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COMMENTS OF THE RETAIL ASSOCIATIONS IN RESPONSE TO EPA'S PROPOSED MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

DOCKET ID NO. *EPA-HQ-RCRA-2007-0932*

I. INTRODUCTION AND SUMMARY

The Retail Industry Leaders Association ("RILA"), the Food Marketing Institute ("FMI"), the National Association of Chain Drug Stores ("NACDS"), the National Retail Federation ("NRF"), the National Grocers Association ("NGA"), and their members (collectively, the "Retail Associations") are pleased to submit these comments in response to EPA's proposed rule, entitled "Management Standards for Hazardous Waste Pharmaceuticals," 80 Fed. Reg. 58,014 (Sept. 25, 2015) ("Pharmaceutical Proposal"). In particular, the Retail Associations appreciate the opportunity to comment on the proposal to streamline the Resource Conservation and Recovery Act ("RCRA") regulations as they apply to retailers of prescription and over-the-counter pharmaceuticals ("OTCs") and dietary supplements. The Retail Associations are also submitting, under separate cover, comments on EPA's companion proposal to establish new rules for managing other hazardous wastes under RCRA. *See* 80 Fed. Reg. 57,918 (September 25, 2015).

The Retail Associations applaud EPA's efforts to streamline and tailor the RCRA regulations for hazardous waste pharmaceuticals. We believe the Agency is generally on the right path with respect to pharmaceuticals sent to disposal facilities, but think the Agency is mistaken in its view that pharmaceuticals are wastes when handled in reverse distribution or reverse logistics systems. In addition, there are several aspects of the Pharmaceutical Proposal that are unnecessarily and inappropriately stringent, ambiguous, or otherwise require modification.

Our specific comments on the rule are summarized briefly below:

Sector-Specific Strategy. The Retail Associations appreciate EPA's willingness to create streamlined, sector-specific RCRA rules. Many of the challenges that health care facilities face when complying with RCRA rules designed for industrial production facilities are also present in the retail sector. The Retail Associations strongly encourage EPA to continue to develop a sector-specific strategy for the retail sector.

Nicotine. The Retail Associations are pleased that EPA is considering possible amendments to the "P075" hazardous waste listing for nicotine and salts, in response to a request we previously made to the Agency. The current classification of low-concentration nicotine products (*e.g.*, gums, lozenges, patches, prescription inhalers/sprays, and e-cigarette products) as acutely

hazardous wastes is unjustifiable, given that (a) the human toxicity data that EPA originally relied upon for such a classification has been thoroughly discredited, (b) nicotine gums and lozenges are chewed/ingested by millions each day without fear of acute toxicity, (c) nicotine patches have likewise proven not to be acutely toxic to humans (even when misused by chewing or swallowing), and (d) the dilute nicotine liquids in prescription and e-cigarette products clearly do not meet the criteria for acute oral toxicity to laboratory animals given that even pure nicotine does not. Correction of the misclassification of low-concentration nicotine products would provide well over $40 million per year in regulatory relief to the retail sector. We believe this can best be done by exempting by name/category all low-concentration nicotine products currently on the market, and any future categories with comparable nicotine concentrations (*e.g.*, less than 3%). In the alternative, we would also support the reclassification of such products as non-acutely hazardous wastes.

Products in Reverse Distribution. We appreciate EPA's willingness to create a health care sector rule that takes into account existing sector practices that have environmental benefits, such as reverse distribution. However, we believe EPA has misunderstood the role of reverse distribution as it applies to prescription as well as OTCs and dietary supplements. Reverse distribution of prescription pharmaceuticals and reverse logistics of OTCs and dietary supplements serve essential business purposes of the retail sector and are not waste management activities. We request that EPA clarify that pharmaceuticals are not solid wastes if they are destined for use/reuse or reclamation. In addition, EPA should not reverse its long-standing guidance that pharmaceuticals destined for evaluation of potential credit are not solid wastes. Also, EPA should clearly state that pharmaceuticals sent for evaluation of potential use/reuse or reclamation options are not solid wastes, subject to RCRA, including the proposed requirements under the Pharmaceutical Proposal. Finally, EPA should establish a simple rule that unsold/returned products in good condition sent from a retailer to a reverse distributor or reverse logistics center for evaluation of use/reuse or reclamation options are not solid wastes subject to the RCRA rules, including the requirements under the Pharmaceutical Proposal.

Requirements for Reverse Distributors. We are asking EPA to reconsider the requirements it has proposed for reverse distributors. Several of the requirements are even more stringent than those that apply to large quantity generators (LQGs) or treatment, storage and disposal facilities. Such extreme requirements are out of sync with EPA's own assessment that pharmaceuticals in reverse distribution pose very little risk of release to the environment and that the parties involved have appropriate incentives to manage them responsibly. In particular, we propose alternatives to the requirements for unauthorized waste reports, biennial reports, contingency plans, on-site accumulation, and security.

Land Disposal Restrictions ("LDR") Requirements. EPA should modify the proposed LDR notification requirement for health care facilities so that such notifications do not have to include the waste codes for hazardous waste pharmaceuticals. EPA should also remove the requirements that health care facilities segregate wastes that are purportedly not eligible for combustion (*i.e.*, metal-bearing low-carbon hazardous waste pharmaceuticals). Such requirements would

eviscerate a primary benefit of the Pharmaceutical Proposal, which is that health care facilities need not make individual hazardous waste determinations. The imposition of the notification and segregation requirements is unreasonable given that EPA has stated that health care facilities are not equipped to make such hazard determinations. More fundamentally, EPA should recognize that the metal-bearing low-carbon hazardous waste pharmaceuticals can be combusted under the existing rules, or should change the rules to allow such combustion. In addition, EPA should establish an alternative treatment standard of combustion (at least for organic hazardous waste pharmaceuticals, if not all hazardous waste pharmaceuticals), so that such wastes can be combusted without having to unnecessarily test the resulting ash.

Residues in Containers. We support EPA's proposal to exempt residues in pharmaceutical containers but we are asking the Agency to clarify and/or modify a few relevant provisions. First, EPA should clarify that, under the proposed exemption for pharmaceutical residues in containers, dispensing bottles, vials and ampules can be emptied by using commonly employed practices. Second, the size of pharmaceutical containers eligible for the residue exemption should not be arbitrarily limited. Finally, destruction of empty containers should not be required, as we are not aware of a diversion risk and question whether EPA's authority extends to addressing any such risks that may exist.

***Key Provisions for Clarification/Modification*.** We are also commenting on and/or asking EPA to modify or clarify several other key provisions of the Pharmaceutical Proposal. First, EPA should allow additional time for transportation to reverse distributors, and for reverse distributors to evaluate pharmaceuticals. Second, EPA's advance notification and confirmation of delivery requirements are not necessary in reverse distribution where products are carefully tracked in the regular course of business. Third, inventory requirements for reverse distributors should be reduced, particularly with respect to non-prescription pharmaceuticals (*i.e.*, OTCs and dietary supplements), and electronic recordkeeping should be allowed. Fourth, EPA should clarify that distribution centers that temporarily store pharmaceuticals in transit to reverse distributors are not reverse distributors. Finally, the definition of non-creditable hazardous waste pharmaceuticals should be limited to what is not potentially creditable.

Key Provisions for Finalization. We support EPA finalizing as is three key aspects of the Pharmaceutical Proposal. First, we strongly support the proposed conditional exemption for hazardous waste pharmaceuticals that are also controlled substances, and encourage its rapid adoption by the states. The Drug Enforcement Administration ("DEA") rules for disposal of controlled substances will ensure that these wastes are properly managed, and removal of the obstacles posed by RCRA will facilitate collection and disposal of these pharmaceuticals. Second, we support EPA's proposal to prohibit the discharge of hazardous waste pharmaceuticals into sewer systems, as a useful and reasonable measure to help protect the nation's water supply. Third, we endorse EPA's proposal to exempt pharmaceuticals that are managed pursuant to the new pharmaceutical waste management standards from "counting" toward a facility's hazardous waste generator status.

The Retail Associations appreciate the opportunity to comment on the Pharmaceutical Proposal. We would welcome the opportunity to provide further input to EPA in order to ensure that any final rule makes sense for retailers of prescription pharmaceuticals, OTCs, and dietary supplements.

II. THE RETAIL ASSOCIATIONS AND THEIR INTEREST IN THIS RULEMAKING

The Retail Associations represent a broad cross section of the retail sector in the United States, including large and small companies, from chains with more than a thousand stores nationwide to regional companies with a handful of stores. Many of the Retail Associations' members fall within the scope of the Pharmaceutical Proposal because they meet the criteria for "health care facilities" as retailers of prescription pharmaceuticals, dietary supplements, and OTCs. A few of the Retail Associations' members may also meet the criteria of "pharmaceutical reverse distributor," to the extent that some of their facilities may receive and aggregate potentially creditable pharmaceuticals from other of their company facilities. Moreover, all of the member companies that sell pharmaceuticals have an interest in the rules for reverse distributors, even if they do not qualify as reverse distributors themselves, given that such rules may affect their options for managing unsold or returned pharmaceuticals. More details about each of the Retail Associations and its members follow.

- RILA is an organization of the world's most successful and innovative retailer and supplier companies – the leaders of the retail industry. RILA members represent more than $1.5 trillion in annual sales and operate more than 100,000 stores, manufacturing facilities, and distribution centers nationwide. The Association's member retailers and suppliers have facilities in all 50 states and the District of Columbia, as well as internationally, and employ millions of workers domestically and worldwide. Many of RILA's members operate pharmacies, and many more of RILA's members sell OTCs and dietary supplements.

- FMI proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. Many of FMI's members operate pharmacies and many more of FMI's members sell OTCs and dietary supplements.

- NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national

companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries.

- NRF is the world's largest retail trade association, representing discount and department stores, home goods and specialty stores, Main Street merchants, grocers, wholesalers, chain restaurants and Internet retailers from the United States and more than 45 countries. Retail is the nation's largest private sector employer, supporting one in four U.S. jobs – 42 million working Americans. Contributing $2.5 trillion to annual GDP, retail is a daily barometer for the nation's economy. NRF's "This is Retail" campaign highlights the industry's opportunities for life-long careers, how retailers strengthen communities, and the critical role that retail plays in driving innovation. Many of NRF's members operate pharmacies and many more of NRF's members sell OTCs and dietary supplements.

- NGA is the national trade association representing the retail and wholesale supermarkets that comprise the independent sector of the food distribution industry. An independent retailer is a privately owned or controlled food retail company operating a variety of formats. The independent supermarket sector is accountable for close to one percent of the nation's overall economy and is responsible for generating $131 billion in sales, 944,000 jobs, $30 billion in wages, and $27 billion in taxes. NGA members include retail and wholesale grocers, state grocers associations, as well as manufacturers and service suppliers.

Each of the individual associations and their members have a clear and strong interest in this rulemaking. Indeed, EPA, in its economic analysis for the proposal, specifically identified pharmacies as being among the affected facilities. *See* 80 Fed. Reg. at 58,075, Table 12 (Proposed Pharmaceuticals Rule Facilities Classified by NAICS Codes and Type of Facility).

Because the Pharmaceutical Proposal does not just regulate prescription pharmaceutical wastes but would also regulate OTCs and dietary supplement wastes, a much larger number of retail facilities would be affected by the rulemaking, including retail facilities that do not have pharmacies (*e.g.*, many grocery stores, convenience stores, and even office supply or hardware stores, to the extent that products such as hand sanitizers might be covered). Thus, EPA's estimates for the number of hazardous waste generators that would be subject to this rule is vastly underestimated. *See e.g.*, EPA, "Regulatory Impact Analysis of EPA's Proposed Regulations for the Management of Hazardous Waste Pharmaceuticals at Healthcare Facilities (June 2015), EPA Docket ID No. EPA-HQ-RCRA-2007-0932-0151, Exhibit ES-1 (Number of LQGs, SQGs, and CESQGs in the Affected Universe by Facility Type) (listing number of pharmacies generating hazardous waste but not showing other retail facilities that sell OTCs and dietary supplements covered by the rule). The number of retail facilities that EPA has failed to account for in its economic analysis could easily number in the tens of thousands.

