredients from prescription and over-the-counter drugs.<sup>5</sup>

Drugs that are flushed down a toilet enter the sewage system and ultimately a sewage treatment plant where complete removal from the plant's effluent is unlikely.<sup>6</sup> According to the Environmental Protection Agency (EPA), the majority of sewage treatment plants lack the technology to remove drugs from wastewater.<sup>7</sup> A recent study examined wastewater treatment plants' ability to remove chemicals and pharmaceuticals. Of the chemicals and pharmaceuticals studied, sewage treatment plants only removed about half effectively.<sup>8</sup> Among those drugs that remained in the effluent were carbamazepine (antiseizure), ciprofloxacin (antibiotic), diclofenac (anti-inflammatory), erythromycin (antibiotic), and trimethoprim (antibacterial).<sup>9</sup> According to another study, "[a] growing body of literature has identified a large number of [pharmaceutical and personal care products] released in sewage effluent and in biosolids."<sup>10</sup> Biosolids form the sewage sludge that treatment plants extract from wastewater. Municipalities often sell biosolids for use as fertilizer, and one study found that earthworms located in fields

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4. See Jan Schwarzbauer et al., *Occurrence and Alteration of Organic Contaminants in Seepage and Leakage Water from a Waste Deposit Landfill*, 36 WATER RES. 2275, 2276 (2002) (investigating a landfill in Germany that was leaching water into the adjacent groundwater where a leak in the bottom sealing of the landfill was discovered).

5. Lubick, *supra* note 2, at A212-13 ("The fact that we found pharmaceuticals wasn't a huge surprise, but the high levels were.").

6. See *How To Dispose of Medicines Properly*, EPA (Apr. 2011), <http://water.epa.gov/scitech/swguidance/ppcp/upload/ppcpflyer.pdf>.

7. *Id.*

8. Brian Bienkowski, *Only Half of Drugs, Other Newly Emerging Contaminants Removed from Sewage*, ENVTL. HEALTH NEWS (Nov. 22, 2013), <http://www.environmentalhealthnews.org/ehs/news/2013/november/emerging-contaminants-report>.

9. *Id.*

10. Fong & Molnar, *supra* note 1 (citation omitted).

fertilized with biosolids contained detectable levels of pharmaceuticals in their bodies.<sup>11</sup>

Drugs designed for humans are described as “pseudo-persistent.”<sup>12</sup> In other words, drugs are chemicals, manipulated to enter the human body and continue to act until they are metabolized or excreted (usually after days or months). When drugs are thrown away or excreted, the same properties that helped make them effective in the body cause their persistence in the aquatic environment.<sup>13</sup> Scientists suspect that most of the drugs in the water pass through us without causing harm, but a small percentage may be toxic.<sup>14</sup>

As referenced above, scientists have recently, and consistently, documented the effects of the presence of low concentrations of pharmaceuticals on aquatic animals. A 2007 study documented the effects of the presence of synthetic estrogen in lakes on fathead minnows.<sup>15</sup> The researchers reported that the male fish showed intersex characteristics and the entire population eventually collapsed.

### B. A Public Health Issue

Leftover drugs exacerbate a growing public health concern. If drugs are disposed of improperly they could wind up—innocently or intentionally—in the wrong hands. According to King County, Washington, “32% of child poisoning deaths in Washington were caused by someone else’s prescription medication.”<sup>16</sup> The Substance Abuse and Mental Health Services Administration reports that 70% of Americans who used prescription pain-relievers for nonmedical purposes received those drugs from family or friends.<sup>17</sup> President Obama’s 2011 Prescription Drug Abuse Prevention Plan lists proper drug disposal as one of the four areas where governments can take action to reduce

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11. Chad A. Kinney et al., *Bioaccumulation of Pharmaceuticals and Other Anthropogenic Waste Indicators in Earthworms from Agricultural Soil Amended with Biosolid or Swine Manure*, 42 ENVTL. SCI. & TECH. 1863, 1868 (2008).

12. Brausch et al., *supra* note 2, at 2.

13. *See id.*

14. *Id.* at 3 (“The potential environmental effects that pharmaceuticals pose in surface waters remain largely unknown, although it is estimated that 10-15% of pharmaceuticals found in surface waters are acutely or chronically toxic for certain endpoints . . .”).

15. *See* Karen A. Kidd et al., *Collapse of a Fish Population After Exposure to a Synthetic Estrogen*, 104 PROC. NAT’L ACAD. SCI. 8897, 8999-9000 (2007).

16. *Secure Medicine Return Rule and Regulation*, KING CNTY., WASH. (Oct. 29, 2013), <http://www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx>.

17. *Epidemic: Responding to America’s Prescription Drug Abuse Crisis*, EXEC. OFFICE OF THE PRESIDENT 1, 7 (2011), [http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx\\_abuse\\_plan.pdf](http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf).

prescription drug abuse.<sup>18</sup> Furthermore, the report recognizes that ensuring citizens have access to safe disposal methods will protect the environment and human health.<sup>19</sup>

### C. *History and Current Practices*

Suggested and required drug disposal methods vary depending on the type of drug being disposed of and the jurisdiction where it is located. If no local or state drug take-back program exists, the Food and Drug Administration recommends following the White House Office of National Drug Control Policy's disposal guidelines.<sup>20</sup> First, the guidelines recommend following instructions on the drug's labels or returning the drugs through a community-run drug take-back program.<sup>21</sup> If neither of those are an option, the guidelines recommend that consumers mix them with an undesirable substance (like coffee grounds), put them in a sealable bag, and place them in the trash.<sup>22</sup>

In September 2010, the Drug Enforcement Agency (DEA) led the first National Prescription Drug Take-Back Day.<sup>23</sup> DEA has supported seven drug take-back days thus far.<sup>24</sup> At the most recent day on October 26, 2013, Americans across the country turned in 324 tons of drugs at 5683 take-back locations.<sup>25</sup>

Other than DEA-led programs, where state and local government take-back programs exist, those state and local governments fund them. Government-run programs often operate periodically, for limited hours, and are often located at inconvenient locations, making it more difficult for consumers to participate.<sup>26</sup> State-run take-back programs can be costly. According to one source, disposing of drugs in a hazardous waste plant can cost governments as much as five dollars per pound of drugs.<sup>27</sup>

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18. *See id.* at 2.

