



August 21, 2024

Dr. Brian King
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD. 20993-0002

Re: FDA's Unlawful Withholding of Remote Sales Rule

Dear Dr. King:

For the reasons explained below, the undersigned organizations urge FDA to adhere to the statutory mandate to issue a rule regarding remote sales of tobacco products, and to prohibit such sales.

I. THE CONGRESSIONAL MANDATE AND FDA'S FAILURE TO ACT

Fourteen years ago, when Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA), it instructed FDA to “promulgate regulations regarding the sale and distribution of tobacco products through means other than a direct, face-to-face exchange between a retailer and a consumer.” 21 U.S.C. § 387f(d)(4)(i) (hereinafter referred to as “remote sales.”) Congress instructed that FDA “shall” do this within 18 months after June 22, 2009, i.e., by December 22, 2010. FDA took no action regarding remote sales within that time frame.

Congress also mandated FDA to “issue regulations to address the promotion and marketing of tobacco products that are sold or distributed through” remote sales, and to do so within 2 years after June 22, 2009, i.e., by June 22, 2011. 21 U.S.C. § 387f(d)(4)(ii).¹ FDA took no action within that time frame.

¹ These mandates to regulate remote sales are within the general authority that Congress gave FDA to issue regulations that restrict the sale and distribution of tobacco products if appropriate for the protection of public health, including consideration of whether existing users will stop using tobacco products and whether non-users will initiate. 21 U.S.C. § 387f(d)(1).

Rather than proposing rules, on September 9, 2011, FDA belatedly opened a docket for an advanced notice of proposed rule-making (“ANPRM”).² FDA requested comment on various aspects of remote sales, including the impact of the PACT Act of 2009 on the remote sale of cigarettes and smokeless tobacco. The docket indicates that FDA received over 300 comments, reflecting a wide range of opinions and depth of experience regarding the issues, from individuals, trade groups, cigar and cigarette manufacturers, public health groups, the co-chairs of the Tobacco Committee of the National Association of Attorneys General (NAAG) and others.³ The comment period has been closed since January 19, 2012.

FDA never proposed a rule and withdrew the ANPRM, without explanation, on August 1, 2017.⁴ The agency docket shows no further action regarding remote sales and the agency’s policy agenda, announced on December 18, 2023 in connection with the issuance of CTP’s five-year Strategic Plan, made no reference to regulation of remote sales as a current or longer-term priority.⁵

In short, not only did FDA fail to issue final rules regarding remote sales within the mandatory 18- to 24- month deadlines set by Congress, FDA still has not even issued a proposed rule on remote sales more than thirteen years after the statutory deadlines elapsed.

FDA’s failure to propose or finalize rules regarding remote sales is an unlawful withholding of agency action. The language in the Tobacco Control Act is an unambiguous mandate that FDA “shall” promulgate regulations regarding remote sales. 21 U.S.C. § 387f(d)(4)(i) & (ii); *see Forest Guardians v. Babbitt*, 174 F.3d 1178, 1187 (10th Cir. 1999) (“‘Shall’ means shall. The Supreme Court and this circuit have made clear that when a statute uses the word ‘shall,’ Congress has imposed a mandatory duty upon the subject of the command.”) (emphasis in original); *American Academy of Pediatrics, Inc. v. FDA*, 330 F.Supp.3d 657, 664 (D. Mass. 2018).⁶

² Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products, 76 Fed. Reg. 55,835-37, docket # FDA-2011-N-0467 (Sept. 9, 2011). For reasons that are not now evident, FDA construed the deadlines for rule-making to be October 1, 2011 and April 1, 2012. *Id.* at 55,835.

³ The public comments included those submitted on January 19, 2012 by the Campaign for Tobacco-Free Kids, joined by the American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Association of State and Territorial Health Officials, and the Legacy Foundation (now Truth Initiative).

[https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/1-19-12%20Non-face-to-face%20sales%20final%20\(Partners\)%20-%20Copy.pdf](https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/1-19-12%20Non-face-to-face%20sales%20final%20(Partners)%20-%20Copy.pdf)

⁴ *See* <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0910-AG43>.

⁵ Available at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/center-tobacco-products-regulation-and-guidance-policy-agenda#1>.

⁶ FDA has also failed to issue regulations to address the promotion and marketing of products sold in non-face-to-face transactions. 21 U.S.C. § 387f(d)(4)(ii).

The Administrative Procedure Act (APA) provides a legal remedy for FDA’s violation of its non-discretionary duty to promulgate these rules by the statutory deadline. The APA instructs that a “court shall ... compel agency action unlawfully withheld.” 5 U.S.C. § 706(1).

