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BIOTECHNOLOGY & PHARMACEUTICAL LAW REVIEW

COMMENT
GIVE AND TAKE-BACK: PHARMACEUTICAL MANUFACTURERS REQUIRED TO DISPOSE OF DRUGS AT LOCAL LEVEL

ALLIE M. CRAVER *

INTRODUCTION

6.5 million Americans use prescription drugs, such as pain relievers, stimulants, and tranquilizers, for purposes other than those prescribed.[1] More than 50% of people ages 12 and older who abused prescription drugs received them from friends or family for free.[2] Placed in the wrong hands, unconsumed and unwanted pharmaceuticals expose vulnerable populations, including the elderly and children, to potential harm by means of ingestion.[3] The United States Food and Drug Administration (FDA) suggest that medications be disposed by either trashing or flushing. Medications that have been trashed, which is the predominant method, can still be reused if not properly mixed with an unpalatable substance. Likewise, flushing medications can lead to toxins in the water supply.[4] By first noting

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1.Nat'l Ass'n of Boards of Pharmacy, The AWAR$_X$E Prescription Drug Safety Program, http://www.awarerx.org (last visited Jun. 16, 2015).

2. *Id*.

3.Carolyn S. Ma *et al*, *Drug Take Back in Hawai'i: Partnership Between the University of Hawai'i Hilo College of Pharmacy and the Narcotics Enforcement Division*, 73 Haw. J Med Pub. Health 28, 26-31 (2014).

4.U.S. Food and Drug Admin., *Disposal of Unused Medicines*, FDA.GOV, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm. (last updated Sept. 16, 2015).

the Environmental Protection Agency's (EPA) recently proposed rule concerning pharmaceutical disposal standards, this comment will explore the current issue of manufacturer-sponsored drug take-back initiatives implemented by local governments in the United States. Furthermore, this comment will address the question of whether pharmaceutical manufacturers should reciprocally give and take-back prescription drugs within the state of North Carolina.

FEDERAL AGENCIES AND LEGISLATIVE HISTORY

Two federal agencies, the EPA and the Drug Enforcement Agency (DEA), are responsible for promulgating and enforcing regulations regarding the disposal of medications. Since the EPA seeks to protect the integrity of the United States' waters, the agency has the authority to pass regulations concerning environmentally hazardous substances, such as pharmaceuticals.[5] Because water treatment facilities in the United States are not equipped with the technology to filter the active compounds within prescription drugs, a low concentration of various pharmaceuticals is present in our water.[6] A recent United State Geological Survey found that 110 of the 139 streams tested in 30 states possessed trace amounts of pharmaceuticals including antibiotics, antidepressants, caffeine, steroids, hypertensive drugs, and reproductive hormones, to name a few.[7] With this in mind, the EPA maintains a specific interest in the passing of federal guidelines regarding drug disposal programs. Furthermore, the EPA favors pharmaceutical take-back programs over the environmentally damaging alternative of flushing pharmaceuticals.[8]

On August 31, 2015, EPA's Administrator signed the proposed Management Standards for Hazardous Waste Pharmaceuticals Rule

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5.U.S. Environmental Protection Agency, *How to Dispose of Medicines Properly*, (2011), http://water.epa.gov/scitech/swguidance/ppcp/upload/ppcpflyer.pdf.
6.See Judith M. Mathias, *Untangling Pharmaceutical Waste Requirements*, 28 OR Manager 5 (May 2012), http://www.ormanager.com/wp-content/uploads/pdf/ORMVo128No5PharmWaste.pdf.
7.Herbert T. Buxton & Dana W. Kolpin, *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams*, U.S. Geologic Survey, http://toxics.usgs.gov/pubs/FS-027-02/index.html (last updated Aug. 4, 2015).
8.U.S. Environmental Protection Agency, *How to Dispose of Medicines Properly*, (2011), http://water.epa.gov?scitech?swguidance/ppcp/upload/ppcpflyer.pdf.

