

July 16, 2018

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

Re: Docket No. FDA-2017-N-6189, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes

The undersigned Attorneys General of California, Hawaii, Massachusetts, Maine, Oregon and Pennsylvania, submit this comment in response to FDA's Advance Notice of Proposed Rulemaking (Notice), 83 Fed. Reg. 11818-43 (March 16, 2018), regarding a maximum nicotine level product standard in tobacco products. We support FDA's effort to obtain information about this important issue.

State Attorneys General have an extensive interest in and engagement with tobacco policy, litigation, regulation and enforcement. We have long attempted to protect our citizens, particularly youth, from the dangers of use of and exposure to tobacco products. For example, nearly every state Attorney General sued the major tobacco companies for the harm their products caused, and, as a result, all states reached settlement agreements, including the 1998 Master Settlement Agreement (MSA). Thanks, in part, to the MSA, smoking rates have declined significantly over the past two decades.

State Attorneys General have substantial experience and expertise regulating the tobacco industry and enforcing state and federal laws relating to tobacco. These include the MSA, the state escrow, directory and fire-safe cigarette laws, state excise tax laws, tobacco manufacturer, distributor and retailer licensing laws, laws prohibiting the sale or furnishing of tobacco products to minors, and, in some states, remote sales laws. We also have experience enforcing federal laws, such as the Prevent All Cigarette Trafficking Act, 15 U.S.C. §§ 375-378 (PACT Act), that intersect with state tax laws. Our enforcement efforts include monitoring, investigation, litigation and administration, and are frequently multi-state in nature.

We have also on numerous occasions commented on various topics to FDA, reported violations to FDA, and recommended that FDA take steps to protect our citizens from the dangers of tobacco use and exposure to tobacco products. Drawing on our enforcement experience and expertise, the undersigned Attorneys General offer these comments and present them in the same format and order as the Notice.

A. Scope (83 Fed. Reg. 11,825–26.)

FDA:

Cigarettes are the tobacco product category that causes the greatest harm to public health. This is because of the prevalence of cigarette use and the toxicity and addictiveness of these products,

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and the resulting tobacco-related disease and death. If FDA were to establish a maximum nicotine standard that covered only cigarettes, some addicted smokers could migrate to other combusted tobacco products to maintain their nicotine dose or engage in dual use with cigarettes and other combusted tobacco products, which would reduce the public health impact of a nicotine standard. Therefore, FDA is seeking comment on whether the standard should cover any or all of the following products: combusted cigarettes (which includes kreteks and bidis), cigarette tobacco, roll-your-own (RYO) tobacco, some or all cigars, pipe tobacco, and waterpipe tobacco.¹

Comment:

FDA initially asks if the nicotine product standard should apply only to cigarettes, or also other combusted tobacco products. **The nicotine standard should apply to all combusted products.** FDA correctly notes that if it applies only to cigarettes, users will migrate to other combusted products and/or to dual use with combusted and non-combusted products. Further, some manufacturers of those other combusted products are likely to modify those products so that they are similar to cigarettes but do not conform to the technical definition of cigarettes and therefore remain outside the nicotine standard. Smokers may migrate to those combusted products to compensate for the lack of nicotine in cigarettes. Thus, the amount of smoking of combusted products of various types would not abate. Yet these combusted products present public health risks similar to cigarettes. (*See National Cancer Institute, Cigars: Health Effects and Trends. Smoking and Tobacco Control Monograph No. 9, 1998; Chang, CM, et al., Systematic review of cigar smoking and all cause and smoking related mortality, BMC PUBLIC HEALTH, doi 10.1186/s12889-015-1617-5, 2015; Nonnemaker, J, et al., Mortality and Economic Costs from Regular Cigar use in the United States, 2010, AM. J. OF PUBLIC HEALTH 104(9):e-86-91, September 2014.*) The public health benefits of the nicotine standard will therefore not be realized.

This is not idle speculation. Rather, on previous occasions, sectors of the tobacco industry and users nimbly moved into regulatory gaps, e.g., the growth in production, marketing, sale, and use of flavored little cigars and cigarillos after the prohibition of flavored cigarettes; the growth in production, sale, and use of so-called pipe tobacco when roll-your-own tobacco was taxed more heavily; and smuggling tobacco products from low- to high-tax rate states.² These trends are

¹ *FDA intends that any nicotine tobacco product standard would cover all brands in a particular product category and, therefore, those products currently on the market and any new tobacco products in a category would be expected to adhere to the standard.*

² For example, the Children's Health Insurance Program Reauthorization Act of 2009 resulted in a tax difference between pipe tobacco and RYO. The Alcohol and Tobacco Tax and Trade Bureau (TTB) relies primarily on the packing and labeling of such products in distinguishing the two types of tobacco, resulting in manufacturers of RYO relabeling their RYO product as pipe tobacco, simultaneously lowering their tax burden and removing their products from the regulation under the Tobacco Master Settlement Agreement (MSA) and complementary legislation. Similarly, the ban on flavored cigarettes (other than menthol and tobacco) under the 2009 Family Smoking Prevention and Tobacco Control Act correlated with reductions in

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likely to repeat if the nicotine standard applies only to cigarettes. We therefore urge FDA to propose a rule applying the nicotine standard to all combusted products.

