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VIA ELECTRONIC SUBMISSION AND HAND DELIVERY

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
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Re: Docket No. FDA-2018-N-0529 (83 Fed. Reg. 11754, March 16, 2018); Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard

The Food and Drug Administration ("FDA") has issued two advance notices of proposed rulemakings ("ANPRMs") concerning tobacco products that raise significant considerations about the likelihood and implications of increasing illicit trade for tobacco products. First, the FDA is seeking comment on the concept of a product standard imposing a nicotine ceiling on cigarettes and perhaps other combustible tobacco products.¹ Second, the FDA is seeking information concerning the role that flavors play in tobacco products to better understand the consequences of a potential product standard that would ban tobacco products with certain flavors.² Along with the ANPRMs, the FDA has issued a "draft concept paper" that attempts to describe the dimensions of the current and likely resulting black market from the imposition of one or more of these product standards, and has invited comment on that paper as well.³

Pursuant to the Family Smoking Prevention and Tobacco Control Act ("TCA") the FDA is permitted to impose a tobacco product standard that is "appropriate for the protection of the public health."⁴ As part of making this determination, the statute requires that the FDA consider the "countervailing effects" of any regulation, "such as the creation of a significant demand for contraband," and other harm from black market trade in tobacco products.⁵ Altria Client Services, LLC ("ALCS"), on behalf of Philip Morris USA, Inc. ("PM USA"), Sherman Group

¹ ANPRM, 83 Fed. Reg. 11818 (Mar. 16, 2018) Docket No. FDA-2017-N-6189.

² ANPRM, 83 Fed. Reg. 12294 (Mar. 21, 2018) Docket No. FDA-2017-N-6565.

³ CTR. FOR TOBACCO PRODS., U.S. FOOD & DRUG ADMIN., DRAFT CONCEPT PAPER: ILLICIT TRADE IN TOBACCO PRODUCTS AFTER IMPLEMENTATION OF A FOOD AND DRUG ADMINISTRATION PRODUCT STANDARD (2018), 83 Fed. Reg. 11754 (Mar. 16, 2018) Docket No. FDA-2018-N-0529.

⁴ 21 U.S.C. § 387g(a)(3)(A) (2009).

⁵ *Id.* § 387g(b)(2). The FDA also has issued an advance notice of proposed rulemaking relating to premium cigars. That advance notice is not addressed here.

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Holdings LLC and its subsidiaries (“Nat Sherman”), John Middleton Company (“JMC”), U.S. Smokeless Tobacco Company LLC (“USSTC”), and Nu Mark LLC (“Nu Mark”),⁶ submits the attached comments in response to the FDA’s draft concept paper. Our submission provides the necessary comprehensive look at what is publicly known about the tobacco black market in the United States, including its components, methods, participants, motivating factors, scope and scale, and costs to society, and examines its relevance for predicting the black market that will emerge if FDA imposes significant product standards.

The information in the attached submission is available for public release.

Sincerely,

A handwritten signature in black ink, appearing to read "Jane L. Murrell". The signature is fluid and cursive, with the first name "Jane" being the most prominent.

⁶ PM USA, JMC, Nat Sherman, USSTC, and Nu Mark are wholly owned subsidiaries of Altria Group, Inc. (“Altria”). PM USA manufactures cigarettes, JMC manufactures cigars and pipe tobacco, and Nat Sherman manufactures cigarettes, cigars and pipe tobacco. USSTC manufactures smokeless tobacco products and oral tobacco-derived nicotine products, and Nu Mark manufactures e-vapor products. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. “We” and “our” are used throughout to refer to PM USA, JMC, Nat Sherman, USSTC, and Nu Mark.

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EXECUTIVE SUMMARY:

On March 15, 2018, the FDA issued an ANPRM seeking public input for developing a potential nicotine product standard that would reduce the current level of nicotine in cigarettes, and potentially other combustible products. Although the FDA has not determined what that reduced nicotine level would be, the FDA is contemplating a maximum level of 0.3, 0.4, and 0.5 mg of nicotine per gram of tobacco filler.⁷ On March 20, 2018, the FDA issued an additional ANPRM seeking public comment on a potential product standard that would restrict the sale of both combustible and non-combustible tobacco products with certain flavors.⁸ These product standards would result in a de facto ban on products subject to the nicotine standard, and a ban on products subject to the flavor standard.

Attempting to significantly restrict the availability of existing tobacco products would expand an already prevalent and robust black market for cigarettes in particular, and would create black markets for other tobacco products. History has demonstrated that banning products that millions of consumers want creates demand for contraband product. As we approach the 100-year anniversary of Prohibition, we are seeing new iterations of the Prohibition black market problem in connection with cannabis and opioids. These examples demonstrate the reality of black markets: even well-intentioned regulatory interventions restricting access to a product create serious black market problems. It is therefore unsurprising the TCA requires that when the FDA is seeking to implement a tobacco product standard that is “appropriate for the protection of the public health,” it also must consider the “countervailing effects” of any regulation “such as the creation of a significant demand for contraband” and other harm from the black market in tobacco products.⁹

Black markets flourish when there is significant consumer demand for a banned product, inadequate substitutes for that product, and willing and able suppliers of the product. Today in the United States, due primarily to price differentials driven by state and municipal taxation, cigarette black markets are thriving. For example, in New York City, which has the highest cigarette taxes in the nation, over half of the cigarettes consumed are contraband smuggled from jurisdictions with lower cigarette taxes. The high cost of cigarettes in New York City has resulted (for those who can no longer afford them or are simply looking for a better price) in a de facto ban on cigarettes subject to those taxes. Because there are no legitimate substitutes for those cigarettes (*i.e.*, cigarettes not subject to the tax in that locale), there exists a cadre of criminals willing and able to smuggle cigarettes into New York City.

New York City is but a microcosm illustrating the current black market in cigarettes, which is massive in scope and scale, with literally billions of illegal cigarettes being consumed annually in the United States and around the world. Extensive black market distribution networks are

⁷ See ANPRM at 9, 83 Fed. Reg. 11818 (Mar. 16, 2018) Docket No. FDA-2017-N-6189 [hereinafter Nicotine ANPRM]. In response to the FDA’s Nicotine ANPRM, ALCS filed comments today that describe in detail how the nicotine ceilings being considered are de facto product bans.

⁸ See *generally* ANPRM, 83 Fed. Reg. 12294 (Mar. 21, 2018) Docket No. FDA-2017-N-6565 [hereinafter Flavor ANPRM].

⁹ 21 U.S.C. § 387g (a)(3)(A), (b)(2) (2009).

already in place. Sophisticated criminal organizations, including those that have funded terrorist activities, have found the black market cigarette trade to be highly lucrative.

Contrary to the FDA's position in its draft illicit trade concept paper that the high prices (as a result of high taxes) that drive the current cigarette black market are distinct from the imposition of a product standard,¹⁰ an FDA-funded study has recognized that "a reduction in nicotine content may be thought of as an increase in the unit price of nicotine,"¹¹ *i.e.*, from an economic modeling perspective, reducing nicotine effectively raises the cost to the consumer of procuring the product they seek. Thus, reducing nicotine in cigarettes will immediately create a stronger incentive for that consumer to seek out illegal cigarettes that deliver what the consumer wants. In fact, the FDA-funded study acknowledges that "[i]f a nicotine reduction policy is implemented, a black market for nicotine-containing cigarettes is likely to be a concern."¹² In other words, at a minimum, the *de facto* nicotine ban under consideration would drive significantly more consumers to the black market where they can find cigarettes and other combustible products with the characteristics they want. The same outcome is highly likely for any flavor ban that applies to these and any other tobacco products. Indeed, additional economic modeling indicates that a nicotine ban alone will result in virtually all combustible cigarettes coming from the black market,¹³ even before accounting for the compounding impact of a flavor ban.¹⁴

Further, if the FDA were to implement standards that in effect ban nicotine in cigarettes and other combustible products and/or ban certain flavors in all tobacco products, consumers may have no alternatives outside of the black market. These problems would be made even worse with a ban in alternative products, such as smokeless tobacco or e-vapor products with a banned flavor. The FDA has yet to communicate to consumers broadly about the health benefits of switching to non-combustible products and has yet to authorize any modified risk claims that may assist consumers in migration decisions. Even if the FDA authorized these alternative products, however, another major impediment is taxation and other regulation by state and local governments that make less accessible the very alternative products to which consumers could otherwise migrate.

Black markets cause serious harm. The manufacture of black market tobacco products is by its very nature unregulated and unmonitored by the FDA and others, which could lead to more dangerous products being consumed, as evidenced by the opioid black market and by alcohol during Prohibition. Also, the wide availability of black market tobacco products would undermine the FDA's cessation and youth smoking prevention efforts by making tobacco

¹⁰ CTR. FOR TOBACCO PRODS., U.S. FOOD & DRUG ADMIN., DRAFT CONCEPT PAPER: ILLICIT TRADE IN TOBACCO PRODUCTS AFTER IMPLEMENTATION OF A FOOD AND DRUG ADMINISTRATION PRODUCT STANDARD (2018), 83 Fed. Reg. 11754 (Mar. 16, 2018) Docket No. FDA-2018-N-0529 [hereinafter FDA Illicit Trade Paper].

¹¹ Tracy T. Smith, Alan F. Sved, Dorothy K. Hatsukami & Eric C. Donny, *Nicotine Reduction as an Increase in the Unit Price of Cigarettes: A Behavioral Economics Approach*, 68 PREVENTIVE MED. 23, 24 (2014). A free copy of the article is available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4446706/>. With respect to funding, the publication "was supported by the National Institute on Drug Abuse and FDA Center for Tobacco Products (CTP) (U54 DA031659 awarded to E.C.D.)." *Id.* at 27.

¹² *Id.* at 27.

¹³ This detailed economic analysis can be found in Section VI of ALCS' comments to the Nicotine ANPRM.

¹⁴ *Id.*; see also ALCS' comments to the Flavor ANPRM.

products both less expensive and increasingly available to minors, without any kind of age verification mechanisms. In addition to undermining basic public health goals, tax revenues would be lost at all levels of government and that revenue would instead end up in the pockets of criminals. With more money at stake in the black market, more violence can be expected, including theft and territory fights. As was the case with Prohibition, the product bans would drive millions of otherwise law-abiding citizens into illegal activity by purchasing contraband tobacco products. In the end, the black market can subvert the FDA's goal of regulating tobacco products to protect the public health.

FDA cannot reasonably expect to address a significant black market through enforcement efforts. Black markets are, and historically have been, exceptionally costly and difficult to combat. For the cigarette black market, enforcement responsibility is spread among numerous federal, state and municipal agencies, all with limited resources to address the problem and a panoply of other priorities, like the opioid crisis. But the most significant impediment would be the size of the tobacco black market itself, which in the face of the contemplated product bans may dwarf law enforcement's ability to contain it short of efforts that would be incompatible with what the American public will accept.

In short, there are many aspects of the product standards being considered, and their potentially negative effects, that by the FDA's own admission need further study to be fully understood.¹⁵ A significant, dynamic and adaptable cigarette black market already exists. Any standard that would, in effect, impose a sudden product ban, with limited, incomplete knowledge of its countervailing effects, would be contrary to the TCA's statutory mandate that the FDA only impose product standards "appropriate for the protection of the public health."¹⁶ This paper is intended to further FDA's understanding and considerations of the black market issue. It provides background on the historic and existing black market for cigarettes, summarizes existing academic research that is relevant to the FDA's decision making, and analyzes the potential consequences of implementation of a product standard that would in effect result in a ban on nicotine or a ban on certain flavored tobacco products.