19. *Id.* at 7.

20. *How To Dispose of Unused Medicines*, U.S. FOOD & DRUG ADMIN. 1-2 (Apr. 2011), <http://www.fda.gov/downloads/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandingover-the-countermedicines/ucm107163.pdf>.

21. *Id.*

22. *Id.*

23. Press Release, *U.S. Drug Enforcement Agency, Americans Turn Out in Drove for DEA's Seventh Prescription Drug Take-Back Day*, U.S. DEP'T OF JUSTICE (Nov. 6, 2013), <http://www.justice.gov/dea/divisions/hq/2013/hq110613.shtml>.

24. *Id.*

25. *Id.*

26. Jennifer Nash & Christopher Bosso, *Extended Producer Responsibility in the United States: Full Speed Ahead?* 17 J. INDUS. ECOLOGY 175, 177 (2013).

27. Woodard, *supra* note 3.

Drug take-back programs, if they include certain prescription drugs, fall under the purview of the Controlled Substances Act (CSA), which regulates the flow of drugs subject to abuse.<sup>28</sup> Currently, the CSA applies to about 11% of all prescriptions; the remaining 89% are for drugs not regulated by the CSA.<sup>29</sup> The CSA requires that law enforcement officers collect controlled substances. Therefore, collection programs must have a law enforcement officer present, which often increases take-back event expenses.<sup>30</sup> To comply with the CSA, communities that operate drug take-back programs may exclude controlled substances.<sup>31</sup>

In 2010, Congress responded to the growing national prescription drug abuse and environmental issues caused by improper drug disposal by amending the CSA to make it easier for local governments to implement drug take-back programs.<sup>32</sup> In the Secure and Responsible Drug Disposal Act of 2010 (the 2010 Act), Congress recognized the importance of drug take-back programs in reducing the amount of pharmaceuticals introduced into the environment and the amount of pharmaceuticals that fall into unauthorized hands.<sup>33</sup> The 2010 Act allows a person who lawfully received a controlled substance (referred to in the 2010 Act as the “ultimate user”) to deliver the controlled substance to someone authorized by the Act.<sup>34</sup> Furthermore, the 2010 Act requires the Attorney General to write regulations for drug take-back programs, taking into account “the public health and safety, as well as the ease and cost of program implementation and participation by various communities.”<sup>35</sup> With these regulations, the Attorney General may not *require* an entity to start or operate a drug take-back program.<sup>36</sup>

The DEA issued a proposed rule interpreting the 2010 Act in December 2012 and opened the rule to comments through February

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28. See 21 U.S.C. §§ 802, 812 (2012). A list of regulated drugs is included in the original text of the CSA, which passed in 1970. *Id.* § 812(c). The list of regulated drugs is revised annually and published in the Federal Register. *Id.* § 812(a).

29. BRIAN T. YEH, CONG. RESEARCH SERVICE, R40548, LEGAL ISSUES RELATING TO THE DISPOSAL OF DISPENSED CONTROLLED SUBSTANCES 5 & n.23 (2010), *available at* <http://www.fas.org/sgp/crs/misc/R40548.pdf>.

30. Lubick, *supra* note 2, at A213.

31. See YEH, *supra* note 29, at 2.

32. Secure and Responsible Drug Disposal Act of 2010, Pub. L. No. 111-273, § 2, 124 Stat. 2858, 2859 (2010).

33. *Id.* (noting that drug take-back programs are a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment).

34. *Id.* § 3, 124 Stat. at 2859-60.

35. *Id.*

36. *Id.*

2013. The final rule has yet to be released.<sup>37</sup> The proposed rule would allow people legally in control of controlled substances to dispose of them at authorized take-back events, mail-back programs, and/or collection receptacle locations.<sup>38</sup> If the proposed rule is adopted as is, it would be easier for entities to operate drug take-back programs because they could operate the events without a law enforcement officer present.

A disclaimer in the proposed rule highlights the complexity of drug disposal:

The requirements of this proposed rule only govern compliance with the Controlled Substances Act. Any selected method of destruction of controlled substances meeting the requirements of this proposed rule must also comply with all applicable federal, state, and local laws and regulations applicable at the time of the destruction. Because of the broad range of such environmental and other laws and regulations, this proposed rule does not purport to address what laws may or may not be applicable in a particular circumstance now or at some future date.<sup>39</sup>

Beyond complying with the CSA, any entity that wants to operate a voluntary take-back program has to concern itself with regulations associated with different elements of the program. These regulations are issued by the EPA, the Occupational Safety and Health Administration, the United States Postal Service, the Department of Transportation, as well as applicable state and local agencies.<sup>40</sup> For example, the Postal Service generally only allows people registered with the DEA (i.e., pharmacists, pharmacies, wholesale distributors, etc.) to mail controlled substances.<sup>41</sup>

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37. See *Drug Disposal Information*, OFFICE OF DIVERSION CONTROL, U.S. DRUG ENFORCEMENT ADMIN., [http://www.deadiversion.usdoj.gov/drug\\_disposal/](http://www.deadiversion.usdoj.gov/drug_disposal/) (last visited Mar. 22, 2014).

38. See *Disposal of Controlled Substances*, 77 Fed. Reg. 75,784 (Dec. 21, 2012) (to be codified at 21 C.F.R. pts. 1300-01, 1304-05, 1307, 1317, 1321).

39. *Id.* at 75,804.