The undersigned urge FDA to recognize its legal obligations, and avoid litigation to enforce those obligations, by commencing and completing the rulemaking process without further delay. As explained in detail below, such proceedings are not only legally required, but they are also necessary to protect public health, and particularly the health of young people, against the risks of various tobacco products sold through the internet and other means not involving face-to-face transactions. We urge that FDA propose, finalize and implement a rule prohibiting such remote sales. We also request a meeting with you and your staff about this subject, as soon as your schedule permits.

II. PUBLIC HEALTH AND OTHER POLICY CONSIDERATIONS

During the time that FDA has failed to act, the landscape of tobacco/nicotine products in the U.S. has changed significantly. There have been three developments of particular significance: (1) the surge in new products – including electronic nicotine delivery devices (here generally referred to as “e-cigarettes”) and new types of oral tobacco/nicotine products like lozenges and pouches; (2) the marketing, and strong appeal, of flavored tobacco products to youth; and (3) the significant increase in underage consumption of these flavored products. These trends have taken place alongside the rapid growth of retail e-commerce, use of social media,⁷ and access to broadband and mobile digital devices. The Census Bureau reports that in 2021 retail trade e-commerce in the U.S. approached a trillion dollars and in 2022 it likely exceeded the trillion-dollar mark.⁸ Young people are significant contributors to this explosion of e-commerce. A 2023 survey revealed that 95% of teens have access to digital devices like smartphones and 90% to desktop or laptop computers, with 96% using the internet every day. The “share of teens who say they are online almost constantly has roughly doubled since 2014-15 (46% now and 24% then).”⁹

As the following discussion shows, the close connection between remote sales of tobacco products, marketing of remote sales, and youth access, is beyond dispute.

A. Youth access to tobacco products through remote sales

As frequently noted by FDA, youth use of tobacco products remains dangerously high. The 2023 National Youth Tobacco Survey (NYTS) revealed that 10% of middle and high school students (2.8 million students) reported current use of a tobacco product, the vast majority of whom used

⁷ The global use of social media by two of the largest tobacco companies – British American Tobacco and Philip Morris International – is detailed in the report issued by the Campaign for Tobacco-Free Kids, *#SponsoredbyBigTobacco: Tobacco & Nicotine Marketing on Social Media* (2023), available at https://assets.tobaccofreekids.org/content/what_we_do/industry_watch/social-media-marketing-tactics/2023_12_08_SponsoredByBigTobacco.pdf.

⁸ <https://www.census.gov/library/visualizations/interactive/e-commerce-activity-across-sectors-2020-2021.html>; <https://www.reuters.com/world/us/us-consumers-spend-record-1-trillion-online-2022-report-2022-03-15/>

⁹ <https://www.pewresearch.org/internet/2023/12/11/teens-social-media-and-technology-2023/>

e-cigarette products.¹⁰ Among middle school students there was an increase in tobacco product use from prior years. The 2022 National Survey on Drug Use and Health indicates that each day more than 4,300 youth under the age of 18 try an e-cigarette product for the first time, and more than 1,400 try their first cigarette.¹¹ A study looking at changes in e-cigarette use and access during the early months of the COVID-19 pandemic, when many brick-and-mortar stores were closed, stated that “Underage youth who found it easier (not harder) to access e-cigarettes during the pandemic reported getting them online and from vape shops/dealers that delivered directly to them or to their friends. These findings underscore the need to effectively verify age online and in person.”¹²

Unlike in-person sales at a brick-and-mortar store, where a sales clerk reviews or scans a government-issued identification document and makes a visual comparison between the photo and the purchaser, remote sales do not include a face-to-face interaction between the seller and the purchaser. Without a check on age and identity, particularly of the person receiving the item, remote sales are an easier way for minors to buy tobacco products.

This problem has long been recognized. In 2007, a federal district judge concluded that “there is no evidence of age verification services or products available on the market to owners of Web sites that actually reliably establish or verify the age of Internet users. Nor is there evidence of such services or products that can effectively prevent access to Web pages by a minor.”¹³

Comments submitted to FDA in 2011 and 2012 left no doubt about the existence and seriousness of the problem. The comment submitted by NAAG stated:

The basic conclusion we wish to convey in our comments is that, despite the enactment of the PACT Act, the existing legal framework with respect to non-face-to-face sales is not adequately protecting the public health. The reason for this conclusion is that . . . the promotion and sale of tobacco products through non-face-to-face sales continue to take place without adequate age and identity verification; such sales continue to evade state tax laws; and states' efforts to enforce their laws continue to be frustrated by jurisdictional limitations and the ability of direct sellers to put up new websites even if a state successfully enforces its law against such sellers.¹⁴

¹⁰ <https://www.fda.gov/news-events/press-announcements/national-survey-shows-drop-e-cigarette-use-among-high-school-students>

¹¹ [Section 2 PE Tables – Results from the 2022 National Survey on Drug Use and Health: Detailed Tables, SAMHSA, CBHSQ](#)

¹² Shivani M. Gaiha, et al., *Underage Youth and Young Adult e-Cigarette Use and Access Before and During the Coronavirus Disease 2019 Pandemic*, JAMA Network Open 3(12)e2027572 (2020).