("Proposed Rule"), which was subsequently published in the Federal Register on September 25, 2015.[9] Because the Proposed Rule impacts the pharmaceutical industry's infrastructure, the EPA received numerous requests to extend the comment period and a public webinar was held on October 13, 2015, to address some of the major concerns.[10] As part of the webinar, EPA representatives highlighted six remaining issues for rulemaking including: (1) pharmaceuticals being flushed and sewered, and (2) the intersection of EPA & DEA regulations.[11]

As one of the key concerns acknowledged by EPA officials, the flushing and sewering of pharmaceuticals is banned under the Proposed Rule. The EPA projects that the ban will prevent more than 6,400 tons of flushed and sewered pharmaceuticals from entering the United States' drinking and surface water each year.[12] Under the current Resource Conservation and Recovery Act (RCRA), the public law that provides the framework for the proper management of hazardous and nonhazardous solid waste, the regulations provide an exemption for all hazardous waste generated by households, such as pharmaceuticals, and as such are not subject to RCRA protocols.[13] Although flushing is allowed by RCRA regulations, the Proposed Rule stipulates that as part of a joint effort, the DEA will similarly ban the flushing and sewering of pharmaceuticals.[14] Since toxins in

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9. Management Standards for Hazardous Waste Pharmaceuticals, 80 Fed. Reg. 58,014 (proposed Sept. 25, 2015) (to be codified at 40 C.F.R. pts 261, 262, 266, 268, and 273).

10.The comment period for this proposed rule closed on December 24, 2015. Management Standards for Hazardous Waste Pharmaceuticals, 80 Fed. Reg. 68,491 (extension Nov. 5, 2015) (to be codified at 40 C.F.R. pts 261, 262, 266, 268, and 273).

11.U.S. Environmental Protection Agency, *Hazardous Waste Pharmaceuticals Proposed Rule*, (2015), http://www.epa.gov/sites/production/files/2015-10/documents/hw_pharmaceuticals_proposed_rule_3.pdf.

12.U.S. Environmental Protection Agency, *Proposed Rule: Management Standards for Hazardous Waste Pharmaceuticals*, (2015), http://www.epa.gov/hwgenerators/proposed-rule-management-standards-hazardous-waste-pharmaceuticals#rule-summary.

13.40 C.F.R. § 261.4(b)(1) (2016).

14.With the proposed rule, the EPA and DEA would join other states with sewer bans for pharmaceuticals, including: Connecticut, Illinois, New Jersey, and

the water supply threaten humans, animals, and aquatic ecosystems, the Proposed Rule seeks to improve compliance and establish safeguards by dividing the regulations into sector-specific standards, which clarify the process of reverse distribution and streamline disposal methods used by healthcare facilities and pharmacies.[15] Although there are over 60 proposed changes to the preexisting regulations, only the pharmaceuticals that are currently considered hazardous waste under RCRA will be covered.[16]

Another area of contention addressed during the webinar involves the convergence of EPA and DEA policies. As the other major federal agency involved in pharmaceutical regulation, the DEA has the power to implement strict guidelines concerning drug disposal, once a drug is identified as a controlled substance.[17] As part of its initiative to promote proper drug disposal, the DEA formulated its own final ruling on the disposal of controlled substances and has sponsored the National Take Back Day, a biannual event held in the spring and fall.[18] However, prior to 2010, the DEA lacked clear guidelines concerning drug disposal.

When Congress passed the Secure and Responsible Drug Disposal Act of 2010*,* the legislation provided long-term care facilities, and ultimate users, individuals originally prescribed the medication, with additional methods for safe and responsible drug disposal.[19] The law also permitted federal, state, tribal and local law enforcement to maintain collection receptacles at law enforcement buildings.[20] Likewise, law enforcement was permitted to collaborate with private entities or community groups to sponsor mail-back initiatives and

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Washington. Management Standards for Hazardous Waste Pharmaceuticals, 80 Fed. Reg. at 58,014.

15.According to the proposed rule, the term "healthcare facilities" includes, but is not limited to: hospitals, pharmacies, health clinics, surgical centers, long-term care facilities, physician offices, veterinary clinics and hospitals, drug compounding facilities, coroners and medical examiners. *Id*.

16.For a definition of hazardous waste pharmaceuticals, see 40 C.F.R. § 261.3 (2016).

17.21 C.F.R §1317.01 (2014).

18.*Id*.

19.Secure and Responsible Drug Disposal Act of 2010, Pub. L. No. 111-273, 124 Stat. 2858.

20.*Id*.

hold take-back events.[21] Take-back events aim to educate participants about the potential for abuse of medications, while providing safe, convenient, and responsible means of disposing of prescription drugs. Take-back events are typically short in duration and are commonly held at unregistered locations that are easily accessible to the public.[22] Despite expanding the ways ultimate users could dispose of pharmaceuticals, participation in these programs is not mandatory, nor could the DEA require an entity to establish or operate a disposal program.