As noted in the comments of RILA, FMI, NACDS, and NRF on the Agency's Notice of Data Availability ("NODA") on the applicability of RCRA to the retail sector, management of hazardous waste pharmaceuticals is of vital interest to retailers. *See* 79 Fed. Reg. 8926 (February 14, 2014) (NODA); Comments of the Retail Associations in Response to EPA's NODA on the Application of RCRA to the Retail Sector (May 30, 2014), Docket No. EPA-HQ-RCRA-2012-0426-0038 ("NODA Comments") (Exhibit 1).

III. THE RETAIL ASSOCIATIONS APPRECIATE EPA'S WILLINGESS TO CREATE STREAMLINED, SECTOR-SPECIFIC RCRA RULES, AND ENCOURAGE THE AGENCY TO CONSIDER A SIMILAR APPROACH FOR THE RETAIL SECTOR MORE GENERALLY

The Retail Associations are encouraged by EPA's recent focus on sector-specific standards for managing hazardous waste, as embodied in the alternative requirements for academic laboratories in 40 C.F.R. Part 262, Subpart K and the proposed requirements for health care facilities in the Pharmaceutical Proposal, which would be codified in 40 C.F.R. Part 266, Subpart P. In setting sector-specific standards for laboratories and health care facilities, EPA has recognized that these sectors face significant challenges from RCRA rules developed for industrial production facilities. *See* EPA, Final Rule, Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material at Laboratories Owned by Colleges and Universities and Other Eligible Academic Entities Formally Affiliated With Colleges and Universities," 73 Fed. Reg. 72,912, 72,915 (Dec. 1, 2008) ("Lab Rule") (discussing need for sector-specific rule for academic laboratories); 80 Fed. Reg. at 58,018 (discussing need for sector-specific rule for health care facilities).

The Retail Associations detailed their own challenges with the RCRA rules in our NODA Comments. In fact, the same factors cited by EPA as supporting its decision to propose a health care sector rule and to finalize an academic laboratory rule are present in the retail sector:

- **Patterns of Waste Generation**. EPA states that "many hazardous waste pharmaceuticals are generated unpredictably and in relatively small quantities by a number of different employees across the facility. This situation differs from a manufacturing facility where fewer employees in a few locations generate comparatively much larger volumes of a smaller range of hazardous wastes." 80 Fed. Reg. at 58,018 (discussing patterns of generation in the health care sector justifying separate rulemaking); *see also* 73 Fed. Reg. at 72,915 (discussing patterns of generation in academic laboratories justifying separate rulemaking). As the Retail Associations have previously explained to EPA, retail stores handle hundreds to tens of thousands of different products that could be hazardous wastes if discarded after being unsold/returned. *See* NODA Comments at 32. These products are handled by different types of store personnel, ranging from customer service clerks accepting a customer's returned item to a stock clerk removing out of date items from a shelf. *Id.* at 33. The

retail stores have very little control over when and how wastes are generated, i.e., by product recalls, seasonality, accidental product damage, and customer returns. *Id.* at 36.

- **Hazardous Waste Determinations.** EPA states that "under the current hazardous waste regulatory scheme, healthcare workers, whose primary focus is to provide care for patients, are typically responsible for making hazardous waste determinations since they are at the point of generation (*e.g.*, a patient's bedside). Yet, healthcare workers, such as nurses and doctors, do not typically have the expertise to make hazardous waste determinations." 80 Fed. Reg. 58,018 (discussing hazardous waste determinations in health care sector justifying separate rulemaking); *see also* 73 Fed. Reg. at 72,915 (discussing hazardous waste determinations in academic laboratories justifying separate rulemaking). The same holds true for retailers. Retailers buy, distribute, and sell products. They do not have specialized knowledge of those products' ingredients or properties that would enable them to make accurate hazardous waste determinations. While safety data sheets may offer some limited assistance in making hazardous waste determinations for some types of products, they are typically not available for prescription pharmaceuticals. Moreover, the store employees that handle unsold or returned consumer products typically experience high turnover. Accordingly, not only do they not possess the education to make detailed regulatory determinations, they may have few opportunities to gain comprehensive knowledge of a store's complete product line. *See* Retail Associations' NODA Comments at 34-35.

- **Variety of Wastes.** EPA states that "a healthcare facility can have thousands of items in its formulary at any one time and these may vary over time" and "come in many different forms, such as pills, patches, lozenges, gums, creams, and liquids, and are delivered by a variety of devices, such as nebulizers, intravenous (IV) tubing, syringes, etc." 80 Fed. Reg. 58,018 (discussing variety of wastes in health care sector justifying separate rulemaking); *see also* 73 Fed. Reg. at 72,915 (discussing variety of wastes in academic laboratories justifying separate rulemaking). Retailers manage products by stock keeping unit ("SKU"). In the retail sector, with tens of thousands of SKUs per store and hundreds of thousands across a national chain, keeping track of which SKUs would be hazardous wastes when discarded is a herculean task, complicated by frequent changes to product formulations or introductions of new products, marketed by thousands of different suppliers. The members of the Retail Associations estimate that they have hundreds to tens of thousands of different products that would be handled as hazardous waste if discarded after being unsold/returned. NODA Comments at 34.

By proposing the Pharmaceutical Proposal, EPA has responded to the challenges manifest in health care facilities grappling with the RCRA rules by proposing a rule that accounts for the unique settings and circumstances in which hazardous wastes are generated and managed in the health care sector, while also accommodating existing sector practices, such as reverse distribution. The Retail Associations strongly encourage EPA to continue the process initiated with the NODA and develop a sector-specific strategy to streamline compliance with hazardous

waste requirements in the retail sector while accommodating existing retail sector practices such as reverse logistics. Such a strategy might include recognition of the non-waste status of consumer products handled in reverse logistics systems, and a universal waste rule for those consumer products that are generated as wastes by the retail sector (and perhaps others).

IV. EPA SHOULD PROCEED WITH AMENDING THE "P075" HAZARDOUS WASTE LISTING FOR NICOTINE, TO REFLECT THE FACT THAT LOW-CONCENTRATION NICOTINE PRODUCTS ARE NOT ACUTELY HAZARDOUS

The Retail Associations are pleased that EPA has included in the proposal a request for comments on possible amendments to the hazardous waste listing for nicotine and salts (EPA Hazardous Waste No. P075). *See* 80 Fed. Reg. at 58,071-73. As noted in our comments on the NODA on the applicability of RCRA to the retail sector (which EPA cites as the basis for its request for comments), this issue is of vital interest to retailers. *See* 79 Fed. Reg. 8926; NODA Comments at 4-13.

In our comments on the NODA, we explained that there is a compelling case that low-concentration nicotine products (*e.g.*, nicotine gums, lozenges, patches, prescription inhalers and nasal sprays, and e-cigarettes) should be exempted from RCRA or reclassified from acutely hazardous wastes to non-acutely hazardous wastes. For example, it is self-evident that nicotine gums and lozenges that millions of people chew and/or ingest multiple times daily – with the encouragement of federal, state, and local health authorities, and the medical community more generally – are not acutely hazardous. An exemption or reclassification would provide tens of millions of dollars in annual regulatory relief to retail stores that, but for the misclassification of nicotine products, would either be conditionally exempt from RCRA regulation or subject to the substantially reduced requirements for small quantity generators ("SQGs").

We show below that low-concentration nicotine products are not acutely hazardous, notwithstanding EPA's concerns about potential limits on current knowledge about the toxicity of such products. We then provide additional information about the substantial economic benefits to be gained by correcting the misclassification of low-concentration nicotine products under the existing regulations. Finally, we discuss various options for remedying the misclassification, concluding that the best approach would be to explicitly exempt by name all the categories of low-concentration nicotine products currently on the market, and any future categories with comparable concentrations of nicotine (*e.g.*, less than 3%).

A. Low-Concentration Nicotine Products Do Not Meet the Regulatory Criteria for Acutely Hazardous Wastes.

EPA states that it "currently lacks sufficient information to conclude that low-concentration nicotine products are not acutely toxic," and asks for "animal and/or human toxicity data for these products." *See* 80 Fed. Reg. at 58,072. We first address the human toxicity data that the

Agency originally used as the basis for classifying nicotine as acutely toxic, and then turn to the toxicity of individual categories of products.

1. The Human Toxicity Data that EPA Originally Relied on to Classify Nicotine as Acutely Hazardous Has Been Demonstrated to be Erroneous.

EPA originally listed nicotine (and salts) as acutely hazardous wastes based primarily on a then-common estimate that the median lethal dose (LD50) to humans through oral administration is only 1 mg per kg of body weight (corresponding roughly to a fatal dose of 50-60 mg). *See* EPA Office of Solid Waste, Background Document entitled "Section 261.33 – Hazardous Waste from Discarding of Commercial Chemicals Products and the Containers and Spill Residues Thereof" (January 1981) ("CCP Background Document"), Appendix A (Exhibit 2). However, as we noted in our comments on the NODA, this estimate has since been thoroughly discredited. The U.S. Surgeon General recently stated that he could find no support for this figure. *See* Office of the Surgeon General, "The Health Consequences of Smoking – 50 Years of Progress" (2014) at 112, *available online at* http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf (Exhibit 3) ("a systematic literature search was performed …; however, no study was located as a source for an estimate of the dose that is fatal to humans, and the figure of 50–60 mg is poorly documented").

The source of the estimate was recently traced to "highly dubious self-experiments performed in the mid of the nineteenth century." *See* B. Mayer, Department of Pharmacology and Toxicology, Karl-Franzens University (Graz, Austria), "How much nicotine kills a human?" *Archives of Toxicology* (2014), *available online at* http://link.springer.com/article/10.1007/s00204-013-1127-0 (Exhibit 4). However, the 1 mg/kg value is clearly inconsistent with more recent "literature reports on nonfatal nicotine intoxications." *Id*. Indeed, researchers have long disputed the validity of the 1 mg/kg figure. *See, e.g.*, D. Matsushima, et al., "Absorption and Adverse Effects Following Topical and Oral Administration of Three Transdermal Nicotine Products to Dogs," *Journal of Pharmaceutical Sciences* (1995) (Exhibit 5) ("Studies of ingestion of tobacco or nicotine polacrilex gum by children – in which doses up to 6 mg/kg nicotine did not result in death – raise … questions about the usefulness of [the 1 mg/kg] estimated lethal oral dose of nicotine in humans"); S. Schneider, et al., "Internet suicide guidelines: Report of a life threatening poisoning using tobacco extract," *Journal of Emergency Medicine* (2010) (Exhibit 6) ("The fatal dose of nicotine for adults [has been] estimated to be [1 mg/kg] but doubts about the validity of these data have been expressed as survival without complication after repeated ingestion of significantly higher amounts of nicotine has been observed").

Clearly, the 1 mg/kg LD50 estimate that EPA originally used to classify nicotine as an acutely hazardous waste was erroneous. Accordingly, the Agency can no longer rely on this figure to continue classifying nicotine, much less low-concentration nicotine products, as acutely hazardous wastes.

2. Nicotine Gums and Lozenges Are Clearly Not Acutely Hazardous.

EPA's assertion that it lacks sufficient data to determine whether nicotine gums and lozenges are acutely hazardous is, quite frankly, baffling. Under the regulations, a waste can only be classified as acutely hazardous if "[i]t has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, [it exceeds certain criteria for acute toxicity in laboratory animals]." *See* 40 C.F.R. § 261.11(a)(2). In the case of nicotine gums and lozenges, the data on human toxicity that EPA is looking for is right under its nose. Since experiments on humans are generally frowned upon, the data necessarily cannot take the form of controlled studies. However, the millions of people who ingest these products multiple times each day provide even more powerful evidence that nicotine gum and lozenges are not "fatal to humans in low doses."

The U.S. Public Health Service has stated that nicotine gums and lozenges are "an effective smoking cessation treatment that patients should be encouraged to use." *See, e.g.*, U.S. Public Health Service, "Clinical Practice Guideline: Treating Tobacco Use and Dependence" (2008 Update), *available online at* http://bphc.hrsa.gov/buckets/treatingtobacco.pdf (Exhibit 7). The National Institutes of Health have indicated that it is safe for people to chew up to 24 pieces of nicotine gum each day, or ingest up to 20 nicotine lozenges each day. *See* NIH, MedlinePlus at http://www.nlm.nih.gov/medlineplus/druginfo/meds/a684056.html (Exhibit 8) ("Do not chew more than 24 pieces [of nicotine gum] a day") and http://www.nlm.nih.gov/medlineplus/druginfo/meds/a606019.html (Exhibit 9) ("Do not use … more than 20 [nicotine] lozenges per day"). The products are readily available without a prescription, and since the products were brought onto the market in the 1980's, millions of people have used the products safely. Indeed, the Food and Drug Administration ("FDA") in 2013 determined that it is safe for people to use nicotine gums and lozenges for extended periods, even if they simultaneously use other nicotine-containing products. *See* 78 Fed. Reg. 19,718 (April 2, 2013).

