

July 16, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-N-0529, Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard

The undersigned state attorneys general submit this comment in response to the Food and Drug Administration's (FDA) publication of a "Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard, and Request for Comments." (Docket No. FDA-2018-N-0529, Federal Register vol. 83, no. 52, March 16, 2018, 11754-55.)

FDA's concept paper does not pose specific questions or identify particular topics about which it seeks further information. Consequently, we proffer general comments about illicit trade and enforcement. These comments are based on the unique position of state attorneys general in relation to the regulation of tobacco products.¹ This position is founded on our securing and enforcing the 1998 Tobacco Master Settlement Agreement (MSA), as well as our enforcement of numerous state laws regulating the sale, distribution, marketing, use, and taxation of tobacco products.

The concept paper recognizes the work done by the National Association of Attorneys General (NAAG) on behalf of the state signatories to the MSA (p. 23). Although not mentioned in the concept paper, NAAG serves as counsel for the attorneys general of the states that signed the MSA. The paper also does not mention all of the other tobacco-related work done by state attorneys general. State attorneys general have long fought to protect their citizens, particularly youth, from the dangers of tobacco products. Thus, we have substantial experience and expertise in regulating the tobacco industry and in enforcing state and federal laws relating to tobacco. This work includes enforcement of the MSA, state escrow and tobacco directory statutes, fire-safe cigarette statutes (which are themselves a product standard), state excise tax statutes, consumer protection laws, laws preventing sales or furnishing of tobacco products to minors (sales to minors being a particularly widespread and pernicious illicit market), and assurances of voluntary compliance with major retailers and common carriers. Some states also have tobacco licensing statutes and laws banning remote sales. Various federal laws, such as the PACT Act and Contraband Cigarette Trafficking Act, also support state tax regimes and public health

¹ We use the term "tobacco products" in this comment to mean all tobacco products over which FDA has regulatory jurisdiction.

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protections, and state attorneys general have significant experience in enforcing those laws as well.

For all of the foregoing reasons, we bring a unique and informed perspective to the issue of illicit trade in tobacco products. Based on our expertise, we urge FDA to do the following:

Ban remote sales of all tobacco products

The most effective step that FDA could take to prevent illicit sales of tobacco products that do not comply with an FDA-established tobacco product standard would be to exercise its authority under 21 U.S.C. § 387f(d)(1) & (4) to prohibit all remote sales of all tobacco products. In this regard, we draw FDA's attention to the comment letter submitted by the NAAG Tobacco Committee Co-Chairs on January 19, 2012, regarding Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion and Marketing of Tobacco Products.² In that letter, the Co-Chairs explained in detail why, despite the enactment of the PACT Act, remote tobacco sales continue to compromise the public health (particularly with respect to youth) and to promote tax evasion. The letter concluded that "unlawful non-face-to-face sales are a nationwide problem requiring a nationwide solution. It appears that the only way to remedy the adverse public health consequences of such sales is to follow the approach taken by eight states and ban them."³

As FDA correctly observes, the internet is the most obvious method for consumers to learn about and access illicit tobacco products, including diverted gray market products and smuggled products. In addition to tax evasion and the marketing and sale of tobacco products to minors, other violations committed by remote sellers include identity theft by unscrupulous age verification site operators, production of fake identification documents (resulting in minors providing personal identification data to fraudulent enterprises in foreign countries), credit card scams and fraudulent use of credit cards, and the posting of deceptive and misleading health and cessation claims on websites. In addition to deterring such crimes, complete prohibition of remote sales would also make inspections and enforcement at ports of entry more effective and expeditious. For all these reasons, we encourage FDA to take this step.

Establish a national tobacco product brand directory

A tobacco product standard could also be successfully enforced through the development and implementation of a national tobacco product brand directory. The directory would list only those tobacco products that are compliant with the nicotine (or other) product standards. This would be a convenient resource for retailers, enforcers and consumers, enabling them to perform a quick check on the legality of any product. There are already similar lists in existence. For

² Docket No. FDA-2011-N-0467 RIN 0910-AG43.

³ We are aware that the PACT Act contains certain exemptions for shipping by USPS, e.g., within Alaska and Hawaii, for consumer testing. We take no position on those enumerated exemptions.

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instance, the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) produces a regular list of vendors that are not compliant with the terms of the PACT Act. Similarly, almost all of the states have a Tobacco Directory listing all the brands of cigarettes and roll-your-own tobacco (RYO) that have been certified for sale and distribution in that state. The state attorneys general would be excellent sources of information and advice if FDA were to consider such a measure.