40. Amy P. McMorrow, *Testing the Limits on Drug Product Stewardship*, NAT. RESOURCES & ENV'T, Summer 2013, at 50, 51. Maine exemplifies just how complicated and political these regulations can be. The state Environmental Protection Commissioner recently advanced a new interpretation of the rules that regulate waste disposal. Woodard, *supra* note 3. Now the state plans to treat drugs as household waste, which could be burned in-state, rather than as hazardous waste, which has to be burned out-of-state at an approved hazardous waste facility. The decision has generated concern about the effects of burning large quantities of drugs. *Id.*

41. See *Publication 52—Hazardous, Restricted, and Perishable Mail*, U.S. POSTAL SERV. 93 (Dec. 2013), <http://pe.usps.gov/cpim/ftp/pubs/Pub52/pub52.pdf>.

### III. THE BROADER CONTEXT: EXTENDED PRODUCER RESPONSIBILITY LAWS

#### A. *Extended Producer Responsibility Laws Across the Country*

Mandatory drug take-back programs fit within a broader history of national and local governments adopting EPR laws. EPR laws have been adopted in countries around the world in response to concerns about increasing consumption, which fills landfills and generates considerable hazardous waste.<sup>42</sup> EPR laws focus not on the pollution generated from creating goods, but the pollution generated from *disposing* goods. In general, the United States' environmental laws and regulations fail to capture the environmental effects of disposing a good (e.g., landfill leachate contaminated with hazardous chemicals).<sup>43</sup>

EPR laws—which place the onus of disposal on producers—provide an incentive for producers to consider the product's disposal when developing the good.<sup>44</sup> As one author writes, “In terms of legal doctrine, take-back laws may be loosely described as transforming the manufacturer's legal relationship with its product by imposing a future property interest which vests upon disposal.”<sup>45</sup> Theoretically, making producers physically and financially responsible for a product at the end of its life cycle should incentivize the producer to design a product that is more easily reused, recycled, or composted.<sup>46</sup>

For state and local governments, EPR laws are attractive for another reason. They can shift the financial responsibility of product disposal to manufacturers. Municipal governments are typically responsible for

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42. See James Salzman, *Sustainable Consumption and the Law*, 27 ENVTL. L. 1243, 1274 (1997).

43. Noah Sachs, *Planning the Funeral at the Birth: Extended Producer Responsibility in the European Union and the United States*, 30 HARV. ENVTL. L. REV. 51, 57-58 (2006) (“Consider, for example, regulation of a U.S. facility that uses solvents and pigments to manufacture paints. The release of Volatile Organic Compounds (“VOCs”) in the solvents to the air would be stringently regulated under the Hazardous Air Pollutant provisions of the Clean Air Act, and any discharge of manufacturing byproducts to water would be controlled under the Clean Water Act. But the same VOCs, when incorporated into the finished paint products and sold to consumers, are entirely unregulated and can later be released to the environment when the paint is applied, or when unused paint is disposed.”).

44. See Salzman, *supra* note 42, at 1274 (writing that EPR laws' goals include “1) encouraging companies to *design* for reuse, recyclability, and materials reduction, 2) *correcting market signals* to the consumer by incorporating waste management costs into the product price, and 3) driving *technological innovation* to recover and reuse materials destined for disposal.”).

45. *Id.* at 1277.

46. Anthony A. Austin, *Where Will All the Waste Go?: Utilizing Extended Producer Responsibility Framework Laws To Achieve Zero Waste*, 6 GOLDEN GATE U. ENVTL. L.J. 221, 236 (2013).



funding disposal costs for municipal waste in the United States, which includes complex waste like lead batteries and mercury thermometers. When municipalities' budgets shrink, EPR programs become more appealing.<sup>47</sup> Municipalities can avoid significant expenses when manufacturers assume the disposal burden. Hennepin County, Minnesota, saved approximately \$682,000 when the state enacted a law that required manufacturers to collect and recycle electronic waste (prior to the enactment, the county was responsible for electronic waste disposal).<sup>48</sup>

States across the country have passed EPR laws. As of 2013, thirty-two states implemented at least one EPR law; a few states had adopted EPR laws for a handful of different product types.<sup>49</sup> EPR laws cover products like mercury thermostats, electronics, mercury automobile switches, fluorescent lamps, pesticide containers, and carpet.<sup>50</sup> Two researchers who studied EPR laws across the United States wrote that EPR has become "firmly established" in some states.<sup>51</sup> The laws vary in their requirements. Some states oblige manufacturers to offer consumers a financial incentive to return the product to a specific site.<sup>52</sup> Some states just ask manufacturers to establish a program, while other states set performance goals.<sup>53</sup> States that have reported statistics for take-back programs for products other than drugs report that they have seen a dramatic increase in recycling after mandatory take-back laws were passed.<sup>54</sup>

### B. One Prior Legal Challenge

Although states have passed more than eighty EPR laws,<sup>55</sup> the author could find no legal challenges to these state laws. However, a municipality-passed EPR law was challenged in court.

In 2008, New York City passed an electronics take-back ordinance that drew similar dormant Commerce Clause criticisms as the drug take-

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47. See Nash & Bosso, *supra* note 26, at 176.

48. *Id.*

49. *Id.* at 175.

50. See *id.* at 178-82 (discussing various state EPR laws).

51. *Id.* at 175.

52. *Id.* at 176.

53. *Id.*

54. Jaymi Heimbuch, *Advocates for Electronics Producer Responsibility Speak Out Against NYC E-Waste Lawsuit*, TREEHUGGER (Jan. 14, 2010), <http://www.treehugger.com/clean-technology/advocates-for-electronics-producer-responsibility-speak-out-against-nyc-e-waste-law-suit.html>.

55. *Extended Producer Responsibility State Laws*, PRODUCT STEWARDSHIP INST. (Jan. 2014), <http://productstewardship.us/displaycommon.cfm?an=1&subarticlenbr=280>.

back ordinances (discussed below in Part V).<sup>56</sup> At the time, New York City was the only municipality to establish a major e-waste law (nineteen states had electronics take-back programs).<sup>57</sup> The city's law required electronics manufacturers to establish and operate the take-back program.<sup>58</sup> Manufacturers criticized the law because it forbade them from requiring residents to mail electronics that weighed more than fifteen pounds. According to the manufacturers, the requirement effectively would have forced electronics manufacturers to operate a door-to-door collection system.<sup>59</sup> The industry groups filed suit in federal court, but the lawsuit was settled after a state law was passed, preempting New York City's ordinance.<sup>60</sup>

The New York State law requires electronics manufacturers to establish free and convenient electronics recycling systems for schools, government offices, individual residents, nonprofits with seventy-five employees or less, and businesses with fifty employees or less.<sup>61</sup> Manufacturers can charge fees to larger businesses and nonprofits. Furthermore, the law requires manufacturers to establish an advertising campaign.<sup>62</sup> The New York State law has not been challenged in court.

