



July 16, 2018

Dockets Management Staff [HFA-305]  
 Food and Drug Administration  
 5630 Fishers Lane, Room 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

Ladies and Gentlemen:

The undersigned organizations submit these comments in the above-designated docket, 83 Fed. Reg. 11754 (March 16, 2018).

The Food and Drug Administration (“FDA”) has published and sought comments on a draft paper entitled Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard. The document addresses the potential for development of an illicit market as a result of a number of different potential product standards, including but not limited to, those that would (1) impose a maximum level of nicotine in cigarettes and other combusted tobacco products at levels that would be insufficient to sustain nicotine addiction; and (2) prohibit the use of menthol in cigarettes and prohibit the use of characterizing flavors in other tobacco products.<sup>1</sup> The purpose of such product standards would be to reduce the use of tobacco products that cause death and disease by making them less attractive to consumers. Illicit markets could limit the

<sup>1</sup> Marketing of cigarettes with characterizing flavors other than menthol has been prohibited since 2009 by the Family Smoking Prevention and Tobacco Control Act. 21 U.S.C. § 387g.

effectiveness of such public health measures if they provide consumers with access to prohibited products that cause death and disease but which some consumers might nevertheless continue to use if they continued to be marketed.

These comments will first describe existing illicit markets in the United States and then discuss illicit markets that might arise from efforts by tobacco product sellers to circumvent the product standards. It will discuss the ways in which product standards might influence consumer behavior (“demand effects”) and ways in which they might influence supply (“supply effects”) and discuss how these demand and supply effects differ from or resemble those that have given rise to existing illicit markets in the United States. Finally, it will discuss ways in which FDA and other government agencies can and should develop and strengthen enforcement efforts to minimize the effects of illicit markets.

The undersigned organizations agree with the conclusion reached by the National Research Council and the Institute of Medicine in their 2015 report that “the limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest.”<sup>2</sup> Moreover, as the NRC-IOM report found, “a market in banned product would necessarily involve large-scale smuggling from outside the country or illegal domestic manufacturing.”<sup>3</sup> Neither condition has prevailed in the United States and neither is likely to occur as a consequence of the promulgation and enforcement of product standards. Rather, the most significant consequence of the product standards currently under consideration by FDA is likely to be to a substantial reduction in the most important illicit market in the United States: the illicit sale of combusted tobacco products to customers too young to buy them legally.

## I. EXISTING ILLICIT MARKETS IN THE UNITED STATES

### A. The most important illicit market is that which provides cigarettes to consumers too young to buy them legally.

The tobacco industry will argue that FDA should not impose any product standard governing nicotine or flavors because – as they claim when any tobacco control measure is proposed – it would cause illicit sales. However, the argument that product standards should not be imposed at all because illicit markets might arise ignores the fact that an illicit market has existed for decades – that is, illegal sales to buyers too young to purchase them legally. Yet no one could credibly argue that the ban on sales to youth should be repealed because it has led to illegal sales.

One of the central purposes of the product standards that FDA has under consideration is to curtail use by and sales to youth, and thus eliminate this illicit market. In this context, it is ironic that product standards are opposed with the argument that they would “create” illicit markets. In reality, given that virtually all smokers start in their youth, today’s tobacco epidemic is in large measure the product of an existing illicit market that makes combusted tobacco products available to consumers too young to buy them legally. The product standards FDA has

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<sup>2</sup> National Research Council and Institute of Medicine, *Understanding the U.S. Illicit Market*, National Academies Press, 2015, at 9 (Hereinafter, “NRC-IOM”).

<sup>3</sup> NRC-IOM, at 8.

under consideration have been proposed because of the recognition that this illicit market will continue to exist so long as products are marketed that are addictive, lethal and attractive to youth. One of the central effects of these product standards would be to sharply reduce or eliminate this illicit market by making tobacco products less addictive and appealing to young people. Moreover, those who argue most vociferously against product standards because of concerns about illicit markets are the very companies whose conduct has been found to have created and sustained the illicit marketing of tobacco products to youth and who continue to derive their customer base from that market.<sup>4</sup> The market for illicit sales to minors is, in effect, a result of the absence of product standards.

- B. Existing illicit markets, largely based on evasion of federal and state taxes and fees, have not nullified the substantial public health gains from tax increases designed to reduce the consumption of tobacco products.

In recent years, federal, state and local jurisdictions have implemented numerous tobacco control policies designed to eliminate, or at least diminish, the illicit market for sales to underage users. Among the most effective of these measures has been the increased taxation of tobacco products to increase the retail price of tobacco. Tobacco tax increases have been effective at reducing tobacco use, especially among youth, as well as generating revenue for state and federal governments.

The tobacco industry has consistently opposed virtually any tax increase by arguing that such an increase will lead to an unacceptable level of illegal sales. The level of such illegal sales attributable to tax increases is, and always has been, far more limited than that claimed by tobacco product manufacturers.<sup>5</sup>

However, illegal sales that may be facilitated by disparities in tax levels among various jurisdictions have not nullified the public health benefit from the decreased usage of tobacco products resulting from tax increases. Research demonstrates that, despite the dire (and self-serving) warnings of the tobacco industry, tax increases produce positive public health outcomes.<sup>6</sup>

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<sup>4</sup> *U.S. v. Philip Morris USA Inc.* 449 F. Supp. 2d 1 at 561-691 (D.D.C. 2006), *aff'd in relevant part*, 595 F. 3d 1095 (D.C. Cir. 2009).

<sup>5</sup> NRC-IOM, at 28.

<sup>6</sup> “Our data showed that despite the potential savings, tax evasion by individual smokers in California did not appear to pose a serious threat to the state’s excise tax revenues or its tobacco control objectives in 1999.” Emery, S, White, MM, Gilpin, EA, Pierce, JP, “Was there significant tax evasion after the 1999 50 cent per pack cigarette tax increase in California?” *Tobacco Control* 11:130-134, 2002; “To the extent that legal and illegal tobacco products are not perfect substitutes, an increase in cigarette taxes translated to increased cigarette prices will reduce their consumption even when smuggling is possible.” (p. 314) International Agency for Research on Cancer (IARC), *Tobacco Control, Vol. 14: Effectiveness of Tax and Price Policies for Tobacco Control*, 2011; “[D]espite this increase in the illicit market, higher tobacco tax does effectively reduce total tobacco consumption.” Tsui, TC, “Does smuggling negate the impact of a tobacco tax increase?” *Tobacco Control* 25(3):361-362, 2016; “Smuggling does not reduce the public health benefits of cigarette taxes.” Merriman, D, “Cigarette smuggling does not reduce the public health

Moreover, research also confirms that tax increases result in net revenue increases for the state despite any effects from an illicit market.<sup>7</sup>

Contrary to the arguments of the tobacco companies, the adoption of product standards governing menthol and/or nicotine could, if anything, reduce the level of illicit sales related to tax avoidance by reducing the attractiveness of the products.