Require cooperation and collaboration between branches of law enforcement

FDA should establish procedures for cooperation and collaboration within federal law enforcement, and between federal, state and local law enforcement in investigating and prosecuting entities not in compliance with FDA product standard rules. Tobacco is regulated by numerous agencies within federal, state, tribal and local government. As a result, FDA should anticipate the need for investigation, enforcement and prosecution by state and local officials as well as federal officials, regarding tobacco products that fail to comply with FDA-established product standards or other FDA rules.

Bolster enforcement aimed at illegal importation and transportation of tobacco products

In our estimation, the concept paper is overly confident about the ability of agencies to intercept tobacco products not in compliance with FDA rules at ports of entry – both sea and airports – and about the degree of cooperation from common carriers and USPS in monitoring, disclosing and preventing the transport of tobacco products within the country. FDA should anticipate a significant need to bolster enforcement in those areas in the event it establishes a product standard. This is an area where joint enforcement powers are important.

- **Importation of foreign tobacco products and delivery through the mail**

State attorneys general cooperate with federal authorities to identify and confiscate unlawful tobacco products at ports of entry. These joint efforts suggest that enforcement, which is already a serious challenge, will become even more difficult if FDA establishes a product standard. For example, great numbers of contraband cigarettes enter the United States daily through one of five International Mail Centers (IMCs), namely, Los Angeles, John F. Kennedy, San Francisco, O'Hare, and Miami International Airports. During a recent 9-day operation at one of the IMCs, over 4,000 parcels containing more than 36,000 cartons of illicit cigarettes were identified before they could be delivered by USPS to addressees in thirty-five states. Some of the delivery sellers shipping the largest number of cartons had already been targeted in prior operations at other IMCs. Additional law enforcement support is already needed at all five IMCs and other ports of entry to reduce international trafficking of unlawful tobacco products.

- **Delivery of illicit tobacco products by common carriers**

The PACT Act prohibits distribution of cigarettes and smokeless tobacco by common carriers on behalf of delivery sellers listed on the ATF's Non-Compliant Sellers List.⁴ Common carriers have violated and continue to violate this provision. For example, a federal district court found, in a case brought jointly by New York and New York City against UPS, that UPS violated the PACT Act, the Contraband Cigarette Trafficking Act, and New York's statute prohibiting carriers from knowingly delivering cigarettes purchased over the Internet to New York consumers. (See *New York v. UPS*, 253 F. Supp. 3d 583 (S.D.N.Y. 2017).) Additionally, the court found that UPS violated the Assurance of Discontinuance ("AOD") entered into between UPS and the New York Attorney General's Office. The court awarded damages and penalties of \$165,817,479 to New York State and \$81,158,135 to New York City. New York and New York City allege that their pending case against FedEx warrants even greater penalties than those awarded in the UPS case, based on the number and seriousness of the violations. See Plaintiffs' Fed. R. Civ. P. 26(a)(1)(iii) disclosures as of May 11, 2017, *City of New York, et al. v. FedEx Ground Package System, Inc.*, No. 13-cv-9173 (S.D.N.Y.), ECF Nos. 469-20 – 469-24 (calculating damages and penalties totaling approximately over \$681 million).

Require packaging or markings that denotes compliance with the product standard

Both consumer awareness and enforcement will be enhanced if FDA requires compliant products to be packaged or marked in ways that draw consumers' attention to the product standard. If there were a product standard reducing nicotine, for example, it would be advantageous if compliant products were required to bear words of assurance for consumers, such as "Reduced Nicotine." A manufacturer of an illicit product containing a greater quantity of nicotine would be unlikely to replicate the "Reduced Nicotine" marking, because it would presumably render the product unattractive to its intended audience. Additionally, such distinguishing markings would enable enforcement agents to recognize and intercept noncompliant products with greater ease.

Develop efficient and effective field testing methods

The development of a field test that is reliable, affordable and convenient will greatly enhance enforcement of a product standard. The efficacy of a field test is well illustrated by the handheld scanner, which is designed to extract extensive information from high-tech cigarette tax stamps. Using such scanners, field agents can instantly determine not only whether boxes of cigarettes are stamped, but whether the stamps are fake or legal. In contrast, there is currently no portable field device available to test for nicotine levels or for flavors in tobacco products. FDA should,

⁴ It is noteworthy that the PACT Act applies only to cigarettes and smokeless tobacco products; it does not apply to cigars, cigarillos, little cigars, electronic smoking devices, heat-not-burn products and several other categories of tobacco products. Consequently, the Act's usefulness as a tool for enforcing a product standard extends only to those products within its purview.