EPA explained in 1981 that wastes should be classified as acutely hazardous only if they are "extremely powerful poisons." *See* CCP Background Document at 22. In particular, according to the Agency, a waste should be classified as acutely hazardous only if "ingestion of less than a teaspoonful … would be fatal to an adult." *Id*. Individual pieces of nicotine gum or nicotine lozenges are approximately one teaspoon in size, and they obviously are not "fatal to an adult." Thus, there can be no doubt that these products are not acutely hazardous as defined under the RCRA regulations.

3. Nicotine Patches Are Not Acutely Hazardous.

Nicotine patches are obviously not intended to be chewed or ingested. Indeed, it is difficult to imagine a scenario in which a person might swallow a nicotine patch. However, we are aware of one study in which adult volunteers chewed on unused nicotine patches, and while some adverse effects were noted, none were lethal. *See* F. Harchelroad, et al., "Oral absorption of nicotine from transdermal therapeutic systems," *Veterinary and Human Toxicology* (1992). Another study reported on incidents in which young children had "bitten, chewed, or swallowed part of a

patch." *See* A. Woolf, "Childhood Poisoning Involving Transdermal Nicotine Patches," *Pediatrics* (1997) ("Woolf Study") (Exhibit 10). Of 18 cases, 13 involved no symptoms; the remaining 5 children had symptoms ranging from fussiness/fatigue to a burning tongue or vomiting, but "[a]ll recovered fully." *Id.* Thus, the patches do not appear to meet the RCRA criteria for acutely hazardous by oral administration.

Although EPA originally listed nicotine as acutely hazardous based on dermal toxicity, as well as oral toxicity, *see* CCP Background Document, Appendix A, it seems clear that nicotine patches are not acutely hazardous by dermal contact, inasmuch as their very purpose is to be applied to the skin. Moreover, the Woolf Study (cited above) reported on 18 incidents in which young children were dermally exposed to nicotine patches. In half the cases, the children showed no symptoms, while in the other half, the children exhibited symptoms ranging from fussiness, pallor, or skin irritation to nausea or dizziness. Once again, "[a]ll recovered fully." In a separate study, the same researcher reported on "[n]ine cases of dermal exposure to 2-20 transdermal nicotine patches … result[ing] from either intentional misuse or suicide attempts [most of which were accompanied by] exposure to other drugs." *See* A. Woolf, et al., "Self-poisoning among adults using multiple transdermal nicotine patches," *Journal of Toxicology – Clinical Toxicology* (1996) (Exhibit 11). Although "[a]ll suffered medical complications" and most required hospitalization, "all recovered." *Id.* While these studies do indicate that nicotine patches may pose a risk, such risks do not rise to the level of warranting an acutely hazardous waste listing.

4. Nicotine Inhaler, Spray, and E-Cigarette Liquids Do Not Meet the Regulatory Criteria for Acutely Hazardous Wastes.

The Retail Associations are not aware of any direct studies on the human toxicity of low-concentration nicotine liquids such as are found in nicotine inhalers, sprays, and e-cigarettes. While we do not think these products are acutely toxic to humans for the reasons set forth in our comments on the NODA, *see* NODA Comments at 7-8, we recognize that the Agency is reluctant to rely on the types of extrapolations discussed in those comments. *See* 80 Fed. Reg. at 58,072 ("The Agency does not think that linear extrapolations from toxicity levels determined using higher-concentration nicotine products can be used to characterize the acute toxicity of low-concentration nicotine-containing products"). However, in the absence of adequate human toxicity data, the regulations specify that the classification should be based on the toxicity of the materials to laboratory animals. With respect to oral toxicity, the standard of acute toxicity is whether the wastes "have an oral LD 50 toxicity (rat) of less than 50 milligrams per kilogram." *See* 40 C.F.R. § 261.11(a)(2). In the present case, there can be no doubt that low-concentration nicotine liquids do not qualify as acutely hazardous under this standard, since even *pure* nicotine does not.

The Committee for Risk Assessment ("RAC") of the European Chemicals Agency ("ECHA") recently issued a report summarizing available toxicity information on nicotine. *See* ECHA, "RAC Opinion Proposing Harmonized Classification and Labeling at EU Level of Nicotine" (adopted September 10, 2015), *available online at*

http://echa.europa.eu/documents/10162/f9510930-4e5e-45ff-bb3a-888cefaf6592 (Exhibit 12). After reviewing numerous studies, RAC concluded that "the oral LD50 of nicotine in rats ranges from 52.5 to 70 mg/kg, while the LD50 for nicotine sulphate in rats ranges from 56.7 to 83 mg/kg." *Id*. at 5. The studies referenced by RAC included the following:

- Lazutka, F.A., *et al*., "Toxicological evaluation of the insecticide nicotine sulfate," Hyg. Sanitation 34(5) at 30-33 (1969) (reporting LD50s of 52.5 mg/kg for nicotine and 56.7 for nicotine sulfate).

- Yam, J., *et al*., "Comparison of the up-and-down method and the fixed-does procedure for acute oral toxicity testing," 29 *Food and Chemical Toxicology* at 259-263 (1991) (Exhibit 13) (reporting an LD50 of 70 mg/kg for nicotine).

- Van den Heuvel, M., *et al*., "The international validation of a fixed-dose procedure as an alternative to the classical LD50 test," *Food and Chemical Toxicology* 28:7, at 469-482 (1990) (Exhibit 14) (reporting an LD50 of 70 mg/kg for nicotine).

- Ben-Dyke, R, *et al*., "Acute toxicity data for pesticides" (1970) (reporting an LD50 of 70 mg/kg for nicotine).

- Sine, C., "Nicotine," *Farm Chemicals Handbook* (1993) (reporting an LD50 of 50-60 mg/kg for nicotine).

- Vernot, E.H., *et al*., "Acute toxicity and skin corrosion data for some organic and inorganic compounds and aqueous solutions," 42 *Toxicology and Applied Pharmacology* at 417-423 (1977) (Exhibit 15) (reporting an LD50 of 75 mg/kg for nicotine sulfate).

- Gaines, T.B., "The acute toxicity of pesticides to rats." 2 *Toxicology and Applied Pharmacology* at 88-99 (1960) (Exhibit 16) (reporting an LD50 for nicotine sulfate of 83 mg/kg).

- Trochimowicz, H.J., *et al.,* "Heterocyclic and miscellaneous nitrogen compounds," Patty's Industrial Hygiene and Toxicology (4th edition, Ed. John Wiley & Sons, Inc., New York, 1994) at 3374-79 and 3489-91 (reporting an LD50 for nicotine of 50-60 mg/kg).

- Dutch Expert Committee on Occupational Safety ("DECOS"), "Nicotine: Health-based Reassessment of Administrative Occupational Exposure Limits" (March 30, 2004), *available online at* http://www.gezondheidsraad.nl/sites/default/files/0015105_0.pdf (Exhibit 17) (referencing a study, cited as "Ray91," that reported an LD50 for nicotine of 188 mg/kg).

o Ambrose. A.M., *et al*., "Some comparative observations on l-nicotine and myosmine," *Proceedings of the Society for Experimental Biology and Medicine*, 63(2) at 423 (1946) (reporting an LD50 for nicotine of 188 mg/kg).

ECHA did not identify, and we have not found, even a single study that reported an oral LD50 (rat) value of less than 50 mg/kg. Given the overwhelming data that the LD50 for nicotine is higher than this value, it is clear that *pure* nicotine does not meet the oral toxicity criteria for an acutely hazardous waste (*i.e.*, "oral LD 50 toxicity (rat) of less than 50 milligrams per kilogram"). *See* 40 C.F.R. § 261.11(a)(2). Even in the absence of any tests on low-concentration nicotine liquids, the same would obviously be true for such products. Accordingly, nicotine inhaler, spray, and e-cigarette liquids do not meet the RCRA regulatory criteria for acutely hazardous wastes.

B. Correction of the Misclassification of Low-Concentration Nicotine Products Would Provide Substantial Regulatory Relief to the Retail Sector

In our comments on the NODA, we estimated that reclassification of low-concentration nicotine products as non-acutely hazardous wastes would provide well over $40 million per year in regulatory relief to the retail sector. *See* NODA Comments at 9-12. In the interest of avoiding unnecessary duplication, we do not repeat the underlying analysis here. However, we want to highlight some new information that underscores the reasonableness of that analysis, and suggests that it was even more conservative than previously thought.

First, we note that in our original analysis, we used two different methodologies to estimate that that the misclassification of low-concentration nicotine products caused approximately 12,000 retail stores to be subject to the RCRA requirements for large quantity generators ("LQGs"), rather than SQGs or conditionally exempt small quantity generators ("CESQGs"). We have since used a third methodology that generally supports the prior estimate. In particular, we searched the latest data (2013) in EPA's Biennial Report ("BR") database, available on the Agency's website at http://www2.epa.gov/enviro/br-search, to identify all the generators that reported generating P075 (*i.e.*, nicotine) wastes. We then identified all of the generators in this group that were readily recognizable as retail facilities. The total was 7,321 retail facilities that reported generating P075 wastes. Although only 4,576 of these facilities reported being LQGs, several members of the Retail Associations have indicated that they *operate* significantly more stores as LQGs than they *report* as LQGs. Specifically, they operate many or all of their stores as LQGs, due to uncertainties about if/when they might exceed the LQG limit of 1 kg/month of acutely hazardous wastes (*e.g.*, P075), but then only report as LQGs those stores that actually end up exceeding the LQG limit. Moreover, the number of stores that are being operated as LQGs in this manner far exceeds the number that reported as P075 generators (*i.e.*, 7,321), since a facility would not be required to report as a P075 generator if it ended up being an SQG or CESQG. In addition, it is widely recognized that many retailers have only recently become aware of their potential obligations under RCRA, such that they might not have reported as

necessary in 2013. In light of these factors, the prior estimate of 12,000 retailer facilities affected by the misclassification of nicotine seems almost certain to be low.

Second, we previously made a conservative estimate that the cost per facility of the misclassification of nicotine wastes was between $3,024 and $5,515 per year. However, under EPA's proposal to overhaul the RCRA requirements for hazardous waste generators, which the Agency issued at the same time as its proposal on pharmaceutical wastes, the costs would escalate dramatically. *See* 80 Fed. Reg. 57,918 (September 25, 2015). As just one example, a store that qualifies as an LQG based on the misclassification of nicotine would become subject to the proposed requirement to keep records on all the determinations it makes that other individual wastes are non-hazardous. *Id*. at 57,993 (proposed to be codified at 40 C.F.R. § 262.11(e)). As discussed more fully in our separate comments on that other proposal, a store might be expected to have to prepare and maintain records on 10,000 to 25,000 such determinations in the first year alone, at a cost of between $12 and $100 each. While a large chain could "spread" the costs over numerous facilities, the per store costs would still be high (and for small chains or individual retailers, the costs could be staggering). As a result, our prior estimate of the costs of nicotine misclassification, which were probably conservative to begin with, may be even more conservative now.

C. EPA Should Reject Narrow Options for Addressing the Misclassification of Low-Concentration Nicotine Products, in Favor of a More Comprehensive Approach

EPA has requested comments on three different approaches for addressing the issue of misclassification of nicotine. *See* 80 Fed. Reg. at 58,072-73. Each option is considered separately below. For the reasons discussed, the Retail Associations strongly favor an exemption by name for all categories of low-concentration nicotine products currently on the market, as well as an exemption for any future categories with comparable concentrations of nicotine (*e.g.*, less than 3%).

1. EPA's First Option of Exempting Only FDA-Approved Over-the-Counter Smoking Cessation Products Would Be Helpful, but Unnecessarily Narrow

The first approach mentioned by EPA would be to issue an exemption from the P075 listing for "FDA-approved over-the-counter nicotine-containing smoking cessation products." *See* 80 Fed. Reg. at 58,072. Such an exemption apparently would cover nicotine gums, lozenges, and patches, but it would not cover prescription inhalers/sprays or e-cigarette products. While a limited exemption of this type would be helpful, the Retail Associations do not see any basis for the limitation. As discussed above, none of the low-concentration nicotine products meet the RCRA definition of acutely hazardous wastes. The fact that some of the products (*i.e.*, inhalers and sprays) "require a prescription to purchase" and use, *id.*, does not in any way affect this conclusion. Similarly, the fact that "e-cigarettes have not been approved by the FDA as smoking cessation products," *id*., does not change the fact that they do not meet the criteria for acutely hazardous wastes.

