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Re: Treatment of E-Cigarettes in the Mail

Dear Mr. Kennedy:

The Public Health Law Center is pleased to submit these comments to the U.S. Postal Service (USPS) regarding its planned issuance of regulations clarifying the applicability of the prohibition on mailing of cigarettes to e-cigarettes (“electronic nicotine delivery systems” or ENDS) following the December 2020 enactment of the Preventing Online Sales of E-Cigarettes to Children Act. The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, Tribal, and global leaders promote health by strengthening public policies. For twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation’s diet, encourage physical activity, protect the nation’s public health infrastructure, and promote health equity.

## **I. Introduction**

The USPS proposes to revise Publication 52, Hazardous, Restricted, and Perishable Mail, to incorporate new statutory restrictions regarding the topics discussed below and, once adopted, to incorporate the revisions by reference into 39 C.F.R. Part 113. These comments are intended to provide the USPS with our perspective, drawing on the Center’s deep experience in the field of commercial tobacco control and prevention.

## II. Title - 47

The USPS proposes to revise the title of 47 from “Cigarettes and Smokeless Tobacco” to read: “Tobacco Products (Including Electronic Nicotine Delivery Systems).” As discussed in our comments, below, we recommend an alternative revision: “Nonmailable Tobacco Products (Including Electronic Nicotine Delivery Systems).” This alternative clarifies that the amended prohibition on mailability applies to some, but not all, tobacco products sold by vendors via the Internet, phone, or fax.

## III. Definition of ENDS

The Prevent All Cigarette Trafficking Act of 2009 (PACT Act) sought to prevent children and youth from obtaining addictive tobacco products over the Internet and through mail, fax, or phone orders. A key finding of the PACT Act was that the majority of Internet and other delivery sales of cigarettes and smokeless tobacco were being made without adequate precautions to prevent sales to children. The Act cited a substantial rise in the number of Internet vendors in the United States and in foreign countries selling cigarettes and smokeless tobacco to U.S. buyers between 2000 and 2005. In the years since then, the ability of youth to purchase addictive, dangerous e-cigarette products online became a national crisis. In response, the December 2020 enactment of the Preventing Online Sales of E-Cigarettes to Children Act, Pub. L. No. 116-160, div. FF, title VI (2020), adds “electronic nicotine delivery systems” (ENDS) to the definition of “cigarettes” regulated under the Jenkins Act, 15 U.S.C. 375 et seq. This statutory change means that ENDS will now be subject to the same mailability restrictions and exceptions already in place for cigarettes and smokeless tobacco. *See* 18 U.S.C. 1716E, relying on the Jenkins Act definition of “cigarettes” at 18 U.S.C. 1716E(a)(1).

The USPS proposes to amend Publication 52, at 471, Definitions, by adding three definitions: ENDS; E-Liquid;; and Tobacco Products. While well-intentioned, the USPS’ proposed approach deviates from and is inconsistent with federal law terminology. This deviation is unnecessary and has the potential to create confusion. Below, we propose an alternative approach that addresses the USPS’ implementation concerns while conforming to the language in federal law.

1. *Amend the 471.1 definition of “Cigarette” to include ENDS. [Note: A proposed modification of the USPS’s proposed definition follows this comment.]*

In enacting the Preventing Online Sales of E-Cigarettes to Children Act, Congress specifically amended the definition of “cigarette” in 15 U.S.C. 375 by adding, after roll-your-own tobacco, “an electronic nicotine delivery system.” By following suit –

by amending the current USPS regulatory definition of “cigarette” to include ENDS, as follows – the USPS will conform to the recent statutory change in federal law and remain consistent with its inclusion of roll-your-own tobacco:

#### 471.1 Cigarette

Any roll of tobacco wrapped in paper or in any substance not containing tobacco, and any roll of tobacco wrapped in any substance containing tobacco, which because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette. The term cigarette includes roll-your-own-tobacco and an electronic nicotine delivery system (ENDS) and excludes cigars.

2. *After the definition of “Roll-your-own tobacco,” insert a definition of “Electronic nicotine delivery system” (ENDS) that fully conforms to the definition in the Preventing Online Sales of E-Cigarettes to Children Act enacted on December 27, 2020, and delete the USPS’s proposed definition of E-Liquid. [Note: A proposed modification of the USPS’s proposed definition follows this comment.]*

Congress has clearly defined ENDS to mean “any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device,” explicitly including an e-cigarette, an e-hookah, an e-cigar, a vape pen, and advanced refillable personal vaporizer, an electronic pipe, and “any component, liquid, part, or accessory of a device” ... “without regard to whether the component, liquid, part, or accessory is sold separately from the device...” The only exception allowed by Congress is a product that is approved by the Food and Drug Administration for sale as a tobacco cessation product, or any other therapeutic purpose, and marketed and sold solely for such a purpose.<sup>1</sup>

In its discussion of how it proposes to address ENDS through revisions to Publication 52, the USPS asserts that it “is not intuitive the ENDS should be understood as a form of “cigarette.” The same could be said of “roll-your-own tobacco,” yet the USPS included that product category in its regulatory definition of “cigarette” in 471.1, above, using wording that is straightforward and unambiguous, and supplemented this by adding a separate definition of “roll-your-own tobacco” that conforms to federal legislation. The same approach will work equally well with

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<sup>1</sup> S. 1253, 116th Cong. (2019), [https://www.feinstein.senate.gov/public/\\_cache/files/0/2/028d87b6-4c20-4a00-be16-eada6852bc72/A3F04E9D160B6FE08FB50AC966A1503A.preventing-online-sales-of-e-cigarettes-to-children-act-2019.pdf](https://www.feinstein.senate.gov/public/_cache/files/0/2/028d87b6-4c20-4a00-be16-eada6852bc72/A3F04E9D160B6FE08FB50AC966A1503A.preventing-online-sales-of-e-cigarettes-to-children-act-2019.pdf); see also Preventing Online Sales of E-Cigarettes to Children Act, H.R. 68, 116th Cong. §§ 601-02 (2020), <https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-116HR133SA-RCP-116-68.pdf>.

regard to ENDS — including it in the definition of “cigarette” and adding a definition of ENDS that conforms to the definition of ENDS in the Preventing Online Sales of E-Cigarettes to Children Act.