#### IV. DRUG TAKE-BACK PROGRAMS

##### A. *Proposed Take-Back Programs at Federal and State Levels*

Federal, state, and county governments have considered manufacturer-funded drug take-back programs, but only two county-

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56. See Kate Sinding, *Fighting Off Industry's TakeBack Attack (While Securing New Yorkers' Right to Recycle E-Waste)*, SWITCHBOARD: NAT. RESOURCES DEFENSE COUNCIL STAFF BLOG (Jan. 15, 2010) [http://switchboard.nrdc.org/blogs/ksinding/fighting\\_off\\_industrys\\_takebac.html](http://switchboard.nrdc.org/blogs/ksinding/fighting_off_industrys_takebac.html); Natural Res. Def. Council & Elecs. TakeBack Coal., *Legal Issues in the New York City E-Waste Lawsuit*, ELECTRONICS TAKEBACK COALITION, <http://www.electronicstakeback.com/wp-content/uploads/Legal%20Issues%20in%20the%20New%20York%20City%20Lawsuit> (last visited Mar. 22, 2014).

57. Nathaniel Gronewold, *Court Showdown Looms for NYC Electronics Recycling Law*, N.Y. TIMES (Jan. 5, 2010), <http://www.nytimes.com/gwire/2010/01/05/05greenwire-court-show-down-looms-for-nyc-electronics-recyc-19622.html>.

58. *Id.*

59. *Id.*

60. Kate Sinding, *NYS Passes Cutting Edge E-Waste Law*, SWITCHBOARD: NAT. RESOURCES DEFENSE COUNCIL STAFF BLOG (May 29, 2010), [http://switchboard.nrdc.org/blogs/ksinding/nys\\_passes\\_cutting\\_edge\\_e-wast.html](http://switchboard.nrdc.org/blogs/ksinding/nys_passes_cutting_edge_e-wast.html).

61. Nathaniel Gronewold, *N.Y. Launches Sweeping, Mandatory E-Waste Recycling Program*, N.Y. TIMES (Apr. 1, 2011), <http://www.nytimes.com/gwire/2011/04/01/01greenwire-ny-launches-sweeping-mandatory-e-waste-recycli-91291.html>.

62. *Id.*

level programs have passed.<sup>63</sup> U.S. Congresswoman Louise Slaughter (D-NY) introduced a bill, the Pharmaceutical Stewardship Act of 2011, which would have required drug manufacturers and brand owners to participate in a national organization that would operate a national drug take-back program.<sup>64</sup> The bill was referred to committee but was never put to a vote.<sup>65</sup>

Nine states have considered statewide drug take-back programs, but none have passed.<sup>66</sup> Florida was the first state to consider legislation in 2009.<sup>67</sup> Washington and California also considered state-wide initiatives in 2011 and 2013, respectively.<sup>68</sup> In Maine, a trade organization, Pharmaceutical Research and Manufacturers of America (PhRMA)—whose name appears often in opposition to these programs—lobbied against a proposed bill.<sup>69</sup>

### B. *Take-Back Ordinances in Alameda and King Counties*

In the past two years, two counties—Alameda County in California, and King County in Washington—passed ordinances requiring drug manufacturers to manage and fund drug take-back programs.<sup>70</sup> Both ordinances were motivated by concern for public health and the environment.<sup>71</sup> In Alameda, the county acknowledged that the ordinance was adopted to shift disposal costs to manufacturers.<sup>72</sup>

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63. See Pauline Bartolone, *California County Pushes Drugmakers To Pay for Pill Waste*, NAT'L PUB. RADIO (Jan. 3, 2014, 4:16 PM), <http://www.npr.org/blogs/health/2014/01/03/259417691/california-county-pushes-drugmakers-to-take-back-unused-pills>.

64. Pharmaceutical Stewardship Act, H.R. 2939, 112th Cong. (2011).

65. *H.R. 2939 (112th): Pharmaceutical Stewardship Act of 2011*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/112/hr2939> (last visited Mar. 22, 2014).

66. *Pharmaceutical Legislation*, PROD. STEWARDSHIP INST., <http://www.productstewardship.us/displaycommon.cfm?an=1&subarticlenbr=540> (last visited Mar. 14, 2014).

67. See *id.*

68. *Id.*

69. John Richardson, *Bill Targeting Unused Drugs Moves Ahead Despite Foes*, PORTLAND PRESS HERALD (Feb. 26, 2010), [http://www.pressherald.com/archive/bill-targeting-unused-drugs-moves-ahead-despite-foes\\_1010-02-07.html](http://www.pressherald.com/archive/bill-targeting-unused-drugs-moves-ahead-despite-foes_1010-02-07.html).

70. ALAMEDA CNTY., CAL., HEALTH & SAFETY CODE § 6.53 (2012); KING CNTY., WASH., BD. OF HEALTH CODE tit. 11.50 (2013).

71. See ALAMEDA, CAL., HEALTH & SAFETY CODE § 6.53.010(C) (“Our groundwater and drinking water are being contaminated by unwanted, leftover or expired prescription drugs passing through our wastewater and treatment centers.”); KING CNTY., WASH., BD. OF HEALTH RULE AND REGULATION 13-03, § 1(E) (“Flushing medicines down toilets and sinks is an inappropriate disposal practice because wastewater treatment facilities cannot effectively remove or degrade all pharmaceutical compounds. Trash disposal of medicines is an undesirable disposal option because trash cans are not secure and mixed pharmaceutical wastes are household hazardous wastes that should not be disposed of in the solid waste stream.”).