FDA asks if the standard should be applied to **premium cigars** and, if not, how premium cigars should be defined. First, we are concerned that if premium cigars are exempt, use of premium cigars will increase because premium cigars will be the only combusted product that contain significant levels of nicotine. Sectors of the tobacco industry may take advantage of this exemption. For example, some manufacturers might produce products that technically meet the definition of premium cigar (and contain significant levels of nicotine) but are in other respects closer to non-exempt combustible products such that they appeal to users of combustible products.

Second, depending on how premium cigars are defined, the definition could be circumvented. A price-based definition could be evaded by promotions and discounts. A definition based on manufacturing standards could be difficult to enforce at point-of-sale. Characterizing flavors might be added to premium cigars so that they are “flavored” and appealing to youth rather than traditionally “flavorful” in the way that they appeal to current premium cigar smokers. High nicotine content premium cigars could be developed. For these and other reasons, individuals who do not currently use premium cigars might migrate to smoke those “premium” cigars. Others might open these “premium” cigars for use as nicotine-containing roll-your-own or pipe tobacco. Such conduct, by consumers and/or manufacturers, would thwart the purposes of the nicotine product standard and/or the premium cigar exemption.

Therefore, in the event that the nicotine standard is not applied to premium cigars, it would be extremely important for FDA to safeguard against such developments. Protective measures that might address the issues identified above include:

- setting a high minimum price for premium cigars
- linking that minimum price to an inflation index
- prohibiting coupons, discounts, mobile apps and promotions for premium cigars to ensure that the minimum price is not circumvented
- prohibiting production or sale of premium cigars with characterizing flavors
- prohibiting production or sale of premium cigars with high nicotine content
- setting a product standard for the pH level of premium cigars so as to limit inhalation
- standardizing packaging for premium cigars to assist enforcement
- using a unique stamp on the packaging of premium cigars
- requiring track and trace reporting by manufacturers of premium cigars
- setting a minimum pack size

cigarette smoking, but increases in use of menthol cigarettes, cigars and pipe tobacco. (See Charles J. Courtemanche, et al., *Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4821570/> 52 AM. J. PREVENTATIVE MED. e139 (2017).)

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To the extent price is used to define the premium cigar product, it should be based on prices and product characteristics that existed no later than the time this Notice was published, so as to forestall gaming the system. The minimum price should be indexed to inflation. The prohibition against discounting should be designed to ensure that the minimum price level is not evaded at point-of-sale, whether through digital coupons or two-for-one type offers. A prohibition on flavors would prevent the emergence of premium cigars with menthol, grape and other flavors not found in premium cigars at present, but common in cigarillos and little cigars. Sales of these flavored cigars, and the range of flavors, have increased rapidly in recent years, and they are popular among youth. (See, e.g., Miech, R.A., et al., *Cigarillo use increases estimates of teen smoking rates by half*, Univ. of Michigan News Service, Dec. 16, 2015. Ann Arbor, MI. (87% of adolescents who used cigarillos in past 30 days used flavored cigarillos); Eaton, D.K., et al., *Youth risk behavior surveillance - United States*, 2011. MORBIDITY AND MORTALITY WEEKLY REPORT. SURVEILLANCE SUMMARIES (Washington, DC), 2012 61(4): p. 1-162. (cigars are second-most commonly used tobacco product by youth).) Further, the flavored tobacco in these cigars is sometimes used to mix with cannabis; this raises a set of public health concerns that is beyond the scope of this comment. A prohibition on the lowering of the pH level of premium cigars would discourage inhalation and be likely to ensure that the products are used only in the manner intended by premium cigar manufacturers and by typical non-cigarette-using cigar smokers. (See Robert N. Proctor, *Golden holocaust: origins of the cigarette catastrophe and the case for abolition*, Berkeley: University of California Press, 2011.) Packaging requirements would ensure that each cigar may be identified, which cannot be done for loose, individual cigars. FDA may consider requiring that a unique stamp be placed on the packaging for the purposes of track and trace reporting, which would ensure a minimum price and facilitate tax collection. FDA should consider all of these measures.

