CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
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Docket No. EPA–HQ– OA–2017–0190

Sarah Rees, Director,
Office of Regulatory Policy and Management
Office of Policy
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Executive Order 13777, *Enforcing the Regulatory Reform Agenda*, Request for Comment, 82 Fed. Reg. 17793 (April 13, 2017), Docket No. EPA–HQ– OA–2017–0190

Dear Ms. Rees:

The Consumer Healthcare Products Association ("CHPA") appreciates the opportunity to provide our comments to the Environmental Protection Agency ("EPA" or "the Agency") on Executive Order (EO) 13777, *Enforcing the Regulatory Reform Agenda*, Request for Comment, 82 Fed. Reg. 17793 (April 13, 2017).

For more than 134 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of over-the-counter medicines and remedies ("OTCs") and dietary supplements that provide safe, effective, and affordable therapies to treat and prevent many common ailments and diseases. Literally from head to toe, OTCs and supplements are the trusted first line of treatment for 240 million Americans every year and recommended by healthcare providers to their patients for a range of health and wellness needs. These accessible, affordable, and trusted medicines and supplements empower individuals and families to meet their everyday healthcare needs.

As you know, EPA has made extensive efforts made in recent years to develop an improved and suitable regulatory approach for the disposal of pharmaceuticals under the Resource Conservation and Recovery Act (RCRA). While well intended, and formulated after extensive forethought and effort, these new requirements would increase costs, complicate very secure, environmentally sound pharmaceutical disposal practices, and severely disrupt existing business relationships that currently remove pharmaceuticals from the supply chain in a safe and responsible manner.

CHPA and its members are committed to ensuring that our OTCs and supplements are managed appropriately, but not burdened with regulations that could unnecessarily impact the cost of these important treatment options for those who rely on them. With healthcare costs continuing to rise, OTCs and dietary supplements are more important than ever in keeping Americans healthy. When disposed of, these widely used consumer

products should not require expansive regulation as hazardous wastes. Burdensome disposal rules would increase the resources needed to manage OTCs and supplements, and that in turn may lead to higher prices.

Thus, we urge your review of the proposed Management Standards for Hazardous Waste Pharmaceuticals[1] (Proposed Rule). We also urge its reevaluation for the burdens they impose upon pharmaceutical disposal since EPA identified no environmental benefits to much of the Proposed Rule and we believe there are many unexamined costs and impacts.

The OTC Industry's Concerns and Recommendations

CHPA's submission to the docket on December 24, 2015[2], included two comments:

- First, CHPA welcomes EPA's efforts to amend the acute hazardous waste listing for nicotine and salts (P075), 80 Fed. Reg. 58071, and urges EPA to move forward quickly to amend P075 to exclude nicotine replacement therapies ("NRT") from the listing. Excluding these FDA-approved products would comport with current science and remove a significant and unnecessary regulatory burden.

- Second, while CHPA believes that OTCs and dietary supplements should not be treated as hazardous wastes under RCRA, if they are, certain additional adjustments would be appropriate to further reconcile the Proposal with how the supply chain is managed for OTCs and dietary supplements. The adjustments will help EPA more fully realize its goals to develop "a tailored, sector-specific regulatory framework" that still ensures proper management of wastes. 80 Fed. Reg. 58015.

As stated in our comments, routine use of NRT products demonstrates that these FDA-approved OTC products cannot be classified as "acutely hazardous" wastes when discarded. By regulation, a waste can only be classified as acutely hazardous if the waste "has been found to be fatal to humans in low doses or, in the absence of data on human toxicity" if it exceeds certain acute toxicity criteria in laboratory animals.[3] In the case of NRT products, there is no need for EPA even to consider animal testing results -- the Agency need only use its common sense, as the data on "human toxicity" is readily available: the millions of people who use NRT products multiple times each day provide the best evidence for EPA that OTC nicotine replacement therapies are simply *not* "fatal to humans in low doses."

Moreover, NRT products also should be exempt from P075 because there is no current, credible toxicity data that would support the continued listing of NRT products

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[1] 80 Fed. Reg. 58014 (Sept. 25, 2015)
[2] Included as Attachment A, for reference.
[3] *See* 40 C.F.R. § 261.11(a)(2).

under P075. In fact, it appears that the original listing was concerned with the use of nicotine in high concentrations in pesticide applications.[4] In 1980, the commercial chemical containing products which contained nicotine were pesticides with very high levels of nicotine, such as Black Leaf 40 which contained 40% nicotine sulfate by weight.[5] Thus, there is reason to believe the original listing was based on a concentration orders of magnitude greater than today's nicotine gum and lozenges (which contain 2-4 mg of nicotine or approximately 0.2 to 2.0% by weight depending on lozenge size) or nicotine patches (which transdermally deliver 7-21 mg of nicotine or approximately 2 to 7% by weight).