¹⁵ The FDA Illicit Trade Paper recognizes that the paper represents "only an initial step toward assessing the potential for demand for illicit tobacco products." FDA Illicit Trade Paper at 24. This recognition is consistent with the numerous conclusions by another FDA-funded paper on illicit markets, wherein those authors provided recommendations for additional research in numerous critical areas. COMM. ON THE ILLICIT TOBACCO MARKET, NAT'L RES. COUNCIL, UNDERSTANDING THE U.S. ILLICIT TOBACCO MARKET: CHARACTERISTICS, POLICY CONTEXT, AND LESSONS FROM INTERNATIONAL EXPERIENCES (Peter Reuter & Malay Majmundar eds., 2015) [hereinafter NRC Illicit Trade Paper].

¹⁶ 21 U.S.C. § 387g(a)(3)(A) (2009).

SECTION I: THE CURRENT TOBACCO BLACK MARKET IS DOMINATED BY CIGARETTES, AND IS SUBSTANTIAL AND ADAPTABLE.

The black market in cigarettes is large and growing. The black market now accounts for between 8.5% and 21% of cigarette sales in the U.S., with substantially higher percentages in states such as New York, Arizona, New Mexico and Washington.¹⁷ These percentages represent roughly 10 to 25 billion cigarettes traded on the black market and \$3 billion in excise tax losses in the U.S. alone.¹⁸ The black markets are adaptable and dynamic and able to rapidly adjust to regulations, in the form of taxation or otherwise, and to consumer desires. Indeed, the Government Accountability Office (“GAO”) has characterized the black market trade in tobacco products as a “whack-a-mole” problem, as illustrated by examples from New York City and other jurisdictions.¹⁹ Black markets come in many forms, including smuggling or bootlegging, illegal domestic manufacture, illegal international manufacture and smuggling, gray markets, counterfeiting, and internet sales, each with their unique problems and harms to consumers and local, state, and federal governments. This section describes black markets generally, and then describes the current cigarette black market specifically, including its profile, adaptability, history, drivers, and size.

A. A Primer on Black Markets and Their Associated Problems.

“Black market” is the term used to describe the illegal trade of goods. The TCA defines “illicit trade,” which is for all practical purposes a synonym for black market, as follows: “any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase of tobacco products including any practice or conduct intended to facilitate such activity.”²⁰ The black market has many other names, including: shadow, informal, hidden, underground, gray, clandestine, illegal and parallel economies.²¹ Black markets typically exist where there is consumer demand for a banned product. The ban can take the form of a legal ban, such as the ban or significant restriction on the design or formulation of a product, or a de facto ban, where the price or regulatory requirements in the legitimate market are high enough that they serve as a ban to obtaining the product for many consumers.

The black market typically involves a crime in which there is no obvious “victim” to alert authorities.²² Unlike “predatory” crimes involving theft, deception, or assault, this inability to easily identify a victim makes it difficult to investigate, measure and combat this type of crime.²³

¹⁷ See NRC Illicit Trade Paper, *supra* note 15, at 4; Jonathan Kulick, James E. Prieger & Mark A.R. Kleiman, *Targeted Enforcement Against Illicit Trade in Tobacco Products*, Pepperdine University, School of Public Policy Working Papers, Paper 64 (2016), available at <https://ssrn.com/abstract=2883415>; William V. Pelfrey, Jr., *Cigarette Trafficking, Smurfing, and Volume Buying: Policy, Investigation, and Methodology Recommendations from a Case Study*, 26 CRIM. JUST. POL’Y REV. 713 (2015).

¹⁸ See NRC Illicit Trade Paper, *supra* note 15, at 4, 102-03; Kulick et al., *supra* note 17.

¹⁹ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-313 ILLICIT TOBACCO—VARIOUS SCHEMES ARE USED TO EVADE TAXES AND FEES (2011).

²⁰ 21 U.S.C. § 387(8) (2009); see also NRC Illicit Trade Paper, *supra* note 15, at 13.

²¹ Matthew H. Fleming, John Roman & Graham Farrell, *The Shadow Economy*, 53 J. INT’L AFFAIRS, 387 (2000).

²² DAVID A. BOYUM, JONATHAN P. CAULKINS & MARK A. R. KLEIMAN, *DRUGS, CRIME, AND PUBLIC POLICY*, Ch. 13 (James Q. Wilson & Joan Petersilia eds., Oxford Univ. Press) (2011).

²³ *Id.*

This, however, does not mean that many aspects of black markets cannot be studied and known, or that a black market transaction is a “victimless” crime.

On the contrary, the victims of black markets are the government, consumers, legitimate manufacturers, and citizens in general due to the significant and varied economic, political, health, safety and other problems that come with black markets. First of all, there is a strong connection between organized crime and the black market, with organized crime being a driver of, and a problem caused by, black markets.²⁴ Black markets also raise costs for governments, as considerable expenditures must be devoted to fighting the black markets. At the same time black markets are raising costs to governments, they are generally avoiding taxation, which undermines enforcement efforts and limits the provision of public goods and services that depends on such tax revenue.²⁵ These additional costs divert resources from fighting other forms of (predatory) crime in particular, and the provision of public goods in general. On a higher level, as a result of black markets, “[t]he nation has less accurate information on which to base fiscal and monetary policies.”²⁶ This has many implications, including ineffective or counterproductive policies because they are based on erroneous information and indicators.²⁷

With respect to tobacco products, the black market undermines product standards, sabotages public health efforts to curb smoking, allows unregulated youth access, exposes more youth to other illegal activities and dangers, supports organized crime, and reduces federal and state tax revenues. These and other negative consequences of the cigarette black market are discussed in detail in Section III below.

B. The Cigarette Black Market Comes in Many Forms.

The black market in cigarettes is extensive, and where one door closes, another door opens.²⁸ There are many opportunities to divert cigarettes from the legal supply chain to the black market, both before the required excise taxes and fees are collected, as well as after such taxes are paid. Furthermore, many cigarettes are manufactured for the sole purpose of being introduced into the black market. The figure below, from a GAO report,²⁹ illustrates the many opportunities that exist in this regard.

²⁴ See Vimal Kumar & Stergios Skaperdas, *On the Economics of Organized Crime* (UNIV. OF CAL.-IRVINE, DEP’T. OF ECON., Working Paper No. 70815, 2008), <https://www.economics.uci.edu/files/docs/workingpapers/2007-08/skaperdas-15.pdf>. Indeed, organized crime was one of the byproducts of Prohibition, as explained herein.

²⁵ Fleming et al., *supra* note 21, at 387-409.

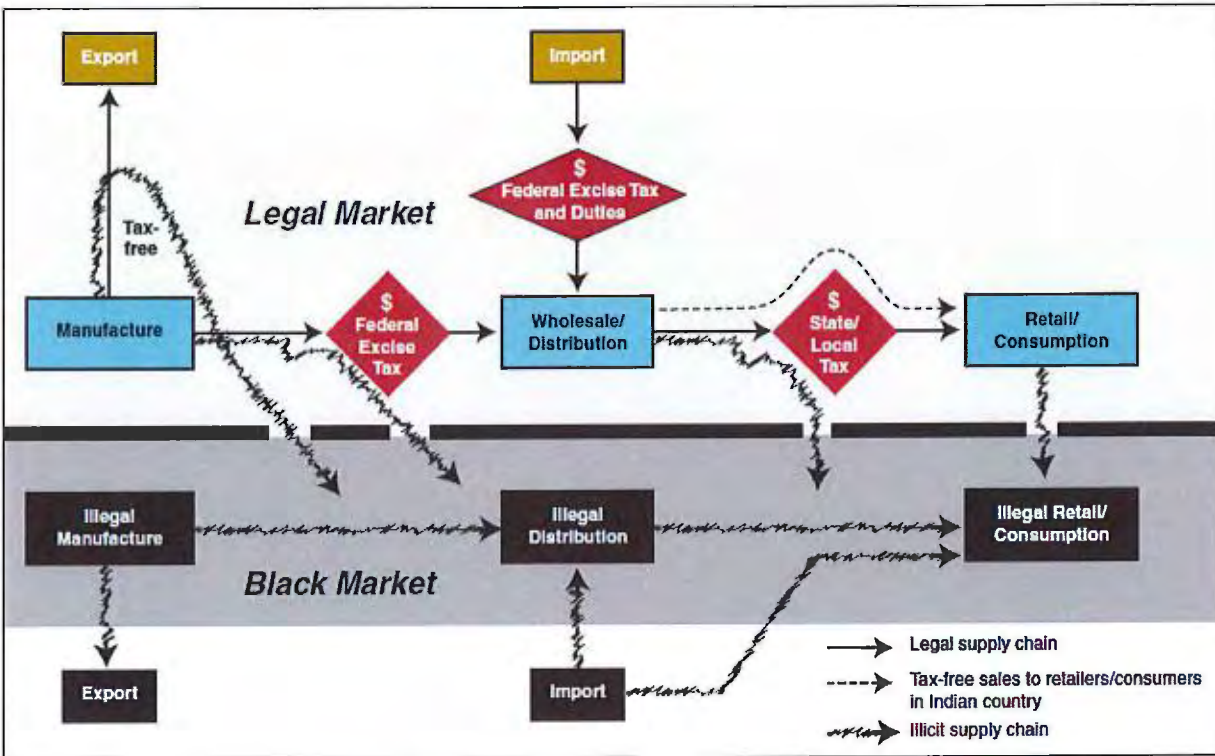
²⁶ *Id.*; DOUGLAS I. KEH, DRUG MONEY IN A CHANGING WORLD: ECONOMIC REFORM AND CRIMINAL FINANCE (U.N. INT’L DRUG CONTROL PROGRAMME, CP TECHNICAL SERIES NO. 4, 1996).

²⁷ Friedrich Schneider & Dominik H. Enste, *Shadow Economies: Size, Causes, and Consequences*, 38 J. ECON. LITERATURE 77 (2000).

²⁸ The size and adaptability of the cigarettes black market is addressed *infra* Sections I.C. & I.E.

²⁹ GAO-11-313, *supra* note 19.

Figure 16: Opportunities to Divert Tobacco Products Into the Black Market



Source: GAO analysis.

Note: Theft of tobacco products can also occur at any point in the supply chain and is not represented on this supply chain graphic. The graphic also does not represent legal manufacturing on Indian country that may by-pass federal and state excise taxes.

The following subsections briefly describe these various schemes, dividing the discussion generally between legally manufactured cigarettes diverted into the black market, and illegally manufactured cigarettes produced solely for the black market. Also, given the unique role that the internet plays for smokers to obtain both legally and illegally manufactured cigarettes, this particular issue is addressed in its own section.