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therefore, invest in the development of field testing technologies and protocols to support enforcement of a product standard.

Require systematic tracking and tracing of all tobacco products

FDA has authority to require reporting that would create a national system of track and trace for tobacco products meeting its product standards. Implementing a track and trace system entails creating a unique identifier on each pack of cigarettes or other unit of tobacco product labeled for individual sale and scanning it at each step of the supply chain to track its progress. Such a system would enable regulators to ascertain exactly where there is leakage in the system and to focus enforcement efforts in those areas. A national track and trace system could greatly reduce the quantity of non-compliant tobacco products in circulation.

We consider FDA's authority to issue recordkeeping regulations for track and trace through the supply chain a powerful enforcement mechanism, and we urge FDA to adopt such regulations. Track and trace protocols would be particularly important if FDA were to establish a product standard for only certain categories of tobacco products, or were to allow non-compliant products to be produced in the U.S. for export only, because recordkeeping requirements could deter diversion of those products back into the U.S. through a gray market. We further urge FDA to enact regulations to make track and trace records available to state and local law enforcement agencies for use in enforcing tobacco-related laws.

Bolster enforcement on tribal lands

The concept paper raises the possibility that tribal manufacturers could produce non-compliant tobacco products, but concludes that existing FDA enforcement tools seem sufficient to control such illegal activity. We have serious reservations about that conclusion. Almost a decade after passage of the Tobacco Control Act, FDA's retail enforcement on tribal lands is still very limited in scope. Few tribal retailers are subject to either a decoy enforcement program, or a retailer education program, both of which are effective in reducing sales of tobacco products to minors. FDA's minimal activity in the tribal retail area suggests that FDA may have limited success in policing a product standard against the tribal tobacco industry. Moreover, FDA itself notes diplomatically in the concept paper that "some tribally-affiliated firms assert a different understanding as to the relationship between federal government authority and their self-governance." (p. 12). FDA should anticipate the need for stronger and more intensive monitoring and enforcement efforts to prevent tribal production of non-compliant products for the domestic market.

We emphasize that our concern is illicit traffic in commercial tobacco, tribal or otherwise. We are well aware that there are tribal and tribal member-owned commercial tobacco enterprises that are in full compliance with state tobacco laws. We are also aware that some Native Americans grow and make ritual use of traditional tobacco that has not been genetically-modified,

hybridized or otherwise developed for industrial production. Thus, in the event that FDA implements a product standard at the level of farming (rather than manufacture), FDA should consider exempting traditional, non-commercial growth of the tobacco plant by Native Americans from such a product standard.

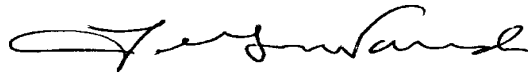
Make any product standard applicable to all tobacco products

Any product standard set by FDA should apply to all tobacco products. FDA notes in the concept paper that if a product standard is applied to some tobacco products and not others, consumers may attempt to modify their products, or switch products to circumvent the standard. Such consumer behavior seems likely if FDA makes a product standard applicable to some products, but not others. An example of this is the current federal prohibition on flavors, other than menthol, in cigarettes. That prohibition has not created an illicit market for flavored cigarettes, but it *has* resulted in an expanded market for flavored cigars and cigarillos. Similarly, if a nicotine standard were established only for cigarettes, it could stimulate lawful sales of other tobacco products having higher nicotine levels. The tobacco industry can be expected to take full advantage of regulatory gaps. The solution is to set a product standard for all tobacco products, without exception.

Respectfully submitted,



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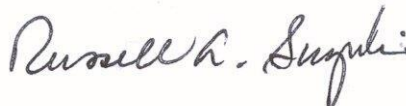
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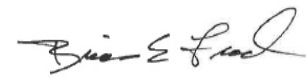
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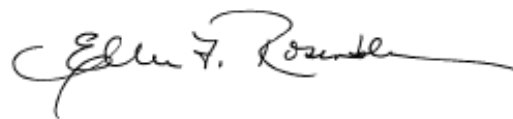
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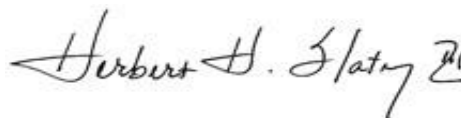
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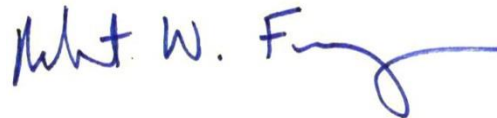
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