72. Bartolone, *supra* note 63. An Alameda County supervisor stated: “This is not something taxpayers should be paying for . . . . It seems like when products have reached their

Alameda County's ordinance, enacted on July 24, 2012, was the first mandatory drug take-back program in the United States to place financial responsibility on drug manufacturers.<sup>73</sup> King County passed a similar ordinance, the King County Board of Health Secure Medicine Return Regulations, on June 20, 2013.<sup>74</sup> Both programs require manufacturers who sell or distribute drugs in their counties to submit a stewardship plan to the designated county agency.<sup>75</sup> Once the stewardship plan is approved, the manufacturer is responsible for collecting, transporting, and disposing of unused drugs.<sup>76</sup> Both ordinances require manufacturers to pay the administrative costs associated with required promotion and outreach for the take-back program.<sup>77</sup>

Both ordinances prohibit manufacturers from funding their take-back programs through point-of-sale fees or point-of-collection fees.<sup>78</sup> With a small nod to producers, King County specifically mentioned that manufacturers may recoup their costs by raising drug prices.<sup>79</sup> Alameda County avoided mentioning in the ordinance that manufacturers could raise the price of drugs, but the manufacturers acknowledge this possibility in their court filings.<sup>80</sup>

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life cycle, it should be the responsibility of the manufacturers to have a way of properly disposing of those products." *Id.*

73. McMorrow, *supra* note 40, at 50.

74. *Secure Medicine Return Rule and Regulation*, *supra* note 16.

75. See ALAMEDA CNTY., CAL., HEALTH & SAFETY CODE § 6.53.050(B); KING CNTY., WASH., BD. OF HEALTH CODE tit. 11.50.060. Alameda County refers to the manufacturer-lead take-back initiative as a "product stewardship plan"; King County refers to it as a "standard stewardship plan."

76. See ALAMEDA CNTY., CAL., HEALTH & SAFETY CODE § 6.53.040(B); KING CNTY., WASH., BD. OF HEALTH CODE tit. 11.50.050.

77. ALAMEDA CNTY., CAL., HEALTH & SAFETY CODE §§ 6.53.040, 6.53.070(C) ("A Product Stewardship Program must prepare education and outreach materials that publicize the location and operation of collection locations in Alameda County and disseminate the materials to health care facilities, pharmacies, and other interested parties. The Program also must establish a website publicizing collection locations and Program operations and a toll-free telephone number that Residential Generators can call to find nearby collection locations and understand how the Program works."); KING CNTY., WASH., BD. OF HEALTH CODE tit. 11.50.070, 11.50.090 (requiring, among other things, that manufacturers establish a Web site and toll-free number with drop-off information).

78. ALAMEDA CNTY., CAL., HEALTH & SAFETY CODE § 6.53.040(B)(3); KING CNTY., WASH., BD. OF HEALTH CODE tit. 11.50.090(C).

79. KING CNTY., WASH., BD. OF HEALTH RULE AND REGULATION 13-03, § 1(H) ("Although producers may not charge a specific point-of-sale or point-of-collection fee, the board does not otherwise intend to preclude producers from recouping the costs of their program through other means, including allocating costs to the prices of their covered drugs in King County.")

80. See Reply in Support of Summary Judgment for Plaintiffs and Opposition to Defendants' Cross-Motion at 23, *Pharm. Research & Mfrs. of Am. v. County of Alameda*, No. 12-cv-6203-RS (N.D. Cal. Aug. 28, 2013).

The ordinances differ on minor points and in one particularly important respect: the type of drug covered. The Alameda County ordinance only covers prescription drugs, whereas the King County ordinance applies to prescription and nonprescription drugs.<sup>81</sup> King County thus incorporates disposal of over-the-counter pain relievers, allergy medication, etc.

#### V. CHALLENGES IN COURT: EXPLORING THE DORMANT COMMERCE CLAUSE

As anyone experienced with the American legal system might expect, manufacturers are challenging both ordinances in federal court.

##### A. *Challenge to the Alameda County Ordinance*

On August 28, 2013, the United States District Court for the Northern District of California upheld Alameda's ordinance.<sup>82</sup> The plaintiffs—PhRMA, Generic Pharmaceutical Association, and the Biotechnology Industry Association—initiated a suit against Alameda County and the Department of Environmental Health. The three trade associations alleged that although the programs may address critical public interests, “the County violates the Commerce Clause by requiring interstate drug manufacturers to conduct and pay for such programs.”<sup>83</sup> At the outset of the lawsuit, the plaintiffs and the county stipulated to numerous facts including that the plaintiffs would incur start-up costs of approximately \$1.1 million and annual costs would average \$1.2 million if they were to initiate take-back programs.<sup>84</sup> Both parties moved for summary judgment.<sup>85</sup>

The court analyzed whether the statute violates the dormant Commerce Clause, which prohibits state and municipal governments from passing regulations that “unduly interfere with interstate commerce.”<sup>86</sup> The United States Supreme Court has advanced a two-tiered approach to be used to analyze state or local economic regulations: (1) if the law clearly discriminates against or regulates interstate commerce, the court will strike it down (a *per se* violation of the

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81. ALAMEDA CNTY., CAL., HEALTH & SAFETY CODE § 6.53.030(3); KING CNTY., WASH., BD. OF HEALTH CODE tit. 11.50.030(B)(1).

82. *Pharm. Research & Mfrs. of Am. v. County of Alameda*, No. 12-cv-6203-RS, 2013 WL 4718986, at \*6 (N.D. Cal. Aug. 28, 2013).

83. *Id.* at \*4.

84. *Id.* at \*3.

85. *Id.* at \*1.

86. *Id.* at \*4.