While the NRT issue is unique to the OTC industry and its partners, numerous public comments addressing this complex situation were provided to the rulemaking docket identifying a host of potential issues.

Of these issues, the Agency's intent to eliminate a critical interpretation of RCRA and solid waste that has been in effect for over 30 years is most concerning to CHPA and its members. For OTCs and dietary supplements, the marketplace has developed a process for managing unsold OTCs and dietary supplements through the commercial supply chain before they are discarded. Historically, EPA recognized this type of process, finding that a product is not a waste until a final determination is made to discard it. In the Proposed Rule, however, EPA has proposed to reverse its previous guidance and treat as a "solid waste" any unsold or unused pharmaceuticals, defined to include OTCs and dietary supplements, which are sent to third party return centers for further processing. CHPA submits this is not consistent with RCRA – and not sound policy. The market has developed a sensible process for safely and efficiently managing these unused consumer products and we ask EPA to continue to align its regulations with those reasonable, commercial practices.

EPA had previously recognized that unused pharmaceuticals that were returned to "reverse distributors" were still products, not solid wastes[6], unless and until the reverse distributor determined the product had to be discarded. In the Proposal, EPA has abandoned that approach. Instead, under EPA's proposed rule, "once the decision is made to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste at the healthcare facility."[7]

When combined with other provisions of EPA's proposal, this new approach would greatly increase the supply chain costs imposed on OTCs and dietary supplements. Specifically, EPA has also proposed to define "hazardous waste pharmaceuticals" to include all OTCs and dietary supplements that otherwise would be (characteristic or listed)

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[4] See 80 Fed. Reg. 58072

[5] Comments of the Retail Associations in Response to EPA's Proposed Management Standards for Hazardous Waste Pharmaceuticals (Dec. 22, 2015), 5-6.

[6] 80 Fed. Reg. 58042-43

[7] 80 Fed. Reg. 58043

hazardous waste.[8] As such, EPA is proposing to treat unused OTCs and dietary supplements as a waste when sent to a reverse logistics center.

CHPA asks EPA to reassess the soundness of this new approach. As a preliminary matter, CHPA submits that OTCs and dietary supplements should not be managed as hazardous waste under any circumstances, and should exempt these products from RCRA subtitle C regulation altogether. OTCs and dietary supplements are safe and effective products purchased without a prescription and used every day by millions of Americans. It is illogical, burdensome, costly and wasteful to ever classify products that consumers eat every day as RCRA hazardous waste when discarded. However, if any OTCs and dietary supplements are potentially subject to RCRA, these consumer products should not be considered wastes when transported to a reverse logistics provider for further processing.

Centralizing the hazardous waste determination at the reverse distributor would enhance the waste determination process simply because of the sheer complexity and scope of managing the determination for thousands of products. The hazardous waste determination process is particularly difficult at retail stores that handle numerous OTCs and dietary supplements, along with thousands of other different products that each would have to be analyzed separately to determine if they could be hazardous wastes if discarded. For each retailer to keep track of which product could be hazardous wastes when discarded is an extremely challenging task, complicated by frequent changes to product formulations or introductions of new products, marketed by different suppliers. Therefore, it would be more efficient and appropriate for EPA to allow a reverse logistics provider to make those determinations at a central consolidation point.

Conclusion

Much work will need to be done to achieve the Agency's objectives as stated in the Proposed Rule. To do so while addressing the supply chain's complex concerns, we believe it will be imperative for EPA to make a concerted effort to revise its approach and gather further input on any contemplated revisions. Thus, we also urge EPA to convene a meeting, workshop or other joint effort to discuss issues, constraints and possible solutions. We leave it to the Agency to determine the best way to accomplish this, but we encourage including as many segments of the supply chain as feasible as well as other regulatory entities charged with governing the safety and security of pharmaceutical products such as FDA and state Boards of Pharmacy.

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[8] 80 Fed. Reg. 58022

We thank you for the opportunity to comment and are available to provide further information or answer any questions.