C. Diversion of domestically manufactured cigarettes to evade federal taxes has not been a major source of illicit sales.

Typically, cigarettes are manufactured in a production facility and then shipped to a bonded warehouse, where they are held prior to being shipped to distributors.<sup>8</sup> The number of cigarette manufacturing facilities and bonded warehouses in the United States is relatively small and it has been monitored by federal tax authorities who police the flow of manufactured goods

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benefits of cigarette taxes,” *Applied Economics Letters*, 9(8):493-496, 2010; “Tax avoidance and evasion undermine the efficacy of high prices in reducing consumption and initiation, especially among price-sensitive groups (IARC 2011). However, IARC concluded that there is sufficient evidence that tax avoidance and evasion reduce, but do not eliminate, the public health and revenue impact of tobacco tax increases (IARC 2011).” U.S. Department of Health and Human Services (HHS), *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014, at 791; “Significant increases in state and local tobacco taxes generate reductions in tobacco use and raise tobacco tax revenues for the jurisdiction, despite the tax avoidance and evasion that results from significant tax and price differentials in the United States.” U.S. Center for Disease Control and Prevention (CDC), *Preventing and Reducing Illicit Tobacco Trade in the United States*, 2015, at 6.

<sup>7</sup> “Every state that has passed a significant cigarette tax increase has enjoyed a substantial, sustained increase in its state cigarette tax revenues. This revenue increase occurs, despite the significant declines in smoking rates and tax-paid cigarette sales caused by the cigarette tax rate increase, and despite any increases in cigarette tax avoidance and evasion.” Chaloupka, F, *Cigarette Smuggling in Response to Large Tax Increase Is Greatly Exaggerated*, 2017, <https://tobacconomics.org/wp-content/uploads/2017/11/2017-generic-smuggling-report.pdf>; “...even though tax avoidance and tax evasion might increase in response to higher taxes, the losses from those actions would be less than the gains from higher taxes.” NRC-IOM report, at 27; “...research demonstrates that many factors besides tobacco taxes are of equal or greater importance in determining the level of tax evasion, and that governments can raise taxes and at the same time effectively decrease tax evasion.” U.S. National Cancer Institute and World Health Organization (NCI-WHO), *The Economics of Tobacco and Tobacco Control*. National Cancer Institute Tobacco Control Monograph 21. NIH Publication No. 16-CA-8029A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; and Geneva, CH: World Health Organization; 2016, at 507; “Experience from many countries demonstrates that illicit trade can be successfully addressed, even while raising tobacco taxes and prices, resulting in increased tax revenues and reduced tobacco use.” NCI-WHO report, at 17.

<sup>8</sup> NRC-IOM, at 32.

into domestic commerce.<sup>9</sup> Likely, enforcement agents would continue to do so to limit or discourage any illegal sales resulting from the adoption of product standards. The federal tax on domestically produced cigarettes is imposed when cigarettes leave the bonded warehouse and are shipped in commerce to distribution companies licensed to place state tax stamps on the cigarettes. Evasion of federal taxation by cigarettes leaving bonded warehouses is believed to be small because the operations of bonded warehouses are supervised by federal tax enforcement personnel.<sup>10</sup>

If FDA imposes product standards to reduce nicotine and prohibit characterizing flavors in the domestic market and domestic manufacturers are still permitted to manufacture cigarettes for export, it will become important for FDA, as well as for government agencies monitoring such products for federal tax purposes, to ensure that cigarettes manufactured for export are not diverted into the domestic market. Typically, cigarettes manufactured for export are shipped from manufacturing plants to warehouses that hold them for export.<sup>11</sup> It will be important for federal officials to monitor the flow of cigarettes into and out of such export warehouses to ensure that they are not diverted into the domestic market.

In recent years, the level of cigarettes domestically manufactured for export, monitored and reported by the International Trade Commission, has been low.<sup>12</sup> Substantial increases in such levels unexplained by other factors would provide a warning sign that product manufactured by domestic manufacturers ostensibly for export was being diverted to undermine a product standard.

Imported cigarettes are subject to import duties that are the equivalent of U.S. federal taxes on cigarettes. When containers of imported cigarettes arrive in the United States the product is placed in warehouses in foreign trade zones and the product is subjected to the federal tax when the product is shipped from the warehouse to a distribution company. Although some imported product evades federal taxation, as the National Academy of Sciences correctly concluded, “large scale smuggling does not appear to be a significant part of the U.S. illicit cigarette market . . . [and counterfeiting] is largely absent from the U.S. market.”<sup>13</sup> The incidence of such sales can be substantially curtailed by imposition of a track-and-trace system. (see *infra*).

D. The majority of illicit sales in the United States is due to interstate tax evasion and avoidance, though the size of the illicit market is much smaller than the tobacco industry claims.

1. Evasion of state and local taxes and fees

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<sup>9</sup> NRC-IOM, at 40. United States Government Accountability Office, *Illicit Tobacco: Various Schemes Are Used to Evade Taxes and Fees*, 2011, GAO 11-313, at 9 (Hereinafter, “GAO 11-313”).

<sup>10</sup> NRC-IOM, at 39.

<sup>11</sup> NRC-IOM, at 32. GAO 11-313, at 9.

<sup>12</sup> GAO 11-313, at 8, chart based on data from International Trade Commission.

<sup>13</sup> NRC-IOM, at 2-3. See also, NRC-IOM, at 35-36.

State and local tobacco taxes are paid by distributors licensed by individual states. Distributors receive shipments of cigarettes from bonded warehouses on which federal tax has been paid. The distributors purchase stamps from the states to which they are authorized to ship product for resale to consumers. The presence of the state tax stamp on the cigarette package evidences payment of the tax and once the stamp of a state is affixed to a pack the distributor is authorized to ship such cigarettes for resale in that state only. An illicit market designed to evade state taxes can arise when cigarettes bearing the stamps of a low-tax state are diverted subsequent to stamping and sold to retail customers in high-tax jurisdictions.<sup>14</sup>

Most of the cigarettes sold in this illicit market are cigarettes manufactured by the major tobacco companies. The manufacturers have sold these cigarettes to distributors before they are diverted and federal tax has been paid on them. Manufacturers receive the same revenue from the sale of cigarettes eventually sold at retail in this illicit market as they do from cigarettes sold legally and they have no economic incentive to limit those illicit sales. However, the government has tools to curtail cross-border state tax avoidance and could do much more if a well-enforced track-and-trace system were implemented. (see *infra*)

A second source of state tax evasion has involved sales from Indian country. Legally, sales from Indian country to non-tribal members are subject to state taxation.<sup>15</sup> Although state governments have often not enforced their law effectively in Indian country, some states have entered into compacts with tribes to minimize illicit trade; the Prevent All Cigarette Trafficking Act (PACT Act), described below, also gave the government another tool to curtail non-taxed sales from Indian country.