The following year, the issue of proper drug disposal was one of four major problem areas targeted by President Obama's 2011 Prescription Drug Abuse Prevention Plan.[23] The government plan proposed that Americans receive access to safe drug disposal methods that, in turn, would protect both their health and the environment.[24] As part of this initiative, in December 2012, the DEA proposed allowing drug manufacturers, distributors, reverse distributors, and retail pharmacies to establish voluntary collection receptacles without the presence of an authorized agent. This proposal was a departure from earlier federal guidelines requiring an authorized agent be present on-site.[25]

As this issue received more attention, the FDA updated its standards on drug disposal, and the DEA's 2013 proposal, "2013 proposal," developed its own non-retrievable standard of destruction for controlled substances. Based on the 2013 proposal, the DEA's non-retrievable standard would have mandated that a controlled substance be permanently altered, making it unavailable and unusable for any purpose.[26] Furthermore, the 2013 proposal noted that simply mixing a substance with coffee grounds or flushing the

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21.*Id*.
22.*See* Office of National Drug Control Policy, Take-back events frequently are held at community centers.
23.Office of National Drug Control Policy, *Prescription Drug Abuse*, The White House (last accessed Jun. 16, 2015),
https://www.whitehouse.gov/ondcp/prescription-drug-abuse.
24.*Id*.
25.*Id*.
26.U.S. Department of Justice: Office of Diversion Control, Disposal Act: *General Public Fact Sheet*, (Oct. 17, 2014),
http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_public.pdf.

substance would not render the substance non-retrievable. Therefore, the 2013 proposal advocated for chemical digestion or incineration of a controlled substance as the proper means of disposal. As noted by other scholars, this was the first time a federal agency specifically undermined the long-established, yet environmentally destructive, method of flushing, mixing, or trashing controlled substances.[27]

On October 9, 2014, components of the 2013 proposal, including the preference for mail-back or take-back programs, were incorporated into the DEA's *Published Disposal of Controlled Substances Final Rule*. In accordance with the Controlled Substances Act, the ruling expands those who are permitted to collect controlled substances through methods such as take-back events, mail-back programs, and collection receptacle locations.[28] As stated in previous regulations, any DEA registrant, or federal, state, tribunal, or local law enforcement agency is authorized to collect medications from an ultimate user or other accepted entity. The final rule further expands the list of authorized collection registrants to include: manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and medical centers with an on-site pharmacy.[29] Considering the current collaboration between the EPA and DEA, as referenced in the EPA's Proposed Rule and accompanying webinar, further regulations concerning proper drug disposal and voluntary collection receptacles should be expected.

THE IMPORTANCE OF TAKE-BACK PROGRAMS

Prescription drug abuse is the fastest growing drug problem in the United States. In order to help stop the non-medical use of prescription drugs, the DEA has developed programs such as take-back events and mail-back programs to facilitate the handling, monitoring, and proper disposal of pharmaceuticals. The efficacy of the DEA-sponsored National Take Back Days is unquestionable: as a

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27. Disposal of Controlled Substances, 79 Fed. Reg. 53,520-01 (Sept. 9, 2014) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1305, 1307, and 1317). See further in *Cook*, *supra* note 34, at 14.
28. *Id*.
29. 21 C.F.R. § 1317.40 (2014).

result of nine events held over the span of four years, over 2,411 tons, or 4,823,251 pounds, were returned.[30]

Although access to these programs may be limited to particular highly-populated regions, the FDA and DEA suggests that if a take-back program is not available in an area and there are no disposal instructions listed on a medication's label, the drug can be thrown in the trash after following two essential steps. First, the drug should be removed from its original container and mixed with an "undesirable" substance, such as dirt, kitty litter, or coffee grounds.[31] Second, the mixture should be placed in a sealable bag or container to prevent leakage after it is thrown out. Although these trashing precautions may seem tedious, labels on certain pharmaceuticals direct that users dispose of the drug by flushing.[32] For example, if a fentanyl patch, an adhesive patch that delivers a powerful pain medicine, is not properly disposed of by flushing, minimal skin contact can cause severe breathing problems that can lead to death in children, adults, and pets.[33] With these issues in mind, establishing a national take-back system would help to prevent non-prescription holders from accessing dangerous medications, while also reducing the amount of toxic chemicals in our waters caused by the flushing of medications.