Commerce Clause); (2) if the law “has only indirect effects on interstate commerce and regulates evenhandedly, [the court examines] whether the State’s interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.”<sup>87</sup>

Using this two-tiered approach, the United States Court of Appeals for the Ninth Circuit has listed three categories to determine whether a local regulation is a *per se* violation of the Commerce Clause. The three categories examine whether the law “1) directly regulates interstate commerce; 2) discriminates against interstate commerce; or 3) favors in-state economic interests over out-of-state interests.”<sup>88</sup> The plaintiffs alleged that the Alameda ordinance violates all three prongs of the Ninth Circuit’s test. The court rejected the plaintiffs’ contention that the ordinance violated the second or third prongs because the ordinance does not discriminate between in-county entities and out-of-county entities.<sup>89</sup> The court reasoned, “In the absence of ‘differential treatment favoring local entities over substantially similar out-of-state interest,’ the kind of discrimination potentially prohibited by the dormant Commerce Clause is not implicated.”<sup>90</sup>

The court also held that the ordinance fails to violate the first prong because the ordinance does not *regulate* interstate commerce.<sup>91</sup> The court emphasized that the ordinance does not alter how producers will conduct business outside Alameda County. The plaintiffs argued that the ordinance regulates interstate commerce just like a tariff; the court found that argument unpersuasive because a tariff is a tax on goods produced outside a jurisdiction, not imposed on the same goods produced within the jurisdiction.<sup>92</sup>

The plaintiffs argued that under all three prongs, the court must look at the ordinance’s effect on interstate commerce and not merely at the regulation’s text.<sup>93</sup> The court responded by citing two Supreme Court cases, which supported the proposition that the “happenstance” that almost all producers are located outside of Alameda County “is

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87. *Id.* at \*4-5 (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 337 n.14 (1989)).

88. *Id.* at \*5 (quoting *Nat’l Collegiate Athletic Ass’n v. Miller*, 10 F.3d 663, 638 (9th Cir. 1993)).

89. *See id.*

90. *Id.* (quoting *Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 343 (2008)).

91. *Id.*

92. *Id.* at \*6 (“A tariff, however, ‘taxes goods imported from other States, but does not tax similar products produced in State.’” (quoting *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 193 (1994))).

93. *Id.*

insufficient to transform what is fundamentally a local measure into one that could be found to burden interstate commerce impermissibly.”<sup>94</sup>

Lastly, the plaintiffs argued—“almost in passing”—that under the Supreme Court’s second tier balancing test, the county’s interests in passing the ordinance could be addressed by a program funded from a different source.<sup>95</sup> The court rejected this argument too, noting the insufficiency of the plaintiff’s argument.<sup>96</sup> Ultimately, the court held that the producer’s “relatively modest compliance costs” do not unduly burden interstate commerce.<sup>97</sup>

The plaintiffs are now appealing the ruling to the Ninth Circuit, employing arguments similar to those used at the district court level: the Alameda ordinance impermissibly shifts costs to outside producers. The plaintiff-appellants argue that the district court focused on the wrong issue: regulation of interstate companies. Instead, the court should have examined the regulation’s effect on interstate *commerce*.<sup>98</sup> The plaintiff-appellants support their argument by hypothesizing that if this regulation is upheld, counties could begin to require interstate newspaper companies to establish newspaper-recycling programs.<sup>99</sup> Ultimately, they argue, “Local politicians would be able to give their constituents something for nothing, while shifting all the costs onto unrepresented consumers and businesses nationwide.”<sup>100</sup>

### B. Challenge to the King County Ordinance

On November 27, 2013, the same plaintiffs challenging the Alameda ordinance and another trade organization, the Consumer Healthcare Products Association, filed a complaint in the United States District Court for the Western District of Washington challenging the King County ordinance. The Consumer Health Products Association represents marketers and manufacturers of dietary supplements and over-the-counter drugs.<sup>101</sup> They most likely joined the lawsuit because the

94. *Id.* (citing *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 126 (1978); *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 68, 88 (1987)).

95. *Id.*

96. *Id.* The court reasoned: “Arguing that an alternative regime would have *no* burden on interstate commerce does not establish that the minimal burden this Ordinance arguably imposes on interstate commerce ‘clearly exceeds the local benefits.’”

97. *Id.*

98. Brief for Plaintiff-Appellants at 15, *Pharm. Research & Mfrs. of Am. v. County of Alameda*, No. 13-16833 (9th Cir. Nov. 15, 2013).

99. *Id.*

100. *Id.* at 15-16.

101. Complaint for Declaratory and Injunctive Relief at 4, *Pharm. Research & Mfrs. of Am. v. King County*, No. 2:13-cv-2151 (W.D. Wash. Nov. 27, 2013).

King County Ordinance requires manufacturers of nonprescription drugs to develop drug take-back programs.<sup>102</sup>

The plaintiffs made similar allegations as were made in the Alameda challenge: the ordinance violates the dormant Commerce Clause. Their three arguments are that (1) the ordinance “transfers a governmental responsibility onto pharmaceutical producers simply for placing their products in the stream of interstate commerce,” (2) “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,” and (3) “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.”<sup>103</sup> The plaintiffs further alleged that disposing pharmaceuticals promptly does not pose an environmental or public health risk.<sup>104</sup> King County filed its response on December 20, 2013.<sup>105</sup>

### C. *Why Were These Ordinances Challenged?*

The above discussion raises the question: why did manufacturers decide to challenge these ordinances but not earlier EPR laws? First, and perhaps most important, these ordinances directly affect well-organized and well-funded manufacturers. PhRMA is referred to as “[o]ne of the most powerful players in health care.”<sup>106</sup> In 2010, pharmaceutical manufacturing companies ranked as the third most profitable sector among the Fortune 500 companies.<sup>107</sup> That same year pharmaceutical manufacturers earned \$44.5 billion in profits (and \$295.7 billion in sales).<sup>108</sup> Furthermore, the pharmaceutical industry took the fourth spot for return on revenue and ranked thirteenth for return on shareholder equity.<sup>109</sup> In terms of political power, in 2013, PhRMA ranked as the

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102. KING CNTY., WASH., BD. OF HEALTH CODE tit. 11.50.030(B)(1) (2013).

103. Complaint for Declaratory and Injunctive Relief, *supra* note 101, at 2.

104. *Id.* at 5.