2. The PACT Act has reduced the level of tax avoidance on Internet sales direct to consumers.

Evasion of both federal and state taxes by Internet sellers of cigarettes was until several years ago a more significant problem. Some foreign-based internet sellers of cigarettes actually advertised that their cigarettes were not subject to federal and state taxation and the cigarettes were offered at prices that reflected the absence of such taxation.<sup>16</sup> However, measures adopted and enforced by both the federal government and state government, including the PACT Act, which made it illegal to ship cigarettes and smokeless tobacco through the United States Postal Service (USPS) and other restrictions have reduced Internet sales and evasion of taxes on cigarettes sold by Internet sellers. Despite these efforts, recent studies show that Internet sales from foreign-based websites, made without adequate age verification and evading taxation, continue to be a problem, and that USPS is not adequately enforcing the ban on mailing of cigarettes.<sup>17</sup> In prior comments, many of the undersigned organizations have called on FDA to

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<sup>14</sup> NRC-IOM, at 3, 34, 53.

<sup>15</sup> NRC-IOM, at 56-58.

<sup>16</sup> GAO, *Internet Cigarette Sales: Limited Compliance and Enforcement of the Jenkins Act Result in a Loss of State Tax Revenue*, GAO-03-714T, May 1, 2002.

<sup>17</sup> E.g., Williams, RS, Derrick, J, & Phillips, KJ, "Cigarette sales to minors via the internet: how the story has changed in the wake of federal regulation," *Tobacco Control* 26:415-420, 2016.

prohibit internet sales of both cigarettes and newly deemed tobacco products.<sup>18</sup> We continue to urge FDA to adopt this recommendation. FDA and other federal agencies have the legal tools to eliminate such sales and we urge them to use these tools vigorously. That this has not yet been done, however, presents no argument against adoption of the product standards FDA has under consideration in the outstanding ANPRMs.

#### E. Recharacterization of product to avoid a product standard

The 2009 Family Smoking Prevention and Tobacco Control Act imposed the first tobacco product standard at the federal level when it prohibited the sale of cigarettes with characterizing flavors other than menthol.

The tobacco industry exploited a loophole in the prohibition by expanding sales of flavored combustible non-cigarette tobacco products, such as cigars and cigarillos.<sup>19</sup> Such products, many of which are functionally indistinguishable from cigarettes, continue to be sold and their presence contributes to the significant youth market for cigars. Recently, FDA announced the filing of enforcement actions against four manufacturers for illegal sales of flavored cigarettes labeled as “cigars” or “little cigars.”<sup>20</sup>

One lesson that can be drawn from this experience is that a product standard designed to limit public health risks from cigarettes can accomplish its purpose only if it is made applicable as well to all combustible tobacco products that could reasonably function as substitutes for cigarettes.

#### *Conclusions Regarding Existing Illicit Markets for Tobacco Products in the United States*

1. Existing illicit trade does not undermine the public health benefits of tobacco control measures and is less significant than the industry claims.
2. Major tobacco product manufacturers benefit from much of the existing illicit trade and have no incentive to reduce it.
3. The proposed product standards will reduce existing illicit trade as it pertains to illegal underage youth sales.
4. Any illicit trade occurring as a result of the product standards under consideration will be easier to police than existing illicit trade because it will require the manufacture, distribution, promotion, and sale of products that would not otherwise be legally sold.

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<sup>18</sup> Comments filed January 19, 2012 by 8 organizations in Docket No. FDA-2011-N-0467; Comments filed by 24 organizations on August 14, 2014 in Docket No. FDA-2014-N-0189, at 27-30.

<sup>19</sup> Delnevo, C, Hrywna, M, “Clove cigar sales following the US flavoured cigarette ban,” *Tobacco Control* 24(e4):e246-50, doi:10.1136/tobacco control-2013-051415, 2015.

<sup>20</sup> FDA, *FDA takes action against four tobacco manufacturers for illegal sales of flavored cigarettes labeled as little cigars or cigars*, Press Release, December 9, 2016, <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm532563.htm>.

## II. RESPONSES OF ILLICIT MARKETS TO PRODUCT STANDARDS

Product standards of the nature under consideration by the FDA would affect both the demand for and the supply of tobacco products in ways that would make the development of illicit markets very different from those observed to date and described above. It would be more difficult to sell tobacco products in illicit markets to evade product standards than it has been to sell tobacco products in illicit transactions to evade taxation.

After examining the potential for development of illicit markets based on potential product standards promulgated by the FDA, the NRC-IOM report determined that the demand is likely to be modest.<sup>21</sup> We concur in that determination.

### A. Demand Effects

#### 1. Demand Effects of a Product Standard Establishing a Maximum Level of Nicotine in Cigarettes.

If FDA promulgates a product standard establishing a maximum level of nicotine in cigarettes at non-addictive levels, the demand effects on non-smokers, principally youth, can be expected to be substantial. Absent finding an addicting level of nicotine in cigarettes, they are very unlikely to find smoking pleasurable and they are unlikely to become smokers. Most important, even if they do experiment with cigarettes they will not inadvertently become addicted to nicotine as a result.

Demand responses among smokers are likely to be more varied. In response to a product standard reducing the level of nicotine in cigarettes to non-addictive levels, smokers can have at least six different responses: (1) stop smoking altogether; (2) continue smoking the reduced-nicotine cigarettes; (3) switch completely to other, legal sources of nicotine such as nicotine replacement therapy products (NRT) or e-cigarettes; (4) find a way to increase the nicotine level in the reduced-nicotine cigarettes so that they satisfy the smoker's addiction; (5) seek illicit cigarettes that are manufactured to provide a conventional level of nicotine; (6) use some combination of the above.

Numerous surveys confirm the finding that the large majority of current smokers regret the fact that they are addicted and wish to quit.<sup>22</sup> For this large group, a reduced-nicotine product standard presents a major opportunity to align their conduct with their aspirations. Importantly, studies to date have found that smokers who use very low nicotine (VLN) cigarettes

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<sup>21</sup> NRC-IOM, at 9.

<sup>22</sup> Fong, G, et al., "The Near-Universal Experience of Regret Among Smokers in Four Countries: Findings from the International Tobacco Control Policy Evaluation Survey," *Nicotine & Tobacco Research*, 6(Suppl 3):S341-S351, December 2004; Nayak, P, et al., "Regretting ever starting to smoke: results from a 2014 national survey," *International Journal of Environmental Research and Public Health* 14(4), 2017; Babb, S, et al., "Quitting Smoking Among Adults—United States, 2000—2015," *MMWR* 65:1457-1464, 2017; O'Connor, RJ, et al., "Exploring relationships among experience of regret, delay discounting, and worries about future effects of smoking among current smokers." *Substance Use & Misuse* 51(9):1245-50, 2016.



in a short time reduce their nicotine dependence.<sup>23</sup> In the research protocols, even those test subjects who supplemented VLN cigarettes with conventional cigarettes experienced a reduced level of nicotine dependence and nicotine exposure.<sup>24</sup> The fact that they have reduced their nicotine dependence means that the likelihood that they will successfully quit smoking completely has increased. Research demonstrates that use of VLN cigarettes is associated with contemplating and making a quit attempt and increasing the likelihood that a given quit attempt is successful.<sup>25</sup>