1. Smuggling of legally manufactured cigarettes.

Generally speaking, smuggling is the unlawful, covert transportation of goods, typically across a border to avoid taxes or other regulation. Regarding tobacco products, smuggling generally refers to the unlawful movement from one jurisdiction to another for the purpose of evading taxes. In the chart above, each of the four entry points from the legal supply chain into the black market would generally qualify as "smuggling."

a. Bootlegging

The term "bootlegging" has historically been used as an informal term for smuggling, with the term adopted to describe the smuggling of alcohol during Prohibition. With respect to cigarettes, bootlegging generally refers to cigarettes purchased from legal wholesalers or regular retail

stores in one jurisdiction, and then illegally sold or consumed in another jurisdiction without payment of the applicable state and local taxes.³⁰ Given the significant differences in state cigarette taxes, criminals profit from even small-scale bootlegging from low excise tax locales to high excise tax locales.³¹ As the Bureau of Alcohol, Tobacco, Firearms and Explosives (“ATF”) has stated, “[i]t is easy to buy a truckload of cigarettes in North Carolina and sell them in New York City for a profit of almost \$30 per carton. Thus a few hours’ ‘work’ can yield several thousand dollars’ profit.”³² Indeed, there are several states where contraband cigarettes make up a high percentage of the market, including cigarettes smuggled in from elsewhere, including: New York (56.9%), Arizona (51.5%), New Mexico (48.1%), Washington (48.0%) and Wisconsin (34.6%).³³

With respect to the United States’ neighbors to the north and south, it is no secret that significant smuggling infrastructure is already in place and in full operation. The Macdonald-Laurier Institute in Canada stated that “[f]or the last 20 years, contraband tobacco has represented one of the most significant challenges to border integrity.”³⁴ The authors describe the small border town of Cornwall in Ontario as being a “contraband haven” given its geography and the jurisdictional vacuum at the frontier.³⁵ But the problem extends clear across the world’s longest undefended border, driven primarily by disparity in price. In fact, “[t]he kind of price gap that exists between North Dakota and Manitoba (about \$5 a pack) is enough to stimulate significant cross-border smuggling.”³⁶ This extensive “smuggling infrastructure established to sustain the tobacco trade has been used for other ‘goods’ and the amount of money involved ha[s] developed into a major law enforcement and security conundrum.”³⁷

The price disparity between cigarettes in the U.S. and Mexico also has been a driver for smuggling across the U.S.-Mexico border. That smuggling, mainly accomplished by individuals bringing small quantities across the border from Mexico, can create a large cigarette black market in the U.S. In December 2009, ALCS conducted a survey of empty cigarette packs discarded in public spaces in a representative set of neighborhoods covering all parts of San

³⁰ See, e.g., NRC Illicit Trade Paper, *supra* note 15, at 33-34. Some authors have distinguished bootlegging from large-scale smuggling, referring to the former as the legal purchase of cigarettes in one jurisdiction and their resale in another without payment of applicable taxes, and using “large-scale smuggling” to describe the sale of cigarettes without the payment of *any* taxes or duties. That distinction is made in this paper.

³¹ Scott Drenkard, *Cigarette Smuggling Can Make You \$4 Million Richer*, TAX FOUND. POL’Y BLOG (Sept. 27, 2012), <http://taxfoundation.org/blog/cigarette-smuggling-can-make-you-4-million-dollars-richer>.

³² BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES, ATF EXECUTES 50 PLUS WARRANTS IN UNDERCOVER ORGANIZED TOBACCO DIVERSION STING (Oct. 19, 2011) (press release), available at <https://www.prnewswire.com/news-releases/atf-executes-50-plus-warrants-in-undercover-organized-tobacco-diversion-sting-132184678.html>.

³³ *Tobacco Taxation and Unintended Consequences, Hearing on Tobacco: Taxes Owed, Avoided, and Evaded, before the Senate Committee on Finance*, 113th Cong. 2 (2014) (statement of Scott Drenkard, Economist and Manager of State Projects, Tax Foundation) (citing Michael LaFaive & Todd Nesbit, *Cigarette Smuggling Still Rampant in Michigan*, *Nation* (Mackinac Ctr. for Pub. Pol’y, Feb. 17, 2014), <http://www.mackinac.org/19725>).

³⁴ Jean Daudelin et al., *Border Integrity, Illicit Tobacco, and Canada’s Security* 6 (Macdonald-Laurier Inst., Nat’l Security Strategy for Canada Ser. No. 4, 2013).

³⁵ *Id.*

³⁶ *Id.* at 9.

³⁷ *Id.* at 6.

Diego.³⁸ Approximately half (49.7%) of the packs collected were either produced outside the U.S. for sale in non-U.S. markets or intended to be sold in duty-free markets and consumed outside the country. No U.S. federal or state taxes are paid on these foreign or duty-free cigarettes. By far the largest share (78.9%) of these non-domestic packs was from Mexico, implying that 39.2% of all Marlboros consumed in San Diego generally, and discarded in public spaces, were from Mexico.³⁹ This translates to over 170,000 packs (over 3.4 million cigarettes) of Mexican Marlboros being smoked daily—enough to fill a 40-foot international shipping container every three days—in San Diego alone. The incentive to evade and avoid taxes was large: fully taxed packs in California sold for about \$5.20 per pack in 2009, whereas Marlboro cigarettes sold in Mexico for the equivalent of only \$1.80 to \$2.00 a pack—a discount of over 60%.⁴⁰

Furthermore, the bootlegging of tobacco products purchased on Native American reservations is a well-known problem. Indeed, the smuggling of tobacco products on and through the St. Regis Mohawk Tribe (U.S.) and the Mohawk Council of the Akwesasne (Canada) reservation lands is well-documented.⁴¹ Residents of the Mohawk nation travel freely across this territory—which straddles the Canada-U.S. border—without interference by custom authorities.⁴² When New York passed legislation in 2010 prohibiting the sale of non-taxed cigarettes to non-tribal members, a subsequent survey in the Bronx revealed that still more than 5% of the discarded cigarette packs contained no tax stamps, indicating they were purchased from a Native American reservation.⁴³ Of significant importance is the reality that the Native American reservations will most certainly continue manufacturing current nicotine level cigarettes (regular and menthol) that could be bootlegged into the U.S. market if a product standard that bans such cigarettes (and other tobacco products) is ultimately proposed and implemented.

b. Large-scale smuggling, including illicit whites and gray market.

The diversion of tobacco products into the black market before *any* taxes are paid is also a recognized problem. This involves a scheme most commonly referred to as “large-scale smuggling.”⁴⁴ The term “large-scale smuggling,” however, does not refer to the scale of the

³⁸ Subsection F below provides more information on empty discarded pack studies, or refer to Alberto Aziani, Jonathan Kulick, Neill Norman & James E. Prieger, *Empty Discarded Pack Data and the Prevalence of Illicit Trade in Cigarettes* (Jan. 17, 2017), <http://dx.doi.org/10.2139/ssrn.2906015>. The case study recounted here relies on internal studies and documents.

³⁹ Marlboro packs from Mexico were manufactured by Philip Morris International, a separate company not affiliated with Altria.

⁴⁰ This case study in San Diego highlights two important points that the FDA Illicit Trade Paper neglects to consider. First, no enforcement mechanism discussed in the FDA Illicit Trade Paper would be effective against this example of smuggling. No legitimate retailers of tobacco products were found to be selling these illicit Marlboro packs, so there is no licensed retailer to which the FDA could send a warning letter or against whom administrative enforcement could be undertaken. Second, criminal enterprises operating in the black market are highly adaptive. Enforcement directed at one form of illicit trade (say, illicit importation via shipping containers) raises the cost of doing business via that channel without materially affecting the demand for the product, and so the industry reorganizes to lower the cost of supply by smuggling.

⁴¹ Daudelin, *supra* note 34, at 28.

⁴² *Id.*

⁴³ See *infra* Section I.E.

⁴⁴ See NRC Illicit Trade Paper, *supra* note 15, at 34-37.

activity—although the scheme does typically involve large shipments of millions of cigarettes—but refers to the organized means by which it occurs.⁴⁵ The cigarettes are typically obtained directly from a manufacturer at factory rates, with no taxes or fees ever being paid on the cigarettes. Although large-scale smuggling of U.S.-made cigarettes does not currently represent a significant source of the tobacco black market, “the United States has been and continues to be a destination country for illegal cigarettes from abroad.”⁴⁶

One form of large-scale smuggling involves cigarettes known as “illicit whites” or “cheap whites.” Illicit whites are cigarettes that are legally produced under unique brand names, or no brand name at all, but are destined primarily or exclusively for black market distribution.⁴⁷ These cigarettes are typically produced in another country and then smuggled into the United States and sold illegally. The manufacturers of illicit whites, who are manufacturing the cigarettes pursuant to that jurisdiction’s laws, are often integrated into the black market, producing large quantities of cigarettes that will find their way into other foreign jurisdictions.⁴⁸

Another form of the large-scale smuggling scheme involves gray market cigarettes. Gray market cigarettes are cigarettes manufactured for sale in foreign countries, but end up in the U.S. domestic market. There are two general categories of gray market cigarettes. The first involves cigarettes that are produced in the United States for export but are never actually exported, or are exported to independent brokers and then re-imported into the United States for resale.⁴⁹ This scenario of domestically manufactured cigarettes produced for export but then reimported has become less common. The second and more common form of gray market cigarettes are cigarettes that are manufactured in a foreign jurisdiction under a common brand name for sale in that foreign jurisdiction, but are then diverted to the United States. This, and other forms of smuggling cigarettes, is depicted in the image below.

⁴⁵ *Id.* at 34.

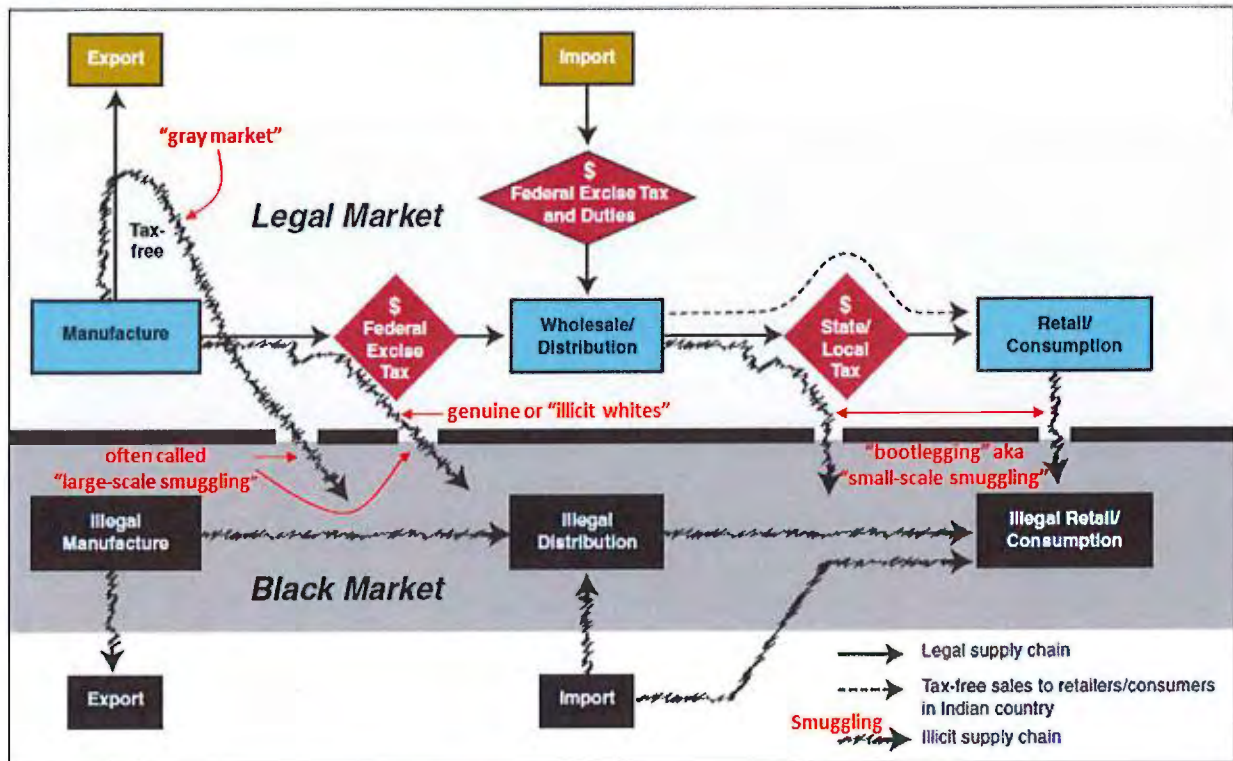
⁴⁶ *Id.* at 35.

