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The Postal Service's proposed revision of Publication 52, *Hazardous, Restricted, and Perishable Mail*, to restrict the mailing of e-cigarettes and e-cigarette components, liquids, parts and accessories, is a positive step toward protecting youth

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The United States Postal Service proposed revisions to Publication 52, *Hazardous, Restricted, and Perishable Mail* (<https://pe.usps.com>) that incorporate new statutory restrictions enacted in December 2020 that generally prohibit the Postal Service from delivering through the mail any e-cigarettes, e-liquids, or e-cigarette components, parts, or accessories (“ENDS”) (86 FR 10218, <https://www.federalregister.gov/documents/2021/02/19/2021-03393/treatment-of-e-cigarettes-in-the-mail>). We enthusiastically support strong laws and regulations that prevent underage youth from accessing e-cigarette products, and the proposed rule takes a good step towards achieving this goal. However, some of the exceptions in the current rule that apply to cigarettes should not apply to e-cigarettes, e-liquids, or other e-cigarette components, parts or accessories. We also support the decision by the Postal Service to treat ENDS as a standalone category based on the material differences between ENDS products and conventional cigarettes, which the Postal Service appropriately noted in its request for comments.

- 1. The broad definition of “Electronic Nicotine Delivery System” that includes all e-cigarettes and e-cigarette liquids, components and parts, regardless of whether the liquids, components, or parts contain nicotine or are sold separately from the devices, helps protect youth from obtaining e-cigarettes that could harm their health**

On December 27, 2020 Congress enacted the Preventing Online Sales of E-Cigarettes to Children Act (“the Act,” Division FF, Title VI of the Consolidated Appropriations Act, 2021, H.R. 133-1955, <https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf>). This law amends the Prevent All Cigarette Trafficking Act of 2009 (the “PACT Act”) to apply to e-cigarettes and all vaping products (including cannabis and nicotine-free products, among others) and prohibits the Postal Service from accepting for delivery or transmitting through the mail any package that it knows or “has reasonable cause to believe” contains “electronic nicotine delivery systems,” in addition to the existing prohibitions against mailing cigarettes and smokeless tobacco.

The new Preventing Online Sales of E-Cigarettes Act modifies the original definition of “cigarettes” in the PACT Act to include Electronic Nicotine Delivery Systems (ENDS) and defines ENDS very broadly to include all e-cigarettes, vaping products, liquids, components, and accessories, whether or not they contain nicotine. ENDS is defined as follows:

(7) ELECTRONIC NICOTINE DELIVERY SYSTEM. — The term ‘electronic nicotine delivery system’[ENDS]—

(A) means any electronic device that, through an aerosolized solution, delivers nicotine, flavor, **or any other substance** to the user inhaling from the device;

(B) includes—

- (i) an e-cigarette;
- (ii) an e-hookah;
- (iii) an e-cigar;
- (iv) a vape pen;
- (v) an advanced refillable personal vaporizer;
- (vi) an electronic pipe; and
- (vii) any component, liquid, part, or accessory of a device described in subparagraph (A), without regard to whether the component, liquid, part, or accessory is sold separately from the device; and

(C) does not include a product that is—

(i) approved by the Food and Drug Administration for—

- (I) sale as a tobacco cessation product; or
- (II) any other therapeutic purpose; and

(ii) marketed and sold solely for a purpose described in clause (i).

In its invitation for comment, the Postal Service makes explicit that “Despite the name, an item can qualify as an ENDS without regard to whether it contains or is intended to be used to deliver nicotine; *liquids that do not actually contain nicotine can still qualify as ENDS, as can devices, parts, components, and accessories capable of or intended for use with non-nicotine-containing liquids.*” [emphasis added]

We strongly support this definition.

The broad definition of “ENDS” included in the Act and the Postal Service’s emphasis of its wide reach is appropriate and important. This means that in addition to nicotine-containing e-

cigarettes, pods, cartridges, vape pens, and e-liquids, the Postal Service is prohibited from delivering e-cigarettes that claim to contain synthetic nicotine (e.g., Puff Bar claims their new e-cigarettes use “tobacco-free nicotine” <https://puffbar.com/pages/about>) as well as so-called “wellness vapes” that have exploded on the market, including e-cigarettes and vaping products that contain cannabis, CBD, THC, melatonin, caffeine, and other substances. Additionally, the Postal Service is prohibited from delivering “flavor enhancers” (e.g., Puff Krush) that can be attached to e-cigarettes to add kid-enticing flavors that are otherwise unavailable in some e-cigarette products.