Respectfully submitted,

Carolyn Herrmann

Carolyn Herrmann
Deputy General Counsel
Consumer Healthcare Products Association
1625 Eye Street NW, Suite 600
Washington, DC 20006
(202) 429-3525
cherrmann@chpa.org

Attachment A: Comments of the Consumer Healthcare Products Association in Response to EPA's Proposed Management Standards For Hazardous Waste Pharmaceuticals – (Docket HQ-RCRA-2007-0932)

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

December 23, 2015

Via e-filing on www.regulations.gov

U.S. Environmental Protection Agency
EPA Docket Center
Mailcode 2822IT
Attention: Docket ID No. EPA-HQ-RCRA-2007-0932
12000 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Comments of the Consumer Healthcare Products Association in Response to EPA's Proposed Management Standards For Hazardous Waste Pharmaceuticals - (Docket HQ-RCRA-2007-0932)

Dear Docket Clerk:

The Consumer Healthcare Products Association ("CHPA") submits these comments in response to EPA's proposed rule under the Resource Conservation and Recovery Act ("RCRA") – "Management Standards for Hazardous Waste Pharmaceuticals," 80 Fed. Reg. 58014 (Sept. 25, 2015) ("Proposal"). CHPA appreciates the opportunity to comment on EPA's Proposal as it applies to over-the-counter medicines and dietary supplements.

Introduction

For more than 134 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of over-the-counter medicines and remedies ("OTCs") and dietary supplements that provide safe, effective, and affordable therapies to treat and prevent many common ailments and diseases. Literally from head to toe, OTCs and supplements are the trusted first line of treatment for 240 million Americans every year and recommended by healthcare providers to their patients for a range of health and wellness needs. These accessible, affordable, and trusted medicines and supplements empower individuals and families to meet their everyday healthcare needs.

Our interest in the Proposal is to ensure that our OTCs and supplements are managed appropriately, but not burdened with regulations that could unnecessarily impact the cost of these important treatment options for those who rely on them. With healthcare costs continuing to rise, OTCs and dietary supplements are more important than ever in keeping Americans healthy. When disposed of, these widely used consumer products should not require expansive regulation as hazardous wastes. Burdensome disposal rules would increase the resources needed to manage OTCs and supplements, and that in turn may lead to higher prices.

CHPA supports EPA's efforts to streamline regulations under RCRA. As outlined below, CHPA has two central comments on the Proposal:

First, CHPA welcomes EPA's efforts to amend the acute hazardous waste listing for nicotine and salts (P075), 80 Fed. Reg. 58071, and urges EPA to move forward quickly to amend P075 to exclude nicotine replacement therapies ("NRT") from the listing. Excluding these FDA-approved products would comport with current science and remove a significant and unnecessary regulatory burden.

Second, while CHPA believes that OTCs and dietary supplements should not be treated as hazardous wastes under RCRA, if they are, certain additional adjustments would be appropriate to further reconcile the Proposal with how the supply chain is actually managed for OTCs and dietary supplements. The adjustments will help EPA more fully realize its goals to develop "a tailored, sector-specific regulatory framework" that still ensures proper management of wastes. 80 Fed. Reg. 58015.

We look forward to working collaboratively with EPA as it develops this Proposal further.

I. EPA Should Amend the Acute Hazardous Waste Listing for Nicotine and Salts (P075) to Exempt All Over-The-Counter Nicotine Replacement Therapy Consumer Products

Currently, EPA effectively interprets its P075 waste listing to treat discarded nicotine replacement therapy products that are sold over-the-counter as a lethal poison that must be managed as "acutely hazardous wastes." This interpretation cannot and should not be sustained, given that *millions of Americans safely consume and use NRT products each and every day.* Because treating these safe OTC therapies as acutely hazardous imposes significant burdens on the supply chain for NRT products, we respectfully ask EPA to promptly amend P075 to exempt by name from the listing all NRT products currently on the market, as well any future NRT products with comparable nicotine concentrations.

A. Treating unused NRT consumer products as hazardous waste imposes unnecessary burdens and significant costs on the supply chain

NRT products are anti-smoking therapies, such as nicotine gums, lozenges, and patches that are approved for use by the Food and Drug Administration ("FDA") and sold over-the-counter without a prescription. These products contain low concentrations of nicotine and help reduce nicotine withdrawal and craving. In 2014 alone, 29 million units were sold across the United States.[1] As such, millions of people chew, ingest and/or apply NRT products multiple times a day – with the encouragement of federal, state, and local health authorities, and the medical community. Consumer access to affordable, over-the-counter NRT has resulted in tens of thousands of people quitting smoking every year, translating into billions of dollars of savings across our economy.[2]

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[1] http://www.chpa.org/OTCsCategory.aspx (compiling OTC sales by product category).

[2] Pfizer, The Value of OTC Medicines (March 2014) (available at https://www.pfizer.com/files/health/VOM_OTC.pdf, citing Keeler, T.E, Hu, T.W., Keith, A., Manning, R., Marciniak, M.D., Ong, M., & Sung, H.Y. *The benefits of switching smoking cessation drugs to over-the-counter status*. Health Economics 11(5):389-402 (July 2002) (available at http://www.ncbi.nlm.nih.gov/pubmed/12112489).