⁴⁷ *Id.* at 38.

⁴⁸ The most common brand of illicit whites is “Jin Ling,” which is manufactured in Russia, Ukraine, and Moldova. *Id.* Also, some of the cigarettes currently produced on Native American reservations would qualify as “illicit whites,” and should the FDA implement a product ban, it would be expected that more manufacturers on reservation lands would become sizeable sources of this type of contraband cigarettes.

⁴⁹ Michael Kwon, *Filtering the Smoke Out of Cigarette Websites: A Technological Solution to Enforcing Judgments Against Offshore Websites*, 30 BROOK. J. INT’L L. 1067, 1072 (2005).

Figure 16: Opportunities to Divert Tobacco Products Into the Black Market



Source: GAO analysis.

Note: Theft of tobacco products can also occur at any point in the supply chain and is not represented on this supply chain graphic. The graphic also does not represent legal manufacturing on Indian country that may by-pass federal and state excise taxes.

Although illicit whites and gray market cigarettes do not currently represent a significant portion of the U.S. black market, the manufacturing of these cigarettes is ongoing and the cigarettes could easily be diverted into the U.S. market if a product standard that bans cigarettes (and other tobacco products) is ultimately proposed and implemented.

2. Illegal manufacturing and associated smuggling.

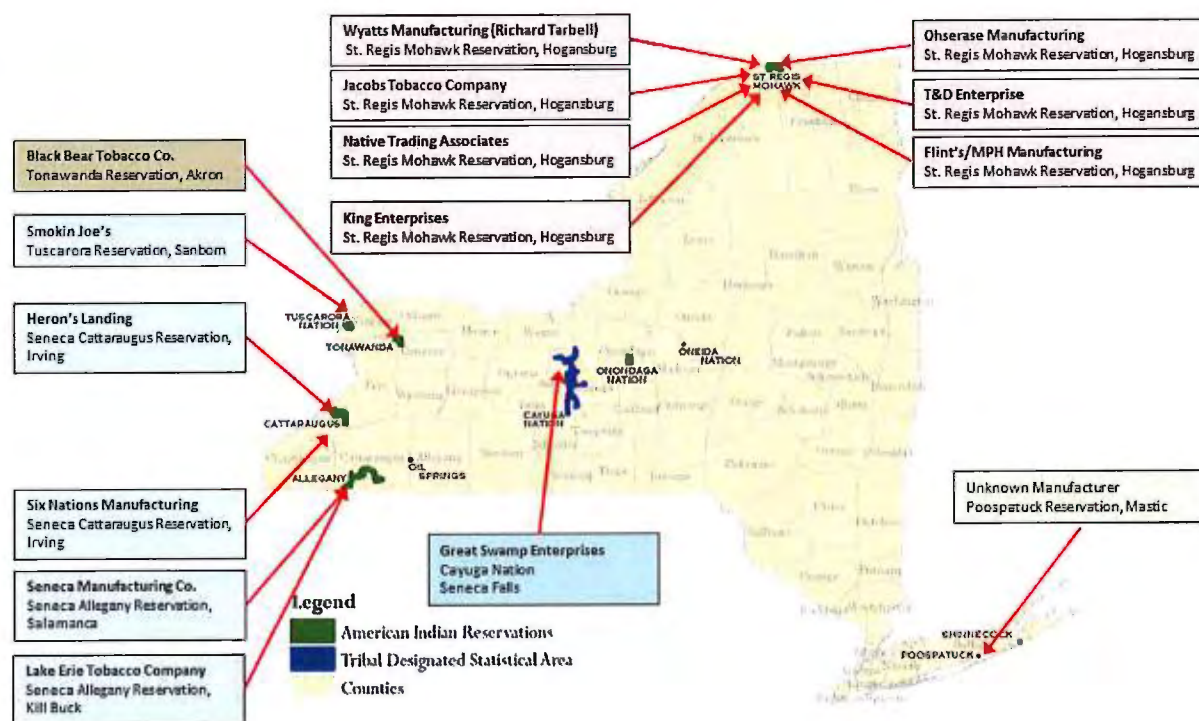
Illegal manufacturing involves the covert manufacture of tobacco products without declaration to the relevant authorities. Low barriers to entry and demand for inexpensive cigarettes support the illegal manufacturing industry. A potential smuggler needs only a shed or small warehouse building large enough to hold a cigarette rolling machine and a packaging machine. These machines can be purchased second hand.⁵⁰ A small industrial rolling machine can produce more than 6,000 cigarettes per minute.⁵¹ Using just one such machine, a manufacturing operation that runs only one shift five days a week can produce as many as 25 million packs of cigarettes per

⁵⁰ See, e.g., ALIBABA.COM, <https://www.alibaba.com/showroom/industrial-cigarette-rolling-machine.html> (last visited June 19, 2018) (offering cigarette rolling machines) and <https://www.alibaba.com/showroom/cigarette-packing-machine.html> (last visited June 19, 2018) (offering cigarette packaging machines).

⁵¹ See, e.g., HAUNI KÖRBER SOLUTIONS, <https://www.hauni.com/en/nc/products/secondary/cigarette-making/filter-cigarette-maker/detail/product/protos-80c.html> (last visited June 19, 2018) (website advertising cigarette making machinery showing lowest-end model capable of producing 6,000 to 7,000 cigarettes per minute).

year. Manufacturers also have ready access to the supplies to manufacture cigarettes. Domestic and international brokers sell whole leaf, processed tobacco and tobacco blends via the internet, which tobacco is ready for processing into cigarettes, cigars or pipe tobacco.⁵² There are few regulations governing the growing and sale of tobacco, which means there are few mechanisms to track and limit these sales. Other raw materials (such as paper or acetate tow) can be purchased from various sellers via the internet.⁵³

In addition to producing legally manufactured cigarettes, Native American reservations are also a key source of illegal manufacturing and produce millions of packs of cigarettes per year. Most unlicensed cigarette manufacturing occurs in northern and western New York on land controlled by New York's nine Indian tribes. As illustrated on the map below, the most recent information collected by ALCS indicates that there are approximately 15 active tribal cigarette manufacturers in New York, only 9 of which had registered with the FDA and appeared to be operating legally.⁵⁴

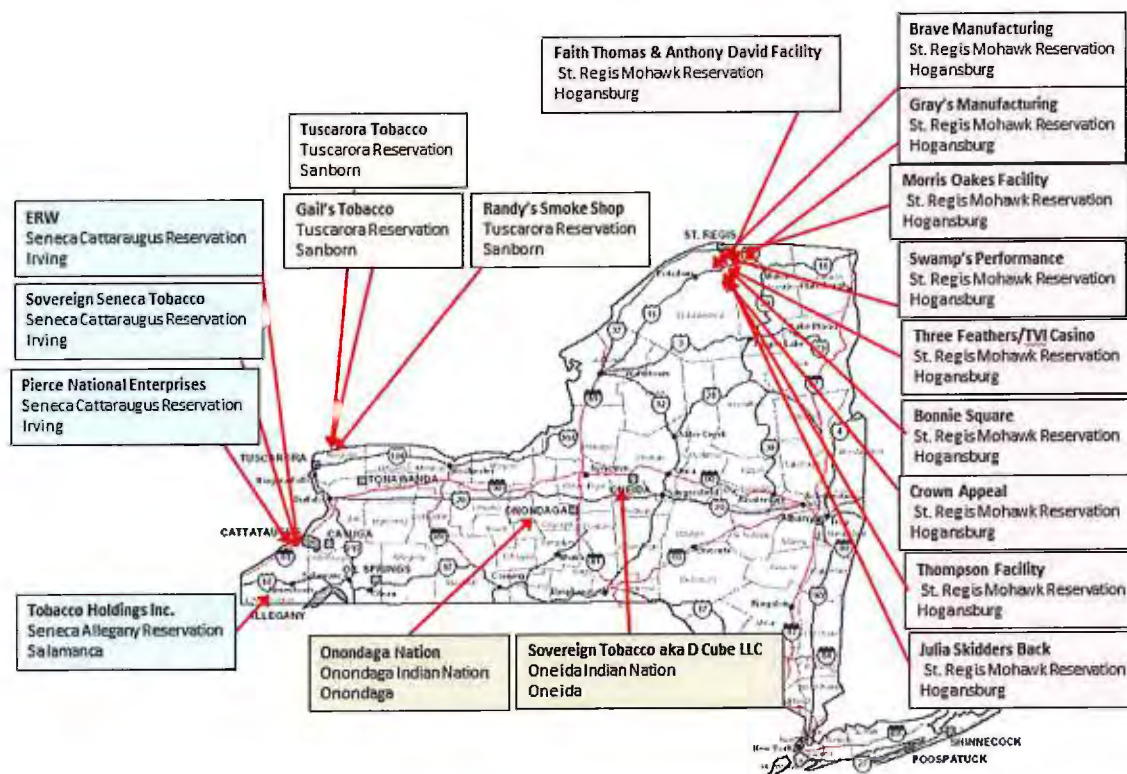


⁵² See, e.g., LEAF ONLY, <https://www.leafonly.com/wholesale/processed-tobacco-leaf.php> (offering varieties of processed tobacco leaves sourced from the United States and other countries) (last visited June 19, 2018); STAR TOBACCO, <http://www.startobacco.biz/> (last visited June 19, 2018) (offering cured leaves, cut and processed tobacco for manufacturing into tobacco products).

⁵³ See, e.g., GOLDEN LEAF TOBACCO CO., <http://goldenleaftobacco.net/index.php/products/leaf-tobacco-a-cut-rag> (last visited June 19, 2018) (tobacco); WHOLE LEAF TOBACCO, http://www.wholeleaftobacco.com/Whole-Leaf-Tobacco-Blends_c17.htm (last visited June 19, 2018) (tobacco); BTS, <http://www.businessstob.com/default.asp?id=398> (last visited June 19, 2018) (acetate tow, cigarette paper, and other supplies).

⁵⁴ ALCS collected this information on Native American manufacturers in New York in 2015 and 2016. The current roster of manufacturers may vary somewhat, as these operations change from time to time.

In addition to those 15 manufacturers, ALCS obtained information on at least another 17 entities that may manufacture cigarettes or that appear to be set up and capable of manufacturing at any given time. None of these 17 manufacturers were registered with the FDA.



These manufacturers produce cigarettes under their own brand names, in traditional packs and cartons, and/or produce “rollies” or “baggies,” which are unbranded bags containing 200 loose cigarettes, as shown in the image below. These “baggies” do not comply with the TCA requirements for packaging cigarettes⁵⁵ and may sell for as little as \$8 each—significantly less than a carton of premium brand cigarettes that sell for over \$100 in New York City.⁵⁶

⁵⁵ See 21 U.S.C. § 387c (2009) (requiring that cigarette packages bear name and location of manufacturer, name of product and quantity, among other requirements); 15 U.S.C. § 1333 (requiring warning statements).

⁵⁶ ACLS’ research has shown that baggies of 200 typically sell for \$22-23 for three bags, and single bags of 200 typically sell for approximately \$10 per bag.

Figure 20: Illicit Cigarettes on Land Controlled by the St. Regis Mohawk Tribe



Source: TTU.