The wording of the ENDS definition proposed by the USPS for inclusion in Publication 52 parallels the text of the applicable ENDS definition in the Preventing Online Sales of E-Cigarettes to Children Act.<sup>2</sup> The definition as it appears in the legislation has been modified by the USPS for readability by reformatting the text, converting it to sentence form. The USPS has proposed adding a separate definition of an e-liquid in Publication 52; however, there is no need for that and doing so would be contrary to the legislated language. The definition of ENDS in the federal legislation and the parallel definition proposed by the USPS for inclusion in Publication 52, include liquids; as such, there is no need to add a separate definition of an “e-liquid.”<sup>3</sup>

As indicated below by the addition of underlined wording to the USPS’ proposed definition of ENDS, we ask the USPS to consider making one modification to clarify that nicotine and any other substances can be natural or synthetic. It is our contention that this addition is consistent with the amended text of 15 U.S.C. 375, and would provide clarification without altering the legislative meaning. Specifically, we propose adding the words “natural or synthetic” as a descriptor before “... nicotine, flavor, or any other substance...” for purposes of this clarification. Again, while the federal legislation does not include this descriptor, we believe the text supports inclusion of nicotine, whether natural or synthetic, and that this clarification will strengthen understanding and support implementation of regulatory measures.

In addition, we urge the USPS to explicitly recognize that heated cigarettes (called heat-not-burn products by the tobacco industry) come within the meaning of “cigarette,” and that this treatment aligns with the applicable definitions of “cigarette” and “ENDS” in federal law. The only heated cigarettes currently approved for sale and marketed in the United States (e.g., IQOS) come within the meaning of “ENDS” and “cigarette.” That said, some brands available outside the United States do not meet the definition of ENDS, yet (if ever authorized for sale in this country) would come within the meaning of “cigarette” in federal law.

The legislated definition of ENDS as well as the definition proposed by the USPS for inclusion in Publication 52 include a list of ENDS product examples. The legislated

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<sup>2</sup> *Id.*

<sup>3</sup> It should also be noted that Congress included solutions that could be “aerosolized,” not “vaporized.” The term “vaporized,” popular in the ENDS industry, is inaccurate. To the extent that USPS wants or needs to use a term for aerosolization in regulations or communications, the terminology used by Congress is accurate.

list is intended to be illustrative, not all-inclusive; this purpose is conveyed by the wording “includes but is not limited to” preceding the examples. This wording makes clear that other products, however named, will come within the meaning of ENDS if they are an “electronic device that, through an aerosolized solution, delivers [natural or synthetic] nicotine, flavor, or any other substance to the user inhaling from the device.” The term “solution,” in chemistry, while commonly applied to the liquid state of matter, also applies to solids and gases.<sup>4</sup> It is the aerosolization of the solution that is determinative here. It is important to ensure that heated cigarettes, those available now, and others that may enter the marketplace in the future, are regulated by the USPS as cigarettes. The applicable USPS regulations should include the device within the meaning of “cigarette,” whether or not sold separately, as the device is integral to the functionality of this type of cigarette (regardless of whether or not the heated cigarette is an ENDS).<sup>5</sup>

**471.X Electronic Nicotine Delivery System (ENDS)** [*Note: A suggested modification to the USPS’s proposed text is noted with underlining.*]

Any electronic device that, through an aerosolized solution, delivers natural or synthetic nicotine, flavor, or any other substance to the user inhaling from the device. ENDS includes but is not limited to an electronic cigarette, an electronic hookah, an electronic cigar, a vape pen, an advanced refillable personal vaporizer, an electric pipe. ENDS also includes any component, liquid, part, or accessory of such an electronic device regardless of whether the component, liquid, part, or accessory is sold separately from the device. The term “ENDS” excludes any product that is approved by the Food and Drug Administration for sale as a tobacco cessation product or for any other therapeutic purpose, and that is marketed and sold solely for such purpose.

3. *After adding a definition of ENDS, add a definition of “nonmailable tobacco products.”*

In its proposed changes to Publication 52, the USPS proposes adding a definition of “tobacco products” and using that term as a catch-all to collectively describe all nonmailable products, as needed, throughout Publication 52. This term is very likely to cause confusion because “tobacco products” – a defined term used by the U.S. Food and Drug Administration (FDA) – encompasses many products, e.g., cigars and pipe tobacco, that are not subject to the prohibition on mailability and can still be

<sup>4</sup> See, e.g., *Solution*, BRITANNICA (2019), [https://www.google.com/search?q=chemical+definition+of+%22solution%22&rlz=1C1GGRV\\_enUS751US752&og=chemical+definition+of+%22solution%22&aqs=chrome..69i57j0i22i30j0i39014.8675j1j15&sourceid=chrome&ie=UTF-8](https://www.google.com/search?q=chemical+definition+of+%22solution%22&rlz=1C1GGRV_enUS751US752&og=chemical+definition+of+%22solution%22&aqs=chrome..69i57j0i22i30j0i39014.8675j1j15&sourceid=chrome&ie=UTF-8).

<sup>5</sup> For more information on heated cigarettes, please consult the resources on this topic available at the Center’s website. *Heated Cigarettes*, PUB. HEALTH L. CTR. (2018), <https://www.publichealthlawcenter.org/topics/commercial-tobacco-control/heated-cigarettes>.

delivered via the USPS. To distinguish between *all* tobacco products and those deemed nonmailable, the USPS could modify its proposal by defining “nonmailable tobacco products” as follows:

**471.X Nonmailable tobacco products** [*Note: Proposed modifications to the USPS’s proposed definition are noted with underlining and strike-throughs.*]

Cigarettes, including roll-your-own tobacco and electronic nicotine delivery systems (ENDS), and smokeless tobacco ~~or ENDS. An ENDS is~~ are included within the term “nonmailable tobacco products.” An ENDS is nonmailable regardless of whether or not it contains any material derived from tobacco or natural or synthetic nicotine.

The rationale for taking this approach to the amendment of terminology in Publication 52 is discussed further below.