Currently, however, unsold NRT products are treated as acutely hazardous waste when discarded. In 1980, EPA listed "Nicotine and salts" as acutely hazardous waste (P075) - long before NRT products were in use and thus without considering whether these types of uses of nicotine presented a risk that should be covered by the P075 listing. Hazardous Waste Management System: Identification and Listing of Hazardous Waste, 45 Fed. Reg. 78529, 78541 (Nov. 25, 1980). Based on that original listing, in 2010, an EPA division director issued an informal guidance letter stating that unused NRT products (including nicotine patches, gum, and lozenges) are listed as acutely hazardous waste (P075) when discarded. *See* Letter from Robert W. Dellinger, EPA, Director, Material Recycling and Waste Management Division, to Charlotte A. Smith, WM Healthcare Solutions (Aug. 23, 2010).

EPA acknowledges that in light of this position, when discarded, these unsold NRT products are causing retailers to incur additional burdens and costs as large quantity generators ("LQGs"), because the threshold for triggering LQG status is only 1 kg/month of acutely hazardous waste. 80 Fed. Reg. 58072. The retailers have documented this burden in submissions made to the agency in the course of this rulemaking.[3] The efforts to streamline regulations in this Proposal could alleviate some of the burdens, because EPA's proposal would include NRT products in a new category of "pharmaceutical hazardous waste" that would not be subject to many LQG requirements. Unfortunately, those changes, while a step in the right direction, do not go far enough. Any covered healthcare facility (which includes pharmacies and retailers) that generates/accumulates more than 1 kg of acutely hazardous waste per calendar month, including hazardous waste pharmaceuticals, would still have to manage hazardous waste pharmaceuticals in line with the Proposal's requirements. 80 Fed. Reg. at 58025-26. That will continue to impose unnecessary costs and burdens throughout the supply chain for NRT products.

B. NRT consumer products are not acutely hazardous wastes and should be explicitly exempted from EPA's P075 listing

1. Common use of NRT consumer products by millions of Americans demonstrates they cannot be acutely hazardous

Recognizing the concerns raised by stakeholders, EPA has stated its intention to collect the FDA's data and other publicly available information evaluating NRT products in order to assess whether the P075 listing should be amended to exclude NRT products. CHPA supports EPA's proposal to reassess the 35-year old P075 listing, and respectfully submits the evidence is abundantly clear that discarded NRT products are not acutely hazardous P075 waste.

Foremost, routine use of NRT products demonstrates that these FDA-approved OTC products cannot under any circumstances be classified as "acutely hazardous" wastes when discarded. By regulation, a waste can only be classified as acutely hazardous if the waste "has been found to be fatal to humans in low doses or, in the absence of data on human toxicity" if it exceeds certain acute toxicity criteria in laboratory animals including "an oral LD 50 toxicity

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[3] Comments of the Retail Associations in Response to EPA's Proposed Management Standards for Hazardous Waste Pharmaceuticals (Dec. 22, 2015) ("RILA Comments"). *See also* Comments of the Retail Associations in Response to EPA's NODA on the on the Application of RCRA to the Retail Industry (May 30, 2014) ("RILA NODA Comments").

(rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 toxicity (rabbit) of less than 200 milligrams per kilogram" or "is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness." *See* 40 C.F.R. § 261.11(a)(2). According to EPA, discarded commercial chemical products are acutely hazardous wastes only if they are "extremely powerful poisons." *See* EPA Office of Solid Waste, Background Document, *Section 261.33 – Hazardous Waste from Discarding of Commercial Chemicals Products and the Containers and Spill Residues Thereof* at 22 (January 1981) ("CCP Background Document"). A waste should be classified as acutely hazardous if "ingestion of less than a teaspoonful … would be fatal to an adult." *Id.*

In the case of NRT products, there is no need for EPA even to consider animal testing results -- the Agency need only use its common sense, as the data on "human toxicity" is readily available: the millions of people who use NRT products multiple times each day provide the best evidence for EPA that OTC nicotine replacement therapies are simply *not* "fatal to humans in low doses." Indeed, for the same reason, it is inconceivable that NRT products which consumers may use multiple times each day could ever be considered "extremely powerful poisons" requiring extraordinary treatment as acutely hazardous waste. On this basis alone, CHPA urges EPA to exempt NRT products from the P075 listing.