A December 2020 study shows that it is common for online platforms to sell and deliver e-cigarettes and e-cigarette components such as flavor enhancers to underage youth.¹ The study found that online retailers are routinely failing to verify the age of its consumers. Other studies also clearly show that youth obtain ENDS online.^{2, 3, 4} Extending the PACT Act to include e-cigarettes and e-cigarette liquids, components, parts, and accessories will make it more difficult for youth to obtain these products.

There has been a recent explosion of companies selling so-called “wellness” vapes online and marketing these products as vitamin delivery devices and to help improve immune systems, relaxation, sleep, energy, weight management, appetite reduction, and with other unsubstantiated health claims.⁵

Following are a few examples of the many vaping products marketed online that appeal to and are currently easily accessible to youth:

- Ripple Single-use Vaporizer Pens are sold online through Urban Outfitters and are marketed in several flavors to help users boost their energy, focus, revive, relax, sleep, and otherwise improve their moods:
<https://www.urbanoutfitters.com/shop/ripple-single-use-vaporizer-pen?category=SAYTPRODUCT&color=064&type=REGULAR&size=ONE%20SIZE&quantity=1>
- Inhale Health markets vapes with caffeine, melatonin, and vitamin B12:
<https://www.inhalehealth.com/products/melatonin-inhaler-lavender-dream>
- Cloudy markets vapes with melatonin:
<https://trycloudy.com/>

¹ Gaiha SM, Lempert LK, Halpern-Felsher B. Underage Youth and Young Adult E-cigarette Use and Access Before and During the Coronavirus Disease 2019 Pandemic. *JAMA Netw Open*. 2020;3(12):e2027572. doi:10.1001/jamanetworkopen.2020.27572

² Williams RS, Derrick J, Ribisl KM. Electronic Cigarette Sales to Minors via the Internet. *JAMA Pediatr*. 2015;169(3):e1563. doi:10.1001/jamapediatrics.2015.63

³ Yang Y, Lindblom EN, Salloum RG, Ward KD. The impact of a comprehensive tobacco product flavor ban in San Francisco among young adults. *Addictive Behaviors Reports*. 2020 Jun 1;11:100273.

⁴ Where are kids getting JUUL? Truth Initiative. Accessed February 15, 2021. <https://truthinitiative.org/research-resources/emerging-tobacco-products/where-are-kids-getting-juul>

⁵ Tatiana Basáñez, Anuja Majmundar, Tess Boley Cruz, Jon-Patrick Allem, Jennifer B. Unger, “E-cigarettes Are Being Marketed as “Vitamin Delivery” Devices.” *American Journal of Public Health* 109, no. 2 (February 1, 2019): pp. 194-196.

- Breathe markets Vitamin B12 vapes:
<http://breatheb12.com/>
- Monq markets aromatherapy and essential oil vapes:
<https://monq.com/bottled-aromatherapy-experiences/>
- Vapor Fi and Allure market hemp and CBD vapes:
<https://www.vaporfi.com/cbd/> <https://www.allure.com/gallery/best-cbd-vape-pens-for-anxiety>

The definition of ENDS in the draft rule appropriately exempts products that have been approved by the Food and Drug Administration for sale as tobacco cessation products or for other therapeutic purposes, but we are not aware that these products – or any e-cigarette product – has received such FDA approval. ***The Postal Service’s proposed rule promulgating the Act appropriately prohibits the delivery to minors of these and any other vaping products with unsubstantiated health claims and potential health harms and would thereby help to reduce use of these products by youth.***

2. The Postal Service’s “reasonable cause to believe” standard for determining nonmailability of ENDS and other products is appropriate; the rule should be strengthened to require shippers to verify that the contents of their packages are mailable