#### **IV. Extension of Existing Provisions to ENDS in General; Terminology**

The suggested changes to definitions, discussed above, respond to the USPS’s interest in facilitating understanding by readers not versed in the statute. The suggested changes conform to the amended federal statutory structure, while also facilitating understanding by readers unfamiliar with the language of the federal law. Rather than list the types and sub-categories of nonmailable products each time mention is required, using a short-hand term – we suggest “nonmailable tobacco products” – will reduce clutter and aid understanding. Adding “nonmailable” as a descriptor of “tobacco product” is necessary to avoid confusion, given that many tobacco products, including cigars and pipe tobacco, are not affected by the recent amendment and remain mailable.<sup>6</sup>

Setting ENDS totally apart from cigarettes for definitional purposes is inconsistent with how the products are characterized elsewhere in federal law and could cause confusion. Again, we urge the USPS to include ENDS within the meaning of “cigarette,” as Congress has directed, yet also add a definition of ENDS that conforms to the federal legislation. We have described how this can be done in a way that respects the integrity of the amendment of federal law while also facilitating understanding and effective implementation processes.

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<sup>6</sup> This change would affect USPS proposed text in, e.g., 472.1, the first sentence of which would be revised to read: “Except as provided in 472.2, nonmailable tobacco products shall not be deposited ...”; see USPS, Treatment of E-Cigarettes in the Mail, 86 Fed. Reg. 32 at 12 (Feb. 19, 2021) (to amend 39 C.F.R. pt. 113), <https://pe.usps.com/FederalRegisterNotice/2021/E-Cigarettes%20Proposed%20Rule.pdf>.

## V. Standards for Determining Nonmailability

While the USPS is correct in placing the entire burden of proof on persons seeking to mail an ENDS product within the limited exception for FDA-approved therapeutic devices, there is no reason at this point for any USPS personnel to humor any ENDS product as mailable under the definition exception established by Congress. No such product has been approved by the FDA, and until one is the USPS cannot accept or consider any evidence supporting the use of this exception. Because no products currently fit the FDA-approved exception, the USPS should only allow persons to supply proof of mailability *after* the FDA issues approvals and provides guidance describing any approved products and listing out the limited number of entities that can credibly ship them (similar to the “designated recipients” information that is required under Title 47 472.221(b)). Only entities on a pre-approved list, compiled based on information provided by the FDA and manufacturers of authorized therapy products, should be allowed to submit evidence of mailability to the USPS.

The USPS is right to question whether each “mailer is acting in good faith” and create systems to prevent mailers “illegitimately treating the therapeutic/tobacco-cessation exclusion as an opportunity to evade the general mailing ban.” The tobacco industry has a long history of deceptive conduct, proven definitively in their violation of racketeering laws as found by the court in *U.S. v. Philip Morris*.<sup>7</sup> In the years since that case was decided, numerous companies producing and selling electronic nicotine delivery systems (ENDS) have been warned by the FDA for selling deceptive and deceptively-marketed products, such as: backpacks and sweatshirts including stealth pockets or openings to hold and conceal ENDS; ENDS products resembling smartwatches; ENDS devices mimicking children’s toys such as handheld game systems or fidget spinners; as well as “e-liquids that imitate packaging for food products that often are marketed and appeal to youth, such as candy, or feature cartoon characters like SpongeBob SquarePants.”<sup>8</sup> Because of the industry’s historic propensity for falsehood, it would be appropriate for the USPS to go further than its draft rule change in assuring that this exception is not exploited.

It follows that the USPS regulation should state that until the FDA informs the USPS of such an approval, all products that fall within the definition of ENDS will be presumed to not have been approved by the FDA as therapeutic or cessation products marketed and sold exclusively for such purpose. If and when the FDA has

<sup>7</sup> See generally Desmond Jenson, *Racketeers at the Table: How the Tobacco Industry is Subverting the Public Health Purpose of Tobacco Regulation*, PUB. HEALTH L. CTR. (2018), <https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-synopsis-racketeers-table-2013.pdf>.

<sup>8</sup> FDA, FDA WARNS MANUFACTURERS AND RETAILERS TO REMOVE CERTAIN E-CIGARETTE PRODUCTS TARGETED TO YOUTH FROM THE MARKET (2020), <https://www.fda.gov/news-events/press-announcements/fda-warns-manufacturers-and-retailers-remove-certain-e-cigarette-products-targeted-youth-market>.

formally informed the USPS that a new product meets this definition, the USPS may find it useful to establish a way to manage a “designated entities” (similar to existing “designated recipients” lists used for 472.221) list of entities that can apply to ship the FDA-approved products. In concert with the FDA and manufacturers of authorized drugs, the USPS should be able to create an authoritative list of authorized medical products distributors, health departments, or healthcare facilities who can apply to mail the approved product. While the USPS may come up with another effective method of identifying legitimate entities in collaboration with the FDA, after relevant products have been authorized, a master list is a proven method, using a system similar to USPS’s existing rules. Whatever methodology is adopted should provide reasonable conditions precedent for any person hoping to provide the USPS with affirmative, credible, and verifiable proof that an ENDS product isailable.

Compiling information on approved products (and potentially also designated entities) would conserve agency resources and cure the information imbalance between the USPS and the ENDS industry. Without such guidance, requiring USPS personnel to make individual determinations about the credibility and truth of every potential mailer’s proffered proof places an unfair burden on staff to vet statements from an industry prone to deception. This may risk exploitation of an exception before the FDA has authorized a single product that would qualify. Because the USPS lacks sufficient resources to track all tobacco product manufacturers and sellers, and because staff lack time to learn the intricacies of the FDA’s opaque drug authorization process in order to determine credibility, there should be clear standards on who may submit proof of mailability and the limited number of products they may be allowed to mail.

Since no product currently qualifies for this exception, the USPS has additional time to discuss with the FDA how to create a formal list or other control, if any ENDS product is eventually authorized as a therapeutic drug. As discussed below, nicotine is a highly poisonous substance; accordingly, if an ENDS product becomes approved by the FDA as a drug it would also be appropriate for the USPS to place limits on its packaging and on who may send or receive such a shipment, consistent with 18 U.S.C. §§ 1716(b)&(d).