FDA asks if the product standard should be applied to **waterpipe tobacco**. We urge FDA to apply the standard to waterpipe tobacco. It is particularly difficult to enforce youth access and smoke-free laws in hookah lounges and bars, and these facilities often proliferate in areas frequented by youth, such as near college campuses. (See Frederick Kates, et al., *Geographic Proximity of Waterpipe Smoking Establishments to Colleges in the U.S.*, 50 AM. J. PREVENTATIVE MED. e9 (2016).) There is a widespread misperception that waterpipe smoking is not harmful or is less harmful than cigarette smoking, even though the amount of nicotine inhaled is considerably higher. (See Centers for Disease Control and Prevention, *Smoking & Tobacco Use: Hookahs at https://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs/index.htm* (accessed June 15, 2018).) Regulating nicotine content in cigarettes but not waterpipe tobacco would only amplify this misconception. Enforcement challenges in this area are likely to intensify if the nicotine standard applies to some tobacco products but not to waterpipe tobacco. The sale and use of waterpipe tobacco is likely to increase, including by minors, and it would be difficult for regulators in the field to ascertain whether a specific product is genuine waterpipe tobacco for hookah use (and thus may contain nicotine) or is other loose tobacco (to which the nicotine standard would apply).

FDA does not ask for comment or information about application of the nicotine standard to certain other non-combusted tobacco products, such as **smokeless, electronic nicotine devices**

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(ENDS) and heat-not-burn products (HNB). As to smokeless tobacco products, we are aware of, and commend, FDA's rulemaking to set a limit on N-Nitrosonornicotine, based on its carcinogenicity. (See Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Products (Proposed Rule), Jan. 23, 2017, 82 Fed. Reg. 8004-8052, Docket No. FDA 2016-N-2527.) That excepted, we are concerned that FDA is not seeking comment about, and is thus apparently not considering, the application of a nicotine standard to these non-combusted tobacco products. If the purpose of the Notice is to gather information about the effects and feasibility of a nicotine product standard, the value of the exercise is diminished if FDA will not consider whether to apply a similar standard to all tobacco products over which FDA has regulatory jurisdiction. FDA should, at a minimum, seek information about setting a nicotine standard for all tobacco products over which it has jurisdiction.

Indeed, as FDA recognizes, if a nicotine standard is applied only to combusted products, it is likely that smokers will migrate to non-combusted products that contain significant levels of nicotine, and use of and exposure to those products will increase. However, there is evidence that those non-combusted tobacco products to which users might migrate - like smokeless tobacco, snus, heat-not-burn products and electronic nicotine devices - are harmful, although in different ways and to different degrees than combusted products. Thus, particularly if FDA anticipates greater use of and exposure to smokeless, heat-not-burn products and electronic nicotine devices, then the application of a nicotine standard to those products is worthy of analysis and consideration. A decision not to do so appears arbitrary. Moreover, even apart from the disputed issue of possible harms arising from use of non-combusted tobacco products, FDA recognizes that exposure to nicotine itself causes harm, e.g., on the developing brain. (83 Fed. Reg. 11821, 11823.) It therefore makes little sense for FDA to seek information regarding when nicotine is delivered by cigarettes, but not when nicotine is delivered by non-combusted tobacco products.

As FDA states, continued presence of nicotine in heat-not-burn products, electronic nicotine devices, or smokeless tobacco will be likely to facilitate or even promote dual use of those products with combusted products that contain little nicotine. If the presence of nicotine in non-combusted products facilitates or promotes continued smoking of combusted products, that raises the question: would there be the same degree of dual use if the nicotine standard were applied to the non-combusted products? As also recognized by FDA, the presence of nicotine in non-combusted products, and their availability, will provide a means for users to combine those products with low-nicotine combusted products, e.g., mixing smokeless products or premium cigar tobacco into roll-your-own tobacco, or adding a measure of nicotine-containing e-liquid to a cigarette or cigarillo.

For all these reasons FDA should obtain information about and consider the application of a nicotine standard to the full range of covered tobacco products. FDA should gather this information and make this assessment either before or during the rulemaking process for combusted products.

We simultaneously caution FDA not to view addiction to smoking as a purely pharmacological phenomenon – and thus as a problem to be solved purely by establishing a nicotine product standard. We draw FDA's attention to the conclusion reached by scientists employed by Philip

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Morris – revealed in documents in the Truth Tobacco Industry Documents Repository that was itself established through the MSA reached by state Attorneys General – that smoking is a “complex, highly interactive behavior involving psychosocial, sensory, and pharmacological elements.” (See Philip Morris Records, Nicotine Addiction Consensus Group Presentation, Feb. 16, 2005,

<https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=qgif0218> (accessed May 22, 2018.) Therefore, while the proposed nicotine product standard is worthy of careful and serious consideration, it should supplement and not replace a holistic tobacco control approach that addresses all aspects of addiction and smoking – such as smoke-free laws, taxation, cessation programs, restrictions on promotions, youth access laws, media campaigns, surveillance, well-funded programs, and more. Those time-tested measures have steadily reduced the consumption of tobacco in the United States even in the absence of a nicotine standard, and they should remain at the center of FDA policy.