105. Answer to Complaint, Pharm. Research & Mfrs. of Am. v. King County, No. 2:13-cv-2151 (W.D. Wash. Dec. 20, 2013).

106. Andrea Seabrook & Peter Overby, *Drug Firms Pour \$40 Million into Health Care Debate*, NAT'L PUB. RADIO (July 23, 2009, 5:05 PM), <http://www.npr.org/templates/story/story.php?storyId=106899074>.

107. Jean Paul Gagnon, *The Research Manufacturing Pharmaceutical Industry*, in PHARMACY AND THE US HEALTH CARE SYSTEM 215, 216 (Michael Ira Smith et al. eds., 4th ed. 2013).

108. *Id.* at 215-16.

109. *See id.* at 216.



ninth largest spender on federal lobbying expenses.<sup>110</sup> And, according to one survey of policy leaders, PhRMA was “voted the best at lobbying, the most effective at having a local and federal presence and the group whose members most frequently ‘mobilize to contact policymakers.’”<sup>111</sup>

Second, as discussed above, operating drug take-back programs requires compliance with laws and regulations at multiple levels of government. For instance, the Alameda County ordinance requires producers to include in their product stewardship plan “[a] description of how support will be provided to any law enforcement agencies within Alameda County that have, or later agree to have, a collection program for Controlled substances.”<sup>112</sup> Two researchers who studied EPR laws extensively underscore the importance of flexibility in EPR laws to manufacturers. They write that manufacturers “prefer laws that give them flexibility in how they implement collection and recycling programs, and that preference is apparent in many of the laws in place today.”<sup>113</sup>

Third, because these are local ordinances—as opposed to state laws—pharmaceutical manufacturers are concerned about the costs if 3000 other counties in the United States adopt similar take-back programs.<sup>114</sup>

## VI. MANDATORY DRUG TAKE-BACK PROGRAMS’ LIKELIHOOD OF SURVIVAL

As discussed above, under the first part of the dormant Commerce Clause test, courts will strike down a statute if it discriminates against or regulates interstate commerce. The Supreme Court’s dormant Commerce Clause precedent routinely addresses cases where laws discriminate by distinguishing between in-state and out-of-state products or producers. For example, in *Oregon Waste Systems, Inc. v. Department of Environmental Quality of the State of Oregon*, the Court explicitly wrote, “As we use the term here, ‘discrimination’ simply means differential treatment of in-state and out-of-state economic interests that

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110. *Top Spenders*, CTR. FOR RESPONSIVE POLITICS, <http://www.opensecrets.org/lobby/top.php?showYear=2013&indexType=s> (last visited Mar. 13, 2014).

111. Megan R. Wilson, *PhRMA Comes Out on Top in Trade Group Rankings*, THE HILL (July 24, 2013, 9:04 PM), <http://thehill.com/business-a-lobbying/313291-phrma-comes-out-on-top-in-trade-group-rankings>.

112. ALAMEDA CNTY., CAL., HEALTH & SAFETY CODE § 6.53.050(A)(11).

113. Nash & Bosso, *supra* note 26, at 177.

114. Reply in Support of Summary Judgment for Plaintiffs and Opposition to Defendants’ Cross Motion, *supra* note 80, at 24.

benefits the former and burdens the latter.”<sup>115</sup> In other cases, the Supreme Court makes clear that the dormant Commerce Clause takes effect when a law discriminates between similarly situated economic interests.<sup>116</sup> Additionally, the Supreme Court refuses to find discrimination and invoke the dormant Commerce Clause just because a regulation affects interstate companies.<sup>117</sup>

The drug take-back ordinances do not discriminate against interstate commerce. The Alameda and King County ordinances treat in-state and out-of-state producers—similarly situated interests—equally. The producers and Alameda County stipulated to that fact before the trial in the case challenging the Alameda ordinance.<sup>118</sup>

Furthermore, the drug take-back regulations do not regulate interstate commerce. The Supreme Court has held that a law regulates interstate commerce when it requires producers to set higher prices for products sold in other states, referred to as an extraterritorial effect.<sup>119</sup> Furthermore, in *Exxon Corp. v. Governor of Maryland*, the Supreme Court held that the Commerce Clause’s reach does not extend to protecting “the particular structure or methods of operation in a retail market.”<sup>120</sup>

When challenging the drug take-back ordinances, the producers argue that the ordinances regulate interstate commerce because they have an extraterritorial effect, which comes into play because the producers will have to change their business practices to set higher drug prices.<sup>121</sup>

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115. 511 U.S. 93, 99 (1994).

116. *See, e.g.*, *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 298-99 (1997) (“Conceptually, of course, any notion of discrimination assumes a comparison of substantially similar entities. . . . [T]his central assumption has more often than not itself remained dormant in this Court’s opinions on state discrimination subject to review under the dormant Commerce Clause.”); *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 88 (1987) (“Because nothing in the Indiana Act imposes a greater burden on out-of-state offerors than it does on similarly situated Indiana offerors, we reject the contention that the Act discriminates against interstate commerce.”).

117. *See Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 126 (1978) (“The fact that the burden of a state regulation falls on some interstate companies does not, by itself, establish a claim of discrimination against interstate commerce.”).

118. *Pharm. Research & Mfrs. of Am. v. County of Alameda*, No. 12-cv-6203-RS, 2013 WL 4718986, at \*2 (N.D. Cal. Aug. 28, 2013) (“4. The Ordinance, on its face, does not impose different requirements on Producers within Alameda County and Producers outside of Alameda County. 5. The Ordinance, on its face, does not impose different requirements on Producers within California and Producers outside of California.”).

119. *See Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). The oft-quoted Justice Cardozo wrote, “New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there.” *Id.*

120. 437 U.S. at 127-28 (“[T]he Clause protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations.”).

121. *See Reply in Support of Summary Judgment for Plaintiffs and Opposition to Defendants’ Cross Motion*, *supra* note 80, at 16.

While complying with the regulation may complicate producers' business operations, it fails to equate to a burden that merits overturning the drug take-back ordinances.