## **VI. Applicability of Exceptions**

While Congress created discrete exceptions for cigarettes and smokeless tobacco, the USPS should reconsider whether most of them are appropriate for ENDS even though they are defined as “cigarettes” under the federal statute. This is because, while all tobacco products are potentially deadly when used as intended, only ENDS pose the possibility of severe dangers to postal employees due to their

characteristics as hazardous and poisonous materials. The USPS has duties and authorities under 18 U.S.C. § 1716 that make any exceptions for ENDS highly questionable.

The proposed regulatory language is correct in stating “ENDS and related products that consist of or contain lithium batteries or liquids (including, but not limited to, those containing nicotine or CBD) may be subject to restrictions or requirements pertaining to hazardous materials or special packaging rules for nonhazardous materials stated elsewhere in this publication,”<sup>9</sup> however this note of caution does not go far enough.<sup>10</sup> Nicotine products are dangerous poisons meriting special caution, and ENDS devices have been shown to be especially troubling fire and explosion risks according to federal agency findings.

The following analysis will first cover the danger of nicotine as a poison and ENDS with batteries as explosion and fire risks, then address how these particular dangers make many of the existing exceptions for cigarettes and smokeless tobacco uniquely inapposite. It seems that under existing standards in 18 U.S.C. § 1716, any exception to ENDS being nonmailable should be seriously restricted or eliminated.

1. *Nicotine is a deadly poison, posing a risk to USPS personnel*

Nicotine has been a listed commercial chemical, toxic, acute hazardous waste since the Resource Conservation and Recovery Act (RCRA) rules governing hazardous waste were promulgated in 1980.<sup>11</sup> The U.S. Environmental Protection Agency (EPA) explained why nicotine was put on the list of most dangerous chemical wastes in a subsequent 2019 rulemaking:

EPA listed nicotine and salts (referred to commonly as just nicotine) as acute hazardous waste P075 in 261.33(e). A chemical substance is listed . . . as an acute hazardous waste if it meets any of the criteria in 40 CFR 261.11(a)(2), which, as described below, are based on human toxicity data, or dose of a chemical given orally or dermally that is lethal to 50 percent of the test animals

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<sup>9</sup> USPS, Treatment of E-Cigarettes in the Mail, 86 Fed. Reg. 32, 10,218 (Feb. 19, 2021) (to amend 39 C.F.R. pt. 113), <https://pe.usps.com/FederalRegisterNotice/2021/E-Cigarettes%20Proposed%20Rule.pdf>.

<sup>10</sup> It is also somewhat confusing that the regulatory language refers to “ENDS and related products” when the definition of ENDS in statute covers all such products, their components, parts, and accessories—it is not clear what meant by “related products” that would go beyond the terms “components,” “parts,” or “accessories,” and USPS may want to take into account that the broad definition of ENDS already encompasses quite a large swathe of items. *See id.*

<sup>11</sup> *See* 45 Fed. Reg. 98, 33124, 33125, 33133 (May 19, 1980), <https://www.govinfo.gov/content/pkg/FR-1980-05-19/pdf/FR-1980-05-19.pdf>.

(LD50) . . . . That is, when the solid waste “has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD50 toxicity . . . or a dermal LD50 toxicity . . . or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness.”

EPA listed nicotine as an acute hazardous waste based on an estimated oral LD50 toxicity to humans of 1 mg/kg and a dermal LD50 toxicity to rabbits of 50 mg/kg. The acute toxicity criterion for humans, as discussed above, is “fatal to humans in low doses” . . . .<sup>12</sup>

However, the EPA’s evaluation of the risk of nicotine poisoning causing severe injury or death is not based only on lab tests from the 1980s, nor on assessments of nicotine outside of the context of e-cigarettes. Indeed, in 2015 the EPA’s office of Solid Waste and Emergency Response were asked whether e-liquids were acute hazardous wastes under the established RCRA rules. The EPA’s experts found that because nicotine is the sole active ingredient in e-liquids that contain nicotine, those e-liquids are acute hazardous wastes under the EPA’s listing.<sup>13</sup> This is for good reason, because these substances have poisoned many unsuspecting people as they became more popular on the market. As the EPA explained:

in the short time that e-cigarettes have been in the U. S. marketplace (since about 2007), the calls to poison control centers related to exposures to this product, mostly among young children, have increased substantially. This significant increase can be attributed largely to the rapid rise in the use of e-cigarettes . . . . [T]he monthly number of exposures among young children . . . associated with e-cigarettes increased by almost 1500 percent from January 1, 2012 (14 exposures) to April 30, 2015 (223 exposures).<sup>14</sup>

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<sup>12</sup> The EPA went on to explain: “an estimated oral LD50 toxicity to humans for nicotine and salts [of] 1 mg/kg . . . corresponds to 50-60 mg of nicotine as a lethal dose for an adult weighing 50-60 kg, and this estimated LD50 value falls within the criterion for “fatal to humans in low doses.” 84 Fed. Reg. 36, 5822 (Feb. 22, 2019), <https://www.federalregister.gov/d/2019-01298/p-237>; *see also id.*

<sup>13</sup> Letter from Director Barnes Johnson to Daniel K. Dewitt, EPA (May 8, 2015), <https://rcrapublic.epa.gov/files/14850.pdf>.

<sup>14</sup> 84 Fed. Reg. 36, 5826 (Feb. 22, 2019), <https://www.federalregister.gov/d/2019-01298/p-275>.

In this exposition the EPA also reasoned through why e-liquids remained more likely to poison unsuspecting people than nicotine-containing drugs authorized by the FDA:

Exposures of children to unregulated nicotine concentrations in e-cigarette cartridges and refill solutions (e-liquids) have the potential to cause much more severe toxic effects compared to exposures of children to FDA-approved [nicotine replacement therapies]. This is because e-liquid refill containers are available in concentrations up to 100 mg/mL that are then diluted before use. The liquid nicotine, ingested or absorbed through skin, is likely to result in more severe toxic effects because it is available in higher concentrations and absorbed rapidly by the body. In December 2014, a 1-year old child died from liquid nicotine poisoning, the first such death in the U.S.<sup>15</sup>

In explaining why the EPA was not going to remove commercial e-liquids for ENDS from its RCRA hazardous waste system, the agency was very clear that regulatory inaction on behalf of the FDA meant that these products posed the same dangers as any other nicotine chemical waste.<sup>16</sup>

Thus, the federal agency with the most expertise on environmental hazard and toxic pollution has determined that discarded ENDS wastes containing nicotine remain acute hazardous wastes, held to some of the most stringent standards under national hazardous waste laws due to their high toxicity—with a high likelihood of causing severe injury and death.