Current law requires the Postal Service to treat shipments of tobacco products as nonmailable when Postal Service personnel have “reasonable cause to believe” that a shipment contains nonmailable items, as well as when they have actual knowledge. Among other circumstances, “reasonable cause” exists where public statements or advertisements indicate an intent to mail nonmailable tobacco products. The proposed rule makes it explicit that this standard would apply to ENDS, and when Postal Service personnel observe circumstances giving rise to a reasonable suspicion that a package contains nonmailable ENDS, they may treat the package as nonmailable. ***In addition to public statements and advertisements in traditional media, social media posts marketing ENDS should also constitute reasonable cause to treat a package as nonmailable.***

This is important given that the marketing of ENDS including wellness devices is often done through social media and online. For example, national data indicate that 40.6% of youth were exposed to e-cigarette ads on the Internet.^{6,7} Such marketing is very influential to youth use of

⁶ Cho, Y. J., Thrasher, J. F., Reid, J. L., Hitchman, S., & Hammond, D. (2019). Youth self-reported exposure to and perceptions of vaping advertisements: Findings from the 2017 International Tobacco Control Youth Tobacco and Vaping Survey. *Preventive Medicine*, 126, 105775. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7487168/>

⁷ Marynak K, Gentzke A, Wang TW, Neff L, King BA. Exposure to Electronic Cigarette Advertising Among Middle and High School Students — United States, 2014–2016. *MMWR Morb Mortal Wkly Rep*. 2018;67(10):294-299. doi:10.15585/mmwr.mm6710a3

these products^{8,9} and so is a reliable source of information for the Postal Service in making a decision that it has a reasonable cause to believe that a package is nonmailable.

The proposed rule acknowledges that the new statutory definition of ENDS excludes products that have obtained FDA approval as therapeutic or tobacco-cessation products, and the fact that a particular ENDS product has obtained such FDA approval may be known or knowable by a mailer, but not by Postal Service personnel. The Postal Service suggests that a shipper of an FDA-approved therapeutic or tobacco-cessation product should identify the package as containing mailable items, and would authorize Postal Service personnel to treat a package as nonmailable if the customer has not affirmatively and verifiably indicated that the contents are mailable.

We agree with the “reasonable cause” standard. However, as the proposed rule indicates, this standard requires a mailer to act in good faith and not illegitimately treat an ordinary ENDS product as one that is entitled to the therapeutic/tobacco-cessation product exclusion in order to evade the mailing ban. For this reason, mailers who wish to ship ENDS products that they claim qualify for the FDA-approved ENDS therapeutic/tobacco cessation product exception should be required to not only indicate with outer package labeling that the contents of their packages are mailable, but should also be required to present to the Postal Service written documentation of FDA’s approval (e.g., an FDA approval letter available at Drugs@FDA (See, for example, the approval letter for Nicorette gum, a nicotine replacement therapy found at:

https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/020066Orig1s062,%200186120rig1s081ltr.pdf).

3. The nonmailability of ENDS to Alaska or Hawaii should be emphasized because the geographic exception for mailings *within* the states of Alaska and Hawaii does not apply to *inter-state* mailings to the states of Alaska and Hawaii

The PACT Act creates a geographic exception (18 USC 1716E(b)(2)) providing that the nonmailability of cigarettes “shall not apply to mailings *within* the State of Alaska or *within* the State of Hawaii.” [emphasis added] Because the Preventing Online Sales of E-cigarettes to Children Act adds “ENDS” to the existing definition of cigarettes in the PACT Act, the proposed rule acknowledges that the geographic exception for *intra-state* shipments within Alaska or Hawaii also applies to ENDS.

The Postal Service should strengthen Publication 52 to make explicit that the rule about nonmailability of ENDS products applies to products mailed from other states to Alaska or Hawaii, and the exception for intra-state shipments does not apply to inter-state shipments.

⁸ Barnes AJ, Bono RS, Rudy AK, Hoetger C, Nicksic NE, Cobb CO. Effect of e-cigarette advertisement themes on hypothetical e-cigarette purchasing in price-responsive adolescents. *Addiction*. Published online April 14, 2020. doi:10.1111/add.15084

⁹ Papaleontiou L, Agaku IT, Filippidis FT. Effects of Exposure to Tobacco and Electronic Cigarette Advertisements on Tobacco Use: An Analysis of the 2015 National Youth Tobacco Survey. *J Adolesc Health*. 2020;66(1):64-71. doi:10.1016/j.jadohealth.2019.05.022