The likelihood that smokers who reduce their nicotine dependence can quit—the optimal public health outcome—would be greatly increased if FDA implemented changes in the regulation by the Center for Drug Evaluation and Research (“CDER”) of medicinal products designed to help smokers quit. *Such changes would make it much more likely that quit attempts by these smokers will be successful.* These changes could include both a broadening of indicated uses for existing medicinal products and lowering the barriers to the development of new medicinal products that could enhance the likelihood that smokers’ quit attempts would be successful.<sup>26</sup>

The likelihood that an appreciable number of smokers would respond to a product standard restricting the nicotine level of cigarettes to non-addictive levels by adding nicotine to the product subsequent to purchase is low. It would be difficult for individual smokers to find a way to produce a cigarette with a consistently satisfying level of nicotine and an acceptable taste and it is unlikely that many smokers would undertake such an effort. Nevertheless, it would be prudent for FDA to include in the product standard a provision prohibiting the promotion or sale of nicotine for the purpose of changing the nicotine content of combusted tobacco products after a retail sale.

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<sup>23</sup> Donny, EC, et al., “Randomized trial of reduced-nicotine standards for cigarettes,” *New England Journal of Medicine* 373:1340-1349, 2015; Donny EC, et al., “Smoking in the absence of nicotine: behavioral, subjective and physiological effects over 11 days,” *Addiction* 102(2):324-34, 2007; Hatsukami, DK, et al., “Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation,” *Addiction* 105:343-55, 2010.

<sup>24</sup> Donny, EC, et al., “Randomized trial of reduced-nicotine standards for cigarettes,” *New England Journal of Medicine* 373:1340-1349, 2015.

<sup>25</sup> Donny, EC, et al., “Randomized trial of reduced-nicotine standards for cigarettes,” *New England Journal of Medicine* 373:1340-1349, 2015; Walker, N, et al., “The combined effect of very low nicotine content cigarettes, used as an adjunct to usual Quitline care (nicotine replacement therapy and behavioural support), on smoking cessation: a randomized controlled trial,” *Addiction* 107(10):1857-1867, 2012. McRobbie, H, et al., “Complementing the standard multicomponent treatment for smokers with denicotinized cigarettes: a randomized controlled trial,” *Nicotine & Tobacco Research* 18(5):1134-1141, 2016.

<sup>26</sup> See, generally, Comments of Campaign for Tobacco-Free Kids and American Academy of Pediatrics in Docket No. FDA-2017-N-6529, “FDA’s Approach to Evaluating Nicotine Replacement Therapies,” February 15, 2018; Supplemental Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2018-N-0128, “FDA’s Approach to Evaluating Nicotine Replacement Therapies,” April 16, 2018.

For those smokers who want to smoke for reasons unrelated to nicotine, cigarettes will remain available. Given the extensive research showing the centrality of nicotine as the attractive feature in smoking, however, it is doubtful that many smokers will continue to smoke cigarettes.

If FDA expands the products approved by CDER for cessation to increase their availability at lower costs, and otherwise carefully regulates other products that deliver nicotine to address the needs of smokers who have been unable to quit, FDA should be able to minimize the risk of a substantial illicit market and at the same time prevent these alternative nicotine delivery products from addicting young non-smokers. From a public health and an individual health standpoint, these alternatives, if implemented in conjunction with requiring the reduction of nicotine in traditional tobacco products, would be preferable to the status quo.

## 2. Demand effects of a product standard prohibiting flavors in tobacco products

As noted above, the Tobacco Control Act prohibited the use of characterizing flavors, other than menthol, in cigarettes. Although there is limited literature on the market response, no substantial market in illicit flavored cigarettes appears to have developed as a result, as noted above. However, following the prohibition on characterizing flavors in cigarettes, the marketing of other flavored tobacco products, especially flavored cigars, expanded. Moreover, many of these flavored cigars were barely distinguishable—if at all—from cigarettes. The lesson from this experience is that any prohibition on flavors must cover not only cigarettes but also other tobacco products.

Also as noted above, the Tobacco Control Act did not prohibit the use of menthol as a characterizing flavor in cigarettes. As described more fully in our comment in the ANPRM on flavored tobacco products, the use of menthol as a characterizing flavor contributes substantially to youth addiction. Moreover, the markets for mentholated and non-mentholated cigarettes are substantially distinct. The evidence indicates that a large number of menthol cigarette smokers would not find non-mentholated cigarettes an acceptable substitute and are therefore more likely to quit smoking in response to a prohibition on mentholated cigarettes than to switch to non-mentholated cigarettes. Research shows that most smokers say that they would either switch to non-menthol cigarettes or quit smoking altogether in response to a ban on menthol cigarettes.<sup>27</sup> The proportion of smokers who say they would quit in response to a menthol ban is higher among African Americans and younger smokers. Further, a 2014 assessment of switching between non-menthol and menthol cigarettes, found that more smokers switched from menthol

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<sup>27</sup> D’Silva, J, et al., “Quitting and switching: Menthol smokers’ responses to a menthol ban,” *Tobacco Regulatory Science* 1(1):54-60, 2015. Wackowski, OA, et al., “Switching to e-cigarettes in the event of a menthol cigarette ban,” *Nicotine & Tobacco Research* 17(10):1286-1287, 2015. Wackowski, OA, et al., “Young adults’ behavioral intentions surrounding a potential menthol cigarette ban,” *Nicotine & Tobacco Research* 16(6):876-880, 2014. Hartman, AM, “What menthol smokers report they would do if menthol cigarettes were no longer sold,” Paper presented at the FDA Tobacco Products Scientific Advisory Committee Meeting, January 2011. Pearson, JL, et al., “A ban on menthol cigarettes: impact on public opinion and smokers’ intention to quit,” *American Journal of Public Health* 102(11):e107-14, 2012.

to non-menthol cigarettes (8%) than from non-menthol to menthol cigarettes (3%).<sup>28</sup> The lower prevalence of menthol use among older adults than younger adults is also indicative of the more common pattern of switching from menthol to non-menthol than vice versa. For that very reason, TPSAC concluded that “In addition, a substantial number of smokers who initiate with menthol cigarettes later switch to non-menthol cigarettes. Thus, menthol initiation also contributes to the prevalence of nonmenthol cigarette smoking in the general population.”<sup>29</sup>

Recently, several Canadian provinces and the federal government have prohibited menthol in cigarettes. A study of the effect of the prohibition in Ontario showed that approximately 30 percent of menthol cigarette smokers had made a quit attempt during the first month after the prohibition went into effect. As the prohibition did not extend to other tobacco products, however, approximately the same percentage of menthol smokers had turned to other menthol tobacco products. There was no evidence of a market for contraband menthol cigarettes.<sup>30</sup> The study was done over too limited a time period to provide definitive evidence of the effect of the menthol prohibition but subsequent studies of the Canadian experience should yield significant results.