Although the exposure pathways for USPS employees would likely be different than for the poisoned children the EPA discussed, the likelihood of acute poisoning remains a concern. Significantly, while children often are poisoned as a result of failing to understand what an e-liquid is and absorbing the substance orally, the EPA's findings in 1980 showed that nicotine is also highly toxic when absorbed dermally, which is how postal employees may become exposed when leaking products are sent through the mail.

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<sup>15</sup> *Id.*

<sup>16</sup> EPA said: “[W]ithout controls on the concentration of nicotine in e-cigarettes and e-liquids or FDA's approval of these products as being safe and effective for people to use, the Agency lacks adequate information and certainty to conclude that these nicotine-containing products will not pose the risks similar to those for which the P075 listing was established.” 84 Fed. Reg. 36, 5826 (Feb. 22, 2019), <https://www.federalregister.gov/d/2019-01298/p-273>.

The potential poisoning of USPS employees is of special concern because, as the exceptions are currently written, the “certain individuals” exception allows “damaged or unacceptable tobacco product returned by a consumer to the manufacturer”<sup>17</sup> and any damaged or unacceptable ENDS product may be leaking nicotine liquid into and through a package. As the EPA said, nicotine products being returned to manufacturers could contain many times the fatal amount of nicotine in an undiluted form, and if these products are shipped when damaged, they will place USPS personnel in danger of becoming poisoned through contact with their skin.

It is also the case that ENDS products are frequently mislabeled with regard to whether they contain nicotine and how much they contain.<sup>18</sup> Studies from Canada, the United States, the United Kingdom, Poland, France, Switzerland, Greece, and South Korea have found inaccuracies in product labeling.<sup>19</sup> It would not therefore be practicable or useful for USPS staff to attempt to determine strictly from labels or paperwork whether a product contains a poisonous amount of nicotine. All ENDS products should be treated with extreme caution befitting their potential to contain a dangerous poison capable of causing serious harm to USPS staff.

The fact that the EPA continues to regulate nicotine e-liquids as deadly poisons should be significant concern to the USPS because 18 U.S.C. 1716(a) would make any nicotine-containing ENDS product unmailable poison or “articles and compositions containing poison.” As discussed below, ENDS have been characterized by federal agencies as “hazardous materials, inflammable materials, infernal machines, and mechanical, chemical, or other devices or compositions which may ignite or explode,” and as a result it seems likely that ENDS “may kill or injure another, or injure the mails or other property, whether or not sealed as first-class matter” making them utterly inappropriate for mailing under 18 U.S.C. 1716(a). It would therefore be consistent with existing law for the USPS to not apply any of the existing exceptions for cigarettes and smokeless tobacco to ENDS products.

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<sup>17</sup> EPA, PUBLICATION 52: HAZARDOUS, RESTRICTED, AND PERISHABLE MAIL at 124 (July 30, 2020), <https://pe.usps.com/cpim/ftp/pubs/Pub52/pub52.pdf>

<sup>18</sup> See, e.g., Christine D. Czoli et al., *E-cigarette nicotine content and labelling practices in a restricted market: Findings from Ontario, Canada*, INT’L. J. OF DRUG POL’Y 58 at 10 (2018), (“When examining the accuracy of nicotine labelling with respect to the presence/absence of nicotine, a total of 10 products (6%) were mislabeled . . . When examining nicotine labelling accuracy with respect to a 10% tolerance in nicotine concentration, a total of 25 products (15%) were mislabeled . . .”), <http://davidhammond.ca/wp-content/uploads/2018/03/2018-Ecig-Nicotine-Labeling-IJDP-Czoli-et-al.pdf>.

<sup>19</sup> *Id.* at 11.

2. *ENDS pose a serious risk of fire and explosion, endangering USPS personnel, USPS property, and the mails*

As the USPS has identified in the draft regulatory language, and as quoted above, ENDS contain lithium batteries that may be subject to additional requirements. However, it is important to realize that these products are uniquely dangerous among the range of consumer products with embedded lithium batteries. As laid out below, federal agencies have regulated and assessed ENDS and found them to be hazardous materials that should not be transported in ways that would allow for them to do catastrophic damage.

While ENDS products have only been on the U.S. market since approximately 2007, they have done a lot of damage in a short period of time. The U.S. Fire Administration assessed ENDS fires and explosions between 2009 and 2016 and found that:

- The combination of an electronic cigarette and a lithium-ion battery is a new and unique hazard. There is no analogy among consumer products to the risk of a severe, acute injury presented by an e-cigarette.
- Fires or explosions caused by the batteries used in electronic cigarette are uncommon; however the consequences can be devastating and life-altering for the victims.
- It is likely that the number of incidents and injuries will continue to increase.
- Since the current generation of lithium-ion batteries is the root cause of these incidents, it is clear that these batteries are not a safe source of energy for these devices. . . .
- The shape and construction of electronic cigarettes can make them (more likely than other products with lithium-ion batteries) behave like “flaming rockets” when a battery fails. . . .<sup>20</sup>

Evidence gathered since this report shows these explosions and fires are causing serious and growing harms.<sup>21</sup> A survey of emergency room data collected by the U.S. Consumer Product Safety Commission (CPSC) revealed 2,035 ER visits for ENDS

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<sup>20</sup> Lawrence A. McKenna Jr, *Electronic Cigarette Fires and Explosions in the United States 2009 – 2016*, FEMA (July 2017),

[https://www.usfa.fema.gov/downloads/pdf/publications/electronic\\_cigarettes.pdf](https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf).