It is important that youth in Alaska and Hawaii are protected by PACT Act shipping restrictions. ENDS use among youth is prevalent in Alaska and Hawaii. In Alaska, 16% of youth in 2018 had used an e-cigarette in the past 30 days. Further, according to the CDC's YRBS 2019 data, 45.8% of high school students in Alaska had ever used an e-cigarette, 26% used it in the past 30 days, and 6.8% of ENDS users used on 20 of the past 30 days.¹⁰ In Hawaii, according to the CDC's YRBS data, 48% of high school students had ever used an e-cigarette, 30.6% have used an e-cigarette in the past 30 days, and more than 10% used an ENDS product frequently (20 of the past 30 days).

4. We support the Postal Service's proposed rule providing that the Consumer Testing and Public Health exceptions should not apply to ENDS because ENDS are not packaged in standard quantities analogous to the specifics outlined in the law.

Existing law confines the exceptions for Consumer Testing and Public Health to packages containing “not more than 12 packs of cigarettes (240 cigarettes).” (18 USC 1716E(b)(5)(A)(ii)) However, e-cigarettes and e-cigarette liquids, components, and parts are not packaged using these standard quantities, so this exception should not apply.

One e-cigarette pod labeled as “5% nicotine” contains about 41 mg of nicotine. In contrast, one cigarette yields about 1-1.7 mg nicotine,^{11,12} and therefore a standard pack of 20 cigarettes yields to the consumer between 20-30 mg of nicotine. This means that one 5% nicotine pod may deliver the amount of nicotine found in between 1-1.5 packs of cigarettes, although the data are still nascent. (The actual number of cigarette-equivalents is probably higher because much of the nicotine in conventional cigarettes ends up in sidestream smoke rather than the smoker’s body. E-cigarettes do not generate sidestream smoke, so all the nicotine ends up in the smoker’s body.) E-liquids are available in containers with varying volumes and concentrations of nicotine, but similarly deliver much higher amounts of nicotine.

Because the nicotine content and concentration of ENDS, as well as other aspects of ENDS packaging, cannot be translated into the standard quantities used for traditional cigarettes, the Postal Service’s conclusion that the Consumer Testing and Public Health exceptions are inapplicable to ENDS should be included in the final regulation.

While we strongly support the goal of preventing youth from obtaining ENDS, a potential concern is that academic researchers should still be permitted to receive products for legitimate research purposes. We suggest that the Postal Service work with academic researchers to develop

¹⁰<https://nccd.cdc.gov/Youthonline/App/Results.aspx?TT=G&OUT=0&SID=HS&QID=QQ&LID=HI&YID=2019&LID2=XX&YID2=2019&COL=T&ROW1=N&ROW2=N&HT=C02&LCT=LL&FS=S1&FR=R1&FG=G1&FA=A1&FI=I1&FP=P1&FSL=S1&FRL=R1&FGL=G1&FAL=A1&FIL=I1&FPL=P1&PV=&TST=True&C1=HI2019&C2=XX2019&QP=G&DP=1&VA=CI&CS=Y&SYID=&EYID=&SC=DEFAULT&SO=ASC>

¹¹ Jarvis MJ, Boreham R, Primatesta P, Feyerabend C, Bryant A. Nicotine yield from machine-smoked cigarettes and nicotine intakes in smokers: evidence from a representative population survey. *J Natl Cancer Inst.* 2001;93(2):134-138. doi:10.1093/jnci/93.2.134

¹² Benowitz NL, Jacob P. Daily intake of nicotine during cigarette smoking. *Clin Pharmacol Ther.* 1984;35(4):499-504. doi:10.1038/clpt.1984.67

and implement procedures that will allow researchers to obtain ENDS to conduct research aimed to promote the public health, while preserving the general nonmailability of ENDS.

Conclusion

We enthusiastically support the nonmailability of ENDS to youth and support the Postal Service's proposed regulations that prevent youth from accessing e-cigarettes and e-liquids, components, and parts. We agree that the Consumer Testing and Public Health exceptions should not apply to ENDS because the standard quantities used for traditional cigarettes are not translatable to e-cigarette pods and liquids, which contain much more nicotine per unit than traditional cigarettes. Academic researchers should still be permitted to receive products for legitimate research purposes while preserving the general nonmailability of ENDS.