2. The findings of the FDA, the U.S. Public Health Service, and the National Institutes of Health all confirm that NRT products are not acutely hazardous

Beyond the safety that is self-evident from the widespread use of millions of NRT products every year, experts charged with protecting and advising the public have already evaluated the data and scientific literature and concluded that people can safely consume many, many times more than "a teaspoonful" of NRT products each day. For one, the FDA has already conducted a careful review of NRT products and associated data before issuing its approval to allow the public to use NRT products – and then again to allow the sale of NRT products over the counter.[4] Indeed, in 2013 FDA 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.[5] The U.S. Public Health Service has likewise stated that nicotine gums and lozenges

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[4] *See e.g.,* Letter from P. Botstein, M.D. (FDA) to M.L. Stewart (Hoechst Marion Roussel) (Feb. 9, 1996) (OTC Approval Letter for Nicorette, NRT gum), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/96/018612s022_Nicorette_approv.PDF ; L. Chin, M.D., M.P.H. (Sept. 7, 1995) (Medical Officer's Review of OTC application for Nicorette), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/96/018612s022_Nicorette_medr.PDF; Letter from C. Ganley, M.D. and B. Rappaport, M.D. to D. Schifkovitz (GlaxsoSmithKline) (Oct. 30, 2002) (OTC Approval Letter for Commit, NRT lozenge), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-330_Commit%20Lozenge_Approv.pdf; C. Winchell (FDA, Medical Officer) (Oct. 9. 2011) (Medical Officer's review of OTC application for Commit), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-330_Commit%20Lozenge_Medr_P1.pdf; and http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-330_Commit%20Lozenge_Medr_P2.pdf

[5] *See* 78 Fed. Reg. 19718 (April 2, 2013).

are "an effective smoking cessation treatment that patients should be encouraged to use."[6] 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.[7]

EPA should defer to the work of the FDA and these public health experts and find that NRT products that millions of consumers routinely use on a daily basis cannot be considered "acutely hazardous waste" under RCRA when discarded.

3. The P075 listing must be amended to expressly exclude NRT products because there are no credible toxicity data that would support listing NRT products as acutely hazardous

Moreover, NRT products also should be exempt from P075 because there is no current, credible toxicity data that would support the continued listing of NRT products under P075. In 1980, EPA based its P075 listing on (i) an estimated median lethal oral dose (LD50) to humans of 1 mg/kg (which would roughly equate to a fatal dose of 50-60 mg) and (ii) a dermal LD50 toxicity of rabbit of 50 mg/kg as a second basis for the listing. *See* EPA CCP Background Document at 45 (1 mg/kg "est."). Neither of these provides a basis for continuing to treat NRT products as "acutely hazardous."

Oral toxicity. With regard to oral toxicity, EPA acknowledges that "the background listing document and its references do not provide sufficient detail to determine the concentration of nicotine that was used to establish the oral LD50 in humans." 80 Fed. Reg. at 58071. In fact, this estimate has been discredited, as the U.S Surgeon General recently stated that there is no identified support for the assertion that nicotine has an LD50 for humans of 1 mg/kg.[8] Researchers believe the estimate was based on "highly dubious self-experiments performed in the middle of the nineteenth century" which is inconsistent with and contrary to more recent literature.[9]

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[6] *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.

[7] *See* NIH, MedlinePlus at http://www.nlm.nih.gov/medlineplus/druginfo/meds/a684056.html (24 pieces of nicotine gum per day) and http://www.nlm.nih.gov/medlineplus/druginfo/meds/a606019.html (20 nicotine lozenges per day).

[8] *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 ("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").

[9] *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. *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) ("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) ("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").

Further it appears that the original listing was concerned with the use of nicotine in high concentrations in pesticide applications. *See* 80 Fed. Reg. 58072. In 1980, the commercial chemical containing products which contained nicotine were pesticides with very high levels of nicotine, such as Black Leaf 40 which contained 40% nicotine sulfate by weight.[10] Thus, there is reason to believe the original listing was based on a concentration orders of magnitude greater than today's nicotine gum and lozenges (which contain 2-4 mg of nicotine or approximately 0.2 to 2.0% by weight depending on lozenge size) or nicotine patches (which transdermally deliver 7-21 mg of nicotine or approximately 2 to 7% by weight).

Beyond the failings of the original listing, more recent animal testing demonstrates that even pure-form nicotine itself is not toxic by the standards established by EPA's rules. As noted, 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). 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).[11] 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."[12] ECHA did not identify any studies that reported an oral LD50 (rat) value of less than 50 mg/kg.[13] 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). Hence, there can be no question that low concentration NRT products are not acutely hazardous under RCRA.

Dermal toxicity. The original listing for dermal LD50 toxicity for a rabbit is equally unreliable as again, the background document provides no references. Regardless, it would seem clear that nicotine patches are surely not acutely hazardous by dermal contact for adults, inasmuch as their very purpose is to be applied to the skin – which millions do every day without toxic effects. We do acknowledge that there are reports in the literature that suggest the potential for effects if young children were improperly[14] exposed to nicotine patches or if adults intentionally misused the patches.[15] However, the effect due to intentional misuse of a lawful

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[10] RILA NODA Comments at 5-6.