<sup>21</sup> For example, at the University of Washington Medical Center fifteen patients suffered severe injuries from ENDS between 2015 and 2016. Elisha G. Brownson et al., *Explosion Injuries from E-Cigarettes*, *NEW ENG. J. OF MED.* 375, 1400-02 (2016),

<https://www.nejm.org/doi/full/10.1056/NEJMc1608478>.

explosion and burn injuries from 2015 to 2017.<sup>22</sup> The researchers who analyzed CPSC's data concluded: "There are more e-cigarette explosion and burn injuries in the USA than estimated in the past reports."<sup>23</sup> This is consistent with public health advocates' analysis of news reports between 2012 and 2020.<sup>24</sup> Also, since the U.S. Fire Administration's report, several deaths have been attributed to exploding ENDS.<sup>25</sup>

Lithium batteries and, specifically, ENDS products, have been shown to cause and menace serious property damage from out-of-control fires, which may imperil USPS properties if ENDS continue to be mailed under exceptions.<sup>26</sup> A battery fire at the South Bayside Waste Management Authority MRF in San Carlos, California caused over 8.5 million dollars in damages.<sup>27</sup> The waste management industry has identified ENDS products, in particular, as an existential threat to their staff and facilities.<sup>28</sup> In Hennepin County, Minnesota, a battery collection site located at a public library had a close call with a serious fire due to an overheated ENDS device.<sup>29</sup> USPS facilities are no less exposed to these dangers, and with mail sorting machines and packages piling up (perhaps pressing buttons or compressing damaged ENDS products), these complex systems may be more exposed to fire risk than a waste pile or a battery collection box at a library.

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<sup>22</sup> Matthew E Rossheim et al., Electronic cigarette explosion and burn injuries, US Emergency Departments 2015–2017, *TOBACCO CONTROL* 28, 472-474 (2019), <https://tobaccocontrol.bmj.com/content/28/4/472>.

<sup>23</sup> *Id.*

<sup>24</sup> AM. NONSMOKERS' RIGHTS FOUNDATION, E-CIGARETTE EXPLOSIONS AND FIRES, <https://no-smoke.org/wp-content/uploads/pdf/E-Cigarette-Explosions-and-Fires.pdf>.

<sup>25</sup> Eli Miexler, *A Florida Man's Death Was Caused by an Exploding E-Cigarette, According to His Autopsy*, *TIME MAG.* (May 17, 2018), <https://time.com/5280288/florida-e-cigarette-explosion-death/>; see also *Exploding e-cigarette kills 24-year-old Texas man*, *BBC* (Feb. 5, 2019), <https://www.bbc.com/news/world-us-canada-47136678>.

<sup>26</sup> According to California legislators: "Waste and recycling collection vehicle, transfer station, and recycling facility fires attributed to illegally disposed of batteries are estimated to have resulted in property losses of several millions of dollars." S.B. 1156, 2019-2020 Leg. Sess. § 1(a)(6) (Ca. 2020), [https://leginfo.ca.gov/faces/billTextClient.xhtml?bill\\_id=201920200SB1156](https://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB1156).

<sup>27</sup> Colin Staub, *Regulators consider mandatory labeling for MRF hazard*, *RESOURCE RECYCLING* (2019), <https://resource-recycling.com/recycling/2019/11/20/regulators-consider-mandatory-labeling-for-mrf-hazard/>.

<sup>28</sup> Katie Pyzyk, *Calls for e-cigarette legislation increase amid growing fire hazard to waste and recycling industry*, *WASTEDIVE* (2020), <https://www.wastedive.com/news/ecigarette-vape-lithium-battery-hazard-waste-recycling/585094/>.

<sup>29</sup> Due to the fire danger of ENDS with push-button activation, Hennepin County has since ended all battery community collection sites. *Hennepin County discontinues battery recycling collection at community spaces*, *HENNEPIN CTY.* (2019), <https://content.govdelivery.com/accounts/MNHENNE/bulletins/268d851>; see also *E-cigarette fire risk leads Hennepin Co. to curb battery recycling*, *MPR NEWS* (2019), <https://www.mprnews.org/story/2019/10/30/ecigarette-fire-risk-leads-hennepin-co-to-curb-battery-recycling>.

Numerous federal agencies have determined that these products are dangerous hazardous material that must be carefully packaged or specially handled. This is why the Federal Aviation Administration, Pipeline and Hazardous Materials Safety Administration, and Department of Transportation (DOT) have consistently restricted the loading of ENDS/their batteries into air cargo.<sup>30</sup> These guidance documents and regulations generally classify ENDS as “hazardous materials.”<sup>31</sup> The regulations also forbid air transport of both damaged and over-sized lithium-ion batteries.<sup>32</sup>

When considering the fire and explosion risk, one exception is particularly troubling when applied to ENDS. Applying the “certain individuals” exception to ENDS may undercut the requirements of 18 U.S.C. § 1716(a), which normally prohibits the mailing of “hazardous materials, inflammable materials, infernal machines, and mechanical, chemical, or other devices or compositions which may ignite or explode.” Specifically, the “certain individuals” exception allows “damaged or unacceptable tobacco product returned by a consumer to the manufacturer,”<sup>33</sup> which means that ENDS containing damaged batteries may be introduced to the mail by individuals who do not understand the danger. This is particularly concerning because existing federal law would say that shipments of damaged ENDS products containing a battery cannot be returned to manufacturers unless the shipment meets the strict requirements of 49 CFR § 173.185(f). Since the “certain individuals” exception falls short of such strict shipping requirements, it either should not apply to ENDS or should be rewritten to more explicitly note the requirements for shipping hazardous materials.

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<sup>30</sup> See 81 Fed. Reg. 97, 31529 (2016) (codified in 49 C.F.R. § 175.10(a)(19)) (“Recent fire incidents involving battery-powered portable electronic smoking devices in checked baggage and actions taken by the Federal Aviation Administration (FAA) and ICAO all of which are described in the October 30, 2015 IFR, prompted action to address this issue. The requirements in this final rule apply only to battery-powered portable electronic smoking devices (*e.g.*, e-cigarettes, e-cigs, e-cigars, e-pipes, e-hookahs, personal vaporizers, electronic nicotine delivery systems”), <https://www.federalregister.gov/d/2016-11729/p-23>; U.S. DEP’T OF TRANSP., HAZARDOUS MATERIALS CARRIED BY AIRLINE PASSENGERS AND CREWMEMBERS at 12 (2015) (Illustrating 9 C.F.R. §175.10), [https://www.faa.gov/about/office\\_org/headquarters\\_offices/ash/ash\\_programs/hazmat/media/Hazardous Materials Carried by Passengers and Crew.pdf](https://www.faa.gov/about/office_org/headquarters_offices/ash/ash_programs/hazmat/media/Hazardous%20Materials%20Carried%20by%20Passengers%20and%20Crew.pdf). See also 49 C.F.R. §§ 173.185(c)(1)-(f) (2016), <https://ecfr.federalregister.gov/current/title-49/subtitle-B/chapter-I/subchapter-C/part-173/subpart-E>.