B. Maximum Nicotine Level (83 Fed. Reg. 11826-29)

FDA:

FDA seeks information about the threshold maximum nicotine level that would minimize addictiveness, as well as related topics such as how that level should be measured, the connection between that level and youth initiation, and variations in sensitivity in different population groups.

Comment:

This is not an area of expertise for the undersigned state Attorneys General. However, closely related to the assessment of an appropriate maximum nicotine level for public health purposes is consideration about how, for each category of product, that level may be measured by enforcement inspectors. Effective enforcement of the nicotine standard will require affordable, reliable, accurate and convenient testing, including field testing. Put another way, the public health benefit of a specific maximum nicotine level could be undercut if testing proves too expensive, time-consuming, uncertain or cumbersome. Rare or inconsistent enforcement could result in excess levels of nicotine remaining undetected in certain products or in the development of products that take advantage of a gap in measurement and testing.

Related to the above, FDA recognizes that substances other than nicotine may contribute to addiction – substances such as tobacco alkaloids and smoke aldehydes. (83 Fed. Reg. 11829.) Therefore, an assessment of the appropriate maximum level for nicotine should also take into consideration whether similar maximum levels should be set for these other potentially addictive substances, as should the issue of effective field testing for addictive substances other than nicotine that are present in tobacco products.

In sum, the determination of the appropriate maximum level of the product standard should take into account issues of field enforcement.

C. Implementation (Single Target vs. Stepped-Down Approach) (83 Fed. Reg. 11829-30)

FDA:

If FDA were to issue a nicotine product standard, such a standard could propose either a single target (where the nicotine is reduced all at once) or a stepped-down approach (where the nicotine is reduced gradually over time) to reach the desired nicotine level. FDA seeks information about these two approaches.

Comment:

This is not an area in which the undersigned state Attorneys General have expertise. However, FDA also asks more specifically:

“5. What would be the likely implementation differences, including implementation timelines and transition costs, between a single target approach or a stepped-down approach involving a sequence of incremental levels and implementation dates?” (83 Fed Reg. 11830.)

From the point of view of state enforcement, assuming that state agencies may enforce this federal regulation, the single target approach is likely to be more effective. A graduated approach over time is likely to lead to periods of uncertainty, frustration and confusion among retailers, consumers and enforcers. It is also likely to result in inconsistent signage at point of sale, and thus uneven enforcement. While a single target approach will likely raise the same issues and require a significant investment in retailer, enforcer and consumer education, that will occur only once.

D. Analytical Testing Method (83 Fed. Reg. 11830)

FDA:

If FDA were to issue a nicotine standard, should it also specify a method for manufacturers to use to detect the level of nicotine in their products? The results of any test to measure the nicotine in such products should be comparable across different accredited testing facilities and products, and should be precise, specific and accurate across different products. FDA asks specifically: “2. Should the Agency require manufacturers to sample their products in a specific manner to ensure that products do not contain excess levels of nicotine? Should manufacturers be required to test each manufactured batch to ensure compliance with a product standard limiting nicotine levels? What criteria should be used to determine if a batch passes or fails testing?” (83 Fed. Reg. 11830.)

Comment:

State Attorneys General have expertise and experience in this area through our role defending public rights, such as consumer protection and right to know laws. Requiring manufacturers to test in a specific manner is likely to provide certain advantages if the batch numbers and results

are publicly available and if the production batches correlate with consumer product batches. Independent testing laboratories will be in a position to confirm or challenge specific results by testing samples from specific batches and matching them to results disclosed by the manufacturer. Transparency will enable the public, as well as enforcers, to observe whether manufacturers are adhering to the testing requirements. It will likely improve compliance because manufacturers will know they may be monitored. Manufacturers will be able to assert affirmative defenses against frivolous claims, pointing to the procedures and specific results of an effective testing program as a defense against a claim that a product was not compliant.³

E. Technical Achievability (83 Fed. Reg. 11830-33)

FDA:

FDA is required to consider the technical achievability of the product standard. Significant reductions in nicotine in cigarettes and other combusted tobacco products can be achieved principally through agricultural practices, tobacco blending, cross-breeding plants, genetic engineering, and chemical extraction. FDA also is considering the timeframe for implementation of a nicotine tobacco product standard to allow adequate time for industry to comply. In addition, FDA is seeking data and information regarding the potential costs to implement such a standard.