[11] *Available online at* http://echa.europa.eu/documents/10162/f9510930-4e5e-45ff-bb3a-888cefaf6592.

[12] *Id.*

[13] *Id.*

[14] The product labels expressly instruct persons under 18 years of age to consult with their doctor before use. http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/018612s061_020066s042lbl.pdf.

[15] *See* A. Woolf, "Childhood Poisoning Involving Transdermal Nicotine Patches," *Pediatrics* (1997) (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); A. Woolf, et al., "Self-poisoning among adults using multiple transdermal nicotine patches," *Journal of Toxicology – Clinical Toxicology* (1996) (study looked at cases of dermal exposure from either intentional misuse or suicide attempts).

product that the FDA has approved for sale over-the-counter cannot be the basis for determining whether EPA should regulate a product as an "acutely hazardous waste" when discarded. Many products could cause toxic effects if not used as directed, but that standard would improperly send EPA down an endless path of regulating innumerable, safe products as acutely hazardous when discarded. In all events, in the few cases where the literature identified that there were effects, all of the patients recovered.[16] Thus, there is ample support for EPA to find that even if there were risks if an NRT patch were misused, such risks do not present "serious irreversible, or incapacitating reversible, illness" and thus do *not* warrant continuing to list these approved products as acutely hazardous waste.

4. When formally evaluating whether to amend the P075 listing to exclude NRT products, EPA should assume the burden of proof

Although CHPA supports EPA's willingness to amend the P075 listing, in conducting its analysis, we urge the Agency not to shift the burden to stakeholders to show that NRT products are not acutely hazardous. Instead, EPA should amend P075 to exclude NRT products, unless the Agency specifically determines the products meet the criteria for an acutely hazardous waste.

Congress authorized EPA to issue rules "for listing hazardous waste" under RCRA. 42 U.S.C. § 6921(a). Following that direction, EPA issued regulations specifying that the "Administrator shall list a solid waste as a hazardous waste *only upon determining* that the solid waste meets" the listed criteria. 40 C.F.R. § 261.11 (emphasis added). Yet, as an agency, EPA has never gone through a notice and comment process in which the Administrator "determined" that NRT products are "acutely hazardous waste." As noted, an EPA division director did issue an opinion letter stating that NRT products fell within the scope of P075. However, that informal letter was premised on an original listing for nicotine which is demonstrably not based on data or analysis with any nexus to these FDA-approved NRT consumer products.

In the absence of data showing NRT products meet the requirements of a listed "acutely hazardous waste" if discarded, the burden should be on EPA to show that regulation is necessary to "promote the protection of health and the environment," not on interested stakeholders to defend an FDA-approved product sold over the counter across the United States. 42 U.S.C. § 6902 (RCRA objectives). EPA should not shift the burden and presume acute toxicity in the absence of actual data demonstrating there is a risk warranting regulation of NRT products as acutely hazardous wastes.

II. EPA should maintain its historic practice finding that unsold pharmaceuticals are not a solid waste until a final determination is made to discard the product

While the many details of RCRA are exceedingly burdensome and complex to implement, the statute's core principle is straightforward: RCRA is a waste management statute. Unless and until a product becomes a "solid waste," it is not covered by RCRA – and an item cannot be a hazardous waste, unless it is first a solid waste. RCRA defines "solid waste" as "any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air

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[16] *See id.*

pollution control facility and *other discarded material....*" 42 U.S.C. § 6903(27) (emphasis added). To be "discarded" means to be "disposed of," "thrown away" or "abandoned." *See Am. Mining Cong. v. U.S. EPA*, 824 F.2d 1177, 1184 (D.C. Cir. 1987); *Ass'n of Battery Recyclers v. U.S. EPA*, 208 F.3d 1047, 1052 (D.C. Cir. 2000) (rejecting EPA's argument that RCRA can be applied to "materials that are not disposed of, abandoned, or thrown away").

For OTCs and dietary supplements, the marketplace has developed a process for managing unsold OTCs and dietary supplements through the commercial supply chain before they are discarded. Historically, EPA recognized this type of process, finding that a product is not a waste until a final determination is made to discard it. In the Proposal, however, EPA has proposed to reverse its previous guidance and treat as a "solid waste" any unsold or unused pharmaceuticals, defined to include OTCs and dietary supplements, which are sent to third party return centers for further processing. CHPA submits this is not consistent with RCRA – and not sound policy. The market has developed a sensible process for safely and efficiently managing these unused consumer products and we ask EPA to continue to align its regulations with those reasonable, commercial practices.