¹³ *Am. C.L. Union v. Gonzales*, 478 F. Supp. 2d 775, 800 (E.D. Pa. 2007), *aff'd sub nom. Am. C.L. Union v. Mukasey*, 534 F.3d 181 (3d Cir. 2008).

¹⁴ NAAG comment (Jan. 19, 2012) at 3, <https://www.regulations.gov/comment/FDA-2011-N-0467-0110>.

The NAAG comment detailed how states attempted in a variety of ways to address this issue, including by legislation (ranging from complete bans on remote sales to restrictions on packaging to requirements for age verification), litigation, negotiated agreements with banks and credit card companies (including American Express, Diner’s Club, Visa and Mastercard, and PayPal), and agreements with certain common carriers. Yet the problems persisted. The comment described flaws in age verification programs and widespread evasion of the provisions of the newly-enacted PACT Act. NAAG bluntly informed FDA that “current [age verification] technologies and methods do not effectively prevent the purchase of tobacco products by underage persons in non-face-to-face sales.”¹⁵ NAAG described how, as credit card use for tobacco product sales declined as a result of an enforcement crackdown, tobacco businesses shifted to other forms of electronic payment and gift cards; how age verification technologies were successfully bypassed when ordering; and how products were delivered without verification.¹⁶ It referenced a study in which youth participants were able to gain access to R.J. Reynolds Tobacco Company's marketing websites in 42% of their attempts.¹⁷

The NAAG comment referred to studies indicating that minors could circumvent online age verification by typing in a false (older) birth date, making up a Social Security number, using a fake ID, and using the ID of an adult.¹⁸ The attorneys general offered evidence that some online retailers claimed to restrict sales to adults but did not actually do so.¹⁹ They described an investigation of First Regional Bank that uncovered that it “facilitated massive numbers of illegal non-face-to-face cigarette sales of a nationwide cigarette seller” including over 166,000 sales to California consumers.²⁰

There is overwhelming evidence that, while state and local governments waited for an FDA rule on remote sales, the problems continued. A survey of hundreds of websites offering little cigars and cigarillos for sale in the U.S. in 2013-14 discovered that almost half of them used ineffective methods of age verification and 10% did not attempt to verify age at all.²¹ A separate study found that 89 out of 91 (97.8%) attempts by 14-17 year olds to purchase cigars online were successful.²² Studies revealed that, in 2014 and 2015, youth successfully purchased e-cigarettes online in 94% to 97% of their purchase attempts,²³ and, during that time, most internet e-

¹⁵ *Id.* at 5.

¹⁶ *Id.* at 7-8.

¹⁷ *Id.* at 8.

¹⁸ *Id.* at 8-9.

¹⁹ *Id.* at 8.

²⁰ *Id.* at 14.

²¹ Rebecca S. Williams, *Internet little cigar and cigarillo vendors: Surveillance of sales and marketing practices via website content analysis*, *Preventive Med.* 109, 51-57 (2018).

²² Rebecca S. Williams, et al. *Age Verification and Online Sales of Little Cigars and Cigarillos to Minors*, *Tobacco Regulatory Science* 6(2) 152-163 (2020).

²³ Rebecca S. Williams, *Electronic cigarette sales to minors via the internet*, *JAMA Pediatrics* 169(3) e1563, doi: 10.1001/jamapediatrics.2015.63 (Epub March 2, 2015); D. Nikitin, *Is the E-Liquid Industry Regulating Itself? A Look at E-Liquid Internet Vendors in the United States*, *Nicotine & Tobacco Research* 18(10) 1967-72 (2016).

cigarette vendors failed to use effective age verification methods.²⁴ In April 2018, FDA announced that eBay had pulled listings for sale of JUUL e-cigarettes, but a subsequent study indicated that JUUL products continued to be listed on eBay.²⁵

A 2019 lawsuit filed by the California Attorney General against JUUL described in detail how JUUL sold its products to minors in California and across the nation even though California has a comprehensive framework to regulate remote sales of tobacco products including e-cigarettes.²⁶ The complaint described frequent and various failures to verify age and identity. JUUL's own sales records showed sales of hundreds of thousands of items to fictitious individuals, an unknown number of whom were minors.²⁷