For RCRA purposes, the status of the products as FDA-approved, over-the-counter, and/or smoking cessation products is simply irrelevant. The only legitimate question is whether they satisfy the criteria for acutely hazardous wastes. Since none of the products meet such criteria, as discussed above, they should all be exempt from the P075 listing.

Although limiting the exemption to nicotine gums, lozenges, and patches would provide some regulatory relief to the retailers currently affected by the misclassification of low-concentration nicotine products, the more appropriate and helpful exemption would be to exempt prescription nicotine products and e-cigarette products, as well as over-the-counter smoking cessation products. Retail pharmacies almost invariably market prescription nicotine products (*e.g.*, inhalers and sprays), as well as the over-the-counter smoking cessation products. Other retailers (*e.g.*, grocery stores and convenience stores) that market the over-the-counter smoking cessation products also commonly carry e-cigarette products. Thus, if only over-the-counter smoking cessation products are exempted from the P075 listing, virtually all of the relevant retailers will be carrying other low-concentration nicotine products that would be subject to the listing. Given the low LQG threshold for such products (*i.e.*, 1 kg/month), some of these stores would likely continue to operate as LQGs, out of concern that they might exceed the threshold at any time. While EPA has separately proposed to enable hazardous waste generators to maintain their generator status (*e.g.*, SQG or CESQG) if they exceed an LQG threshold only on an episodic basis, as we explain in our separate comments on that rulemaking, the Agency's proposal would be of only limited help. As a result, even if that proposal were to be finalized, the problems with misclassification of any low-concentration nicotine products would persist.

2. EPA's Second Option of Establishing a Concentration-Based Exemption for Low-Concentration Nicotine Products Is More Promising, But May Require Some Modifications

The second approach mentioned by EPA would be to issue a concentration-based exemption from the P075 listing for low-concentration nicotine products. *See* 80 Fed. Reg. at 58,072-73. To the extent that this option would exempt all of the low-concentration products, the Retail Associations would favor it. However, the Agency's discussion of this option raises important questions about how such an exemption would be structured, such as whether it would list exempted product categories or simply provide a numerical concentration limit, and whether it would exempt the products from all RCRA regulation or just reclassify them as non-acutely hazardous wastes. We see advantages and disadvantages to each approach, as outlined briefly below:

- A rule identifying the specific product categories covered (*e.g.*, gums, lozenges, patches, prescription inhalers/sprays, and e-cigarette products) has the advantage that it would be easier for regulators and the regulated community to determine which products would be covered. However, it would also complicate matters in the future, as new products might be developed. For this reason, we believe the optimal approach would be a hybrid, listing

product categories that that are known to be misclassified, and providing a concentration-based exemption that could be used for other product categories.

- o A concentration-based exemption would require generators to determine the nicotine concentration in each product. However, in many instances, that information is not readily available on product packaging, inserts, or related documentation. To minimize burdens on generators, we think EPA should exempt categories by name, wherever possible. The Agency has also expressed concern that the nicotine concentration in products not regulated by FDA (*e.g.*, e-cigarettes) may be "unpredictable." *See* 80 Fed. Reg. at 58,072. However, FDA is currently engaged in a series of rulemakings that are likely to result in FDA controls over the content of e-cigarettes. *See, e.g.*, 79 Fed. Reg. 23,142 (April 25, 2014) (proposing to designate e-cigarettes as tobacco products subject to FDA controls). Moreover, even before such government controls, we believe the larger manufacturers of e-cigarettes have internal controls and procedures to ensure the consistency of their products. Such manufacturers might be able to provide certifications or other documents sufficient to ensure that the products are below any numerical concentration threshold that might be established (although, as noted above, our preference is for a categorical exemption for e-cigarette products, as well as for the other current product categories).

- o Because the main concern that retailers have with the current regulation of low-concentration nicotine products is that such products are regulated as acutely hazardous wastes subject to a 1 kg/month LQG threshold, it is of limited importance to the industry whether these products are completely exempted from regulation or merely reclassified as non-acutely hazardous wastes. However, we believe that a total exemption is likely warranted, given that the concentrations of nicotine in the products are generally comparable to those in tobacco products which are not regulated as hazardous wastes. *See* NODA Comments at 8-9 (discussing ordinary filtered cigarettes and smokeless tobacco). In addition, any environmental risks associated with the small quantities of nicotine products discarded by retailers or other non-household generators (*e.g.*, healthcare facilities) are almost certainly far lower than the risks associated with the much larger quantities discarded by households (either used or unused). Moreover, we note that an exemption would be a simpler solution from a regulatory perspective. If EPA were to reclassify low-concentration nicotine products as non-acutely hazardous wastes, it would have to establish a new waste code, issue new treatment standards for that waste code under the RCRA land disposal restrictions ("LDR") program (which might, at least initially, be the same as for P075), and take steps to ensure that TSDFs authorized to manage P075 wastes could continue to handle the new waste code without interruption.

In light of the above, the Retail Associations believe that the best approach would be establish an exemption for all of the specific categories of low-concentration nicotine products currently on the market, and for any future categories with comparable concentrations of nicotine (*e.g.*, less

than 3%). However, in the alternative, we would also support the reclassification of such product categories as non-acutely hazardous wastes. Either approach would address our main concern with misclassification of the products as acutely hazardous wastes, and would be protective of human health and the environment.

3. EPA's Third Option of Regulating Low-Concentration Nicotine Products, Including E-Cigarette Products, as Pharmaceutical Wastes Would Provide Only Limited Regulatory Relief

The third and final approach mentioned by EPA for addressing the issues associated with low-concentration nicotine products would be simply to regulate them as pharmaceutical wastes under the proposed Subpart P of 40 C.F.R. Part 266. However, this approach would perpetuate the misclassification of these products as acutely hazardous wastes. Moreover, it would not provide the full measure of regulatory relief that is warranted.

Under this approach, retailers that currently qualify as LQGs based solely on their nicotine wastes would not have to "count" such wastes toward their generator status, and thus could qualify as CESQGs or SQGs – but only if they manage the nicotine wastes pursuant to the new Subpart P. If the nicotine wastes are potentially creditable and sent to a pharmaceutical reverse distributor, they would be subject to only limited requirements in the hands of the retailer, but would become subject to essentially full regulation after being evaluated by the pharmaceutical reverse distributor. Moreover, if the nicotine wastes are non-creditable and sent to a TSDF, they would be subject to significant requirements, including the requirement to use a hazardous waste transporter and a hazardous waste manifest.

However, given that the low-concentration nicotine wastes are not acutely hazardous (and may not be hazardous at all), these regulatory requirements are not warranted and represent an undue burden on retailers and the rest of the regulated community. A complete exemption would enable the low-concentration nicotine wastes to be managed as non-hazardous wastes. Alternatively, a reclassification of these products as non-acutely hazardous wastes would enable them, in most cases, to be managed as CESQG or SQG wastes, depending upon the generator's total rate of hazardous waste generation (including the low-concentration nicotine products). Particularly in those situations where the generator would qualify as a CESQG, these results would be better than imposing the proposed Subpart P controls.

Notwithstanding the above, if EPA does not move forward with an amendment to the P075 listing, the Retail Associations would favor taking the minimal step of allowing all low-concentration nicotine products to be managed as pharmaceutical wastes under proposed Subpart P. For both over-the-counter and prescription smoking cessation products (*e.g.*, gums, lozenges, patches, inhalers, and sprays), it seems clear that the products would qualify as pharmaceuticals and thus be eligible for Subpart P. *See, e.g.*, 80 Fed. Reg. at 58,084 (proposed to be codified at 40 C.F.R. § 266.500) (defining pharmaceutical to include "any chemical or biological product that is intended for use in the … cure, mitigation, care, treatment, or prevention of disease or

injury of a human"). However, the Agency requests comments on "whether [it] should include e-cigarettes and nicotine-containing e-liquids for the e-cigarettes within the scope of the definition of pharmaceutical." *Id.* at 58,073.

We believe that these e-cigarette products would also fall within the proposed definition of pharmaceutical, inasmuch as that definition explicitly covers "any chemical or biological product that is intended to affect the structure or function of the body of a human." *Id*. at 58,084 (proposed to be codified at 40 C.F.R. § 266.500). Moreover, e-cigarettes are used by many people to help them stop smoking regular cigarettes (*i.e.*, to "cure" or "mitigate" their addiction to regular cigarettes), although the efficacy and advisability of such use may be a matter of debate. *See, e.g.*, National Institute on Drug Abuse, "Drug Facts: Electronic Cigarettes" (August 2015) at 3 ("at this point it is unclear whether e-cigarettes may be effective as smoking-cessation aids"), *available online at* https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/drugfacts_e-cigs_9_15.pdf (Exhibit 18). Accordingly, discarded e-cigarette products are properly classified as pharmaceutical wastes under the proposal. This classification would also help ensure that retailers would obtain at least some degree of regulatory relief from the misclassification of nicotine for the full range of low-concentration nicotine products, which is of critical importance for the reasons discussed above.

V. EPA SHOULD MODIFY THE PHARMACEUTICAL PROPOSAL TO REFLECT THE FACT THAT REVERSE DISTRIBUTION AND REVERSE LOGISTICS ARE NOT WASTE MANAGEMENT PROCESSES

The Retail Associations are encouraged by EPA's willingness to recognize the importance of beneficial sector-specific practices, such as reverse distribution, and to facilitate regulatory compliance for such practices by creating a streamlined set of hazardous waste rules for the health care sector. However, we believe EPA has misunderstood the role of reverse distribution as it exists in the retail sector. We note that the process for consolidating *prescription* pharmaceuticals for purposes of determining manufacturer credit is generally known as"reverse distribution." However, consumer products, including OTCs and dietary supplements, are commonly sent from a store to a "return center" or to a third party logistics provider and consolidated in a process known as "reverse logistics."

Reverse distribution of prescription pharmaceuticals and reverse logistics of other consumer products, including OTCs and dietary supplements, are essential business processes of the retail sector. In retail, products are moved through these processes for purposes of inventory management, assessment of manufacturer credit, accounting (including tax), product recall confirmation, sale (*e.g.*, through liquidation), donation for use, and reclamation of commercial products. These processes function seamlessly and contribute billions of dollars to the retail business each year. Moreover, the products handled in reverse distribution and reverse logistics in the retail sector are in substantially the same form and packaging as products handled safely by retailers in forward distribution, by store personnel, and by consumers. These processes are part of the retailer's continuous process of distributing and selling products. Products sent

through reverse distribution and reverse logistics are not wastes. Nor are these processes waste management.

To be clear, retailers have separate waste management systems for items that are not suitable for use, such as broken or leaking packages. Such items are not sent through reverse distribution or reverse logistics, but are segregated in the stores and sent off-site from the stores for proper waste management.

EPA's proposal to modify its policy regarding the status of pharmaceuticals in reverse distribution jeopardizes this hugely important retail process. EPA proposes to define all pharmaceuticals sent to a reverse distributor as solid wastes. *See* Pharmaceutical Proposal at 58,043 ("the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical."). However, this view is fundamentally flawed. We discuss below a few key scenarios in which pharmaceuticals going through reverse distribution or reverse logistics would not qualify as solid wastes, and thus should not be subject to any RCRA regulation, including the proposed new Subpart P.

A. EPA Should Clarify That Pharmaceuticals Destined for Use or Reclamation Are Not Solid Wastes Subject to the Pharmaceutical Proposal

EPA's proposal seems to ignore the possibility that some pharmaceuticals going through reverse distribution or reverse logistics are destined to be used or reclaimed. In fact EPA, in a webinar on the proposed rule, stated that the Agency believes "little to no" redistribution of pharmaceuticals is actually occurring during reverse distribution. This is incorrect, especially considering the potential for donation to charities of OTCs and dietary supplements. As discussed below, pharmaceutical products are often destined for use/reuse or reclamation. And, in these instances, there should be no doubt that the pharmaceuticals do not qualify as solid wastes and should not be subject to any RCRA regulation, including the proposed Subpart P.