As is true for a product standard restricting the level of nicotine in combusted tobacco products, the likelihood that an appreciable number of smokers would respond to a product standard prohibiting menthol as a characterizing flavor in combusted tobacco products by increasing the menthol level subsequent to purchase is low. It would be difficult for individual smokers to find a way to produce a cigarette with a consistently satisfying level of menthol and an acceptable taste and it is unlikely that many smokers would undertake such an effort. Moreover, the survey of Canadian smokers referred to above showed that none of the survey participants resorted to such a practice. Nevertheless, it would be prudent for FDA to include in the product standard a provision prohibiting the promotion or sale of menthol additive for the purpose of mentholizing combusted tobacco products after a retail sale.

Also, as with a product standard reducing nicotine levels in combusted tobacco products, the likelihood that smokers of menthol cigarettes would quit using tobacco products in response to a prohibition on the use of menthol as a characterizing flavor—the optimal public health outcome—would be greatly increased if FDA implemented changes in the regulation by the Center for Drug Evaluation and Research (“CDER”) of medicinal products designed to help smokers quit. (See discussion above.)

B. Supply considerations from a product standard reducing nicotine in combusted tobacco products to non-addictive levels or for flavored products.

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<sup>28</sup> Kasza, KA, et al. “Switching Between Menthol and Nonmenthol Cigarettes: Findings From the U.S. Cohort of the International Tobacco Control Four Country Survey,” *Nicotine & Tobacco Research* 16(9):1255-1265, 2014.

<sup>29</sup> Tobacco Products Scientific Advisory Committee, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, July 21, 2011, <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>.

<sup>30</sup> Chaiton, M, et al., “Association of Ontario’s ban on menthol cigarettes with smoking behavior one month after implementation,” *JAMA Internal Medicine* 178(5):710-1, 2018.

The development of a significant illicit market as a result of a product standard reducing nicotine in combusted products to non-addictive levels would encounter numerous obstacles that are not presented for illicit markets based on tax avoidance. It is easier to develop an illicit market based on tax avoidance because the product sold in such a market is physically indistinguishable from legally sold product. The only distinguishing characteristic of such product is that appropriate tax has not been paid on it. By contrast, both in the case of high-nicotine and flavored tobacco, the product would have to be manufactured using different processes and having different physical characteristics. Moreover, a significant illicit market could be developed only by marketing the products as different—and non-compliant with law.

### 1. Manufacturing the products

A GAO study of the illicit cigarette market provides a useful description of the supply chain.<sup>31</sup> As noted above and in the GAO study, the overwhelming majority of domestic cigarettes are manufactured in a small number of factories, making it more likely that FDA can police the domestic manufacturing of cigarettes efficiently. It should not be difficult for FDA enforcement personnel to supervise the sampling of each batch of manufactured product before it is shipped from the factory. This policing is important because it could not otherwise be assumed that manufacturers would comply with the standard. The establishment of a clandestine manufacturing facility capable of manufacturing and shipping a substantial number of cigarettes—an action that would violate any number of federal laws—is highly implausible.

Regulations and enforcement personnel would have to ensure that product intended for export was shipped to bonded warehouses for export and not illegally diverted to the domestic market. Given the manageable number of domestic manufacturing facilities, FDA should be able to prevent any such large-scale diversion.

### 2. Wholesale distribution of the products

Even if high-nicotine or flavored product were manufactured for export or illicit sale domestically, development of a substantial illicit market would require a sophisticated system of distribution. FDA and other law enforcement agencies must take steps to ensure that major distributors would not take the risk of handling non-compliant product. It is important to note that the current illicit tax-avoidance market involves the diversion of product *after* it has been legally stamped for sale in a low-tax state. The product stamped by the distributor is physically the same—regardless of whether it is actually sold at retail in the low-tax state or subsequently diverted for illicit sale in a high-tax state. Smokers who purchase such product may not even realize that the cigarettes they are purchasing are contraband.

By contrast, smokers would certainly know—and government officials could easily identify—if the tobacco products have a characterizing flavor or have a full nicotine content. It would be very difficult to develop a substantial illicit market for high-nicotine or flavored products without packaging and advertising them in a way that would make them clearly distinct to potential customers. Any such distinction, however, would be obvious both to the distributor and to FDA enforcement personnel. Thus, it would be far more difficult to develop a substantial

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<sup>31</sup> GAO-11-313, at 9.

illicit market for such products than it has been for products that are illicit only because they have not been subjected to the appropriate tax.

### 3. Products manufactured abroad

Manufacturers located abroad will continue to manufacture high-nicotine cigarettes for markets in other countries as long as these products are allowed in those countries. Although some manufacturers or other sellers may seek to export such cigarettes to the United States, there is no evidence they are a major problem today.<sup>32</sup> Whatever illicit market exists is of modest proportions.

It is important to note, however, that even this modest illicit market exists only because the smuggled cigarettes are passed off as indistinguishable from cigarettes sold legally in the United States. By contrast, development of an illicit market for high-nicotine or flavored product depends on a seller's ability to inform consumers that the product is different from products marketed legally in the United States. Such products would have to be packaged, marketed, and promoted in a way that made them readily distinguishable from legally sold product and therefore easily identifiable as illicit. It is difficult to conceive of how such packaging, marketing and promotion could be done on any substantial scale without bringing the illicit products to the attention of enforcement officials.

It is conceivable that some illicit product could be sold over the Internet by foreign sources and shipped direct to consumers. In fact, a market for illicit sales of cigarettes based on tax avoidance and avoidance of minimum-age laws did develop prior to the enactment of the PACT Act. However, as mentioned previously, the PACT Act, combined with agreements under which common carriers agreed not to ship cigarettes, has sharply reduced such illegal sales of these products direct to consumers through the Internet.<sup>33</sup> Enforcement of these restrictions should be strengthened and the restrictions should be extended to other tobacco products.

Moreover, it would be difficult for Internet marketers to develop a substantial illicit market for high-nicotine or flavored products without advertising the availability of those products on the Internet or in social media and that advertising would inevitably permit enforcement personnel to identify the sellers. As noted above in Section I.D., the undersigned organizations recommend that FDA prohibit the sale of tobacco products on the Internet. Whether or not Internet sales are permitted to continue, however, FDA should institute an effective program of monitoring the advertising and marketing of tobacco products on the Internet and through social media to identify potential sources of illicit product. If Internet sales are allowed to continue, FDA should limit potential illicit sales over the Internet by developing and enforcing regulations restricting credit card payments for Internet purchases. In addition, developing and implementing state-of-the-art technology for examining packages entering the United States would help limit illicit sales.

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<sup>32</sup> *Supra* at 13.

<sup>33</sup> Williams, RS, et al., "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.