A sense of the volume and scale of tribal manufacturing can be gleaned from the bankruptcy filings of Native Wholesale Supply (“NWS”), a tribal importer and distributor affiliated with Canadian tribal cigarette manufacturer Grand River Enterprises (“GRE”). NWS’ monthly operating reports show that in 2017, it alone sold close to 120 million packs of GRE cigarettes to wholesalers and tribal reservations across the United States.⁵⁷

Tribal manufacturers are often supported by retail stores operating on reservation lands. These stores sell cigarettes without the required federal and/or state taxes, often sell rollies or other cigarettes that do not comply with the TCA’s packaging requirements, and violate FDA’s prohibition on self-service displays at retail.⁵⁸ In New York alone, there are approximately 175 tribal retail cigarette stores, similar to the one pictured below. Tribal stores also operate on reservation lands in more than a dozen other states. For instance, a retail store on Stillaguamish tribal trust land in Washington sold more than \$55 million of contraband cigarettes without the payment of state excise taxes. According to court documents, “more than \$25 million in Washington state excise taxes were avoided as a result.”⁵⁹

⁵⁷ See *In Re: Native Wholesale Supply Co.*, Debtor’s Post-Confirmation Monthly Operating Report at 4-7, Case No. 11-14009-CLB (W.D.N.Y. Jan. 31, 2018).

⁵⁸ See 21 C.F.R. §1140.14(e).

⁵⁹ DEP’T OF JUST., TWO PLEAD GUILTY IN FEDERAL COURT TO ILLEGALLY MANUFACTURING CIGARETTES ON THE ST. REGIS MOHAWK RESERVATION (Jan. 18, 2013) (press release).

Figure 22: Tonawanda Retail Store Selling Tax-Free Cigarettes



Source: ATF

Another illegal manufacturing scheme involves counterfeiting, *i.e.*, the illegal manufacture of products using someone else's well-known brand name (a.k.a. trademark) without their consent.⁶⁰ These cigarettes tend to be sold on street corners or through the internet to unsuspecting purchasers. Taxes are rarely, if ever, paid on counterfeit products.⁶¹ "Chinese counterfeit cigarette factories [reportedly] churn out an unprecedented 400 billion cigarettes a year, enough to supply every U.S. smoker with 460 packs a year."⁶² That is the equivalent of roughly 25 cigarettes per day per smoker—nearly double the average of 14.2 cigarettes per day estimated by the CDC.⁶³ The ATF has noted that the "trade of counterfeit tobacco products is also a rapidly growing global problem."⁶⁴ This is buoyed by the fact that counterfeit products, on their face, are largely indistinguishable from their genuine counterparts, as demonstrated by the image below.

⁶⁰ *Fact Sheet: Illicit Trade in Tobacco 1* (Action on Smoking and Health, 2017), <http://ash.org.uk/information-and-resources/fact-sheets/illicit-trade-in-tobacco/>.

⁶¹ *Id.*

⁶² *Tobacco Taxation and Unintended Consequences, Hearing on Tobacco*, *supra* note 33 (citing Te-Ping Chen, *China's Marlboro Country: A Massive Underground Industry Makes China the World Leader in Counterfeit Cigarettes* 3 (The Ctr. for Pub. Integrity, June 28, 2009), https://reportingproject.net/underground/index.php?option=com_content&view=article&id=9:chinas-marlboro-country&catid=3:stories&Itemid=22).

⁶³ CTRS. FOR DISEASE CONTROL & PREVENTION, ADULT CIGARETTE SMOKING RATE OVERALL HITS ALL-TIME LOW (2014), <https://www.cdc.gov/media/releases/2014/p1126-adult-smoking.html>.

⁶⁴ *Fact Sheet: Illicit Trade in Tobacco*, *supra* note 60.



“A range of schemes have been used to evade duties and excise taxes on both genuine and counterfeit tobacco products as they are imported into the United States and distributed in the black market. According to [Customs and Border Patrol (“CBP”)] officials, smugglers have imported counterfeit tobacco products by falsely declaring them as other commodities. For example, a CBP press release revealed that more than 22,000 cartons of counterfeit Marlboros were intercepted after being shipped from China and seized at the Los Angeles/Long Beach seaport complex. The counterfeit cigarettes, pictured [below], were falsely declared as hang tags and hang plugs.”⁶⁵

Figure 18: Seizure of Counterfeit Cigarettes



Source: CBP.

⁶⁵ See GAO-11-313, *supra* note 19.

3. Internet sales.

Sellers of legally and illegally manufactured cigarettes use the internet to sell in the black market. As early as January 2004, hundreds of websites already existed selling cigarettes. These websites can obtain cigarettes from many different sources: tribal manufacturers, illicit manufacturers, foreign manufacturers (gray market), distributors in low tax jurisdictions and peddlers of counterfeit. “The Internet may also play a role in connecting domestic buyers with foreign suppliers of illegal tobacco products.”⁶⁶ The current internet business model relies on avoidance of taxes and other regulations in order to provide inexpensive cigarettes. “Offshore cigarette websites often remove the cigarettes from their original packaging and disguise them [to look like books] to avoid detection by customs agents.”⁶⁷

“[U]sing the internet to market and sell cigarettes is a simple, straightforward exercise. There are few barriers to entering this market. In less than one month, an entrepreneur can set up a website, register with the top search engines, identify a wholesaler, secure inventory, set up delivery with United Parcel Service, and sell cigarettes directly to consumers. Estimated startup costs are less than \$3,000.”⁶⁸

Youth access is a significant issue with cigarette sales through the internet. As then-Connecticut Attorney General Richard Blumenthal stated, “Internet tobacco sales outlets almost never make a meaningful effort to enforce age restrictions.”⁶⁹ Of the twenty-seven sites examined in a study recently conducted by the American Wholesale Marketers Association, only two required submission of a driver’s license to ensure the sale was legal.⁷⁰ The study concludes that given the “lack of meaningful controls by 25 of the 27 sites studied, it can be concluded that an under-age person can easily find and purchase cigarettes online with no difficulty.”⁷¹ “Most Internet cigarette sales are completed without payment of proper state and local taxes and violate laws regarding sales to minors.”⁷² Furthermore, in 2007, “78 percent of [Internet cigarette vendors] advertised that they sold cigarettes ‘tax free.’”⁷³

The relatively easy access and ability for minors to obtain cigarettes over the internet is supported by a JAMA research study. The authors recruited non-smoking minors ages 15 and 16 and asked them to “find an Internet tobacco vendor on their own; purchase 1 carton of cigarettes

⁶⁶ NRC Illicit Trade Paper, *supra* note 15, at 191.

⁶⁷ Kwon, *supra* note 49.

⁶⁸ John H. Knowles, Kay L. Wanke & Ichiro Kawachi, *Internet Sales of Tobacco: Heading Off the New Epidemic*, 25 J. PUB. HEALTH POL’Y 58, 61 (2004). Although there are more legal barriers to entry now than in 2004, such as agreements by the major delivery services not to deliver cigarettes and a federal prohibition on using the U.S. Postal Service for cigarettes, *see* 18 U.S.C. § 1716E (2018). Internet sellers still disguise cigarettes as other products and use these delivery services. Other delivery services also have stepped in to fill the vacuum, particularly for Native American sellers.

⁶⁹ Richard Blumenthal, *Tobacco Control: A State Perspective*, 3 YALE J. HEALTH POL’Y L. & ETHICS 150, 154 (2013).

⁷⁰ *Internet Cigarette Sales—an Illegal Rip-off of Our Nation* 7 (Am. Wholesale Marketers Ass’n, 2010).

⁷¹ *Id.*

⁷² NRC Illicit Trade Paper, *supra* note 15, at 117.

⁷³ Kurt M. Ribisl et al., *Effectiveness of State and Federal Government Agreements with Major Credit Card and Shipping Companies to Block Illegal Internet Cigarette Sales* (Joseph Ross ed. 2011), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0016754>.

using their parents' credit card; lie about their age and birth date when asked; and have the carton delivered to their home."⁷⁴ Tellingly, twenty-nine out of thirty of these minors found a tobacco vendor and placed an order within approximately 20 minutes. In fact, many were able to find a site and place an order within only 7 minutes.⁷⁵ Fourteen different internet sites were used by the participating youth. Thirteen sites required the participants to click a box indicating that they were old enough to make the purchase, and only one site required entering an actual birth date.⁷⁶ Twenty-three of the 30 youth received the tobacco they had purchased in the mail, and 91% of products were delivered without requests for proof of age.⁷⁷ Notably, the average cost of a cigarette carton online was \$22.91 compared to \$43.00 at a competing California store—demonstrating a huge savings to online consumers. The ease with which the youth in this study were able to locate and obtain tobacco products over the Internet is nothing short of astonishing. "Such results strongly suggest that it is easier and cheaper for youth to purchase tobacco online than from other commercial sources."⁷⁸

In recent years, government agreements with credit card and major shipping companies to ban transactions and shipments of internet cigarette sales have been effective in limiting the internet as a means for illegal purchases. In addition, passage of the Prevent All Cigarette Trafficking Act ("PACT Act") in 2010 imposed more requirements on internet cigarette sellers and provided new federal and state enforcement tools.⁷⁹ Currently, however, there are ways to evade the law and avoid the agreements: Internet vendors now accept other forms of payment (such as Bitcoin), and they can use other delivery options or disguise their product.⁸⁰

Internet sales are especially difficult to quantify and to control owing to the nature of the internet itself. Notably, the layers of the internet go far beyond the surface content that we generally see in our daily lives. As depicted below, beyond the content that is indexed by traditional search engines such as Google, lies the so-called "Deep Web," and within that, the "Dark Web."⁸¹ The Dark Web "contains content that has been *intentionally* concealed. The Dark Web may be used for legitimate purposes as well as to conceal criminal or otherwise malicious activities. . . ."⁸² It is ready-made for a large scale and uncontrolled market for all manner of black market trade.

⁷⁴ Jennifer A. Jensen et al., *Availability of Tobacco to Youth Via the Internet*, 291 JAMA 1837, 1837 (2004).

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

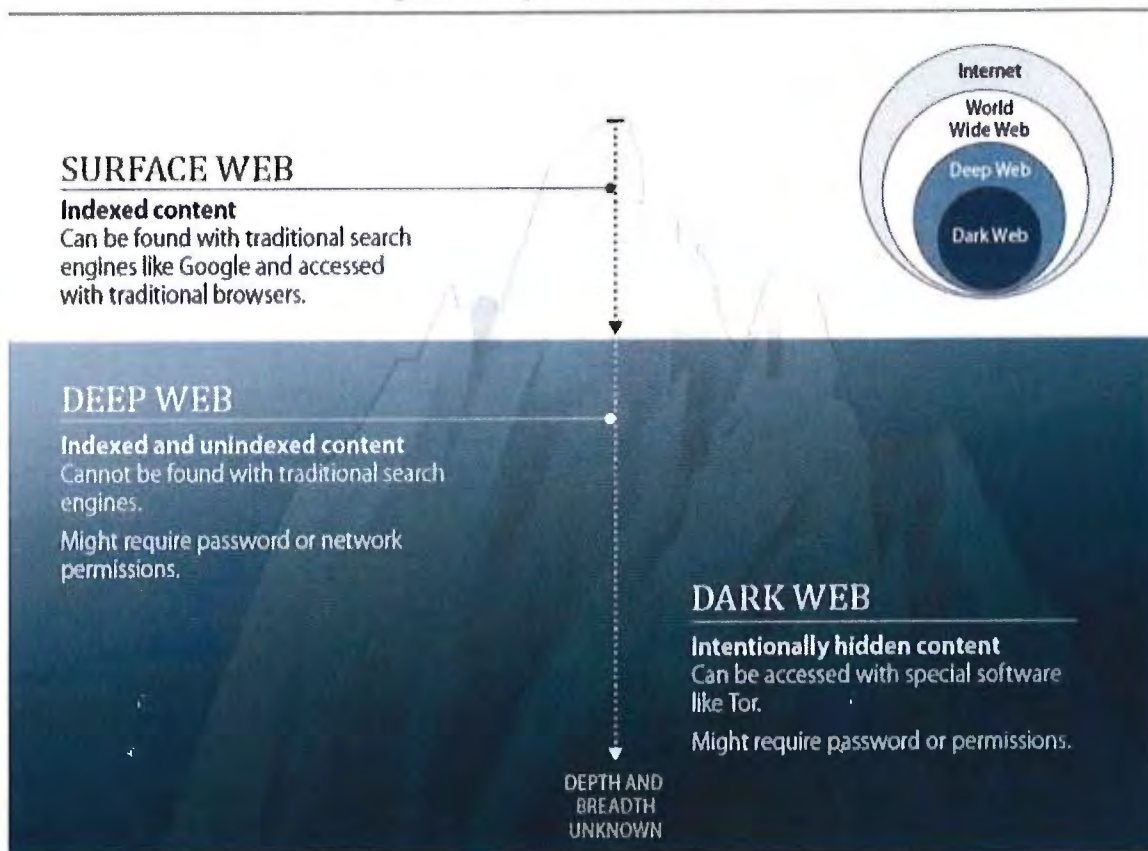
⁷⁹ 15 U.S.C. §§ 375-378 (2018).