While take-back and drug disposal programs benefit both consumers and the environment, the issue of who is responsible for funding divides the pharmaceutical industry. Recently passed legislation from Alameda County, California and King County, Washington requires pharmaceutical manufacturers to fund drug disposal programs. However, the major controversy now concerns which entity should be responsible for the costs of these widespread initiatives.

30.U.S. Drug Enforcement Administration, *DEA and Partners Collect 309 Tons of Pills on Ninth Prescription Drug Take-Back Day*, DEA (Nov. 4, 2014), http://www.dea.gov/divisions/hq/2014/hq110514.shtml.
31.U.S. Food and Drug Admin., *Disposal of Unused Medicines*, FDA.GOV, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm. (last updated Jun. 4, 2015).
32.*Id*.
33.*Id*.

THE ALAMEDA COUNTY ORDINANCE

In December of 2012, Pharmaceutical Research and Manufacturers of America, the Biotechnology Industry Organization, and the Generic Pharmaceutical Association filed a lawsuit in the United States District Court for the Northern District of California challenging an Alameda County Ordinance as unconstitutional.[34] Originally approved by county supervisors in July 2012, the Safe Drug Disposal Ordinance of Alameda County established a countrywide, manufacturer-sponsored drug disposal program applied to all manufacturers that make their drugs available in the county without respect to the manufacturer's geographic location.

In Alameda County alone, pharmaceutical companies collect $950 million a year in sales.[35] Considering this influx of dispensed medications, the county spends $330,000 a year to operate approximately 30 medication drop-off sites where consumers can discard their pills.[36] County officials who backed the ordinance claimed drug companies should bear the cost of disposing their products for the sake of the environment and their consumers' health.[37] Yet, drug manufacturers estimated that the annual cost of complying with the ordinance would be $1.2 million a year as compared to the county's estimate of $330,000.[38] Officials for the county argued that the manufacturers could recoup their costs by raising prices in Alameda County by one cent for each $10 in sales.[39] Given these differences in opinion, pharmaceutical trade groups filed suit in federal court,

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34.Bryan Cook, Comment, *$H_2Whoa?!$: An Examination of the Presence of Pharmaceuticals in America's Waters*, 35 J. Legal Med. 211, 16 (2014).
35.Mark Lowery, *Federal Court Upholds Groundbreaking Drug-Disposal Law,* Modern Medicine Network (Jun. 16, 2015), http://drugtopics.modernmedicine.com/drug-topics/news/federal-court-upholds-groundbreaking-drug-disposal-law?page=0,1.
36. Bob Egelko, *Alameda County's Pioneering Drug Disposal Law Upheld in Federal Court*, SFGate (Sept.30,2014), http://www.sfgate.com/bayarea/article/Alameda-County-s-pioneering-drug-disposal-law-5791624.php.
37.*Id*.
38.*Id*.
39.Mark Lowery, *Federal Court Upholds Groundbreaking Drug-Disposal Law,* Modern Medicine Network (Jun. 16, 2015).

alleging an unconstitutional burden on interstate commerce, in violation of the Commerce Clause.[40]

The pharmaceutical manufacturer trade groups claimed the ordinance was unconstitutional because it was a "*per se* violation of the [Commerce C]lause," and created an inherently excessive burden on interstate commerce.[41] More specifically, they argued that the ordinance was an illegal violation of interstate commerce since it placed local costs on out-of-state producers. The trade groups found further support from the California Healthcare Institute, who claimed that these take-back programs may lead to higher priced medications and that the financial burden was unfairly placed on a single stakeholder, the manufacturer, rather than spread amongst other stakeholders, such as local governments, hospitals, pharmacies, healthcare organizations, and patients.[42]

In *Pharmaceutical Research and Manufacturers of America v. County of Alameda*, the court granted summary judgment in favor of Alameda County, stating that the "[d]efendants have adequately shown that the Ordinance serves a legitimate public health and safety interest, and that the relatively modest compliance costs producers will incur should they choose to sell their products in the county do not unduly burden interstate commerce.[43] This decision was appealed to the U.S. Court of Appeals, where, in a 3-0 decision, the Ninth Circuit affirmed the lower court's ruling. The court held that the county's ordinance does not infringe against, regulate, or unreasonably burden interstate business since it applied to every manufacturer supplying in the area.[44] The court further added, "[t]he fact that the county could run a similar program does not nullify the