#### 4. Quality of the product

Sellers who seek to develop an illicit market for either high-nicotine or menthol cigarettes will have a difficult time providing cigarettes that will satisfy smokers. Cigarettes developed by the major tobacco manufacturers currently account for approximately 84 percent of the market<sup>34</sup> and are carefully engineered to satisfy consumer tastes and, in many cases, to appeal to niche markets. Manufacturers with fewer resources and much less sophistication will find it very difficult to produce illicit product that can satisfy most smokers' taste. The difficulty of doing so has been demonstrated by the inability of smaller manufacturers who enjoy substantial price advantages over the major tobacco companies to capture more than a very small percentage of the cigarette market. In short, would-be sellers of high-nicotine or mentholated cigarettes in an illicit market will find it difficult to supply product that is satisfactory to many smokers.

FDA can control the problem by implementing sufficient surveillance to ensure that the major tobacco companies are not complicit in the creation of an illicit market.

### III. TOBACCO INDUSTRY ARGUMENTS BASED ON THE FEAR OF ILLICIT MARKETS ARE NOT CREDIBLE

For decades, and on a worldwide basis, tobacco companies have consistently overestimated the size and significance of illicit markets in order to discourage governments from implementing tobacco control measures by arguing that the effectiveness of these measures would be diminished by implausibly large increases in illicit sales. In reality, their opposition to such measures stems not from a belief that such tobacco control measures would be ineffective at reducing the use of combusted tobacco products, but rather from the fear that those measures would effectively reduce the sales of such products and the profits derived from selling them.

For example, a recent study comparing tobacco company estimates of illicit markets in Poland with those of unbiased observers concluded that the tobacco companies' estimates were 50 percent higher than those of the unbiased observers. The authors of the study described their results as follows:

Our findings are consistent with previous evidence of the tobacco industry exaggerating the scope of illicit trade and with the general pattern of the industry manipulating evidence to mislead the debate on tobacco control policy in many countries. Collaboration between governments and the tobacco industry to estimate tobacco tax avoidance and evasion is likely to produce upward-biased estimates of illicit cigarette trade. If governments are presented with industry estimates, they should strictly require a disclosure of all methodological details and data used in generating these estimates, and should seek advice from independent experts.<sup>35</sup>

Public health experts have reached conclusions similar to these after analyzing tobacco industry estimates of illicit markets in numerous countries, and, in some cases, comparing them

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<sup>34</sup> GAO-11-313, at 7.

<sup>35</sup> Stoklosa, M, Ross H, "Contrasting Academic and Tobacco Industry Estimates of Illicit Cigarette Trade: evidence from Warsaw, Poland," *Tobacco Control* 23:e30-34, 2014.

with the estimates of unbiased observers.<sup>36</sup> An examination of the industry studies reveals that they are often based on data that cannot be verified and often is not disclosed at all.<sup>37</sup> Frequently the industry studies are based on improper methodologies designed to achieve results that would support the industry's favored, predetermined outcome.<sup>38</sup>

For example, tobacco companies have long argued in numerous countries that increases in tobacco taxes would lead to increased smuggling that would nullify the public health benefits of such increases. However, an examination of the evidence demonstrates that there is little correlation between rates of smuggling and prices and many of the countries with the highest rates of smuggling impose low taxes on tobacco products.<sup>39</sup>

Similarly, major tobacco companies opposed plain packaging regulations by arguing that imposition of such measures would lead to substantial increases in illicit packs.<sup>40</sup> However, studies conducted by unbiased observers in Australia subsequent to the imposition of a plain packaging requirement concluded that no such increase occurred.<sup>41</sup>

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<sup>36</sup> Gilmore, AB, et al., "Exposing and addressing tobacco industry conduct in low-income and middle-income countries," *Lancet* 385(9972):1029-43, 2015. Rowell, A, Evans-Reeves, K, Gilmore, AB, "Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK," *Tobacco Control* 23(e1):e35-43, 2014. Gilmore, AB, et al., "Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded 'Project Star' report," *Tobacco Control* 23(e1):e51-61, 2014.

<sup>37</sup> Rowell, A, Evans-Reeves, K, Gilmore, AB, "Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK," *Tobacco Control* 23(e1):e35-43, 2014. Gilmore, AB, et al., "Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded 'Project Star' report," *Tobacco Control* 23(e1):e51-61, 2014.

<sup>38</sup> Rowell, A, Evans-Reeves, K, Gilmore, AB, "Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK," *Tobacco Control* 23(e1):e35-43, 2014.

<sup>39</sup> Joossens, L, Raw, M, "How can cigarette smuggling be reduced?" *BMJ* 321(7266):947-50, 2000. Skafida, V, et al., "Change in tobacco excise policy in Bulgaria: the role of tobacco industry lobbying and smuggling," *Tobacco Control* 23(e1):e75-84, 2014. Smith, KE, Savell, E, Gilmore, AB, "What is known about tobacco industry efforts to influence tobacco tax? A systematic review of empirical studies," *Tobacco Control*, 22(2):144-53, 2013. Joossens, L, Raw M, "Smuggling and cross border shopping of tobacco in Europe," *BMJ* 310(6991):1393-7, 1995. Joossens, L, Raw, M, "Cigarette smuggling in Europe: who really benefits?" *Tobacco Control* 7(1):66-71, 1998. Gilmore, A, McKee, M, "Tobacco control policy: the European dimension," *Clinical Medicine (London, England)* 2(4):335-42, 2002. Joossens, L, Raw, M, "Turning off the tap: the real solution to cigarette smuggling," *International Journal of Tuberculosis and Lung Disease* 7(3):214-22, 2003.

<sup>40</sup> Rowell, A, Evans-Reeves, K, Gilmore, AB, "Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK," *Tobacco Control* 23(e1):e35-43, 2014.

<sup>41</sup> Scollo, M, et al., "Early evidence about the predicted unintended consequences of standardised packaging of tobacco products in Australia: a cross-sectional study of the place of purchase, regular brands and use of illicit tobacco," *BMJ Open* 4:e005873. doi:10.1136/bmjopen-2014-005873, 2014. Scollo, M, et al., "Use of illicit tobacco following introduction of standardised

FDA should evaluate such industry studies with skepticism and rely instead on its own research and that of commentators who are truly independent.

#### IV. THE TOBACCO INDUSTRY SHOULD HAVE NO ROLE IN SHAPING POLICIES TO CONTROL ILLICIT MARKETS.

It is important for FDA to develop enforcement policies to prevent illicit transactions independently and without the participation of tobacco companies. As noted above, the tobacco industry opposes the development of effective tobacco control measures that would decrease their profits and if any such measures are actually adopted, in seeing that they fail. The enforcement policies they would urge are not designed to produce optimum results from a public health standpoint; rather, they are designed to serve the tobacco industry's profit-maximizing strategy.

##### A. The tobacco industry has been complicit in creating and fostering illicit markets in the United States and around the world.