⁸⁰ NRC Illicit Trade Paper, *supra* note 15, at 191.

⁸¹ KRISTIN FINKLEA, CONG. RESEARCH SERV., R44101, DARK WEB 3 (2017).

⁸² *Id.*, Summary.

Figure 1. Layers of the Internet

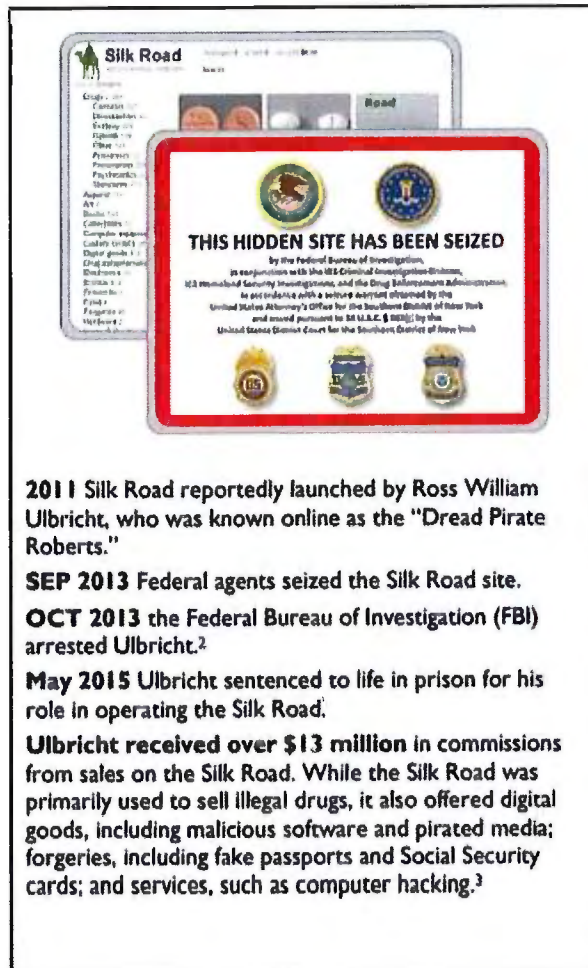


Source: Congressional Research Service (CRS).

Note: Proportions in the figure may not be to scale.

“Take for instance the Silk Road—one of the most notorious sites formerly located on the Dark Web. The Silk Road was an online global bazaar for illicit services and contraband, mainly drugs. Vendors of these illegal substances were located in more than 10 countries around the world, and contraband goods and services were provided to more than 100,000 buyers. It has been estimated that the Silk Road generated about \$1.2 billion in sales between January 2011 and September 2013, after which it was dismantled by federal agents” as indicated below.⁸³

⁸³ *Id.* at 1.



Although law enforcement's efforts with respect to this particular illegal drug website were successful, Section V describes why this type of enforcement, which was created to combat illegal drugs, is not and will not be a priority for law enforcement in combating the illegal trade in tobacco products.

C. History of the Cigarette Black Market in the United States and the Numerous Failed Attempts to Mitigate the Problem.

The cigarette black market easily adapts to change. History shows that when federal or state officials focus on or ban one type of product, the black market finds a way to supply consumer demand. Although black market trade in cigarettes has been around for decades, it began to increase around 1998 as the Master Settlement Agreement and increased state taxes resulted in price increases. As shown in the table below, the sale of black market cigarettes began to attract attention with the sale of gray market cigarettes in the late 1990s, which were not then illegal. Following passage of state and federal laws prohibiting sales of gray market cigarettes, the black market shifted to counterfeit, then to internet sales and most recently to smuggled and illegally manufactured tribal cigarettes. In each stage, the market reacted to increased enforcement against one type of contraband and quickly adjusted to the new circumstances.

YEARS	TYPES OF CONTRABAND	ACTIONS TO ATTEMPT TO MITIGATE
1998 – 2000	Gray market cigarettes begin appearing at retail stores in the domestic markets following the signing of the Master Settlement Agreement and domestic price increases. ⁸⁴ At that time, the price of cigarettes manufactured for export was a fraction of the price of those manufactured for domestic consumption. Even with the costs of export, return shipping, and customs duties and taxes, the gray market cigarettes still could be sold for less than their domestic counterparts. Neither state nor federal laws clearly prohibited the sale of gray market cigarettes.	States began passing gray market laws in the late 1990s, followed by the passage in 2000 of the federal Imported Cigarette Compliance Act (“ICCA”). The ICCA prohibited importing cigarettes into the United States bearing U.S. registered trademarks, without the trademark owner’s permission. These laws gave states and the federal government tools to prevent and prosecute gray market sales.
2002 – 2004	Rise in incidence of counterfeit cigarettes . This rise occurred as state cigarette taxes began to increase and the presence of gray market products decreased in the market due to new enforcement tools.	Counterfeit cigarettes became less prevalent only after PM USA sued over 3,000 entities for the sale of counterfeit Marlboro cigarettes.
2002 – present	Internet sales grew rapidly in the early 2000s to become a significant portion of nationwide cigarette sales. Analysts estimate that internet-based remote cigarette sales grew from approximately 2% of total domestic cigarette sales in 2002, to as high as 14% in 2005, comprising 50 billion cigarettes and revenues of over five billion dollars. ⁸⁵	Enforcement actions against Otamedia, the largest international internet seller of gray market cigarettes, resulted in a significant decline in these sales. In November 2004, law enforcement officials seized roughly 150,000 cartons of gray market cigarettes from a DHL plane at JFK Airport that had been sold through Otamedia. ⁸⁶ The seizure followed PM USA’s own

⁸⁴ ALCS’ Brand and Trade Channel Integrity group (“BTCI”) has been actively involved in combating the illicit trade in cigarettes, and has collected data on this type of activity for several years. This information has been obtained from that data, and is based on BTCI’s experience with these matters. Any information in these comments that does not cite to a specific source is based on BTCI’s knowledge and experience relating to combating the illicit trade in tobacco products.

⁸⁵ See *Internet Sales of Tobacco Products—Reaching Kids and Evading Taxes* (Center for Tobacco-Free Kids, Apr. 28, 2008).

⁸⁶ See Erika Martinez, *Crooks Travel Light: Cig Bonanza at JFK*, N.Y. POST, Nov. 17, 2004, <https://nypost.com/2004/11/17/crooks-travel-light-cig-bonanza-at-jfk/>.

	<p>Sellers were both domestic and international. Foreign-based internet cigarette sellers appeared in the early 2000s, selling both gray market and counterfeit. By mid-2005, domestic-based cigarette websites—primarily remote sellers located on Native American reservations—eclipsed the foreign gray-market websites and grew to represent, at one point, over 90% of the total volume of internet cigarette sales.</p>	<p>litigation against Otamedia in which the court transferred Otamedia's domain names to PM USA.⁸⁷</p> <p>In 2005, the major credit card companies and PayPal agreed not to allow their credit cards or payment processes to be used for unlawful purchases of cigarettes over the internet.⁸⁸ Also in 2005, New York's Attorney General reached agreements with the major delivery companies (FedEx, UPS and DHL) to cease delivery of cigarettes to individual consumers.⁸⁹</p> <p>Passage of the PACT Act in 2010 imposed significant requirements on remote sales of cigarettes and prohibited use of the U.S. Mail to ship cigarettes. The PACT Act gave federal law enforcement officials additional tools to fight internet sales, seize cigarettes sold through the internet, and limit delivery options. Most of the internet sites today are based outside the United States and outside the reach of U.S. law enforcement agents.</p>
2010 – present	<p>Tribal manufacturing and state-to-state smuggling began to increase to take the place of internet sales.</p>	<p>There has been a lack of consistent and vigorous enforcement to combat this type of illicit activity.</p>

⁸⁷ *Philip Morris USA Inc. v. Otamedia Ltd.*, 331 F. Supp. 2d 228, 233 (S.D.N.Y. 2004).

⁸⁸ BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES, ATTORNEYS GENERAL AND ATF JOINT INITIATIVE WITH CREDIT CARD COMPANIES (Mar. 17, 2005) (press release).

⁸⁹ See Attorney General of the State of New York's Assurance of Discontinuance in the Matter of DHL Holdings USA, Inc., and DHL Express (USA), Inc. (Jul. 1, 2005); Attorney General of the State of New York's Assurance of Discontinuance in the Matter of United Parcel Service, Inc. (Oct. 21, 2005); Attorney General of the State of New York's Assurance of Compliance in the Matter of Federal Express Corporation, and FedEx Ground Package Systems, Inc. (Feb. 3, 2006).

D. Tax Increases and Differentials are the Primary Drivers of the Current Cigarette Black Market.

Taxation imposed on cigarettes at the federal and state levels is undeniably an enormous driver of illicit trade in cigarettes. It encourages black market sellers to capitalize on the price differentials between jurisdictions. The figure below, from a GAO report on black market tobacco, gives examples of various illegal trade schemes, identifies their relationship to the supply chain, and indicates the taxes and fees that can be avoided using each scheme. Notably, “schemes that avoid federal excise taxes originate earlier in the supply chain.”⁹⁰

Figure 17: Illicit Trade Schemes Profit by Evading Taxes and Fees

Relationship to supply chain	Examples of illicit trade schemes	Taxes and fees avoided			
		Customs duty	Federal excise tax	State/local excise tax	MSA/escrow payment
Import	<ul style="list-style-type: none"> Smuggling genuine or counterfeit cigarettes into the United States Purchasing cigarettes from foreign Internet Web sites without appropriate payment of tax 	✓	✓	✓	✓
Export	<ul style="list-style-type: none"> Diverting export-only cigarettes into U.S. commerce 	NA	✓	✓	✓
Manufacture	<ul style="list-style-type: none"> Manufacturing cigarettes in the United States without a license Underreporting cigarette production to federal government 	NA	✓	✓	✓
Wholesale/distribution	<ul style="list-style-type: none"> Purchasing tobacco products from wholesaler in one state for illegal transportation and resale in another state Underreporting tobacco product sales to state governments 	NA	Paid	✓	✓
Retail	<ul style="list-style-type: none"> Purchasing tobacco products from retailer in one state for illegal transportation and resale in another state Purchasing cigarettes in Indian country for resale to nontribal members Purchasing cigarettes from domestic Internet Web sites without appropriate payment of tax 	NA	Paid	✓	✓
Other	<ul style="list-style-type: none"> Underreporting cigarette sales to MSA states 	NA	Paid	Paid	✓

Source: GAO analysis.