<sup>31</sup> See U.S. DEP’T OF TRANSP., HAZARDOUS MATERIALS CARRIED BY AIRLINE PASSENGERS AND CREWMEMBERS at 12 (2015), [https://www.faa.gov/about/office\\_org/headquarters\\_offices/ash/ash\\_programs/hazmat/media/Hazardous Materials Carried by Passengers and Crew.pdf](https://www.faa.gov/about/office_org/headquarters_offices/ash/ash_programs/hazmat/media/Hazardous%20Materials%20Carried%20by%20Passengers%20and%20Crew.pdf).

<sup>32</sup> EPA, PUBLICATION 52: HAZARDOUS, RESTRICTED, AND PERISHABLE MAIL at 124 (July 30, 2020), <https://pe.usps.com/cpim/ftp/pubs/Pub52/pub52.pdf>.

<sup>33</sup> 49 C.F.R. §§ 173.185(c)(1)-(f) (2016), <https://ecfr.federalregister.gov/current/title-49/subtitle-B/chapter-I/subchapter-C/part-173/subpart-E>.

Postal employees cannot be expected to determine the size or amount of damage to a particular ENDS product's battery. It seems likely that it would be especially difficult for staff to police the "certain individuals" shipments for this issue because individual users of these products are not expert in these products, and are unlikely to realize the danger of putting inappropriate products into the regular mail system.

### 3. *Additional concerns regarding the use of the "certain individuals" for ENDS*

The "certain individuals" exception is also particularly concerning because ENDS companies are waiting in the wings to restart programs that have encouraged consumers to mail them ENDS trash. If the USPS does not carefully consider these existing market players, it will risk being overwhelmed by large amounts of shipments under what is intended to be a minor exception. Allowing the industry to use the "certain individuals" exceptions for broad self-promotional used product returns programs would be a perversion of the exception, which Congress expressly limited to "noncommercial purposes."

For example, the leading ENDS producer in the nation, JUUL Labs, has an ongoing pilot program whereby it sends its customers a mailing package to send used nicotine-containing cartridges through the mail to a recycling facility.<sup>34</sup> Another example that has allowed the return of disposable ENDS,<sup>35</sup> the "Bidi Cares" program, is "currently unavailable,"<sup>36</sup> but the company previously incentivized customers to mail up to 30 used devices at a time back to them for disposal.<sup>37</sup> The company's FAQ on the program made no mention of what to do with damaged products, and did not discuss any particular packaging requirements to prevent poisonings or fires.<sup>38</sup> Today, the company is encouraging its customers to stockpile their used devices to presumably send them through the mail or through another shipping alternative as soon as the legal uncertainty has been resolved.<sup>39</sup> This same ENDS company has announced it intends to continue delivering ENDS products to consumers in the meantime, using the private convenience sales and delivery company, goPuff, which will mean customers continue to receive ENDS deliveries regardless of whether

<sup>34</sup> JUUL, JUUL LABS RECYCLING PROGRAM, <https://www.juul.com/recycling>.

<sup>35</sup> A disposable ENDS product includes a lithium battery but is not meant to be refilled or recharged, so it becomes waste as soon as the nicotine e-liquid within it is mostly used up or the battery runs out of available electricity. By contrast, a cartridge system like those made by JUUL produce nicotine-tainted e-waste in the cartridges, but the devices may be recharged a limited number of times before they are discarded.

<sup>36</sup> BIDICARES, BIDICARES RECYCLING PROCESS, <https://bidicare.com/faqs/>.

<sup>37</sup> BIDICARES, BIDICARES RECYCLING PROCESS FAQs (Sept. 30, 2020), <http://web.archive.org/web/20200930142256/https://bidicare.com/faqs/>.

<sup>38</sup> *Id.*

<sup>39</sup> A pop-up on the website currently reads: "**BIDI® Cares Is Temporarily Unavailable** We are updating our processes to serve you better. In the meantime, keep your empty BIDI® Sticks for now because we will be back." BIDICARES, BIDICARES RECYCLING MOVEMENT, <https://bidivapor.com/bidi-recycle/>.

their products are nonmailable.<sup>40</sup> Extending the “certain individuals” exception to the return of this company’s products would flood the USPS system with ENDS trash that, while mailed by individuals in relatively small amounts, would add up to a considerable amount of dangerous mail, all heading through the same USPS facility at the receiving end.

It is also the case that ENDS companies are selling ENDS accessories that are dangerous enough to be more stringently regulated by DOT’s existing rules for undamaged lithium batteries. JUUL Labs sells products that it acknowledges can only be sent by ground shipping, by law,<sup>41</sup> presumably referring to 49 CFR § 173.185(c)(1). Allowing the “certain individuals” exception to apply to ENDS and their components, parts, and accessories would permit private people to send these products through the mail, and potentially via air mail.

Rather than putting USPS facilities and staff in danger, these products should be disposed of as hazardous waste using the system already overseen by the EPA and states that have been delegated authority to administer RCRA.<sup>42</sup> Existing hazardous waste disposal companies are capable of legally-compliant hazardous waste recycling and incineration of these products.<sup>43</sup> The USPS should inform any ENDS company encourages returns by mail that such programs may already violate 18 U.S.C. 1716(a), and that in any case these companies can apply their resources toward funding the established hazardous waste system rather than trying to create a dangerous stop-gap return system that puts USPS staff and resources in danger.

4. *The USPS should limit the remaining exceptions as much as possible, consistent with 18 U.S.C. 1716*

As already discussed above, the “certain individuals” exception allowing limited mailing of cigarettes and smokeless tobacco products would be too dangerous to apply to ENDS, but that is not the only exception that should be reevaluated against

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<sup>40</sup> *Bidi Vapor Advances to PMTA Final Substantive Review Phase for Bidi Stick Flavors*, CSTORE DECISIONS (2021), <https://cstoredecisions.com/2021/02/26/bidi-vapor-advances-to-pmta-final-substantive-review-phase-for-bidi-stick-flavors/>.