Rather than having an interest in eliminating illicit markets, the major tobacco companies have on many occasions been complicit in creating and fostering such markets in many countries.<sup>42</sup> Some such activities have involved cigarettes manufactured in or shipped to the United States. For example, in the late 1990s Canadian tobacco companies were complicit in organizing the movement of smuggled cigarettes from Canada to the United States and back into Canada to avoid higher tax rates and blame the government for seemingly higher smuggling rates. An affiliate tobacco company of R. J. Reynolds pleaded guilty to assisting in the smuggling operation and paid significant fines to the Canadian government.<sup>43</sup>

Moreover, many current sources of illicit transactions serve the interests of the major tobacco companies. Most of the cigarettes bearing the tax stamps of low-tax states, such as Virginia, that are bootlegged for sale in high-tax states such as New York, are manufactured by the major tobacco companies. When these cigarettes are sold in New York at prices that do not reflect the New York tax rate, the major tobacco companies benefit because the sale of their products—and their profits—increase as a result. The major tobacco companies have no interest in eliminating these illicit markets.

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packaging of tobacco products in Australia: results from a national cross-sectional survey,” *Tobacco Control* 24:ii76–ii81, 2015.

<sup>42</sup> NRC-IOM, at 62-63.

<sup>43</sup> Gilmore, AB, et al., “Tobacco industry’s elaborate attempts to control a global track and trace system and fundamentally undermine the Illicit Trade Protocol,” *Tobacco Control*, epub ahead of print, pii: tobaccocontrol-2017-054191, doi: 10.1136/tobaccocontrol-2017-054191, 2018 and sources cited therein at notes 2, 4-10; van Walbeek, C, et al., “Price and tax measures and illicit trade in the framework convention on tobacco control: what we know and what research is required,” *Nicotine & Tobacco Research* 15(4):767-76, 2013. Joossens, L, Raw, M, “How can cigarette smuggling be reduced?” *BMJ* 321(7266):947-50, 2000. See also the many examples of tobacco industry complicity in creating or expanding illicit markets cited in public comments filed in this docket by Eric Crosbie, et al., of the University of California at San Francisco.



Most important, as was demonstrated by overwhelming evidence in *U.S. v. Philip Morris USA Inc.*,<sup>44</sup> the major tobacco companies intentionally created and fostered the nation's most significant illicit market, the provision of cigarettes to consumers too young to buy them legally. The economic incentives that led the major tobacco companies to adopt these policies have not changed and it would be unrealistic to look to those companies—or to researchers and consultants financially supported by them—for advice on strategies that are likely to diminish their profits.

B. In developing enforcement strategies to prevent illicit markets, FDA should follow the FCTC Protocol on Illicit Trade.

In developing systems to prevent illicit markets from undermining the effectiveness of product standards, FDA can build on extensive learning and experience in worldwide efforts to combat illicit markets in tobacco products. Article 15 of the Framework Convention on Tobacco Control identifies measures governments can adopt for reducing illicit trade in tobacco products. Pursuant to Article 15, the State Parties to the FCTC adopted a more detailed protocol.<sup>45</sup> The protocol has been ratified by 37 State Parties and will enter into force once 40 State Parties have ratified it.<sup>46</sup>

The Protocol emphasizes the importance of countries developing their own methods to monitor precisely the manufacture, transportation, distribution, and sale of tobacco products and to ensure that this system is totally independent from and uninfluenced by tobacco product manufacturers. The Parties that drafted the protocol were aware of the tobacco industry's consistent efforts to subvert tobacco control measures and to foster illicit markets whenever they perceive opportunities to do so. Implementation of the product standards FDA has under consideration—that would prohibit flavors in tobacco products and reduce the nicotine content of combusted tobacco products to non-addictive levels—would almost certainly result in substantial declines in the profitability of the major manufacturers of combusted tobacco products. Tobacco companies should have no role in developing or implementing the measures adopted to prevent or control illicit transactions that could undermine the effectiveness of these product standards.

## V. DEVELOPING AN EFFECTIVE ENFORCEMENT POLICY

Developing an effective enforcement policy will reduce the risk of illicit trade and is important to ensure the success of product standards.

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<sup>44</sup> *U.S. v. Philip Morris USA, Inc.*, 449 S. Supp. 2d 1 at 561-691 (D.D.C. 2006), *aff'd in relevant part*, 595 F. 3d 1095 (D.C. Cir. 2009).

<sup>45</sup> World Health Organization (WHO), *The Protocol to Eliminate Illicit Trade in Tobacco Products*, November 2012, [http://www.who.int/fctc/protocol/illicit\\_trade/protocol-publication/en/](http://www.who.int/fctc/protocol/illicit_trade/protocol-publication/en/).

<sup>46</sup> WHO, *India is the 37th Party to the Protocol: only 4 more to go until entry into force*, accessed June 6, 2018 from <http://www.who.int/fctc/mediacentre/news/2018/india-4-party-to-protocol/en/>.

#### A. Address every aspect of the supply chain

All illicit product must be manufactured, domestically or abroad, and transported to the point where it is provided to the ultimate consumer. In order to identify illicit product and keep it off the market, FDA should develop a method of tracking the transportation of all tobacco products to determine whether the product made available to consumers meets legal requirements—including compliance with any product standard.<sup>47</sup>

FDA should develop policies for policing compliance at every level of manufacture, distribution and sale. For domestically manufactured product, this effort requires effective supervision of the product in manufacturing plants, bonded warehouses, and distribution facilities. Effective methods of testing and sampling of product must be implemented and audits must be done to ensure that all product manufactured is accounted for.

For imports, it is important to improve methods of identifying containers that contain tobacco products.

#### B. Track and Trace Systems

Section 920 of the Tobacco Control Act directs FDA to implement a track-and-trace system.<sup>48</sup> Many of the undersigned organizations and many other stakeholders have repeatedly urged FDA to do so.<sup>49</sup> Such a system would permit FDA and other law enforcement authorities to identify the source and distribution history of product packages and greatly increase the effectiveness of law enforcement. These systems have been most effective when they have included encrypted cigarette stamps. The results of these initiatives have been encouraging both in the United States, where several states have adopted similar systems, and in other countries.<sup>50</sup>

Under a track-and-trace system, each tobacco product produced or sold in the United States would bear a unique, counterfeit-resistant identifying code that allows its origin to be identified and links to a computer database of required records that permits the product to be tracked and traced. Such a system would enable FDA to track goods from manufacture or importation to the point of retail sale and provide it with the ability to trace back those goods to their point of origin. This kind of system would be of great value in enforcing compliance with product standards in addition to deterring smuggling and trafficking and preventing illegal diversion. With the advanced cryptographic techniques that have enabled block chain technology, it should be easy to identify and track the movement of cigarettes as they move through the chain from production to sale.

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<sup>47</sup> NRC-IOM at 111-138.

<sup>48</sup> 21 U.S.C. 387t.

<sup>49</sup> See Citizen Petition of New York City Department of Health and Human Hygiene, March 6, 2013; Letter by 22 Public Health and Medical Groups to CTP Director Mitch Zeller, April 5, 2016.