Note: In some wholesale/distribution and retail schemes, state excise taxes are paid in the state where the tobacco products are purchased, but unpaid in the state where the tobacco products are illicitly resold.

John D’Angelo, a then-spokesman for ATF, and now Assistant Special Agent in Charge at ATF, stated “[t]here is no doubt that there’s a direct relationship between the increase in a state’s tax to an increase in illegal trafficking.”⁹¹ This correlation—increased taxes resulting in increased black market trade—was confirmed in an expansive study of cigarette taxes and black market trade in Europe. Analyzing data from 1999 to 2013 in the European Union, researchers found that “[a]t higher prices (more precisely, at higher differentials between licit and black-market prices) consumers substitute more toward illicit cigarettes.”⁹² Accordingly, “raising prices in any one country would, on average, lead to substantial increases in the expected illicit market share

⁹⁰ See GAO-11-313, *supra* note 19.

⁹¹ Marisa Schultz, *Raised Tax on Smokes May Stoke Illicit Sales*, THE DETROIT NEWS, Jul. 21, 2002.

⁹² James E. Prieger & Jonathan Kulick, *Cigarette Taxes and Illicit Trade in Europe*, Abstract (Feb. 22, 2018), <http://dx.doi.org/10.2139/ssrn.2718519>.

and volume in that country.”⁹³ Specifically, a “one euro increase in tax per pack in a country is expected to increase illicit market share by 5 to 12 percentage points and increase illicit cigarette sales by 25% to 120% of the average consumption.”⁹⁴

New York also provides a clear example of high cigarette taxes resulting in a black market problem.⁹⁵ As of 2011, New York City held the top position as the highest net importer of black market cigarettes, with “smuggled cigarettes totaling a staggering 60.9 percent of the total market.”⁹⁶ Not coincidentally, New York also “has the nation’s highest state cigarette tax at \$4.35 per pack, plus another \$1.50 levied in New York City.”⁹⁷ As researchers have recognized:

[L]ike other forms of prohibition, [high taxing] has led to a spike in smuggling-related criminal activity as smokers turn to illicit distribution channels. . . . The destructive consequences of rampant tobacco smuggling include the corruption of government officials, violence, theft, counterfeiting and dangerous, adulterated products.⁹⁸

When the New York City tax per pack of cigarettes increased from \$0.08 to \$1.50 in 2002, street vendors, dubbed the “\$5 Man,” openly sold black market cigarettes without paying New York taxes. “The \$5 man was the commonly used term for a highly visible network of bootleggers who appeared after the [2002] tax increase throughout the community on street corners, in busy shopping areas, outside subway entrances, and in apartment buildings.”⁹⁹ At that time, the retail prices averaged \$7.50–\$8.00 per pack.¹⁰⁰ More recently, small neighborhood-based grocery stores (also called bodegas) that compete against a large number of similar local stores and larger more distant supermarkets, have become a popular place for the sale of black market cigarettes. While records indicate that bootlegged cigarettes have been sold in New York, including bodegas, since at least the 1960s,¹⁰¹ in more recent years, there has been a reported rise in the number of stores that engage in the sale of bootlegged cigarettes.¹⁰² Statistics from the Tobacco Task Force Office of Tax Enforcement of the New York City Department of Finance (2016), Office of the Sheriff, which conducts regulatory inspections of stores that hold a cigarette license, show that “between August 1, 2011 and December 31, 2015, 49.7 percent (1,980) of the

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ See *infra* Section II.C.3.

⁹⁶ Michael D. LaFaive & Todd Nesbit, *Higher Cigarette Taxes Create Lucrative, Dangerous Black Market* (Mackinac Ctr. for Pub. Pol’y, Jan. 8, 2013), <https://www.mackinac.org/18128>.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Donna Shelley et al., *The \$5 Man: The Underground Economic Response to a Large Cigarette Tax Increase in New York City*, 97 AM. J. OF PUB. HEALTH 1483, 1484 (2007). This article also cites reporting in local newspapers that popular brands of cigarettes could be purchased from bootleggers for as little as \$5.00 per pack.

¹⁰⁰ *Id.* at 1483.

¹⁰¹ See, e.g., Patrick Fleenor, *Cigarettes Taxes, Black Markets, and Crime Lessons from New York’s 50-Year Losing Battle*, 468 POL’Y ANALYSIS 1, 6-9 (Feb. 6, 2003); M. Arnold, *Illegal Cigarettes Still Selling Well Despite Penalties: Bootlegged*, N.Y. TIMES, Oct. 2, 1966.

¹⁰² Scott MacFarlane & Rick Yarborough, *The Tobacco Trail: Smuggling Cigarettes Out of Virginia*, NEWS4 (Nov. 25, 2013) (quoting New York City Sheriff Edgar Domenech: “[f]orty-eight to 49 percent of the stores in New York City are selling inappropriately taxed cigarettes”), <https://www.nbcwashington.com/investigations/The-Tobacco-Trail-Smuggling-Cigarettes-Out-of-Virginia-233392681.html>.

stores inspected sold bootlegged cigarettes.”¹⁰³ In 2009, almost “one-half of all New York smokers reported purchasing cigarettes from low-tax locations, such as Native American reservations, the Internet, duty-free shops, by mail from toll-free telephone numbers, neighboring states, and Canada.”¹⁰⁴

The figure below demonstrates the tax difference between a lower-tax and a higher-tax jurisdiction—Richmond, Virginia v. New York City, New York.¹⁰⁵

Figure 15: Tax Differentials for a Pack, Carton, and Domestic Case Between New York, New York, and Richmond, Virginia, 2010

	Pack	Carton	Case
			
New York City	\$6.86	\$68.60	\$4,116.00
Richmond	1.31	13.10	786.00
Differential	\$5.55	\$55.50	\$3,330.00

Source: GAO analysis.

The South Bronx is well-known as “one of the hot spots of the illegal cigarette trade in the United States.”¹⁰⁶ While the percentage of the total cigarette market represented by illicit sales in New York is estimated to be near 45 percent,¹⁰⁷ collections of discarded cigarette packs indicate that in some parts of New York City, and especially in economically deprived neighborhoods such as the South Bronx, this share is even higher.¹⁰⁸ In a study conducted in the South Bronx, almost every participant “routinely and knowingly purchased and consumed illicit cigarettes.”¹⁰⁹ The participants smoked legal cigarettes “only when illicit cigarettes were not

¹⁰³ Klaus von Lampe & Marin K. Kurti, *The Illegal Cigarette Trade in New York City*, 19 TRENDS IN ORGANIZED CRIME 329, 341 (2016).

¹⁰⁴ NRC Illicit Trade Paper, *supra* note 15, at 149.

¹⁰⁵ GAO-11-313, *supra* note 19.

¹⁰⁶ Klaus von Lampe et al., *I Wouldn't Take My Chances on the Street—Navigating Illegal Cigarette Purchases in the Bronx*, J. OF RES. IN CRIME AND DELINQUENCY 1, 7 (2016).

¹⁰⁷ NRC Illicit Trade Paper, *supra* note 15, at 102-03.

¹⁰⁸ Marin Kurti et al., *The Intended and Unintended Consequences of a Legal Measure to Cut the Flow of Illegal Cigarettes Into New York*, 105 AM. J. OF PUB. HEALTH 1, 6 (2015).

¹⁰⁹ Von Lampe, *supra* note 106, at 11.

available, which was rarely the case.”¹¹⁰ While a substantial number of participants reported buying illegal cigarettes in packs, the majority indicated that they primarily or exclusively purchase “loosies”—single cigarettes for one dollar or three for two dollars. The reason for purchasing these single black market cigarettes is simple—the consumers “could not afford to spend several dollars at a time on a whole pack of cigarettes[,]”¹¹¹ which, by law, are sold in packs of twenty so that youth are less likely to have access to them.¹¹²

Although the cost savings from buying loosies as opposed to legal packs were fairly modest—at a unit price of \$0.50 “20 loosies cost \$10.00 compared to about \$12.50 for a legal pack of 20 cigarettes”¹¹³—that modest price differential was enough to render the legitimate cigarettes unaffordable and drive consumers to the black market. Moreover, “[c]onvenience also played a role in all illicit purchases, given that participants reported illicit cigarettes to be readily available in their neighborhood.”¹¹⁴ In fact, different techniques were reported by smokers to identify whether illegal cigarettes are sold in a neighborhood. “For example, a ‘lighter hanging from a string’ was viewed as a clear signal that a store sells loosies (Anita, female, 18–24).”¹¹⁵ The South Bronx study demonstrates that the methods used for accomplishing black market trade are highly adaptable and aim to satisfy consumer demand. It is undeniable that the “increasing cost of cigarettes related to tax and other factors has had the unintended consequence of contributing to an informal economy where single cigarettes as well as other low-cost tobacco products are readily available.”¹¹⁶

As of 2014, the price of black market cigarettes in New York City was about \$8-9, while the average price of legally retailed packs was around \$13.¹¹⁷ The New York City Sheriff’s Office,

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² Although illegal under state and federal laws, selling “loosies” on the black market is prevalent in urban, low socio-economic communities. Through the Master Settlement Agreement in 1998 with the states (and previous settlements), cigarette manufacturers agreed not to manufacture or sell cigarettes in packages of less than twenty for a period of five years. One of the main goals of this measure was to reduce youth access to cigarettes. *See, e.g.,* National Association of Attorneys General, *The ABCs of the Tobacco Master Settlement Agreement*, 1 NAAGAZETTE ARCHIVE, http://www.naag.org/publications/naagazette/volume_1_number_2/the_abcs_of_the_tobacco_master_settlement_agreement.php. Additionally, the TCA prohibits the sale of cigarettes in packages containing fewer than twenty cigarettes. 21 C.F.R. §§ 1140.16(b), 1140.14(d) (2018). The sale of “loosies” occurs regularly in certain areas in the United States, despite their illegality.

¹¹³ Von Lampe, *supra* note 106, at 11.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 14.

¹¹⁶ Frances A. Stillman et al., *Out of View but in Plain Sight: The Illegal Sale of Single Cigarettes*, 91 J. URBAN HEALTH 355, 362 (2014).

¹¹⁷ A seller of illicit single cigarettes told a reporter in 2014: “Everybody on Staten Island know[s] if you want to pay \$8 for a pack of cigarettes, go to Bay Street. Any place else is \$9 and better.” Solange Uwimana, *How illegal Cigarettes Get Smuggled and Sold in New York City*, VICE (Oct. 23, 2014), https://vice.com/en_us/article/bn5333/i-spent-a-day-with-a-guy-selling-illegal-cigarettes-on-the-streets-of-nyc-1023. This article also refers to licit prices of a pack of cigarettes in the range of \$11-15, with an average of approximately \$13. *Id.* For another contemporaneous source citing an \$8/pack street price for illegal cigarettes in New York City and an average licit price of \$13, see Christopher Mathias, *Inside New York City’s Dangerous, Multimillion-Dollar Cigarette Black Market*, HUFFINGTON POST (Apr. 3, 2014, updated Dec. 6, 2017), https://huffingtonpost.com/2014/04/03/cigarette-smuggling-new-york-n_5041823.html (“Down the street, walk into another bodega and ask for cigarettes, and the clerk will go into a back room to get you a pack. The price: \$8.”).

the agency tasked with fighting evasion of tobacco taxes in the city, notes the competitive disadvantage to retailers of fully taxed cigarettes that the discount for black-market product creates: “‘If one store is selling Virginia cigarettes at \$8 or \$9 a pack, it unfairly costs honest businesses money If you’re not selling (bootlegged) cigarettes, then you’re not getting people to come in to buy the soda and to buy the lotto tickets. They’re really at a competitive disadvantage to get customers in the store if they’re selling legitimate cigarettes at \$12.75, \$14, \$15 a pack.’”¹¹⁸

Like New York, the City of Chicago also provides a telling example of the nexus between high cigarette taxes and a thriving black market. In 2013, Cook County increased its cigarette tax, bringing the total city, county and state taxes to \$5.66 per pack. Per an official in Cook County, the standard price difference between Chicago and the rest of the state was approximately \$5 on a \$12 legal pack of cigarettes, driving a robust black market in Chicago.¹¹⁹

As these specific examples demonstrate, there is no question that tax increases and differences in price due to tax levels are principal drivers of the vibrant and versatile cigarette black market in the United States.