The Supreme Court found the extraterritorial-effect argument unpersuasive in a different case, *Pharmaceutical Research & Manufacturers of America v. Walsh*, where PhRMA challenged a Maine statute that requires drug manufacturers to pay a rebate to the state so that the state can offer prescription drugs at lower prices.<sup>122</sup> The plaintiffs made two arguments: (1) the rebate constituted an extraterritorial regulation, and (2) the regulation subsidized sales in Maine by discriminating against interstate commerce.<sup>123</sup> The Court rejected both arguments. First, regarding the regulation argument, the Court held that the law does not regulate prices outside the state.<sup>124</sup> Second, the law does not discriminate because even if a drug manufacturer were located in Maine, the statute would still affect it.<sup>125</sup>

Defendants in both cases challenging the Alameda and King County ordinances focused their arguments on the ordinances' regulation of interstate commerce. However, given that the Alameda County and King County ordinances regulate in-state and out-of-state entities evenly, their better argument would be to focus on the second part of the dormant Commerce Clause test, which was developed explicitly for regulations that burden interstate commerce. Under this second part, a court must examine whether

“the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits.” Moreover, “the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.”<sup>126</sup>

Although no Supreme Court precedent explicitly addresses a state or local ordinance that requires manufacturers to take back a product, a few dormant Commerce Clause cases offer some guidance on how a court might rule on a drug take-back program. The Supreme Court held in *American Trucking Ass'n v. Scheiner* that a state law that required truck drivers to pay a fee for a registration tag in order to drive through

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122. 538 U.S. 644, 649 (2003).

123. *Id.* at 669.

124. *Id.*

125. *Id.* at 670.

126. *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 471 (1981) (citation omitted) (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)).

Pennsylvania was unconstitutional.<sup>127</sup> The Court's reasoning could be applied to the drug take-back program ordinances. Just as the Court reasoned that the flat tax had the "inevitable effect [of] threaten[ing] the free movement of commerce by placing a financial barrier around the State,"<sup>128</sup> a court could find that the costs of complying with the take-back ordinances constitute a financial barrier making it prohibitively expensive for drug manufacturers to operate within Alameda and King Counties.

In *Minnesota v. Clover Leaf Creamery Co.*, the Court upheld a state statute that prohibited milk to be sold in plastic nonrefillable, nonreturnable containers, but allowed it in paper containers that were nonrefillable and nonreturnable.<sup>129</sup> The Court reasoned that interstate commerce would be burdened only slightly: "Milk products may continue to move freely across the Minnesota border, and since most dairies package their products in more than one type of containers, the inconvenience of having to conform to different packaging requirements in Minnesota and the surrounding States should be slight."<sup>130</sup> Furthermore, the Court noted, "Even granting that the out-of-state plastics industry is burdened relatively more heavily than the Minnesota pulpwood industry, we find that this burden is not 'clearly excessive' *in light of the substantial state interest in promoting conservation of energy and other natural resources and easing solid waste disposal problems . . .*"<sup>131</sup>

The Minnesota ban survived the dormant Commerce Clause challenge because although the law imposed a burden on companies (selling their product in a certain container), the costs were not substantially burdensome; at certain times, the regulated companies already sold containers that complied with the law. Therefore, the companies could comply with the statute without adopting new practices. In the cases at hand, it is possible that the Court will find that the compliance burden is high. Unlike in *Clover Leaf Creamery*, drug manufacturers are unaccustomed to running drug take-back programs. The manufacturers would have to develop new systems and be subject to inconsistent legal requirements. Rather than continuing a practice in which they already engage, as was the case in *Clover Leaf Creamery*,

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127. 483 U.S. 266, 286-87 (1987).

128. *Id.* at 284.

129. 449 U.S. at 473.

130. *Id.* at 472.

131. *Id.* at 473 (emphasis added).

drug manufacturers will incur thousands of dollars of start-up and annual compliance costs.<sup>132</sup>

However, despite the substantial compliance costs and the financial barrier, a court will likely find these costs are justified “in light of the substantial state interest in . . . easing solid waste disposal problems” cited in *Clover Leaf Creamery*.<sup>133</sup> Therefore, it is likely that both take-back ordinances will be upheld and will survive the dormant Commerce Clause challenges.

## VII. CONCLUSION

No matter the outcome of the lawsuits, the municipal take-back ordinances may prompt the California and Washington state governments to take action. California has enacted the largest number of EPR laws of any state; its laws cover seven product categories.<sup>134</sup> More importantly, in 2013, the California legislature considered legislation modeled in part after the Alameda County ordinance.<sup>135</sup> Washington, as of January 2014, has enacted two EPR laws covering electronics and fluorescent lighting.<sup>136</sup> The Washington legislature introduced a bill to require manufacturers to establish a drug take-back program in 2011 and reintroduced it in 2012.<sup>137</sup>

Both take-back ordinances deserve recognition as the federal government and nine state governments have introduced, but not passed, drug take-back legislation.<sup>138</sup> If states see that courts are willing to uphold drug take-back programs, states will be prompted into action. And, perhaps one day soon, as the Director of the Office of National Drug Control Policy once envisioned, drug disposal will become “second-nature to most Americans, in much the same way as proper and responsible recycling of aluminum cans has become.”<sup>139</sup>

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132. *Pharm. Research & Mfrs. of Am. v. County of Alameda*, No. 12-cv-6203-RS, 2013 WL 4718986 \*3 (N.D. Cal. Aug. 28, 2013).

133. 449 U.S. at 473.

134. *Extended Producer Responsibility State Laws*, *supra* note 55.

135. See McMorrow, *supra* note 40, at 51.

136. *Extended Producer Responsibility State Laws*, *supra* note 55.

137. See *SB 5234-2011-12: Creating a Statewide Program for the Collection, Transportation, and Disposal of Unwanted Medicines*, WASH. STATE LEGISLATURE, <http://apps.leg.wa.gov/billinfo/summary.aspx?bill=5234&year=2011> (last updated Mar. 22, 2014).

138. *Pharmaceutical Legislation*, *supra* note 66.

139. YEH, *supra* note 29, at 1.