Comment:

The undersigned state Attorneys General do not have expertise as to the general issue of technical achievability. However, we do have experience regarding some of the specific questions posed by FDA, as follows:

FDA asks whether a 2-year, 4-year, or 6-year timeframe for the effective date of the rule would be appropriate, noting the pace of the regulatory procedure and the requirement to give extensive notice to those who might be dislocated by such a product standard. (83 Fed. Reg. 11830-33.) In light of the fact that the proposed nicotine standard was announced in 2017, the likely pace of the adoption of the rule, the statutory requirement that the effective date must be at least two years after publication of the final rule, and the great and ongoing harm to public health, FDA should move with deliberate speed and should not provide for an extended timeframe for the effective date. Further, the scale of the anticipated public health benefits of the proposed standard counsel that there should be no unnecessary delay in realizing those gains. The timeframe should be two years.

FDA also asks:

³ On the other hand, a strict liability scheme for the nicotine product standard may be easier to administer and enforce, and that would weigh against requiring a particular testing protocol.

“Should the standard include provisions that would allow manufacturers, distributors, or retailers to sell off existing nonconforming inventory of manufactured combusted tobacco products? If so, what would be a reasonable sell-off period?” (83 Fed. Reg. 11833.)

The great majority of the state Attorneys General administer Tobacco Directories that list cigarettes and roll-your-own tobacco brands whose manufacturers are compliant with various state laws. On occasion, brands are delisted and may no longer be sold.⁴ On the basis of over fifteen years’ experience enforcing Directory statutes, including delisting, a 60-day sell-off period is sufficient.

FDA also asks:

“What are the potential outcomes of implementing methods to reduce nicotine content in cigarettes in terms of impact on characteristics of cigarettes (flavor, taste, aroma, etc.) and user experience?” (83 Fed. Reg. 11833.)

The goal of the proposed nicotine standard – to reduce use of combusted tobacco products – would be advanced by concurrent restrictions on flavored tobacco products, in particular, prohibitions on menthol-flavored cigarettes and on all non-tobacco flavors in all other combusted tobacco products. Research suggests that flavor restrictions will reduce youth initiation and promote quitting. (*See, e.g.*, Charles J. Courtemanche, et al., *Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4821570/> 52 AM. J. PREVENTATIVE MED. e139 (2017).) Further, FDA recognizes the probability of dual use of combusted products subject to the nicotine standard and non-combusted products that contain higher levels of nicotine. (83 Fed. Reg. 11825-26, 11833.) Unavailability of flavored combusted products will likely reduce this type of dual use, and also reduce switching to another type of combusted product that is flavored. FDA should therefore implement flavor restrictions in conjunction with the proposed nicotine standard. Note also that many state Attorneys General previously expressed support for a prohibition on menthol cigarettes and characterizing flavors in other tobacco products. (*See* Comment from 29 Attorneys General to FDA re Deeming Tobacco Products, Aug. 8, 2014, Docket No. FDA-2014-N-0189; Comment from 27 Attorneys General to FDA re Menthol in Cigarettes, Nov. 8, 2013, Docket No. FDA-2013-N-0521.)

F. Possible Countervailing Effects (83 Fed. Reg. 11833-34)

FDA:

FDA recognizes that there may be effects that diminish the population health benefits expected as a result of a nicotine standard. FDA would need to assess these effects in comparison to the expected benefits, including among population subgroups. One possible countervailing effect is continued combusted tobacco product use. Current smokers of tobacco products subject to a

⁴ For instance, under California law, 60 days following removal of a brand from the Directory those cigarettes are contraband and may not be purchased or sold in California. (*See* Cal. Rev. & Tax. Code § 30165.1(c)(3)(E).)

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nicotine tobacco product standard could turn to other combusted tobacco products to maintain their nicotine dependence, both in combination with cigarettes (i.e., dual use) or in place of cigarettes (i.e., switching). Coverage of other combusted tobacco products, as FDA is considering, is one way to limit this product migration or dual use. Another possible countervailing effect is the potential for increased harm from altered smoking behaviors (e.g., increase in number of cigarettes smoked, increased depth of inhalation). Another possible countervailing effect could be users seeking to add nicotine in liquid or other form to combusted tobacco products. Therefore, FDA is considering whether any action it might take to reduce nicotine in cigarettes should be paired with a provision that would prohibit the sale or distribution of any tobacco product designed for the purposes of supplementing the nicotine content of the combusted tobacco product (or where the reasonably foreseeable use of the product is for the purposes of supplementing the nicotine content). FDA is also considering whether illicit trade could occur as a result of a nicotine standard, how that could impact the marketplace, and how comprehensive interventions could reduce the size of the illicit tobacco market through enforcement mechanisms and collaborations across jurisdictions.

Comment:

We agree that FDA should give careful consideration to all of the countervailing effects identified in the Notice.