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40.Pharmaceutical Res. & Manufacturers of Am. v. County of Alameda, 967 F.Supp.2d 1339 (N.D. Cal. Aug. 28, 2013), *aff'd*, 768 F.3d 1037, (9d Cir. 2014).
41.*Id*. at 1344.
42.Letter from Consuelo Hernandez, Vice President State Gov't Affairs, California Healthcare Inst, to Honorable Nathan A. Miley, Pres. Alameda County Board of Supervisors (July 9, 2012), http://calpsc.org/admin-document-upload/doc-download/823-california-healthcare-institute-letter-of-opposition-7-9-12. See Cook, *supra* note 34, at 232-33.
43.*Pharm. Research & Mfrs. & Manufacturers of Am. v. Cnty. County of Alameda*, 967 F.Supp.2d 1339, 1346 (N.D. Cal. 2013), *aff'd*, 768 F.3d 1037, (9d Cir. 2014).
44.*Pharm. Research & Mfrs. & Manufacturers of Am. v. Cnty. County of Alameda*, 768 F.3d 1037 (9d Cir. Sept. 30, 2014).

program's benefits…Moreover, even if the Ordinance did nothing other than save the county money that is not equivalent to 'no public benefits.'"[45]

Because the pharmaceutical industry has the lobbying power to prevent similar manufacturer-sponsored drug disposal programs at the state level, the court's decision to uphold these local ordinances was decisive in regards to future legislation.[46] These judgments concerning local take-back ordinances may lead to significant action in both California and Washington state governments. Scholars have noted that, in 2013, the California legislature considered legislation modeled in part after the Alameda County ordinance. Likewise, the Washington legislature introduced a bill requiring manufacturers to establish a drug take-back program in 2011, which was reintroduced in 2012.[47] With the success of both California's and Washington's localized take-back ordinances, nine state governments have introduced, but not yet passed, pharmaceutical take-back legislation.[48] If federal courts are willing to uphold drug take-back programs, perhaps more state or local governments will be inclined to develop similar legislation.

IMPLEMENTING LOCAL TAKE-BACK PROGRAMS IN NORTH CAROLINA

The EPA, FDA, and DEA highly recommend that individuals take their expired or unwanted pharmaceuticals to drug take-back programs and disposal sites and only trash drugs if there are no programs available in the area. Despite the fact that some states readily maintain take-back initiatives, these programs are commonly underfunded and are primarily available in larger cities.[49]

45.*Id*. at 1045 (citing *United Haulers Ass'n Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth*., 550 U.S. 330, 346).
46.Mark Lowery, *Federal Court Upholds Groundbreaking Drug-Disposal Law,* Modern Medicine Network (Jun. 16, 2015).
47.Caroline Wick, Comment, *Mandatory Drug Take-Back Programs: Will They Survive the Dormant Commerce Clause Challenge?*, 27 Tul. Envtl. L.J. 371, 391 (2014).
48.*Id*. at 391.
49.*Id*. at 375.

In North Carolina, the total number of retail prescription drugs filled at pharmacies during 2014 was 102,887,597.[50] Considering the large quantity of prescription drugs dispensed within the state, there are only 193 locations, primarily local law enforcement agencies and police departments, which operate throughout the year as drug disposal sites.[51] These locations are unevenly dispersed throughout North Carolina's 100 counties, not properly publicized, and, given their settings, could dissuade some consumers from taking action.[52] Even though the biannual National Take Back Days raise awareness for the necessity of proper pharmaceutical disposal, they are too infrequent, and are too limited to make a significant impact in North Carolina.[53]

As part of the National Take Back Day held on September 27, 2014, North Carolina had 74 groups of law enforcement participating at 119 collection sites, and a total weight of 10,154 pounds of pharmaceuticals collected.[54] Considering Virginia's participation of 146 groups of law enforcement, 210 collection sites, and a total of 21,872 pounds, North Carolina's performance should have equaled or surpassed Virginia's efforts, due to North Carolina's larger population.[55] Based on the 2014 United States Census, North Carolina ranks in the top ten for highest state population, with an estimate of 9,943,964 people.[56] During the same National Take Back Day, other heavily populated states maintained significantly higher numbers than North Carolina: they had more than 150 groups of law

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50.The Henry J. Kaiser Family Foundation, *Total Number of Retail Prescription Drugs Filled at Pharmacies*, KFF (Jun. 1, 2015), http://kff.org/other/state-indicator/total-retail-rx-drugs/?state=NC.