For example, JUUL made 17 shipments to an individual named "Beer Can" in San Francisco, including two JUUL devices, five starter kits, and 41 pod packs. Of course, there was no individual in California with that name.²⁸ JUUL shipped thousands of products to addresses other than the purchasers' legal addresses because JUUL and its age verification provider, Veratad, set the verification program not to require a full address match.²⁹ JUUL and Veratad also allowed would-be purchasers to make multiple attempts to pass the age verification screen by resubmitting different information.³⁰ The complaint stated that "By allowing consumers to alter their personal information and attempt age verification up to three times, [Juul] was able to increase its database match pass rate from 49.2% to 61.2%."³¹ JUUL even allowed its customer service representatives to modify customers' addresses and encouraged customers to make multiple accounts to circumvent age verification.³² In this way product purchases that were age verified for one person and one address could be – and were – shipped to another person at another address.³³ Even though California law expressly forbids shipping to mailboxes, JUUL shipped thousands of devices and pods to mailboxes.³⁴ JUUL made 15 shipments to one such mailbox, some of them containing as many as 20 devices.³⁵ JUUL also sent marketing emails to minors including to minors who had failed age verification.³⁶ JUUL's own internal analysis

²⁴ Rebecca S. Williams, et al. *Content analysis of age verification, purchase and delivery methods of internet e-cigarette vendors, 2013 and 2014*, Tobacco Control 27(3), 287-293 (2018).

²⁵ L. Laestadius, *Youth access to JUUL online: eBay sales of JUUL prior to and following FDA action*, Tobacco Control, (published online Sept. 5, 2018); *see also* <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm605432.htm>

²⁶ Cal. Bus. & Prof. Code, § 22963.

²⁷ *People v. JUUL Labs, Inc.*, No. RG19043543 (Cal. Super. Ct., Alameda Cnty., Nov. 18, 2019) Complaint at ¶ 138 (hereinafter *People v. JUUL*).

²⁸ *Id.* at ¶ 139.

²⁹ *Id.* at ¶¶ 141, 146.

³⁰ *Id.* at ¶ 165-66.

³¹ *Id.* at ¶ 166.

³² *Id.* at ¶ 169.

³³ *Id.* at ¶ 170.

³⁴ *Id.* at ¶ 177.

³⁵ *Id.*

³⁶ *Id.* at ¶ 180-89.

determined that, as of August 3, 2018, JUUL had approximately 529,000 unique email addresses on its digital marketing list that had never been age-verified.³⁷

In other words, even though states and cities had laws and ordinances regulating remote sales and youth access, there was massive evasion.

B. Remote sales and tax evasion

The NAAG comment to FDA in 2012 described in detail how taxes were evaded through remote sales. In the section below discussing the PACT Act we provide information about ongoing tax evasion. This evasion results in loss of excise and sales tax revenue. Moreover, there is a recognized association between tobacco product price and use, especially by young people who are more price sensitive. As Tobacco-Free Kids explained in a 2012 comment:

Because a portion of the total cost of tobacco products— especially cigarettes—is taxes, tax evasion has an impact on the selling price of cigarettes. . . It is well-established that the price of tobacco products is a major factor in determining the level of consumption. Moreover, price differentials have an even greater impact on youth smoking rates than on adult smoking rates. The ability of internet sellers to evade payment of state excise taxes on tobacco products has a substantial effect on both youth smoking and smoking by adults. The availability of cigarettes on the internet not only makes cheap cigarettes available through purchases from internet sellers, but also depresses the price level in face-to-face sales by sellers who must compete with internet sites.³⁸

C. The Limitations of the PACT Act of 2009

Soon after passage of the Tobacco Control Act, Congress amended the Jenkins Act by passing the Prevent All Cigarette Trafficking or PACT Act, which imposed various restrictions on remote sales of cigarettes and smokeless tobacco.³⁹ When FDA issued its 2011 ANPRM regarding remote sales it requested information about the effects of the PACT Act on access to

³⁷ *Id.* at ¶ 190.

³⁸ Tobacco-Free Kids comment to FDA (Jan. 19, 2012) at 3, <https://www.regulations.gov/comment/FDA-2011-N-0467-0095>; see also Report of the Surgeon General, *ECigarette Use Among Youth and Young Adults* (2016) at 155 (“[t]he sizeable body of research examining the effects of taxes and prices on the sale and use of conventional cigarettes . . . leads to the conclusion that price increases resulting from higher excise taxes are effective tools for reducing cigarette consumption, especially among youth”); Nathan J. Doogan, *The impact of a federal cigarette minimum pack price policy on cigarette use in the USA*, *Tobacco Control*, 27:203-208 (2018).