FDA also asks specifically:

“1. In addition to a nicotine tobacco product standard, should FDA consider any additional regulatory action to address the possibility of migration to, or dual use with, other tobacco products?” (83 Fed. Reg. 11334.)

FDA should consider additional regulatory action to address migration to, and dual use with, other tobacco products. The likelihood of dual use and of switching to other combusted products is a powerful reason to apply the nicotine standard to all combusted products and, possibly, to all tobacco products. Similarly, FDA should consider a flavor restriction. For instance, a restriction on flavored cigarillos and small cigars and a restriction on menthol flavored cigarettes is likely to act against this countervailing effect.

FDA also asks:

“2. If FDA were to issue a product standard setting a maximum nicotine content for cigarettes, would smokers seek to add liquid nicotine to their VLNC cigarettes? Therefore, should such a regulation include provisions prohibiting the sale or distribution of any tobacco product designed for the purposes of supplementing the nicotine content of a combusted tobacco product (or any product where the reasonably foreseeable use is to supplement this nicotine content)? How could such a provision be structured to efficiently and effectively achieve this purpose? Should FDA consider other means to prevent supplementing the nicotine content of a combusted tobacco product subject to a nicotine tobacco product standard?” (83 Fed. Reg. 11334.)

It is likely that some smokers will seek to add liquid nicotine to combusted products and that a sector of the manufacturing industry will offer products for this purpose. FDA only identifies liquid nicotine as potentially being used for supplementing the nicotine content of a combusted tobacco product, but, as discussed above, if FDA regulates only some tobacco products, it is likely that some manufacturers and retailers will exploit this regulatory gap and produce other forms of nicotine-containing products. For example, nicotine-containing blunts, powders, waxes, or oils could be produced to circumvent a partial product standard. Because FDA should anticipate that regulatory gaps in this area are likely to be exploited, any regulation of this kind should not be limited to liquid nicotine. Further, and at a minimum, FDA should restrict all consumer-size containers of nicotine in all forms because unavailability and inconvenience are likely to deter many smokers from adding nicotine to combusted products.

FDA also asks:

“3. Would a nicotine tobacco product standard affect the current illicit trade market, and, if so, to what extent? How would users obtain their sources of tobacco in an illicit market? How would manufacturers distribute their illicit products and develop consumer awareness of such products? How would such sales take place?” (83 Fed. Reg. 11334.)

It is likely that a nicotine standard would impact illicit trade because it is likely that non-compliant tobacco products will be produced, imported, distributed, sold and/or smuggled in the U.S. However, because FDA proposes a national standard there is less basis for concern about inter-state trade of the kind seen in cigarettes obtained in low-tax states and sold in high-tax states. Closer comparisons that FDA may wish to consider are illicit trade in flavored cigarettes (other than menthol and tobacco), Cuban cigars, roll-your-own tobacco masquerading as pipe tobacco, and cigarettes not complying with the fire-safe ignition propensity standard that applies under state law in all states.

We agree with the observations regarding large-scale commercial manufacture made in FDA’s March 15, 2018, draft concept paper on “Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard,” that it is unclear to what extent such manufacturers would be willing to risk their businesses by producing unlawful products. (p. 8.) However, noting prior conduct, FDA should anticipate a need for increased monitoring and enforcement efforts to prevent production of non-compliant products for the domestic market.⁵ However, of more concern is the likelihood that, if the product standard exempts certain categories of tobacco

⁵ As FDA is aware, manufacturers have attempted to evade regulations in the past. For example, as FDA is aware, Jacobs Tobacco Company, a small tribal tobacco manufacturer, refused to pay federal excise tax for a certain period. Similarly, for many years, Native Wholesale Supply Company, a distributor owned by a tribal member, failed to pay its Tobacco Trust Fund assessments required under the Fair and Equitable Tobacco Reform Act of 2004. (See 7 U.S.C. § 518.) Grand River Enterprises, a manufacturer located on a reservation within Ontario, Canada, for many years produced and exported brands of cigarettes into the U.S. that were not compliant with state fire-safe product standards.

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products, manufacturers will develop products that technically skirt the parameters of the standard and thus avoid regulation.⁶

There is also reason for concern that tobacco products manufactured in the U.S. for export purposes only, that do not comply with the nicotine standard, will be diverted and made available in the U.S. through the gray market, often through internet sales.