The Pharmaceutical Proposal defines "hazardous waste pharmaceutical" as a "pharmaceutical that is a solid waste, as defined in § 261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C." *See* Proposed 40 C.F.R. § 266.500, 80 Fed. Reg. at 58,083. Therefore, in order to fall within the scope of the Pharmaceutical Proposal, the material must first be a solid waste under the existing regulations. As discussed below, pharmaceuticals destined for reuse or reclamation are not solid wastes under such regulations.

- ***Pharmaceuticals Destined for Reuse.*** EPA's regulations specifically exclude from the definition of solid waste materials that will be used or reused. 40 C.F.R. § 262.2(e) (materials used or reused as effective substitutes for commercial products are not solid wastes); Letter from Sylvia K. Lowrance, Director, Office of Solid Waste, EPA, to N.G. Kaul, Director, Division of Hazardous Substances Regulation, New York State Department of Environmental Conservation, Feb. 23, 1993 (RCRA Online #11726) ("Lowrance Letter") (Exhibit 19) (materials recycled by use or reuse would not be solid

wastes provided they are legitimately recycled). EPA has explicitly acknowledged that "the Agency has no jurisdiction over reused [products]." *See* 67 Fed. Reg. 40,508, 40,510 (June 12, 2002) (proposal to conditionally exclude cathode ray tubes from solid waste). In fact, EPA has extolled the virtues of systems that facilitate reuse of products as a way of keeping products out of the waste management system. When discussing reuse of computers, EPA stated that reuse is "a responsible way to manage these materials, because preventing or delaying the generation of waste often conserves resources. [Reuse] extends the lives of valuable products and keeps them out of the waste management system for a longer time. Reuse also allows schools, non-profit organizations, and individual families to use equipment that they otherwise could not afford." *Id.* In the retail sector, such reuse occurs by moving products through reverse distribution and reverse logistics systems.

While the opportunities for reuse of prescription pharmaceuticals may be limited due to legal restrictions (*see* 80 Fed. Reg.at 58,043 for EPA discussion of state and federal restrictions on reuse of prescription pharmaceuticals, including controlled substances), such opportunities do exist. The Food and Drug Administration ("FDA") has stated that it "would not object to the donation of drugs that are past … the expiration date shown on the label when provided with sufficient information to show the expired lot(s) are safe and effective." *See* FDA, "Questions and Answers for the Public: Donating Drugs to International Humanitarian Relief Efforts" (2011) ("FDA Donation Guidance") at 3 (Answer to Q6) (Exhibit 20). EPA has long stated that products that are generally prohibited from sale may nevertheless not be wastes if there are still some legal avenues available for distribution. *See, e.g.*, 52 Fed. Reg. 11,319, 11,332 (April 8, 1987) (pesticide products that have had their registrations suspended or cancelled by EPA may not qualify as solid wastes to the extent that "sales to a foreign purchaser" may be legally permitted).

With respect to OTCs and dietary supplements, the state and federal restrictions cited by EPA do not restrict further distribution through sale or donation. OTCs and dietary supplements that may fall within the rule's definition of pharmaceutical include energy bars, vitamins, sunscreen, medicated shampoo, personal care items, pain relievers, cough and cold medicines, and nicotine replacement products available without a prescription. These items are regularly donated and liquidated, and reverse distribution and reverse logistics operations help maximize these opportunities. One retailer estimates that in 2013, 97.2% of the products that would exhibit a hazardous waste characteristic or be listed as hazardous and shipped from retail stores to reverse logistics centers were ultimately donated, liquidated or returned to the supplier. Another retailer estimates that 95% of the products that would be hazardous and were sent through reverse logistics were ultimately donated, liquidated or returned to the supplier.

- ***Pharmaceuticals Destined for Reclamation.*** EPA's regulations also specifically exclude from the definition of solid waste commercial chemical products destined for

> reclamation. 40 C.F.R. § 261.2(c)(3) (commercial chemical products being reclaimed are not solid wastes); Lowrance Letter (commercial chemical products includes all commercial products that exhibit a hazardous waste characteristic, regardless of whether they are considered chemicals); 50 Fed. Reg. 14,216, 14,219 (April 11, 1985) ("Although we do not directly address non-listed commercial chemical products in the rules, their status would be the same as those that are listed in § 261.33"); EPA, Monthly Hotline Report, August 1996 (RCRA Online # 14012) (Exhibit 21) ("commercial chemical product" in 261.2(c)(3) includes commercial chemical products that are not listed in 261.33 but exhibit a characteristic of hazardous waste). Notably, EPA regulations do not prohibit speculative accumulation of commercial chemical products prior to reclamation. *See* 40 C.F.R. § 261.2(c)(4).
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> Opportunities for reclamation of pharmaceutical products definitely exist. For example, EPA recently reviewed a process for reclamation of nicotine from unused and unsaleable smoking cessation products for sale to manufacturers of new nicotine-containing products and confirmed that "the nicotine-containing products would not be considered solid waste and thus are not subject to RCRA hazardous waste regulation when sent for [legitimate] nicotine reclamation." *See* Letter from Barnes Johnson, Director, Office and Resource Conservation and Recovery, EPA, to Scott DeMuth, Vice President, Business Development, g2 revolution, LLC (May 8, 2015) (RCRA Online 14851) (Exhibit 22). Alcohol-based OTCs may be reclaimed to recover their alcohol content. *Cf.* 40 C.F.R. § 261.6(a)(3)(i) (providing an exemption for used industrial ethyl alcohol destined for reclamation). In addition, aerosol forms of pharmaceuticals (or other pharmaceutical delivery devices) may be reclaimed for their non-pharmaceutical components (*e.g.*, metals or propellants).

Clearly, there are numerous situations where pharmaceuticals may be destined for use or reclamation. Under the current regulations, these items would not be classified as solid wastes. Accordingly, they should not be subject to any regulation, including the proposed Subpart P.

B. EPA Should Not Abandon Long-Standing Guidance that Pharmaceuticals Destined for Evaluation of Potential Credit Are Not Solid Wastes

Even in those instances where it is known that the pharmaceuticals going through a reverse distribution or reverse logistics process will ultimately be destroyed/discarded after being evaluated for potential manufacturer credit, they cannot properly be classified as solid wastes because they have not yet been discarded. As EPA acknowledges in the preamble to the proposal, this has long been the Agency's position. *See* 80 Fed. Reg. at 58,042-43. Although EPA is now proposing to change this position, it should instead reaffirm the long-standing rule.

Courts have consistently held that EPA's authority under RCRA is limited to "discarded materials." *See, e.g., American Mining Congress v. EPA*, 824 F. 2d 1177, 1178 (D.C. Cir. 1987) ("*AMC*") (ruling that EPA exceeded its authority "in seeking to bring materials that are not

discarded or otherwise disposed of within the compass of 'waste'"). In the present case, pharmaceuticals being sent back through reverse distribution or reverse logistics have clearly not been discarded. On the contrary, one of the main purposes of the reverse distribution and reverse logistics processes is to preserve the pharmaceuticals to maximize the potential for receiving credit. This is the opposite of discard. Although it might be clear in some cases (as we are hypothesizing in this section) that the pharmaceuticals will eventually be discarded after the decision on credit has been completed, that does not mean that the pharmaceuticals have already been discarded on their way to the place where the decision on credit will be made. Even EPA recognizes that store personnel are not making the decision regarding discard. *See* 80 Fed. Reg. at 58,022-23 (discussing that health care facility employees are not capable of knowing at a given time what the manufacturer's policy dictates). Clearly, while the pharmaceuticals are in transit to that place and before credit has been assessed, they are still in use by the retailer and have not yet been discarded. *See AMC* at 1190 (materials that are still in use by the generating industry "are not yet part of the waste disposal problem."); *see also Association of Battery Recyclers, Inc. v. U.S. EPA*, 208 F.3d 1047 (D.C. Cir. 2000) (reaffirming *AMC* and finding that storage prior to use does not render the materials discarded). In the case of reverse distribution and reverse logistics, the products are still part of a continuous loop of product distribution that is fundamental to the retail business.

In light of the above, a reversal of policy by EPA on this issue would be an unlawful attempt to extend the Agency's authority to materials that are not discarded. Such a move would also be inconsistent with, and call into question, EPA's long-standing guidance on several closely related issues. For example, the Agency has stated that explosives and related materials seized by the Bureau of Alcohol, Tobacco, and Firearms ("BATF") are not solid wastes while being held as evidence – even if it us known that they will eventually be destroyed/discarded – but rather "become waste when the court (or BATF) no longer has any use for them (*i.e.*, when no longer needed for evidence …)." *See* Letter from Sylvia K. Lowrance, Director, Office of Solid Waste, EPA, to Phillip C. McGuire, Associate Director, Law Enforcement, BATF (August 11, 1988) (RCRA Online #11363) (Exhibit 23) ("When explosives are stored pending judicial proceedings, they are not subject to the hazardous waste regulations. However, when they are to be discarded, the become waste. At that point, RCRA requirements … become applicable"). Similarly, EPA has stated that at testing ranges for military munitions, "unexploded ordnance … would not be a solid waste if shipped off-range for further evaluation" (*e.g.*, to determine why it did not detonate as intended). *See* 62 Fed. Reg. 6622, 6628 (February 12, 1997). In both instances, the materials have vital information value that is being preserved such that the materials are not yet discarded, and are not yet solid wastes, notwithstanding the fact that they will eventually be destroyed/disposed. The same is true for the pharmaceuticals being sent for a determination of potential manufacturer credit, or that have other valuable information (*e.g.*, information needed for tax/accounting purposes, confirmation of product recalls, or as evidence in a contractual dispute or tort action).

C. Pharmaceuticals Sent for Evaluation of Potential Use/Reuse or Reclamation Options Should Not Be Classified as Solid Wastes

Even if EPA decides, despite the discussion above, to change its long-standing policy and declare that pharmaceuticals going through a reverse distribution/logistics process are solid wastes if it is *known* that they will ultimately be destroyed/discarded after being evaluated for potential manufacturer credit, that would generally not be determinative of the status of the pharmaceuticals, since in most, if not all, situations, there may still be viable use/reuse or reclamation options other than destruction/discard available (as discussed previously). Of course, the extent to which the non-waste options are available will vary from product to product. However, EPA cannot make a blanket rule that all pharmaceuticals going through reverse distribution/logistics are solid wastes.

Indeed, it would be environmentally counterproductive to classify pharmaceuticals as solid wastes whenever there is a chance – even a significant or substantial chance – that they will ultimately be disposed. In many instances, particularly for OTCs and dietary supplements, the materials are sent through reverse distribution or reverse logistics not for potential manufacturer credit, but to determine whether they can be used/reused or reclaimed. Health care facilities do not have the specialized knowledge necessary to make these determinations. That is what the reverse distribution and reverse logistics facilities are deigned to do. If all items with the potential to be discarded are classified as solid wastes, the healthcare facilities will have no choice but to handle all of the items as wastes, thus foreclosing any use/reuse or reclamation options. The same would be true if EPA were to try to establish some standard for deciding which pharmaceuticals are wastes, such as if there is more than a 50% chance that the items will be destroyed/disposed, since the healthcare facilities would not be in a position to determine when the threshold would or would not be exceeded. In other contexts, EPA has stated that when a person does not have the specialized knowledge necessary to determine what will happen to a product, he/she should not be subject to regulation as a hazardous waste generator. *See, e.g.*, 67 Fed. Reg. 40,508, 40,511 (June 12, 2002) ("Because the typical original user [of a CRT] usually lacks the specialized knowledge needed to decide the future of a CRT, … we do not consider a user sending a CRT … for potential reuse to be a RCRA generator"). The Agency should take a similar approach here, and declare that pharmaceuticals sent for evaluation of potential use/reuse or reclamation options are not solid wastes, and thus are not subject to RCRA regulation, including the requirements of the Pharmaceutical Proposal.

D. EPA Should Provide a Simple Rule for Unsold/Returned Products in Good Condition Sent Through Reverse Distribution/Reverse Logistics for Evaluation

Given that retailers are sending products, not wastes, through reverse distribution and reverse logistics, the Retail Associations request that EPA establish a simple rule for retailers using reverse distribution and reverse logistics. In particular, EPA should either clarify in the preamble or create an exclusion in 40 CFR § 261.4(a) that unsold/returned products that are in good condition (*i.e.*, not leaking) and sent by a retailer through reverse distribution or reverse logistics for evaluation of use/reuse or reclamation are not solid wastes and, thus, would not be subject to

RCRA regulation, including the proposed Subpart P. A simple rule of this type is essential given that retail employees, and retail companies in general, commonly do not know the ultimate disposition of the pharmaceutical products they send through reverse distribution/logistics. *See, e.g.*, 80 Fed. Reg. at 58,022-23 (noting that health care facility employees are not capable of knowing at a given time what the manufacturer's policy dictates).