³⁹ 15 U.S.C. §§ 375-378 and 18 U.S.C. § 1716E, amended in 2020 to include electronic nicotine delivery system within the definition of “cigarette,” 15 U.S.C. §§ 375(2), (7). It is significant that the TCA’s mandate to FDA to issue regulations governing remote sales applies to all “tobacco products” as defined in the TCA and thus is broader in scope than the PACT Act as originally passed and as amended in 2020.

cigarettes and smokeless tobacco.⁴⁰ The comments filed with FDA made clear the need for further action.

The 2012 NAAG comment to FDA pointed to gaps in the PACT Act that were apparent almost immediately after it passed. For instance, the NAAG comment stated that “large volumes of cigarettes and smokeless tobacco” continued to be shipped because some remote sellers were able in practice to ship by mail despite the Act’s non-mailability provision and because other remote sellers bypassed common carriers and set up their own transport systems.⁴¹ The NAAG comment concluded that “[n]either the PACT Act nor the state laws now in effect have proven adequate to protect the public health against the two principal adverse effects of non-face-to-face sales of tobacco products — i.e., making such products less expensive through evasion of state taxes and making them more readily available to youth.”⁴² A study published in 2017 revealed that evasion and access of cigarettes by youth persisted.⁴³

In 2020, Congress extended the PACT Act to cover e-cigarettes, but it still has no application to cigars or to new oral nicotine products that do not contain tobacco.⁴⁴ Further, a recent study has found that, despite the PACT Act restrictions placed on e-cigarettes, online e-cigarette vendors do not use adequate age-verification methods that would prevent youth purchasing, and some still list the United States Postal Service (USPS) as their delivery service.⁴⁵

Because the PACT Act is limited in multiple ways, it cannot sufficiently address the problems created by remote sales. Although it requires all online retailers of cigarettes, smokeless tobacco and e-cigarettes to register and provide monthly reports of shipments, that information is only provided to tax authorities⁴⁶ – not to the state and local agencies that enforce youth access laws, licensing ordinances, and restrictions on the sale of flavored products. In fact, the PACT Act prohibits those tax administrators from sharing this information with others.⁴⁷ Similarly, while

⁴⁰ Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products, 76 Fed. Reg. 55835-37, docket # FDA-2011-N-0467 (Sept. 9, 2011).

⁴¹ NAAG comment (Jan. 19, 2012) at 18, <https://www.regulations.gov/comment/FDA-2011-N-0467-0110>.

⁴² *Id.* at 18-19.

⁴³ Rebecca S. Williams, *Cigarette sales to minors via the internet: how the story has changed in the wake of federal regulation*, Tobacco Control 26(4), 415-420 (2017).

⁴⁴ 15 U.S.C. §§ 375(2), (7) (13), as amended. It is important to be aware of the rapid growth in sales of these oral nicotine products and of the fact that they are offered in many flavors and with high levels of nicotine. *See, e.g.,* Anuja Majmundar, et. al., *Nicotine Pouch Sales Trends in the US by Volume and Nicotine Concentration Levels From 2019 to 2022*, JAMA Network Open 2022;5(11):e2242235 (Nov. 15, 2022) (reporting six-fold increase in sales between 2019 and 2022). *See also* Letter from public health groups to Dr. Brian King re PMTAs for Nicotine Pouch Products (April 23, 2024).

⁴⁵ Adrian Bertrand, et al., *Easy access: identification verification and shipping methods used by online vape shops*, Tobacco Control (published online Jan. 8, 2024) doi: 10.1136/tc-2023-058303 (hereinafter Bertrand, *Easy Access*).

⁴⁶ 15 U.S.C. § 376(a).

⁴⁷ *Id.* § 376(c).

delivery sellers⁴⁸ must retain records and make them available, they need do so only to tax authorities.⁴⁹ Further, while the obligation to verify age and identity applies to delivery sellers, it does not apply to the common carrier or private delivery service that delivers the product to the consumer.⁵⁰ In other words, while the law obliges the seller to check ID remotely, it does not require an ID check by the only entity that actually interacts face-to-face with the recipient. Finally, although the Act made cigarettes, smokeless tobacco, and e-cigarettes nonmailable, that applies only to the USPS, not to private delivery companies. Further, since e-cigarettes have been added to the PACT Act, many private delivery companies now ship products for online e-cigarette vendors.⁵¹

In 2019, the City of New York and several states filed suit against the USPS seeking declaratory relief.⁵² The complaint described innumerable inventive schemes by remote sellers of cigarettes to circumvent the PACT Act by shipping from foreign locations, and a litany of investigations uncovering huge numbers of cigarettes entering the U.S. illegally through international airports.⁵³

It is clear the PACT Act offers a solution to only a small subset of the problems arising from remote sales – most importantly because, even if enforced and even if adhered to by the USPS – it does not apply to products like oral nicotine products and small flavored cigars.