Thus, in general terms regarding illicit trade in tobacco products, we urge FDA to consider the following when formulating a proposed rule:

(a) Prohibit all internet or remote sales of tobacco products

FDA's Office of Compliance and Enforcement has in place an effective tobacco retailer inspection program, and states have in place various retail compliance programs – for state taxation, licensing, under-age sales, and other provisions – but internet sales of tobacco products present unique challenges to regulators. It is not difficult for minors to purchase tobacco products over the internet. (*See* Williams, RT, et al., "Electronic cigarette sales to minors via the internet." *JAMA PEDIATRICS*, online March 2, 2015, 169(e):e1563.) To prevent illicit non-face-to-face sales of products that do not comply with an FDA-established product standard, one of the most effective measures that FDA could take is to exercise its authority under 21 U.S.C. § 387f(d)(1) & (4) to prohibit all internet or remote sales of cigarettes and other tobacco products. A complete prohibition could be policed at many levels, including monitoring websites and social media; conducting undercover buys; establishing cooperative agreements with and enforcing the regulation when necessary against businesses that host websites or provide internet vending and merchant services; and extending existing agreements with credit card companies, USPS, and common carriers. A complete prohibition of internet and remote sales of tobacco products would also go a long way towards resolving other public health and consumer protection issues and reducing tax evasion. These issues include the sale and marketing of tobacco products to minors, identity theft by unscrupulous age verification site operators, production and sale of fake identification documents (resulting in minors providing personal identification data to fraudulent enterprises often in foreign countries), evasion of state excise taxes and state sales taxes, credit card scams and fraudulent use of credit cards, and deceptive and misleading health and cessation claims on websites and social media. For all these reasons FDA should consider taking this step.

⁶ This is illustrated by the fact that many little cigars are little different from cigarettes yet evade regulation as cigarettes because they fall just within the TTB definition of little cigars. (*See generally* State of Montana, et al., Petition for Rulemaking, *In the Matter of the Repeal of the definitions of "Cigar" and "Cigarette" in 27 C.F.R. § 40.11, 27 C.F.R. § 41.11, 27 C.F.R. § 44.11 and 27 C.F.R. § 45.11 and Proposed New Rules Defining "Cigar" and "Cigarette" and Proposed New Procedural Rules for Cigar and Cigarette Rulings*, Alcohol Tobacco Tax and Trade Bureau (May 19, 2006) (describing impact of TTB definitions of cigars on state enforcement of cigarette regulations); <https://hestiatobacco.com/> (accessed May 20, 2018) (little cigars - impliedly cigarettes - made from "totally natural tobacco leaf . . . rolled in natural papers without flame retardants.").)

(b) Develop national tobacco product brand directory

Another important measure to consider when establishing a product standard is a national tobacco product brand directory. The directory would list only brands and product types that are compliant with the nicotine (or other) product standard. This would be a convenient resource for distributors, wholesalers, retailers, enforcers and consumers, enabling them to perform a quick check on the legality of any brand under federal law. As a model for this, almost all of the states have a Tobacco Directory listing all the brands and types of cigarettes and roll-your-own tobacco that have been certified for sale and distribution in that state. The state Attorneys General would be a resource if FDA considers such a measure.

(c) Track and trace reporting system

Related to the above, FDA has authority under section 920(b) of the Tobacco Control Act to require reporting that would create a national track and trace system for tobacco products. Unlike a directory, this would provide information about specific products. Track and trace would be particularly important for regulators and retailers 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 purposes only. We urge FDA to consider such reporting. In the event FDA implements a broad product standard across all tobacco products, track and trace reporting may be of less utility.

(d) Promote cooperation and collaboration between federal and state regulators

We urge FDA to promote cooperation and collaboration between federal and state regulators. Tobacco is highly regulated by numerous agencies within federal, state, tribal and local government. As a result, regulation, monitoring, inspections, investigation, data collection, and prosecution is frequently silo-ed, with the result that regulatory requirements are at once unnecessarily burdensome on good actors and less effective against bad actors. We urge FDA to anticipate the need for and value in investigation, enforcement and prosecution by state and local officials, as well as federal officials, regarding distribution, diversion, import, transport, possession for sale, sale, and/or unlawful possession, of tobacco products that fail to comply with FDA-established product standards or other FDA rules. We urge FDA to establish opportunities and procedures for cooperation and collaboration within federal law enforcement and between federal, state and local law enforcement, to investigate and prosecute entities not in compliance with the FDA product standard.

(e) Distinctive packaging of compliant products

Enforcement will be enhanced and simplified if FDA requires that compliant products are packaged and marked in ways that are distinctive. Enforcement agencies will more easily identify non-compliant products if they are visually distinct from compliant products. In this way enforcement priorities will overlap with consumer forces – a potential customer will also seek to

know from the appearance of the product whether it is high or low nicotine, flavored or not, or what type of flavor.