As a practical matter, such a rule would not be significantly different from the proposed requirements for health care facilities managing potentially creditable pharmaceuticals under Subpart P. These requirements are mostly limited to advance notification and recordkeeping. *See* Proposed §§ 266.503, 266.509. Because retailers are in the business of distributing and selling products, they are already carefully tracking products in reverse distribution and reverse logistics through existing inventory and accounting practices. So, EPA's proposed requirements in this regard are unnecessary, even if these products were deemed to be wastes.

Additional EPA requirements for health care facilities, such as export and import requirements should not apply to products in reverse distribution and reverse logistics. *See* Proposed § 266.509(d)-(e). Other regulatory agencies have jurisdiction over export and import of pharmaceutical products. As discussed above, the FDA has specifically stated that it would allow export of even expired pharmaceuticals, if the drugs are still safe and effective. *See* FDA Donation Guidance at 3 (Answer to Q6).

Finally, the stringent requirements for reverse distributors in the proposed Subpart P should not apply to unsold/returned products in good condition when sent for evaluation for use/reuse or reclamation. As previously discussed, retailers are in the business of distributing and selling products. Reverse distribution and reverse logistics are continuous parts of the processes of distribution and sale. Significant amounts of products are resold or donated as a result of the evaluation processes performed by reverse distributors and reverse logistics providers. Declaring these products as "wastes" prior to that evaluation process has the adverse consequence of shifting these otherwise useful products into the waste management system. This result would be antithetical to EPA's stated preference for reuse whenever possible. *See* 67 Fed. Reg. at 40,510 (reuse "extends the lives of valuable products and keeps them out of the waste management system for a longer time. Reuse also allows schools, non-profit organizations, and individual families to use [products] that they otherwise could not afford.") Accordingly, the Retail Associations request that EPA either clarify in the preamble or create an exclusion in 40 CFR § 261.4(a) that unsold/returned products that are in good condition (*i.e.*, not leaking) and sent by a retailer through reverse distribution or reverse logistics for evaluation of use/reuse or reclamation are not solid wastes and, thus, would not be subject to RCRA regulation, including the proposed Subpart P.

VI. REQUIREMENTS FOR REVERSE DISTRIBUTORS ARE OVERLY BURDENSOME

EPA is proposing to impose on pharmaceutical reverse distributors the same or in some cases more stringent reporting and other requirements than would apply to fully regulated hazardous

waste treatment, storage and disposal facilities ("TSDFs") and large quantity generators ("LQGs"), regardless of the amount of hazardous waste actually handled by pharmaceutical reverse distributors. For example, a reverse distributor receiving three tablets of a RCRA-listed pharmaceutical in a year would be subject to more stringent requirements in some respects than a TSDF receiving 3 tons of hazardous waste per week or an LQG generating 3 tons of hazardous waste in a month. Such stringent requirements are simply not warranted for these pharmaceuticals, which even EPA admits pose considerably less risks than other hazardous wastes, given their packaging, volumes, and value to the parties involved. EPA recognizes "the value of the potentially creditable pharmaceuticals creates an incentive for proper management and the risk of release is low." *See* 80 Fed. Reg. at 58,061. The Retail Associations request that EPA reconsider the requirements for reverse distributors and tailor them appropriately to the limited risks posed by pharmaceutical wastes.

In particular, the Pharmaceutical Proposal would subject reverse distributors to the following requirements:

- **Unauthorized Waste Reports.** Proposed § 266.510(a)(8)(i) would require pharmaceutical reverse distributors that receive a shipment from a healthcare facility that includes non-creditable hazardous waste pharmaceuticals or non-pharmaceutical hazardous wastes to submit an unauthorized waste report to the EPA Regional Administrator within 15 days of receiving the hazardous waste. The pharmaceutical reverse distributor must also send a copy of the unauthorized hazardous waste report to the healthcare facility that sent the unauthorized hazardous waste. EPA requires the same of a fully regulated TSDF. *See* 40 C.F.R. §§ 265.76. The proposed § 266.510(a)(8)(i) would be even more stringent than the TSDF requirements because it would require reporting even if the waste received was from a CESQG that is voluntarily taking advantage of the Subpart P regime for pharmaceuticals.

- **Biennial Reports.** Proposed § 266.510(c)(9) would require pharmaceutical reverse distributors to develop and submit biennial reports for evaluated hazardous waste pharmaceuticals sent off-site, regardless of the amount of hazardous waste involved. *See* Proposed § 266.510(c)(9). EPA requires fully regulated TSDFs to prepare and submit biennial reports. *See* 40 C.F.R. § 265.75. The proposed § 266.510(b)(9) requirement for biennial reports from reverse distributors would be more stringent than the TSDF requirements because it would require reporting even if the wastes received by a reverse distributor were exclusively from CESQGs voluntarily taking advantage of the Subpart P regime for pharmaceuticals. It would also be more stringent than LQG requirements, where generators of hazardous waste are only required to submit a biennial report if they generate 1000 kg in a given month or accumulate 6000 kg at a given time. *See* 40 C.F.R. § 262.41 (biennial reporting requirement) and § 261.44 (exempting SQGs from this requirement).

- **Contingency Plans**. Proposed § 266.510(a)(6) would require pharmaceutical reverse distributors to develop and maintain contingency plans and emergency procedures, regardless of the amount of hazardous waste actually handled by the facility. EPA requires fully regulated TSDFs to develop and maintain contingency plans and emergency procedures. *See* 40 C.F.R. Part 265, subpart D. The proposed § 266.510(a)(10) requirement for contingency plans from reverse distributors would be more stringent than the TSDF requirements because it would require reporting even if the wastes received by a reverse distributor were exclusively from CESQGs voluntarily taking advantage of the Subpart P regime for pharmaceuticals. It would also be more stringent than LQG requirements, where generators of hazardous waste are only required to develop and maintain contingency plans if they generate 1000 kg in a given month. *See* 40 C.F.R. § 262.34(a)(4) (incorporating the contingency plan and emergency procedure requirements in 40 C.F.R. Part 265, Subpart D, into the LQG rules) and § 262.34(d) (imposing different emergency procedure requirements – not including a contingency plan requirement – for SQGs).

- **On-Site Accumulation.** Proposed § 266.510(a)(4) and § 266.510 (a)(10) would allow pharmaceutical reverse distributors to accumulate evaluated hazardous waste pharmaceuticals for only 69 days after the period for credit allocation has expired, regardless of the amount of hazardous wastes handled by the facility. This is less than the 90 days allowed for LQGs generating at least 1000 kg per month and significantly less than the 180 days (or 270 days in some instances) allowed for SQGs generating at least 100 kg per month of hazardous wastes. *See* 40 C.F.R. § 262.34.

- **Security.** Proposed § 266.510(a)(3) would require reverse distributors to meet the same security requirements imposed on TSDFs under 40 C.F.R. § 265.14 and LQGs under 40 C.F.R. § 262.34, regardless of the amount of hazardous waste pharmaceuticals received by the reverse distributor. These security requirements would be more stringent than the TSDF requirements because they would require the security measures even if the wastes received by a reverse distributor were exclusively from CESQGs voluntarily taking advantage of the Subpart P regime for pharmaceuticals. They would also be more stringent than LQG requirements, where generators of hazardous waste are only required to meet these security requirements if they generate more than 1000 kg in a given month.

This regime for pharmaceutical reverse distributors is excessive and cannot be justified. EPA itself states that it "is not aware of any incidents of mismanagement resulting in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors." 80 Fed. Reg. at 58,061. Moreover, EPA recognizes that reverse distributors have every incentive to handle incoming pharmaceuticals carefully because of their value. *See* 80 Fed. Reg. at 58,060 (recognizing incentive for careful handling, citing value estimated by one retailer at $1 billion a year). As for evaluated pharmaceuticals, EPA also recognizes that these pharmaceuticals "generally present a low risk of release to the environment as they typically are still in the manufacturer's packaging." *Id.*

The heightened measures imposed on pharmaceutical reverse distributors in the Pharmaceutical Proposal may relate to EPA's expressed change in policy that all pharmaceuticals sent through reverse distribution are wastes when sent from health care facilities. As discussed above in Section V, the Retail Associations disagree strongly and assert that the vast majority of pharmaceuticals in reverse distribution or reverse logistics are non-wastes. And even if they were wastes, there is no basis for subjecting them more stringent requirements than if they were handled at TSDFs and LQGs, particularly in light of the fact that they pose considerably less risks than other hazardous wastes, given their packaging, volumes, and value to the parties involved. Because the pharmaceuticals are in substantially the same form, quantity, and packaging as products handled safely by retailers in forward distribution, by store personnel, and by consumers, reverse distribution simply does not warrant these extremely stringent requirements.

As previously discussed, maintaining the existing reverse distribution system is best for protecting the environment and human health because reverse distributors have specialized staff to characterize and handle pharmaceutical wastes appropriately. Imposing TSDF requirements for reverse distributors would discourage use of reverse distributors by the increasing costs associated with using reverse distributors. EPA has not adequately justified why imposing onerous requirements on reverse distributors is necessary. As previously explained, the Retail Associations believe reverse distribution results in overall public benefit including both minimizing waste generation by encouraging donation, liquidation and reclamation as well as relying on the expertise of reverse distributors to properly handle pharmaceuticals that become wastes.

The Retail Associations request that EPA tailor the requirements for reverse distributors to the nature and volumes of the pharmaceuticals being handled. In particular, we propose that EPA replace the proposed requirements for unauthorized waste reports (§ 266.510(a)(8)(i)), biennial reports (§ 266.510(c)(9)), contingency plans (§ 266.510(a)(6)), on-site accumulation (§ 266.510(a)(4) and § 266.510 (a)(10)), and security (§ 266.510(a)(3)) with the following:

- ***Revised*** **Unauthorized Waste Reports.** Reverse distributors would document any amount of non-pharmaceutical hazardous waste received from a health care facility and communicate such receipt to the health care facility. This would create a record of every unauthorized shipment, which would be available to EPA upon inspection or request. Reverse distributors would then report to EPA receipt of non-pharmaceutical hazardous waste if the amount received from a single health care facility in a calendar month exceeds 100 kg. Thus, EPA would be directly informed when the amount of unauthorized shipments reaches more than a de minimis amount. Reporting should not be required for receiving non-creditable hazardous waste pharmaceuticals. As EPA recognizes, manufacturer policies determine creditworthiness, these policies can change frequently, and store personnel do not know at any given time whether the pharmaceuticals they are sending to a reverse distributor will be eligible for credit. *See* 80 Fed. Reg. at 58,022-23. It makes no sense for health care facilities to be penalized for sending non-creditable pharmaceuticals to reverse distributors when the health care

facilities, as even EPA admits, are not capable of evaluating creditworthiness based on the ever-changing manufacturer policies.

- ***Revised*** **Biennial Reports.** Reverse distributors would submit a biennial report only if 1000 kg of hazardous waste is evaluated or received per month, or if 6000 kg of hazardous waste is accumulated at any given time. We believe using these LQG thresholds is sufficient because the biennial report is not necessary for EPA for keep tabs on which facilities are operating as reverse distributors. EPA will have received notification of a facility's status as a pharmaceutical reverse distributor under proposed §266.510(a)(1). Also, the recordkeeping requirements in proposed §266.510(a)(2) are sufficient for tracking the identities and quantities of pharmaceuticals handled by reverse distributors.

- ***Revised*** **Contingency Plans.** Reverse distributors would develop and maintain a contingency plan under 40 C.F.R. Part 265, subpart D, only if 1000 kg of hazardous waste is evaluated or received per month, or if 6000 kg of hazardous waste is accumulated at any given time, which is the threshold for hazardous waste generators to develop and maintain contingency plans. EPA has already determined a contingency plan is not necessary if a facility is handling fewer than these volumes of hazardous waste as a SQG. The nature and value of pharmaceutical wastes does not warrant a more stringent requirement.