A. There is a well established "reverse logistics" process for managing unsold OTCs and dietary supplements

As the Proposal acknowledges, the market has established a process for pharmacies, retailers and other healthcare providers to centralize the management of unsold or unused products, including unused prescription pharmaceuticals, OTCs and dietary supplements. In general, in this established process, the retailer contracts with a "reverse distributor" (for prescription pharmaceuticals) or a third-party logistics provider (for OTCs and dietary supplements) to process the unused product. In the case of OTCs and dietary supplements, these consumer products are routinely sent to a return center and consolidated for further handling.

This reverse logistics of consumer products, including OTCs and dietary supplements, are essential aspects of today's advanced supply chain management. OTCs and supplements are moved through these processes for a range of business purposes, as well as to assess whether the unused products and packaging can be donated for further use, reclaimed, or recycled – or, if necessary, must be discarded. Indeed, it has become increasingly critical to an efficient supply chain to have a centralized return center make these determinations as manufacturers have a range of return policies. Some OTC manufacturers have traditional return policies, while others have adopted swell allowances of adjustable rate policies under which a customer may request instructions authorizing the return of unsold, unexpired products. Under these policies, products that could otherwise be classified as hazardous waste under current rules if sent for disposal or destruction are sent to the designated logistics provider for evaluation for donation. Moreover, manufacturer return policies can and do change frequently, making it far more efficient to send all products that cannot be sold to a return center for evaluation, rather than expect a store clerk to be familiar with dozens of return policies. The products and packaging of OTCs and dietary supplements that move through this process are in substantially the same form as products handled safely in forward distribution, by store personnel, by healthcare providers, and by consumers. Items that are not suited for this process, such as broken or leaking packages, are segregated for proper waste management.

B. EPA should recognize that OTCs and dietary supplements sent to a third party for further processing are not wastes

EPA had previously recognized that unused pharmaceuticals that were returned to "reverse distributors" were still products, not solid wastes, 80 Fed. Reg. 58042-43 (citing examples), unless and until the reverse distributor determined the product had to be discarded. In the Proposal, EPA has abandoned that approach. Instead, under EPA's proposed rule, "once the decision is made to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste at the healthcare facility." 80 Fed. Reg. 58043.

When combined with other provisions of EPA's proposal, this new approach would greatly increase the supply chain costs imposed on OTCs and dietary supplements. Specifically, EPA has also proposed to define "hazardous waste pharmaceuticals" to include all OTCs and dietary supplements that otherwise would be (characteristic or listed) hazardous waste. 80 Fed. Reg. 58022. As such, EPA is proposing to treat unused OTCs and dietary supplements as a waste when sent to a reverse logistics center.

CHPA asks EPA to reassess the soundness of this new approach. As a preliminary matter, CHPA submits that OTCs and dietary supplements should not be managed as hazardous waste under any circumstances, and should exempt these products from RCRA subtitle C regulation altogether. OTCs and dietary supplements are safe and effective products purchased without a prescription and used every day by millions of Americans. It is illogical, burdensome, costly and wasteful to ever classify products that consumers eat every day as RCRA hazardous waste when discarded. However, if any OTCs and dietary supplements are potentially subject to RCRA, these consumer products should not be considered wastes when transported to a reverse logistics provider for further processing.

1. EPA should confirm that OTCs and dietary supplements that are clearly destined for donation, recycling or reclamation are not "solid wastes" subject to the Proposal

First, CHPA would ask EPA to confirm that it would continue to apply its historic interpretation when it is known that the unsold OTCs and dietary supplements are going to be sent to a reverse logistics provider for donation or to be reclaimed. In that case, by law, those products are clearly not "solid wastes" as they have not been discarded and thus would not be subject to RCRA. *See supra* at 7. EPA's existing RCRA rules in fact explicitly 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), as well as unused commercial products destined for reclamation. 40 C.F.R. § 261.2(c)(3) (commercial chemical products being reclaimed are not solid wastes). We presume EPA did not intend to supersede these clear and basic elements of RCRA as applied to OTCs and dietary supplements and would ask EPA to confirm this in any final rule. Indeed, in the case of NRT products, EPA has already recognized that nicotine-containing products, when reclaimed via a nicotine reclamation process, "would not be considered solid waste and thus are not subject to RCRA hazardous waste regulation when sent for nicotine reclamation." Letter from Barnes Johnson,

Director, Office of Resource Conservation and Recovery, U.S. EPA, to Scott DeMuth, Vice President of Business Development, g²revolution, LLC, (May 8, 2015). This type of salvaging and reclaiming of useful constituents should be encouraged and confirmation in the final rule would avoid confusion among interested parties.