<sup>50</sup> Ross, H, “Tracking and tracing tobacco products in Kenya,” *Preventive Medicine* 105:S15-S18, 2017. NCI-WHO, *The Economics of Tobacco and Tobacco Control*. National Cancer Institute Tobacco Control Monograph 21, at 532-533. CDC, *Preventing and Reducing Illicit Tobacco Trade in the United States*, 2015, at 25-28, 29-33.

To accomplish all of these goals, a national track and trace system should, at minimum, have the features outlined by the World Health Organization's Framework Convention on Tobacco Control's (FCTC) analysis of available technologies,<sup>51</sup> including:

- Non-predictable serialization of all tobacco products to the level of the smallest saleable unit (generally a pack), with each unique code linked to a secure database of information about that product (such as manufacturer, manufacture date, brand, sub-brand, payment records, shipping information, etc.);
- Common numbering standards for serialization, which should, at minimum, contain information about the manufacturer, date of manufacture, brand, and sub-brand;
- Human-readable printing/labeling of serialization numbers on all traded units. Human readability can also facilitate compliance of less technologically advanced manufacturers and participants along the distribution chain;
- Establishment of parent-child relationships between different packaging units so that individual cartons and cases can be separated from master cases during shipping without need to open and scan each pack (aggregation). Aggregation allows easier tracking of shipping movements, while preserving tracing capacity for individual packs;
- Recordkeeping of any changes in the parent-child relationship along the supply chain (recording changes in aggregation ensures that track and trace is preserved);
- Recordkeeping of any shipping and receiving events to the level of each pack along the supply chain. This is the most critical element in establishing accountability for legal sales of a product;
- Maintenance of relevant data by supply-chain partners;
- Query interfaces between the databases of the supply-chain partners and enforcement authorities, which would allow authorized users to verify products' legal status, as well as get information needed to assist in tracing the origins of diverted products (e.g. with scanners, mobile devices, etc.);
- A standardized protocol for transferring queries and data.

It is important for any track and trace system implemented by FDA to be under the direct management and control of the federal government. In addition, such a system should be designed to allow states and local jurisdictions shared access to data systems storing shipping and receiving information to and from local jurisdictions (all of which is technologically feasible

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<sup>51</sup> World Health Organization, Framework Convention on Tobacco Control, Conference of the Parties, Intergovernmental Negotiating Body on a Protocol on Illicit Trade in Tobacco Products, fourth session, Geneva, Switzerland, 14-21 March 2010, *Analysis of the available technology for unique markings in view of the global track-and-trace regime proposed in the negotiating text for a protocol to eliminate illicit trade in tobacco products: note by the Convention Secretariat*, 2010, <http://www.who.int/iris/handle/10665/75715>.

today), to ensure that required taxes have been paid and to assist with enforcement. FDA should reject efforts by the tobacco industry to participate in the development of such a system or to use the industry-sponsored “Codentify” system. As a recently published study concluded,

“Governments should assume the [tobacco industry] seeks to control [track and trace] systems in order to avoid scrutiny and minimize excise tax payments and that any [track and trace] system based on Codentify, on intellectual property currently or previously owned by the [tobacco industry], or being promoted or implemented by companies with [tobacco industry] links, is incompatible with the [Illicit Trade Protocol] and would not serve to reduce illicit trade.”<sup>52</sup>

Despite the fact that a Citizen’s Petition urging creation of an effective track and trace system was filed and widely supported,<sup>53</sup> FDA has failed to move forward to establish such a system. The undersigned organizations once again urge FDA to take immediate steps create and implement an effective track and trace system.

### C. Coordination with other federal agencies

Other federal agencies have been exercising authority that is highly relevant to the task FDA will face. The Bureaus of Immigration and Customs Enforcement (“ICE”) and Customs and Border Protection (“CBP”), agencies of the Department of Homeland Security, have been responsible for identifying imported tobacco products and ensuring that appropriate taxes and import duties are paid and the Department of Justice’s Bureau of Alcohol, Tobacco, Firearms and Explosives (“ATF”), has been responsible for administration of the PACT Act, although less than 3 percent of ATF’s personnel have been involved in investigating the diversion of tobacco products and a 2009 audit report from the DOJ’s Office of the Inspector General was sharply critical of the agency’s performance of this function.<sup>54</sup> Similarly, for domestic products, the Alcohol and Tobacco Tax Bureau in the Department of the Treasury (“TTB”) has been responsible for monitoring the shipment of domestically manufactured tobacco products and ensuring that taxes are paid.

In developing a policy for effective enforcement of product standards, FDA must coordinate its activities with those of other federal agencies with experience in these areas. Measures that FDA can implement pursuant to the Tobacco Control Act, such as implementation of an effective track and trace system, can provide substantial assistance to other federal agencies in the performance of their functions, particularly in the identification of product on which taxes or import duties have not been paid. Effective coordination between FDA and other federal enforcement agencies is essential.

FDA should also coordinate its enforcement efforts with those of state law enforcement agencies and those of Indian tribal governments. These agencies already have substantial experience in trying to prevent the development of illicit markets through evasion of state, local

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<sup>52</sup> Gilmore, AB, et al., “Tobacco industry’s elaborate attempts to control a global track and trace system and fundamentally undermine the Illicit Trade Protocol,” *Tobacco Control*, epub ahead of print, pii: tobaccocontrol-2017-054191, doi: 10.1136/tobaccocontrol-2017-054191, 2018.

<sup>53</sup> See Citizen Petition of New York City Department of Health and Human Hygiene, *supra*.

<sup>54</sup> NRC-IOM, at 142.

and tribal taxes. Effective enforcement of such tax requirements will also serve the national policy of reducing the use of combusted tobacco products.

Respectfully submitted,

Action on Smoking and Health  
American Academy of Family Physicians  
American Academy of Oral and  
Maxillofacial Pathology  
American Association for Respiratory Care  
American Cancer Society Cancer Action  
Network  
American College of Preventive Medicine  
American Heart Association  
American Lung Association  
American Medical Student Association  
American Psychological Association  
American Public Health Association  
American School Health Association  
American Society of Addiction Medicine  
American Society of Clinical Oncology  
Americans for Nonsmokers' Rights  
Association of State and Territorial Health  
Officials  
Big Cities Health Coalition  
Campaign for Tobacco-Free Kids  
Community Anti-Drug Coalitions of  
America  
Counter Tools  
Eta Sigma Gamma - National Health  
Education Honorary  
Mesothelioma Applied Research Foundation  
National Association of Pediatric Nurse  
Practitioners  
National Hispanic Medical Association  
National Network of Public Health Institutes  
Oncology Nursing Society  
Oral Health America

Prevention Institute  
Public Health Law Center | Tobacco Control  
Legal Consortium  
Public Health Solutions  
Society for Cardiovascular Angiography and  
Interventions  
Society for Public Health Education  
Students Against Destructive Decisions  
The Society for State Leaders of Health and  
Physical Education  
Trust for America's Health  
Truth Initiative