- ***Revised*** **On-site Accumulation.** Reverse distributors would have one year to accumulate potentially creditable and evaluated hazardous waste pharmaceuticals on-site, exclusive of the evaluation period. The proposed 90 day limit is insufficient, given existing sector practices. Vendor credits for some pharmaceuticals will not issue until the pharmaceutical's expiration date or within one year after the expiration date, so a 90-day accumulation limit would undermine the functionality of the reverse distribution system. A one year accumulation limit is sufficiently protective of human health and the environment in this case where EPA has recognized that there is a low risk of release of these pharmaceuticals to the environment. In fact, EPA has proposed a one year accumulation period for health care facilities accumulating non-creditable hazardous waste pharmaceuticals, even though such health care facilities would be subject to even less stringent management standards than reverse distributors. *See* Proposed § 266.502(f). We also note that universal waste handlers are generally allowed to accumulate universal wastes that they generate or receive from offsite for one year (or even longer in some cases). *See, e.g.*, 40 C.F.R. § 273.35 (accumulation time limits for large quantity handlers of universal wastes).

- ***Revised Security.*** The security requirements should be removed in their entirety because they are duplicative of other requirements imposed on reverse distributors of prescription pharmaceuticals and simply not necessary for OTCs and dietary supplements. Facilities handling prescription pharmaceuticals are already subject to security requirements

imposed by state Boards of Pharmacy and, in the case of controlled substances, federal security requirements imposed by the DEA. EPA has not demonstrated that additional security measures are necessary to protect the environment or human health. For OTCs and dietary supplements, the security requirements are particularly burdensome and unnecessary, as retailers and reverse distributors have every incentive to secure their inventory and prevent product losses.

VII. EPA SHOULD SUBSTANTIALLY MODIFY THE PROPOSED LDR REQUIREMENTS FOR PHARMACEUTICAL WASTES

The Pharmaceutical Proposal would require both health care facilities and pharmaceutical reverse distributors to comply with EPA's LDR regulations, and in particular 40 C.F.R. § 268.7(a). *See* Proposed 40 C.F.R. § 266.502(g) (LDR for health care facilities sending off-site non-creditable hazardous waste pharmaceuticals); § 266.510(c)(8) (LDR for pharmaceutical reverse distributors sending off-site evaluated hazardous waste pharmaceuticals). In addition, the Pharmaceutical Proposal would require health care facilities accumulating non-creditable hazardous waste pharmaceuticals to segregate those hazardous waste pharmaceuticals that are purportedly prohibited from being combusted due to the dilution prohibition in 40 C.F.R. § 268.3(c). *See* Proposed § 266.502(d)(4). These proposed requirements are problematic in several respects, each of which is discussed separately below.

A. EPA Should Provide Relief from the Requirement to Identify Waste Codes for Hazardous Waste Pharmaceuticals on LDR Notification Forms

EPA has proposed to provide relief to health care facilities managing non-creditable hazardous waste pharmaceuticals from the burden of assigning hazardous waste codes, for example on hazardous waste manifests. *See* Proposed § 266.508(a)(2)(i). The Agency based this proposal on the unique challenges health care facilities face in making hazardous waste determinations. *See* 80 Fed. Reg. at 58,018 ("The combination of having thousands of different pharmaceutical products and little expertise in hazardous waste regulations makes it difficult for healthcare workers to make appropriate hazardous waste determinations when pharmaceuticals are disposed."). Given these challenges, EPA has proposed to allow health care facilities to manage hazardous and non-hazardous pharmaceutical wastes together and thereby relieve health care facilities of the burden of making individual hazardous waste determinations. *See* 80 Fed. Reg. at 58,032 ("However, health care facilities may choose to manage all of their pharmaceutical wastes as hazardous, and thus, if a health care facility chooses this approach, they would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their waste pharmaceuticals are hazardous and manage them as hazardous waste pharmaceuticals in accordance with the proposed requirements in 40 C.F.R. part 266, subpart P.").

However, EPA also states that heath care facilities must comply with the LDR notification requirements in 40 C.F.R. § 268.7(a), which explicitly require that LDR notices include waste

codes. *See* 40 C.F.R. § 268.7(a)(2). This may have been an oversight by the Agency. In any event, it is imperative that the LDR notice provision be modified to waive the waste code requirement for hazardous waste pharmaceuticals. Otherwise, the relief being touted by EPA would be meaningless.

B. EPA Should Establish an Alternative LDR Treatment Standard of Combustion for Organic Hazardous Waste Pharmaceuticals

EPA has stated that, although organic hazardous waste pharmaceuticals may all be incinerated, the resulting ash would always have to be tested for seven specific organic pharmaceutical constituents, because (a) the LDR treatment standards for those constituents are numerical, and (b) the manifests from the health care facilities would not specify whether the waste codes for those constituents were present. *See* 80 Fed. Reg. at 58,038. The Retail Associations urge EPA to abandon this approach in favor of an approach similar to one discussed as a possible alternative in the preamble, namely specifying combustion as a permissible alternative treatment standard for organic hazardous waste pharmaceuticals.

This approach would be protective of human health and the environment, and satisfy the statutory requirements for LDR treatment standards, since the numerical treatment standards are already based on combustion. As EPA notes, the only reason that the treatment standards for the seven constituents were established as numerical treatment standards is that the Agency generally prefers numerical standards to specified technologies "in order to allow maximum flexibility." *Id*. at 58,039. In this instance, however, the numerical treatment standards are actually reducing flexibility, unnecessarily making it harder to achieve LDR requirements for hazardous waste pharmaceuticals. Here, flexibility would be maximized by allowing either combustion or, if other treatment methods are used, achieving the numerical standards.

EPA also tries to justify retaining the numerical treatment standards by saying that incinerator facilities will still have to test the ash for the seven constituents "if they received the organics from another non-pharmaceutical source." *Id*. This statement is, of course, true (unless EPA also includes an alternative treatment standard of combustion for these same constituents when they come from non-pharmaceutical sources). However, some incinerators may not receive these constituents from non-pharmaceutical sources, or may do so at different times. Moreover, even if they do receive these constituents from non-pharmaceutical sources, they will in those instances be receiving notice of the relevant waste codes, so they will know to test the ash accordingly. Indeed, they will be used to doing just that. However, this is not a reason not to provide an alternative combustion standard for organic hazardous waste pharmaceuticals.

C. EPA Should Allow All Hazardous Waste Pharmaceuticals to be Combusted, Without Having to Segregate Metal-Bearing Wastes with Low Organic Carbon Content

It is beyond comprehension how EPA could envision that the very health care facilities that it acknowledges are not in a position to make individual hazardous waste determinations could nonetheless identify and segregate the wastes that are purportedly not allowed to be combusted under the LDR program (*i.e.*, wastes that are hazardous based on their metal content and that contain less than 1% organic carbon). Not only would this require health care facilities to make the very hazardous waste determinations that EPA is trying to provide relief from, but it would also require the health care facilities to further determine whether their wastes are hazardous due to the presence of metals and have greater than 1% organic carbon content. If a health care facility does not have the basic capabilities of determining whether a waste is hazardous, how does EPA expect it to make these even more detailed and technical determinations? Moreover, requiring segregation would completely eviscerate the relief EPA is providing by not requiring individual hazardous waste determinations.

The Retail Associations do not believe any of this is necessary. As an initial matter, the LDR dilution prohibition provides an exception for wastes that are "co-generated with wastes for which combustion is a required method of treatment." *See* 40 C.F.R. § 268.3(c)(4). The limited number of metal-bearing low-carbon hazardous waste pharmaceuticals will almost invariably be co-generated with other wastes (*e.g.*, D001 ignitable hazardous waste pharmaceuticals) for which combustion is one of the specified methods of treatment. Thus, combustion for all the co-generated wastes should be allowed.

Moreover, even if EPA continues to believe that combustion is currently prohibited for metal-bearing low-carbon hazardous waste pharmaceuticals, it can and should change the rules to allow combustion (*e.g.*, by modifying the dilution prohibition to allow combustion, by establishing a new treatability group for these wastes with combustion as a required or allowed method of treatment, or by establishing alternative treatment standards for these wastes as has been done for hazardous waste debris or soil). As noted above, it is generally not practical for healthcare facilities to identify and segregate the small proportion of pharmaceutical wastes that fall within this category. Thus, it is inappropriate to apply the dilution prohibition to these wastes, and the best demonstrated available technology for these wastes is combusting them together with all the other pharmaceutical wastes. *Cf.* 40 C.F.R. § 268.44(a)(2) (allowing variances from treatment standards where applying such standards would be "inappropriate").

Finally, allowing combustion of these wastes would be protective of human health and the environment. The wastes would have to be combusted in hazardous waste combustion units subject to stringent requirements under both RCRA and the Clean Air Act, requiring tight controls on metal feed rates, among other things. *See generally* 80 Fed. Reg. at 58,039 (explaining how these controls would be protective with respect to mercury-containing hazardous waste pharmaceuticals). The ash would almost certainly also have to meet universal treatment standards for all of the relevant metals, based on other materials being combusted in the units (although, to be sure, EPA might require that the ash from hazardous waste pharmaceuticals meet these standards). It is worth stressing that, as EPA acknowledges in the proposal, the total amount of hazardous waste pharmaceuticals generated by a health care facility

is small, and the proportion of those wastes that are metal-bearing low-carbon wastes is also very small. It makes no sense to require health care facilities to do what EPA states is not practical for them to do (*i.e.*, identify and segregate these wastes), just to pursue an unnecessarily rigid view of the LDR program. This is especially true because health care facilities would rarely, if ever, generate more than 100 kg of these metal-bearing low-carbon hazardous waste pharmaceuticals, and that same quantity would be totally exempt from LDR requirements if it represented the only wastes generated at a health care facility.

VIII. EPA SHOULD CLARIFY AND/OR MODIFY CERTAIN ASPECTS OF THE EXEMPTION FOR RESIDUES IN PHARMACEUTICAL CONTAINERS

EPA is proposing in § 266.507 to exempt from regulation pharmaceutical residues in certain types of containers. The Retail Associations are generally in favor of this exemption because it will relieve retailers from the burdens of measuring the contents remaining in non-acute hazardous waste containers and from triple rinsing containers that previously held P-listed pharmaceutical wastes, while adequately protecting human health and the environment. However, we request that EPA make three changes to the proposed rule.

A. Clarify Status of Dispensing Bottles, Vials, and Ampules.

The Retail Associations request that EPA revise the proposed rule in § 266.507(a) to clarify that "using the practices commonly employed to remove the materials from that type of container" modifies pharmaceuticals removed from a "dispensing bottle, vial, or ampule" as well as a unit-dose container. As currently written, the placement of the semi-colon after "ampule" makes the language of the exclusion appear to read that bottles, vials and ampules must be emptied of all residues in order to qualify for the exemption, while unit dose containers must be emptied by commonly employed practices even if some residues remain. Such a result would be even more stringent than the existing empty container rule. *See* 40 C.F.R. § 261.7 (containers are "RCRA empty" if wastes are removed using commonly employed practices and the container holds one inch or less of a non-acute hazardous waste or if the container held an acute hazardous, it has been triple rinsed). This cannot have been EPA's intent. *See* 80 Fed. Reg. at 58,052 ("if the contents of the container have been fully dispensed by removing all pharmaceuticals that can be removed using the practices commonly employed to remove materials from that type of container, the residues (and therefore the container) may be disposed of as non-hazardous waste); *id.* at 58,051-55 (discussing reduced hazards associated with pharmaceutical containers emptied by commonly employed practices). We ask that EPA revise the proposed § 266.507(a) to make clear that pharmaceuticals in dispensing bottles, vials, and ampules need only be removed by commonly employed practices.

Likewise, we ask that the Agency modify the provision so that it does not appear to require removal of "all" the pharmaceuticals (arguably including any residues), but rather removal all of the pharmaceuticals that can be removed using the common practices. We believe this was EPA's intent, and it would track more closely the existing requirements (except for the

measurement of the residues). *See* 40 C.F.R. § 261.7(b)(1)(i) (requiring that "[a]ll wastes have been removed that can be removed using the practices commonly employed).

B. Do Not Arbitrarily Limit Size of Pharmaceutical Containers.

It is not necessary to limit the size of the containers (*i.e.*, to 1000-count or 1 liter containers) that are eligible for the exemption in § 266.507(a). There is no data showing that imposing such a size limitation would have any benefit to the environment or human health. The nature of the pharmaceuticals does not change with the container size. If all pharmaceuticals have been removed using commonly employed practices, the amount of residue in a larger container would be just as insignificant as in a smaller container. *See id.* at 58,051-55 (discussing reduced hazards associated with pharmaceutical containers emptied by commonly employed practices). Indeed, the amount of residues in a large container is likely to be less than the residues in a number of small containers with the same total capacity, since the smaller containers would have more surface area that the residues might cling to. Accordingly, we ask that EPA remove this arbitrary size limitation from § 266.507(a).