(f) Field testing

As mentioned earlier, enforcement of a product standard will be enhanced if a field test is available that is reliable, affordable and convenient. Two examples will suffice: states have extensive experience with tax stamps on tobacco products and some of these stamps are technically advanced. In many instances, a field agent with a scanner can instantly determine if a pack is stamped or not, if the stamp is fake or legal, and, if legal, can glean additional information. The handheld scanner is an effective law enforcement tool. In contrast, there is no portable field device available to test nicotine levels or flavors in tobacco products. This impedes enforcement. FDA should, concurrent with setting and implementing a product standard and devising improved methods of enforcement, develop field testing technologies and protocols for that standard.

FDA also asks:

“5. If a nicotine tobacco product standard were in effect, the following outcomes could occur: (1) Smokers could continue to smoke but use the low nicotine products; (2) smokers could completely switch to, or dual use low nicotine products with, other legal tobacco or nicotine products; (3) smokers could quit using any nicotine or tobacco product; or (4) smokers could seek to buy illegal cigarettes in an illicit market. Are there data that would provide information on which of these outcomes is most likely? Is there some other outcome that could occur?” (83 Fed. Reg. 11834.)

State Attorneys General do not have specific data or expertise in this area, but urge FDA to continue to communicate to the public, and youth in particular, that smoking combusted products remains profoundly harmful even if those combusted products contain minimal amounts of nicotine. It is possible, even likely, that, with the reduction in the amount of nicotine, users might believe or be encouraged to believe that combusted products are less harmful; that because the probability of addiction has been reduced or eliminated there is no reason against experimenting with tobacco products or using them until such time that the user feels like quitting; or that dual use is the functional equivalent of actual cessation. Thus, effective warnings, robust public education, and regulation of marketing, all of which are within FDA’s regulatory authority, will be essential to counter the emergence of perceptions that reduced nicotine must mean reduced harm.

FDA also asks:

“9. What mechanisms may be used to prevent, control, or contain illicit markets in conventional cigarettes that may develop if FDA establishes a product standard? What State and Federal entities may be responsible for these mechanisms, and how much would they cost?” (83 Fed. Reg. 11834.)

As discussed above, it is likely that certain illicit markets will develop, and that these markets will be for other non-compliant products as well as cigarettes. We urge FDA to consider adopting the measures (a) to (f) above to address this issue.

G. Other Considerations (83 Fed. Reg. 11834)

FDA:

FDA recognizes that, if the agency were to proceed to the stage of proposing a rule in this area, potential costs and benefits from a possible nicotine tobacco product standard would be estimated and considered in an accompanying preliminary impact analysis, including the potential impacts on growers of tobacco and current users of potentially regulated products. Thus, FDA is also seeking comments, data, research results, and other information regarding economic impacts of a potential nicotine tobacco product standard. FDA then poses the specific questions:

Comment:

FDA specifically asks:

“1. What data may be helpful to assess the universe of tobacco products that are currently available to consumers and their relevant characteristics, such as nicotine levels? How can available sources of information, such as manufacturer registrations and/or product listings with FDA, be used in this assessment?”

The most important source of information would be to require ingredient listings, including nicotine levels. Unfortunately, these are not at present available. We urge FDA to make this a priority.

FDA also asks:

“2. How should potential consumer surplus or utility loss from the removal of nicotine in cigarettes be considered, given the availability of other sources of nicotine such as ENDS and the continued availability of combusted tobacco products?”

In the context of use of cigarettes, a calculation of consumer surplus or utility loss is inappropriate and unnecessary. There is no basis for such a calculation for use of products that, when used as intended, are harmful and addictive, and are intentionally designed and manufactured to be addictive. Further, this question lacks a foundation because it assumes that there is a pleasure, whereas there is evidence that use of combusted tobacco products causes numerous diseases, reduces economic capacity, is expensive, and has other negative effects. These factors go to explain the results of consumer surveys revealing that the great majority of smokers wish to quit. There is no utility loss to consider, only a gain in pleasure or loss in discontent. (See, e.g., Pechacek TF, et al., “Reassessing the importance of ‘lost pleasure’ associated with smoking cessation: implications for social welfare and policy” *Tobacco Control*

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2017:0:1-9.) Further, to the extent that nicotine may have certain medical benefits in some contexts, there are products already on the market that do not have the adverse health effects of cigarettes. As noted by FDA, the ANPRM does not propose to eliminate all sources of nicotine or all tobacco products, or even all combusted tobacco products.

Summary:

We applaud FDA for considering a nicotine product standard and for seeking public comment on this important topic. We request FDA to consider these comments regarding implementing a maximum level of nicotine in all tobacco products and regarding enforcement of a nicotine standard if it is applied to only some tobacco products. Simultaneously, we urge FDA to establish such a standard as a supplement to – not to replace – the time-tested elements of a well-developed tobacco control program.

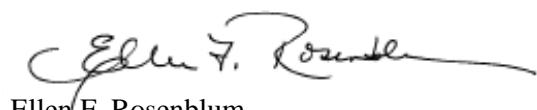
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