D. Remote sales and evasion of state and local sales restrictions on flavored products

Over the last decade many states and local governments have sought to discourage youth initiation of tobacco products by restricting the sale of flavored tobacco products. As discussed above, the litigation against JUUL in California demonstrated how remote sales directly frustrate these local efforts.⁵⁴

⁴⁸ A delivery seller is a person who sells cigarettes, e-cigarettes or smokeless tobacco to a consumer when the consumer places the order by means of the internet, telephone or mail, or the seller is not in the physical presence of the buyer when the order is made, and the item is delivered to the buyer by any method of remote delivery or the seller is not in the physical presence of the buyer when the buyer obtains possession of the item. *Id.* § 375 (5), (6).

⁴⁹ *Id.* § 376a(c).

⁵⁰ *Id.* § 376a(b)(4). Also, penalties apply to the delivery seller, and not to the common carrier except in very exceptional circumstances. *Id.* § 376(a)(2)(b).

⁵¹ Bertrand, *Easy Access*.

⁵² *City of New York v. United States Postal Serv.*, No. 1:19CV05934 (E.D.N.Y. Oct 22, 2019) (hereinafter *New York City v USPS*); see also *City of New York v. United States Postal Serv.*, 519 F. Supp. 3d 111, 116 (E.D.N.Y. 2021) (concluding that plaintiffs stated a claim under the PACT Act and can seek a declaratory judgment that USPS has violated the Act.).

⁵³ *New York City v. USPS*, Complaint at ¶¶ 44-135. The parties ultimately reached a settlement requiring USPS to implement certain measures designed to improve compliance with the PACT Act's prohibition on the mailing of cigarettes through USPS, particularly those shipped from a foreign location. See <https://www.nyc.gov/site/law/news/22-10/mayor-adams-city-new-york-coalition-states-secure-settlement-usps-improve-practices>.

⁵⁴ For instance, the litigation against JUUL in California revealed that JUUL sold its flavored products to addresses within cities that had enacted flavor bans. *People v. JUUL*, Complaint at ¶

Recent research suggests that remote sales may also reduce the effectiveness of California’s statewide ban on sales of flavored tobacco products.⁵⁵ The California statute only applies to flavored tobacco products that are sold or offered for sale from stores with physical retail locations.⁵⁶ The study showed that internet searches in California about online purchase of flavored e-cigarette products and menthol cigarettes increased markedly at the time the flavor ban went into effect in December 2022.⁵⁷ The week the policy went into effect, shopping queries by Californians were 194% higher than expected for cigarettes and 162% higher than expected for e-cigarette products and remained elevated significantly for many weeks. The results of these searches all included links to websites offering flavored e-cigarettes or menthol cigarettes to consumers in California. This suggests that consumers sought to turn to remote sales to obtain the items they could no longer purchase at law-abiding brick and mortar stores in their communities. In another study in California, adult researchers posing as minors were able to pass age verification and make online purchase attempts for flavored e-cigarettes over half of the time in spring 2022, before California’s law went into effect, and over 60% of the time in spring 2023, after the law went into effect.⁵⁸

Thus, state and local efforts to reduce youth use of tobacco products by prohibiting sale of flavored products may be undercut by FDA’s failure to abide by the statutory mandate to issue regulations to address remote sales.

E. Continuing need to issue remote sales rules

Not only has FDA unlawfully withheld agency action, but it has done so despite a demonstrable, continuing need to act. FDA should issue remote sales rules forthwith.

The 2022 investigation by the HHS Office of the Inspector General (OIG) examining FDA’s approach to remote sales reached the same conclusion.⁵⁹ The OIG report states:

This rulemaking could offer FDA insight for revising its oversight of online tobacco retailers that incorporates input from a wide range of public stakeholders. In its 2011 advance notice of proposed rulemaking on non-face-to-face sales of tobacco products, FDA asked for information on a number of topics including how the PACT Act (passed in 2009) would affect online sales; how retailers use communication technology to market tobacco products; and which forms of

149. Large quantities were sold, e.g., 56 starter kits and 289 refill kits, to a single address in Manhattan Beach, California, a city with a flavor ban. *Id.*

⁵⁵ Cal. Health & Safety Code § 104559.5.

⁵⁶ *Id.*

⁵⁷ Eric C Leas, et al., *E-commerce licensing loopholes: a case study of online shopping for tobacco products following a statewide sales restriction on flavoured tobacco in California*, Tobacco Control 2023;0:1–4. doi:10.1136/tc-2023-058269 (2023).