51.N.C. Dept. of Ins., *North Carolina Operation Medicine Drop*, N.C. D.O.I. (last visited Feb. 13, 2016), https://apps.ncdoi.net/f?p=102:1:8854982067030::NO:::.

52.*Id*.

53.*Id*.

54.Drug Enforcement Administration, *Diversion Control Program: National Take Back Day, September 27, 2014*, DEA (Sept. 27, 2014), http://www.dea.gov/divisions/hq/2014/hq110514.pdf.

55.*Id*.

56.U.S. Census Bureau, *American Fact Finder: Community Facts*, (last visited Jun. 16, 2015), http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk.

enforcement, more than 200 collection sites, and the majority had double the weight of pharmaceuticals collected.[57] Going forward, supporters of drug disposal programs in North Carolina should not be concerned with its ranking or numbers in regards to the National Take Back Days. Adhering to their newly implemented rule, the DEA will not continue to sponsor nationwide take-back events in order to prevent competition with local efforts conducted in accordance with the new regulations.[58] Realizing the impressive national total of 617,150 pounds, or 309 tons, from this past National Take Back Day and the call to action for which it creates, the question remains as to how successful localized efforts will be compared to those sponsored by the DEA.

Under North Carolina's Operation Medicine Drop, a statewide event sponsored by Attorney General Roy Cooper, the State Bureau of Investigation, local sheriffs and police, the North Carolina Department of Insurance, and the DEA, approximately 61 million doses of pharmaceuticals were properly disposed of in a span of five years.[59] During the week-long event held in March 2014, more than eight million doses of old prescription drugs and over-the-counter drugs were collected. However, as the collection results were tallied, it became apparent that the larger county police departments were responsible for the majority of the collections.[60] Similarly, statewide efforts should be made to establish permanent and diversified location sites, which in turn would prompt higher totals throughout the year.

However, initiating a local take-back program is not an easy task. One of the major obstacles concerning take-back initiatives is the amount of public education required to foster a successful event. Some earlier take-back events permitted only controlled substance disposal because the FDA and DEA maintained strict regulations on which drugs fell under the classification as well as those which could

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57.Drug Enf't Admin., *supra* note 50.
58.U.S. Dep't. of Justice: Drug Enf't Admin., *supra* note 30.
59.N.C. Dept. of Justice, *More Than 8 Million Pills Turned in During Operation Medicine Drop*, N.C. D.O.J. (Mar. 27, 2014), http://www.ncdoj.gov/getdoc/50606996-0e97-4ac3-9f0f-9539f056c2c3/More-than-8-million-pills-turned-in-during-Operati.aspx.
60.*Id*.

be mixed.[61] Because of the costs of separating medications, today, most take-back events allow for the comingling of controlled and non-controlled substances, as seen in Operation Medicine Drop.[62] Likewise, this comingling ensures the proper disposal of all pharmaceuticals in a non-retrievable fashion. However, sponsors of these events may specify that only controlled substances will be accepted and could offer a separate receptacle designated for non-controlled substances. Regardless of the classification, all of the collected pharmaceuticals should be securely stored or transferred until rendered non-retrievable. Becoming non-retrievable by incineration, the collected drugs will be incapable of being re-sold, repackaged, or re-dispensed.[63]

Another issue concerning the take-back event is safety. The DEA believes that it is imperative to establish active law enforcement participation for the safety of event participants and the community.[64] Because of the low physical security at such locations, the presence of law enforcement will help deter theft and prevent the diversion of controlled substances. Since there is not a national requirement for pharmaceuticals to be in their original packaging, nor is there a requirement that anyone provide personal information about themselves, their prescription, or their physician, some organizations are concerned that these events may incite greater crime.[65]

Although establishing a take-back event could be seen as an arduous task for a local organization, some alternative groups within North Carolina could help expand the effort. As noted by other scholars, the Veterans Health Administration (VA) medical system is the largest healthcare network in the United States and should be utilized in the expansion of local and statewide pharmaceutical take-back programs.[66] Noting the VA's extensive network of 1,700 care locations, its integrated medical system, and its on-site pharmacies

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61.U.S. Drug Enf't Admin., *supra* note 50.
62.N.C. Dep't. of Justice, *supra* note 55.
63.U.S. Dep't of Justice: Drug Enf't Admin., *supra* note 30.
64.*Id*.
65.*Id*.
66.Tamika Brown, Implications for a Drug Take Back Program in the Veterans Affairs Healthcare System (2014) (M.A. of Environmental Assessment thesis, North Carolina State University).

reaching 8.76 million veterans annually, the VA has the resources, facilities, and patrons to become a major benefactor.[67] Likewise, given the DEA's recent ruling, pharmacies, hospitals, and other medical facilities are now able to purchase containers for the disposal of pharmaceuticals.