2. OTCs and dietary supplements should not be considered "wastes" as when sent to a third party logistics provider for further processing

EPA should also continue to apply its historic approach to OTCs and dietary supplements more broadly, because it is consistent with one of the fundamental purposes of RCRA – the recovery of useful materials where possible. 42 U.S.C. § 6901(c) (Congressional findings). Because OTCs and dietary supplements are still products in commerce that are not yet *discarded* and may yet be recycled, reclaimed, donated or otherwise repurposed by the reverse logistics provider, the OTCs and dietary supplements are not yet solid wastes. Hence, as outlined above, these products are not subject to RCRA.

EPA bases its change in policy on the belief that these unused products are rarely recycled, 80 Fed. Reg. 58043, however, they in fact are recycled more often than EPA believes. According to the Retail Industry, unsold OTC products and dietary supplements are regularly reclaimed in some fashion, and reverse distribution and reverse logistics operations help to maximize these opportunities. In fact, the Retail Industry reports that one retailer estimated that in 2013 over 97% of the products that would have been a characteristic or listed hazardous waste under RCRA if disposed of, were *not* disposed of but were donated or repurposed in some way after the products were shipped to a reverse logistics center.[17] Likewise, a second retailer similarly estimates that 95% of products that would be hazardous waste if discarded were sent through reverse logistics and were ultimately donated or otherwise repurposed.[18] However, regardless of the exact percentage, even the products that ultimately are disposed of are not discarded until a final disposition is made on whether reclamation or donation is available.

3. If it proves to be necessary, it would be a far more sensible rule if EPA permits the waste determination to be made at a reverse logistics provider

Further, EPA should also retain its historical approach because it provides for a better waste determination process, and because it would be far more efficient for EPA and more commercially practical across the supply chain to allow reverse logistics centers to determine how to dispose of OTCs or supplements that cannot be repurposed.

Foremost, centralizing the hazardous waste determination at the reverse distributor would enhance the waste determination process simply because of the sheer complexity and scope of managing the determination for thousands of products. As EPA well knows, determining whether a particular product is a hazardous waste can be a costly and complex process. *See e.g.*,40 C.F.R. §262.21 (the hazardous characteristic of "ignitability" would mean a retailer would have to determine whether a particular alcohol-based OTC medicine met that regulatory

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[17] RILA Comments at 20.

[18] *Id.*

criteria). The hazardous waste determination process is particularly difficult at retail stores that handle numerous OTCs and dietary supplements, along with thousands of other different products that each would have to be analyzed separately to determine if they could be hazardous wastes if discarded. For each retailer to keep track of which product could be hazardous wastes when discarded is an extremely challenging task, complicated by frequent changes to product formulations or introductions of new products, marketed by different suppliers.

It would be more efficient and appropriate for EPA to allow a reverse logistics provider to make those determinations at a central consolidation point. Rather than have thousands of individual determinations made in the store rooms of individual retail locations, many fewer centralized reverse logistics facilities would be responsible. That would create substantial efficiency, by managing the items together at the centralized facility, and would facilitate safer handling and do so more cost effectively. It would also allow EPA and state inspectors to focus their resources on those locations, rather than being dispersed across thousands of locations.

Further, leaving the waste determination at the reverse logistics center would have other efficiencies – and likely improve the prospects of compliance with complex RCRA rules. This is due largely to the size and quality of the reverse logistics center work force, which is typically a smaller group that is focused on evaluating and handling products for further processing. That facilitates both the implementation of the training needed to perform the necessary tasks under RCRA, as well the development of the employee expertise needed to comply with applicable regulations.

By contrast, the typical retail employee would not have the specialized knowledge of the ingredients or properties of OTCs and dietary supplements that would enable them to make accurate hazardous waste determinations. Moreover, the retail work force that handles unsold or returned consumer products typically is younger, more inexperienced, and with high turnover rates, making it more difficult and more costly to sustain a trained work force knowledgeable about what is needed to comply with complex RCRA requirements. Accordingly, not only do they generally not possess the education to make detailed regulatory determinations, the employees may have few opportunities to gain comprehensive knowledge of a store's complete product line.

In other contexts, EPA has recognized 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. 40508, 40511 (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 unused OTCs and dietary supplements sent for evaluation of potential donation, reclamation or other repurposing options are not solid wastes, and thus are not subject to RCRA regulation, unless and until a decision is made to discard the product.

Conclusion

CHPA urges EPA to amend the P075 listing to expressly exclude NRT products and to adjust the proposed rule to align with the reverse logistics process used to manage unused and unsold OTCs and dietary supplements. We thank you for the opportunity to comment and are available to provide further information or answer any questions.

Respectfully submitted,

Carolyn Herrmann

Carolyn Herrmann
Associate General Counsel
Consumer Healthcare Products Association
1625 Eye Street NW, Suite 600
Washington, DC 20006
(202) 429-3525
cherrmann@chpa.org