⁵⁸ Scott I. Donaldson, et al., *Online Purchase Attempts of Flavored E-Cigarettes to Minors in California Before and After Senate Bill 793*, JAMA Network Open, 2023;6(12):e2348749. doi:10.1001/jamanetworkopen.2023.48749 (2023)

⁵⁹ OIG Report, p.13.

technology, advertising themes, and techniques are appealing to minors. Ten years later, these questions remain relevant given changes in technology and the tobacco marketplace, as well as expansion of the PACT Act in 2021.⁶⁰

FDA responded ambiguously to the OIG report:

FDA remains committed to issuing rules to implement the Tobacco Control Act. We note that many of the benefits of such a rule are also realized in other restrictions and requirements such as those under the PACT Act, imposed by states and other jurisdictions, and those placed on tobacco product manufacturers upon receiving a Marketing Granted Order from FDA for their premarket tobacco product application.⁶¹

This response is unsatisfactory. First, it offers no explanation as to why, if the agency “remains committed to issuing rules to implement the Tobacco Control Act,” it has still not issued the rules mandated by that statute. Second, it provides no information about when remote sales rules might be issued. Third, comments submitted to FDA in 2011 and 2012 indicated that the PACT Act and state and local laws did not fulfill “many of the benefits of such a rule” and are frequently evaded. Fourth, FDA’s claim that the “benefits” of a remote sales rule are realized in the restrictions placed on marketing orders issued to manufacturers is a stark exaggeration. Most obviously, FDA has issued only a handful of marketing orders for e-cigarettes, while applications for products with significant market shares remain pending.⁶² Further, manufacturers and importers have not even submitted applications for a large number of the products that are dominating the market, including some that are very popular among youth, like Elf Bar, Esco Bar and Mr. Fog.⁶³

Finally, it cannot be said that FDA’s marketing orders actually regulate remote sales. As FDA’s marketing orders recognize, even if a manufacturer stated that a product would only be sold in face-to-face transactions, this would be merely a statement of intention, not an enforceable commitment. To take one example, from the Marketing Granted Order to NJOY LLC for NJOY Daily Rich Tobacco, NJOY indicated in its marketing plan that it would allow remote sales, would require age and identity verification, and would prohibit sale of the product on third-party websites.⁶⁴ FDA’s marketing order did not bind NJOY to follow these commitments, merely stating that “[w]e encourage you to implement these measures.”⁶⁵ Further, as noted above, there is evidence that remote sellers manipulate the age and identity verification processes, and,

⁶⁰ OIG Report at 16.

⁶¹ OIG Report, p.23, appendix A, letter dated October 22, 2022.

⁶² *See Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-883 (D. Md.) Status Report Document No. 218 (January 22, 2024).

⁶³ 2023 National Youth Tobacco Survey, available at <https://www.fda.gov/news-events/press-announcements/national-survey-shows-drop-e-cigarette-use-among-high-school-students>

⁶⁴ FDA to NJOY, LLC. Marketing Granted Order, available at <https://www.fda.gov/media/165233/download?attachment> (June 10, 2022) at 2.

⁶⁵ *Id.* at 3.

contrary to NJOY’s assurance in its marketing plan, this product is available for purchase in the U.S. on third-party websites.⁶⁶

For all of these reasons, we reiterate the OIG’s recommendation that FDA complete rulemaking regarding remote sales.

F. FDA should prohibit remote sales

The statutorily mandated rules on remote sales should prohibit such sales and marketing of items for remote sale. Anything less will simply perpetuate easy access to tobacco products by young people.

The one constant in the preceding discussion is that the efforts to regulate remote sales have consumed significant government resources over many years, but continue to fail. The 2012 NAAG comment to FDA described the games of whack-a-mole and concluded: “Given the difficulties in addressing the problem of the facilitation of payments for illegal sales of tobacco products, . . . a ban on such sales may be the only effective means of preventing such sales.”⁶⁷ In 2019, the Attorneys General of California, Connecticut, Illinois, New York, Pennsylvania, Rhode Island, and Vermont repeated the request to FDA to ban online sales in a comment letter regarding e-cigarette products.⁶⁸ These law enforcement officials wrote:

The FDA Should Ban Online Sales of ENDS. Despite its acknowledgement that minors utilize online retailers to obtain ENDS, the FDA seeks to prioritize enforcement against only certain online sales—those without a quantity limit and those without independent age and identity verification. This prioritization is unlikely to be effective at preventing all sales of ENDS to minors, and the FDA should therefore ban all online sales of ENDS instead. Additionally, this prioritization is inadequate to address another effect of online sales of tobacco products – i.e., making such products less expensive through evasion of state taxes, which makes them more readily available to youth.⁶⁹