Yet, some pharmacies are wary of forming partnerships with local take-back programs. According to the American Pharmacist Association, there are two major concerns: cost and liability.[68] Some American companies offering this disposal service price a set of 50 envelopes at $249 plus shipping and handling along with the additional charge of state tax.[69] Furthermore, pharmacies would incur the expenses of providing permanent receptacles, fees for transportation and disposal, as well as outreach and publicity materials. With respect to liability, the DEA ruling mandates that an employee be present at the receptacle site; therefore, the question of who would be liable if the receptacles are tampered with or stolen remains unanswered.[70]

Quite possibly, the easiest solution is to follow the examples set by Alameda County, California and King County, Washington. Having noted the successful ordinances in both locations, North Carolina state and local governments should devise a similar approach because drug manufacturers have the finances, accessibility, and manpower to assist disposal programs.

Located in North Carolina, The Research Triangle Park (RTP) is the largest research park in the country and is home to more than 200 companies in the fields of micro-electronics, telecommunications, biotechnology, chemicals, environmental sciences, and pharmaceuticals.[71] These RTP industries invest more than $296 million in research and development in North Carolina, which is double the average investment for other national innovation clusters, and could easily help fund, publicize, and supervise a drug disposal

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67.*Id*.
68.Desiree Hodges, Prescription Take-Back Programs 23 (March 26, 2015) (PharmD. Candidate 2015 thesis, New Mexico Pharmacists Association).
69.*Id*.
70.*Id*.
71.The Research Triangle Park, *About Us*, RTP (last visited Jun. 16, 2015), http://www.rtp.org/about-us/.

program within the state.[72] If RTP manufacturers challenge whether an ordinance could be successful long term, proponents of take-back programs should cite the British Columbia Waste Management Act of 1997.[73] The act fostered the Post-Consumer Pharmaceutical Stewardship Association, a group that placed collection bins in pharmacies throughout the province, and facilitated the transfer and incineration of collected pharmaceuticals.[74] The association, fully funded by pharmaceutical manufacturers and brand owners, helped collect 4,500 kilograms of medications from 75% of pharmacies in the area in 2000.[75] Only ten years later, 60,500 kilograms were collected from 96% of the area pharmacies. According to researchers, if the same amount of Americans participated in a similar manufacturer-sponsored disposal program, more than 5.4 million kilograms, or 12 million pounds, of pharmaceuticals would be collected.[76] Advocates of the drug take-back events should extend their North Carolina campaign to RTP since the site offers plentiful resources as well as a diverse field of related industries. In North Carolina, a manufacturer-sponsored drug take-back ordinance should be implemented to ensure that both urban and rural residents have access to facilities that can properly and safely dispose of unused pharmaceuticals.

CONCLUSION

Drug take-back initiatives have the potential to modernize the system of pharmaceutical distribution. Medical professionals could use the data collected from unused and overprescribed medications to streamline the healthcare system, which would have a positive impact on the environment and the overall health of society. If pharmaceuticals were prescribed as based on these findings, it is less likely they would be improperly disposed or consumed. Coincidentally, the Director of the Office of National Drug Control Policy projects a similar future of pharmaceutical disposal that will

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72.*Id*.
73.See Cook, *supra* note 34, at 16.
74.*Id*.
75.*Id*.
76.*Id*.

become "second-nature to most Americans, in much the same way as proper and responsible recycling of aluminum cans has become."[77] As clarified by the EPA's recently Proposed Rule, pharmaceutical waste poses a threat to the environment, to consumers, and to corporations responsible for their manufacture. Given the decisions in California and Washington requiring drug manufacturers to sponsor local take-back programs, many other counties and districts in North Carolina, and throughout the United States, could adopt similar ordinances. In regards to the current state of pharmaceutical development, these impending costs on pharmaceutical manufacturers may lead to raised prices and stricter guidelines regarding drug manufacture and distribution. However, upon realizing the health benefits of drug disposal programs, it is all a matter of give and take.

77.See Wick, *supra* note 47, at 391.