<sup>41</sup> See, e.g., JUUL, PORTABLE CHARGING CASE, <https://www.juul.com/shop/accessories/portable-charging-case>.

<sup>42</sup> For more information on this topic, and presentations from the EPA, hazardous waste, and public health experts see Hudson Kingston et al., *What a Waste! Legally Disposing of E-Cigarettes and Nicotine Products*, PUB. HEALTH L. CTR. (2021), <https://www.publichealthlawcenter.org/webinar/what-waste-legally-disposing-e-cigarettes-and-nicotine-products>.

<sup>43</sup> See, e.g., VEOLIA, ECIGARETTES - A RESPONSIBLE RECYCLING SOLUTION, <https://www.veolianorthamerica.com/ecigarettes-responsible-recycling-solution>.

the danger of these products. All existing exceptions should be eliminated, tightened, or reassessed to address the inherent risks of ENDS.

There is no reason to believe that intrastate shipments in Alaska or Hawaii would be any less dangerous than mailing ENDS in other parts of the country, just the opposite. To best protect USPS resources and avoid burdening personnel in some of the most difficult assignments in the nation, it would appear to be a valid exercise of 18 U.S.C. 1716(a) to conclude that ENDS shipments in Alaska and Hawaii (by small aircraft or seaplanes,<sup>44</sup> which largely should not be used to transport ENDS), are even more likely to cause damage to USPS personnel, property, or the mails. As such, it makes sense to take steps to ensure that ENDS do not fall within the intrastate shipment exception that currently applies to cigarettes and smokeless tobacco.

If the USPS does not eliminate the use 18 U.S.C. §§ 1716E(b)(3) consistent with 18 U.S.C. § 1716(a), it should be restricted as follows. Use of the “business/regulatory purposes” exception that survives prohibition under 18 U.S.C. § 1716(a) should be restricted under 18 U.S.C. § 1716(e) so that businesses cannot use this exception as a bulk distribution method to sell ENDS products. Tobacco products are generally distributed through specific licensed entities that states and the federal government regulate to prevent tax evasion and assure the uniform application of tobacco tax laws. By restricting the “business/regulatory purposes” exception so that it only applies to ENDS when fully consistent with 18 U.S.C. § 1716(e), the USPS can both decrease the amount of poisons circulating in the mail system and better support the existing tax regimes that exist for tobacco products across the country. Consistent with 18 U.S.C. § 1716(e), the “business/regulatory purposes” exception should not be allowed where ENDS manufacturers or distributors seek to use the mail system to distribute products to retail businesses or to send shipments of ENDS chemicals to vape shops who manufacture products for retail sales. The “business/regulatory purposes” exception should remain available to state agencies engaged in enforcement and those engaged in bona fide research, but not retailers.

The “consumer testing” exception rightly should not apply to ENDS, their components, parts, or accessories. The USPS has correctly articulated why the wide variety of ENDS products that Congress covered in its definition cannot be measured in terms of packs, and Congress appears to have not expressed any intent for this exception to apply to ENDS products. Moreover, consumer testing ENDS products by mail is an unnecessary and potentially harmful use of the mail that would be difficult for the USPS to police effectively—there are thousands of ENDS

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<sup>44</sup> USPS, TRANSPORTATION MAIL RATES, [https://about.usps.com/handbooks/po508/po508\\_ch2\\_004.htm](https://about.usps.com/handbooks/po508/po508_ch2_004.htm); GOVERNMENT CONTRACTS, INTRA-HAWAII AIR TRANSPORTATION AND ANCILLARY SERVICES (2019), <https://www.governmentcontracts.us/government-contracts/opportunity-details/NBD00159789841384335.htm>.

companies who may make totally unverifiable statements about consumer testing that USPS personnel cannot realistically arbitrate. Additionally, there is a high likelihood that any products used in consumer testing would normally be mailed back to the tobacco manufacturer that supplied them in order to protect the company's trade secrets. Again, this would place USPS staff and facilities in danger from potentially damaged and poorly-packaged products being returned by "certain individual" end consumers who may be unaware of or fail to appreciate the danger ENDS products pose. The USPS is right to close this exception to ENDS products.

While the same logic regarding Congress's definition of the quantity of cigarette packs may apply to the "public health" exception, the above concerns about misuse of the "consumer testing" exception are absent for this exception. Consistent with 18 U.S.C. § 1716(e), if federal agencies need to send some quantity of ENDS, their components, parts, or accessories by mail, it is possible that the USPS and the agency could come to an agreement on whether the shipment in question is sufficiently small to comply with the intent of Congress articulated in 18 U.S.C. § 1716E(b)(6). For example, the federal agency could articulate the use of the products to be mailed and explain how the study being conducted is similar in scope to a study using a limited number of cigarettes. The USPS can consult with the U.S. Centers for Disease Control and Prevention and U.S. National Institutes of Health to make any amendments to the "public health" exception that may be necessary to avoid impeding those agencies' research agendas. Some amount of flexibility in the "public health" exception, consistent with 18 U.S.C. § 1716(e), may be appropriate to foster public health research regarding ENDS.

## **VII. Conclusion**

The Center is pleased that the USPS has endeavored to align its instant rulemaking with the updated definition of ENDS that Congress supplied. Congress's comprehensive definition should be followed as closely as possible, and the USPS should consider a wide swathe of ENDS and cigarettes nonmailable, consistent with legislative intent.

There are no ENDS products that could qualify for the FDA-approved therapeutic drug exception, so the USPS need not provide a way for that exception to be used at this point. It is also consistent with what we know about the tobacco industry that the USPS implement controls to limit the use of the FDA-approved therapeutic drug exception to only credible and verifiable statements by known entity mailers. To best protect USPS personnel and resources, the use of exceptions to 18 U.S.C. § 1716E should be severely limited by 18 U.S.C. § 1716's controls on the mailing of poisons and hazardous materials, which are accurate designations for ENDS. Due to

the dangers of these products, it is possible that they should be designated as nonmailable under 18 U.S.C. § 1716(a) regardless of 18 U.S.C. § 1716E(b).

Respectfully,



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Director



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