C. Eliminate Proposed Requirement for Destruction of Empty Containers.

EPA's proposed exemption for container residues is conditioned on the health care facility destroying "[a]ny dispensing bottle or unit-dose container that is an original manufacturer's product package" to prevent illicit use of the container (*e.g.*, for packaging counterfeit pharmaceuticals), such as by shredding or crushing. *See* Proposed 40 C.F.R. § 266.507(a)(2). The Retail Associations request that EPA remove this condition from the rule. Requiring retailers to destroy containers would create major challenges without commensurate benefits. Pharmacies would have to obtain specialized equipment for container destruction and train personnel on its use, imposing additional costs on health care facilities that EPA has not accounted for. Furthermore, these additional costs are unnecessary. The Retail Associations are not aware of diversion being a problem for empty prescription stock containers. Pharmacies routinely lock their dumpsters in order to prevent disclosure of Protected Health Information ("PHI"), which is protected under the Health Insurance Portability and Accountability Act ("HIPAA"). Nor are we aware that these types of containers pose a risk of diversion when disposed in the municipal waste stream. Indeed, if someone is sophisticated enough to counterfeit pharmaceuticals, they presumably would also have the capability to counterfeit a container and label. It is difficult to imagine a counterfeiter instead sifting through municipal waste to find a few isolated and widely dispersed containers of the particular pharmaceutical that he/she is counterfeiting, and trying to restore them to a condition that could pass as new.

EPA has certainly offered no evidence to support its assertion that diversion is an issue for empty containers that held products that would be acutely hazardous wastes. In particular, EPA has not stated why the risk of diversion is a particular concern for these containers, nor how preventing diversion would fall within the Agency's authority to address under RCRA. Diversion is clearly not one of the issues that RCRA was designed to address. To the extent there may be a

legitimate diversion issue for the empty containers, it should instead be addressed by other agencies whose mandate more clearly covers these issues, such as the Drug Enforcement Administration and FDA. Notably, these agencies do not currently impose the types of stringent requirements that EPA is now proposing.

Even if EPA were to adequately justify its interest in diversion of empty containers under this RCRA rule, EPA should clarify that destruction need not take place at the health care facility. EPA should allow health care facilities to decide where and how to destroy the containers. At a minimum, health care facilities should be allowed to send the containers to a third party vendor for destruction, perhaps with some minimal tracking to prevent diversion, assuming there is a legitimate risk of diversion. Such a mechanism would be similar to how our members handle currently handle empty containers with PHI under HIPAA. Finally, EPA should clarify that empty containers that have not yet been destroyed are not subject to hazardous waste storage requirements, and that the destruction process is not subject to regulation as hazardous waste treatment.

IX. OTHER KEY PROVISIONS OF THE PHARMACEUTICAL PROPOSAL WARRANT CLARIFICATION AND/OR MODIFICATION

A. Expand Times for Transportation and Evaluation.

With respect to transportation, proposed § 266.509(c) would require health facilities to take certain steps if pharmaceuticals sent from health care facilities are not received by the reverse distributor within 7 calendar days. We think this is an unreasonably short amount of time, given that hazardous waste generators have either 35 days or 60 days, depending on LQG or SQG status, to track down manifested shipments of hazardous waste to TSDFs. *See* 40 C.F.R. § 262.42. As previously discussed, EPA has recognized that health care facilities and reverse distributors have an incentive to carefully track and manage pharmaceuticals because of their credit value. *See* 80 Fed. Reg. at 58,061. Therefore, we request that the time period for reverse distributors to receive shipments of potentially creditable pharmaceuticals be expanded to 60 days.

With respect to evaluation, proposed § 266.510(a)(10) would allow only 21 days for a reverse distributor to determine creditworthiness of pharmaceuticals. We believe allowing 60 days for evaluation would be more reasonable. Given that the Pharmaceutical Proposal includes OTCs and dietary supplements, it would be extremely difficult for some reverse distributors to sort and process large quantities of OTCs and dietary supplements within the proposed time frame. Additional time is also needed for large scale recalls involving complex, large retailers. Allowing 60 days would accommodate times of particularly high volume, such as large recalls or seasonal changes in inventory (*e.g.*, the end of flu or allergy season). Moreover, because reverse distributors have a financial incentive to carefully manage these pharmaceuticals, expanding the evaluation time to 60 days will not have an adverse effect on the environment or human health.

B. Remove Advance Notification and Delivery Confirmation Requirements.

Proposed § 266.509(a)(1) would require health care facilities to send advance notification of shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Proposed § 266.509(b) would require reverse distributors to send delivery confirmation notices to health care facilities. In the retail sector, pharmaceutical shipments are already carefully tracked through existing inventory and accounting practices of the retailers and the reverse distributors or reverse logistics providers. These practices may differ from company to company, but their aim is the same—to diligently track valuable products through these processes until they are evaluated and their final disposition (whether it be use/reuse, reclamation or disposal) is determined. EPA should either remove the notification and delivery confirmation requirements or modify the proposal to allow health care facilities (at least retailers) and reverse distributors to use existing inventory and accounting practices to track shipments sent to and received by reverse distributors.

C. Modify/Clarify Inventory and Recordkeeping Requirements.

Proposed § 266.510(a)(2) would require reverse distributors to keep detailed inventories of all potentially creditable and evaluated pharmaceuticals that are accumulated on-site, including the identity and quantity. As an initial matter, the Retail Associations question whether it is practical for reverse distributors to prepare such an inventory for potentially creditable pharmaceuticals immediately "upon arrival," as proposed. EPA elsewhere proposes to provide the reverse distributors 21 days to perform their evaluation, and a significant part of that evaluation is identification of the materials. Reverse distributors do not obtain item-level information until individual items have been scanned into their systems. Moreover, the inventory requirements were clearly developed with prescription pharmaceuticals in mind. Given that OTCs and dietary supplements are also covered by the proposed inventory requirements, the level of inventory detail required is inappropriate and unduly burdensome. The Retail Associations request that EPA allow less specific inventory information, such as simply an estimate of the number of containers, rather than National Drug Code ("NDC") numbers and pill quantities, which would only be relevant for prescription pharmaceuticals. Because products in reverse distribution and reverse logistics are still in use by the retail business, they are tracked using inventory and accounting practices. EPA should modify the proposal to allow reverse distributors to use existing inventory practices to track the shipments they receive.

Proposed § 266.510(a)(9) would require reverse distributors to keep certain records. The Retail Associations request that EPA clarify that these records may be kept electronically.

D. Clarify Status of Distribution Centers.

As proposed, some retail distribution centers could potentially fall within the definition of pharmaceutical reverse distributor in § 566.500. Retailers use distribution centers in forward logistics as a central hub that receives products from vendors and that sends products out to

individual stores for sale. In reverse distribution or reverse logistics, some retailers send unsold or returned products from individual stores to distribution centers, where they may be transferred to other transport vehicles or stored temporarily in closed totes or boxes before being transported to a reverse distribution or reverse logistics center for sorting and evaluation. The Pharmaceutical Proposal defines pharmaceutical reverse distributor as "any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation of manufacturer's credit is considered a pharmaceutical reverse distributor." *See* Proposed 40 C.F.R. § 266.500.

Although distribution centers may receive and accumulate potentially creditable hazardous waste pharmaceuticals, they would not process the pharmaceuticals for assessing manufacturer's credit. Accordingly, they would not fall within the definition of pharmaceutical reverse distributor. Instead, they would operate similarly to transfer facilities under the existing RCRA rules (except that the pharmaceuticals might remain longer than 10 days). The Retail Associations request that EPA clarify that distribution centers that receive and temporarily store potentially creditable hazardous waste pharmaceuticals en route to their delivery to a reverse distributor would not qualify as reverse distributors under the rule. We also ask that this temporary stop at a distribution center would not count towards the limit of three reverse distributors. *See* 80 Fed. Reg. at 58,064.

E. Definition of Non-Creditable Hazardous Waste Pharmaceuticals Should Not Include Specific Categories of Pharmaceuticals.

The Pharmaceutical Proposal would define "non-creditable hazardous waste pharmaceutical" as "a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer's credit," while "potentially creditable hazardous waste pharmaceutical" would be defined as "a hazardous waste pharmaceutical that has the potential to receive manufacturer's credit and is: (i) unused or un-administered; and (ii) unexpired or less than one year past expiration date." *See* Proposed § 266.500. The Retail Associations generally support these definitions, but we want to ensure that EPA does not view generic prescription pharmaceuticals as non-creditable. EPA has presented several webinars that state that there is never a reasonable expectation of credit for generic drugs. This is incorrect; many generic drugs are creditable

In the retail sector, most pharmaceuticals are reasonably expected to receive credit. Our data show that of prescription pharmaceutical returns, a median of 91.2% receive credit. Moreover, as EPA acknowledges, whether a pharmaceutical is eligible for credit depends on the manufacturer's policy, which varies over time. *See* 80 Fed. Reg. at 58,022-023. Store personnel are not capable of knowing at any given time whether a particular pharmaceutical will be creditable. Therefore, we are asking EPA to clarify that only if a pharmaceutical does not meet the definition of a potentially creditable hazardous waste pharmaceutical would it not be expected to be eligible for credit.

X. EPA SHOULD FINALIZE AS IS SEVERAL KEY PROVISIONS OF THE PHARMACEUTICAL PROPOSAL

A. Finalize Conditional Exemption for Hazardous Waste Pharmaceuticals that Are Controlled Substances

The Retail Associations support the proposed conditional exemption for hazardous waste pharmaceuticals that are also controlled substances. *See* Proposed § 266.506. The DEA rules for disposal of controlled substances will ensure that these wastes are properly managed. Moreover, removal of the obstacles posed by RCRA will facilitate collection and disposal of these pharmaceuticals. It is imperative that authorized states adopt this provision as soon as possible in order to have maximum environmental benefits. Accordingly, we ask EPA to finalize this aspect of the proposal and encourage adoption by the states as soon as possible.

B. Finalize the Proposed Prohibition on Disposal of Hazardous Waste Pharmaceuticals in Sewer Systems

The Retail Associations support EPA's proposal to prohibit the discharge of hazardous waste pharmaceuticals into sewer systems. *See* Proposed § 266.505. We note that the amount of hazardous wastes entering sewer systems through the operations of retailers and other health care facility is likely negligible, especially in comparison to other sources, such as disposal by households through flushing of unused pharmaceuticals, washing of skin surfaces to which topical pharmaceuticals have been applied, and excretion of pharmaceuticals (and their metabolites) by end-users. Nevertheless, we believe the proposed prohibition is a useful and reasonable measure to help protect the nation's water supply.

C. Finalize the Proposed "Counting" Exemption for Hazardous Waste Pharmaceuticals

The Retail Associations endorse EPA's proposal to exempt pharmaceuticals that are managed pursuant to the new pharmaceutical waste management standards from "counting" toward a facility's hazardous waste generator status. *See* Proposed § 261.5(c)(8). This approach is consistent with the approach EPA has long taken for wastes subject to special management standards, such as used oil, spent lead-acid batteries, universal wastes, and wastes from academic laboratories. *See* 40 C.F.R. § 261.5(c)(4)-(7). It will also help ensure that retailers and other health care facilities are not inappropriately classified as LQGs subject to the same stringent requirements as industrial facilities based on generation of very small quantities (*e.g.*, 1 kg/month) of acutely hazardous pharmaceutical wastes (*e.g.*, nicotine or warfarin products) or larger quantities of non-acutely hazardous pharmaceutical wastes that EPA has acknowledged should not trigger full regulation for the pharmaceutical wastes, much less for other hazardous wastes that may be generated by the same facility.

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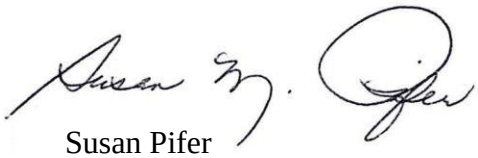
The Retail Associations appreciate the opportunity to provide our comments on this important rulemaking. We would welcome the opportunity to provide further input to EPA in order to help ensure that any final rule that makes sense for retailers of prescription pharmaceuticals, OTCs, and dietary supplements. Please do not hesitate to contact us for further information.

Sincerely,



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