⁶⁶ See, e.g., <https://www.electrictobacconist.com/njoy-daily-rich-tobacco-extra-p8249> ; <https://www.gopuff.com/p/njoy-ace-device/p42856>. In a related phenomenon, there are numerous examples of tobacco products that are unlawful for sale in the U.S., but are readily available to U.S. customers on foreign websites that accept U.S. currency and ship to the U.S. For instance, Vuse Go 5000 disposable vapes, which are unlawful for sale in the U.S. and which Reynolds itself does not sell in the U.S., are available from dozens of Canadian websites including <https://bayvape.ca/products/vuse-go-edition-5000-disposable-vape>; <https://hazetownvapes.com/collections/vuse-go-5000-rechargeable-disposable>; <https://www.wicksandwires.com/products/mint-ice-vuse-go-5000>.

⁶⁷ NAAG comment (Jan. 19, 2012) at 16, available at <https://www.regulations.gov/> docket FDA–2011–N–0467.

⁶⁸ Modifications to Compliance Policy for Certain Deemed Tobacco Products: Draft Guidance for Industry [Docket No. FDA-2019-D-0661] letter comment (April 30, 2019), <https://www.regulations.gov/comment/FDA-2019-D-0661-15252>.

⁶⁹ *Id.* at 4 (emphasis in original).

A complete prohibition would remove uncertainty and simplify monitoring, inspections, and enforcement. If remote sales were prohibited there would be no uncertainty if a product offered for sale on a website, purchased on a website, in transit, or being delivered, is tax-paid or not, counterfeit or not, flavored or not, sold, shipped or delivered to a minor or not, subject to FDA import alert or not, authorized for marketing and sale by FDA or not. The task of enforcers would be greatly simplified at all points of the remote sales cycle, starting with offers and marketing on websites and ending with delivery. Further, local, law-abiding retailers would no longer be undercut by scofflaw remote sellers.

G. Regulation of “hybrid” remote sales of tobacco products

Finally, we draw FDA’s attention to variants of remote sales (hereinafter referred to as “hybrid remote sales”). One variant occurs when the purchaser places the order online, usually through an app, and the product is later delivered in a face-to-face transaction, usually at the door of a residence.⁷⁰ Another variant (brick-and-click) occurs when the purchaser places the order on a digital tablet at the entrance of a retail establishment and picks up the item shortly thereafter either at the counter or at an adjacent pick-up area. Little research has been published about these hybrid transactions and it appears that federal, state, and local enforcement is rare or non-existent.

These types of hybrid remote sales present novel legal issues and difficult enforcement problems. It is not evident whether the seller is the owner/operator of the brick-and-mortar business from which the product is supplied, the owner/operator of the app, website or device where the order is placed and the monetary transaction is completed, the individual who completes the delivery (who is often an independent contractor) and has face-to-face contact with the purchaser, or the owner/operator of the delivery service (sometimes the same as the app owner/operator.) It is similarly unclear where age verification procedures should occur, who is responsible for performing them, whether those conducting them are trained, who is liable for a failure to check ID and/or a sale to a minor, and how and to whom items may be returned in the event a purchaser fails age or identity verification. We urge FDA to include these types of hybrid remote sales within any remote sale rule issued by FDA and to prohibit such hybrid transactions.

III. CONCLUSION

In the 2009 Tobacco Control Act, Congress foresaw the adverse public health consequences of allowing unregulated remote sales of tobacco products, particularly the risk of easy access by youth. Recognizing the importance of addressing this risk, Congress required FDA to issue a rule regulating such sales by December 22, 2010. It is now more than thirteen years past that deadline and no rule has issued, even though, during that period, Congress passed legislation twice in efforts to reduce the public health risks of remote sales, once imposing additional restrictions on such sales of cigarettes and later applying those restrictions to e-cigarettes.

It is now clear that, despite this additional legislation to attempt to regulate remote sales, only a prohibition of such sales will adequately protect young people from easy access to tobacco products. It is far past time for FDA to comply with its statutory obligations, issue regulations governing remote sales that prohibit such transactions and make the prohibition sufficiently

⁷⁰ See also Duffl, a delivery service operating on college campuses that includes Elf Bar, Hyppe, Vuse, JUUL, Breeze, Lost Mary, Flum and Zyn in its inventory. See <https://www.duffl.com/>

broad to encompass all “hybrid” and other forms of remote sales that provide easy access to tobacco products. We urge FDA to take action with no further delay. We also reiterate our request to meet with you and your staff about this issue as soon as your schedule permits.

Respectfully,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Parents Against Vaping e-cigarettes (PAVe)

Truth Initiative