E. The Cigarette Black Market Remains Substantial, Dynamic, and Adaptable.

As the FDA is undoubtedly aware, the current cigarette black market in the United States is substantial.¹²⁰ It is no secret that the volume of cigarettes smuggled from lower tax to higher tax jurisdictions is big business. Indeed, as many as one-fifth of the cigarettes smoked in the United States are not taxed in the same state where they are consumed.¹²¹ Using its own estimate and plausible estimates from other methods, the National Research Council and the Institute of Medicine of the National Academy of Sciences “determined that the percentage of the total market represented by illicit sales in the United States is between 8.5 percent and 21 percent. This range represents between 1.24 to 2.91 billion packs of cigarettes annually and between \$2.95 billion and \$6.92 billion in lost gross state and local tax revenues.”¹²² Illicit trade in tobacco products, including cigarettes, is “a large and growing economic activity in the U.S.”¹²³ It is beyond dispute that illicit trade is increasing, and not decreasing.

¹¹⁸ Frank Green, *Efforts to Curb Illicit Cigarettes Sold Widely in New York City*, RICHMOND TIMES-DISPATCH (Mar. 14, 2015) (quoting Maureen Kokeas, New York City Sheriff’s Office), https://richmond.com/news/efforts-to-curb-illicit-cigarettes-sold-widely-in-new-york/article_1e46495b-1be8-54d4-b726-b93ad8886ce3.html.

¹¹⁹ Ted Cox, *Untaxed Cigarettes Targeted by Cook County*, DNAINFO (Sept. 12, 2013), <https://www.dnainfo.com/chicago/20130912/downtown/untaxed-cigarettes-targeted-by-cook-county/>.

¹²⁰ ALCS’ BTCI, on behalf of PM USA, Philip Morris Duty Free, Inc., USSTC., and more recently, on behalf of JMC, Nu Mark, and Nat Sherman, regularly submits reports to TTB and ATF in support of efforts to address the illegal trade in tobacco products and in connection with provisions set forth in Section 920(d) of the TCA (21 U.S.C. § 387t (2009)).

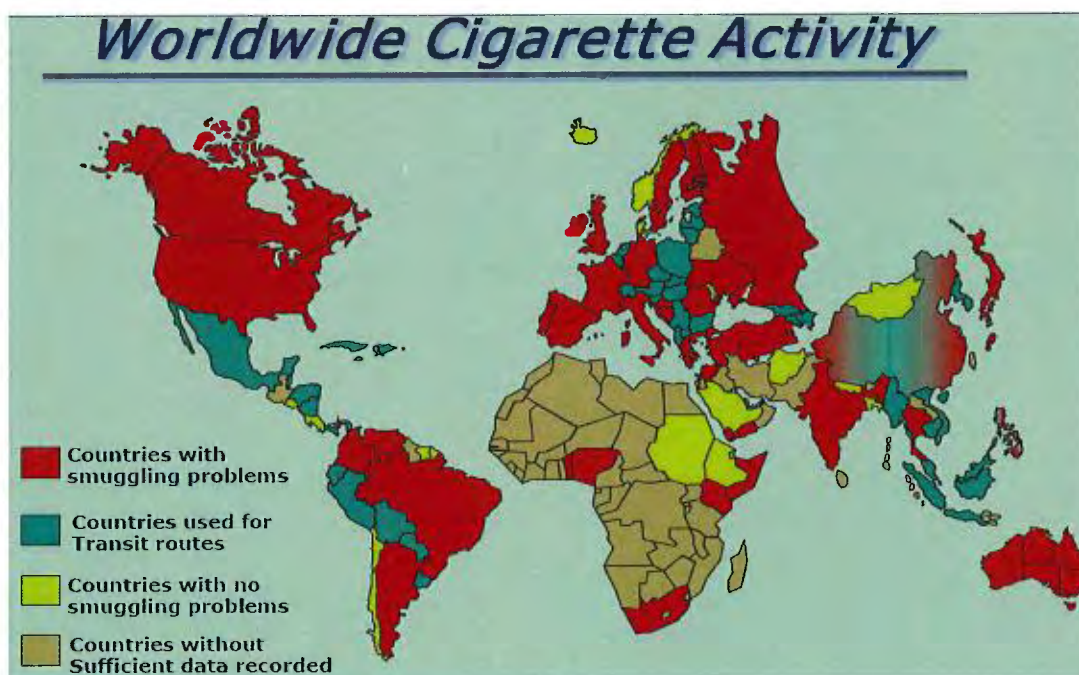
¹²¹ Brian V. Fix et al., *A Novel Approach to Estimating the Prevalence of Untaxed Cigarettes in the USA: Findings from the 2009 and 2010 International Tobacco Control Surveys*, 23 TOBACCO CONTROL i61, i64 (2014).

¹²² NRC *Illicit Trade Paper*, *supra* note 15, at 4; Kulick et al., *supra* note 17, at 1.

¹²³ Kulick et al., *supra* note 17, at 1; NRC *Illicit Trade Paper*, *supra* note 15, at 108 (“[T]he net percentage of sales subject to tax evasion and avoidance grew from 3.2 percent in 1992-1993 to 8.5 percent in 2010-2011.”).

According to federal and state law enforcement officials and experts, the patterns of black market cigarette smuggling and diversion schemes are not static, but change in response to many factors, including changes in tobacco taxes, tobacco regulations, and law enforcement activity. “Officials characterize illicit trade in tobacco products as like a whack-a-mole problem, stating that although illicit trade may decrease immediately following successful law enforcement efforts, these activities usually resume after a period of time.”¹²⁴ Officials from ATF also noted that black market trade in cigarettes is “often connected to other crime and criminals may use proceeds from illicit trade in tobacco to fund other crimes.”¹²⁵

On a global scale, “[i]llicit trade in cigarettes is the biggest illegal trade in a legal product in terms of value and second only to illegal drugs in terms of revenue generated by smugglers.”¹²⁶ Euromonitor International 2012 estimates 600 billion cigarettes—10% of all cigarettes consumed worldwide—are illegal. Governments lose between \$40 and \$50 billion in taxes each year.¹²⁷ Indeed, “[t]he illegal trade in untaxed cigarettes has come to be recogni[z]ed as a significant problem around the world. According to some estimates, almost one third of the global cigarette exports is funneled into black markets.”¹²⁸



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¹²⁴ GAO-11-313, *supra* note 19, at 16.

¹²⁵ *Id.*

¹²⁶ Euromonitor International, Passport Database.

¹²⁷ *Id.*

¹²⁸ Klaus von Lampe, *Explaining the emergence of the cigarette black market in Germany*, in *THE ORGANISED CRIME ECONOMY, MANAGING CRIME MARKETS IN EUROPE* 209, 209 (Petrus C. van Duyne et al. eds. 2005).

¹²⁹ Jeff Cohen, Associate Chief Counsel, Bureau of Alcohol, Tobacco Firearms and Explosives, U.S. Dep’t of Just., *Illegal Cigarette and Trafficking Legal Issues* (PowerPoint presentation).

Empty discarded pack (“EDP”) surveys demonstrate the severity of the illegal trade in cigarettes. In an EDP study, teams of researchers collect all cigarette packs discarded as litter or in trash receptacles in the public spaces of selected neighborhoods. The packs are then “examined for the absence of local tax stamps, signs of non-authentic packaging or stamps, and other indications of potential tax evasion or counterfeit product.”¹³⁰ An EDP analysis of packs collected in 10 U.S. cities between 2010 and 2014 paint a picture of widespread and varied cigarette black markets, ranging from primarily tax avoidance to counterfeiting.

Specifically, tax evasion and avoidance were demonstrated in all regions, though both were much more prevalent in New York City and Buffalo, New York, than other regions studied. In New York City during the period studied, 62.6% of packs lacked a valid state tax stamp, and in Buffalo the figure was 50.7%. This compares to 17.5% for Boston, 15.9% for Chicago, 8.6% for Miami and 4.4% for Minneapolis. Given that New York State had the nation’s highest taxes (\$4.35 per pack compared to a national average of \$1.48 in 2013), the higher rates of illegal trade in New York metropolitan areas support the view that higher tobacco taxes result in illicit trade.¹³¹

Tax-paid and ITTP [Illicit Trade in Tobacco Products] status of empty discarded cigarette packs in 10 markets, 2010-2014

Market	Applicable state tax not paid, %	Applicable local tax not paid, %	ITTP (Counterfeits + domestic cigarettes without a genuine tax stamp), %
Boston	17.52	17.52	0.84
Buffalo	50.69	50.69	31.38
Chicago	15.92	69.53	0.28
Dallas	7.37	7.37	2.24
Houston	7.92	7.92	0.87
Los Angeles	8.12	8.12	0.63
Miami	8.64	8.64	2.54
Minneapolis	4.40	4.40	0.63
New York City	62.58	73.99	13.71
Oklahoma City	7.79	7.79	1.43

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The EDP researchers catalogued the various methods of black market trade in tobacco products. Such methods include interstate smuggling (marked by tax stamps from the wrong state), packs without a stamp (most likely reflecting interstate smuggling but possibly diversion from Native American reservations), foreign-market packs lacking domestic tax stamps, illicit and cheap whites, packs with counterfeit tax stamps, and counterfeit product. Given the relative ease and low risk of interstate trafficking of genuine domestic cigarettes in the U.S., the market for cheap whites is rather small. At the time of the study, there was some evidence of illicit cheap white

¹³⁰ Aziani et al., *supra* note 38, at Abstract.

¹³¹ See *supra* Section I.D.

¹³² Aziani et al., *supra* note 130, at Tables 5, 8, & 10.

cigarettes in every region, but they were relatively rare, representing less than 1% of discarded packs in each area. The small scale suggests the cheap whites originated from international travelers for personal use. If the option of interstate smuggling of legal product is taken away by a product ban, then cheap whites would likely grow in importance as a potential source of black market supply.

The adaptability of the black market was on full display after the 2010 tax increase in New York. In June 2010, as part of an emergency budget measure, the state of New York raised its cigarette tax from \$2.75 to \$4.35 per pack. In an effort to prevent smokers from circumventing state cigarette taxes, the state also amended its tax law to prevent Native American reservations from selling untaxed cigarettes (which generally do not bear tax stamps) to non-tribal members.¹³³ Interestingly, “[b]efore the tax amendment, 42% of discarded cigarette packs collected in the South Bronx had no tax stamp [(indicating they were purchased from a Native American reservation)]. After the tax law went into effect, the percentage of cigarette packs without tax stamps declined to 6.2%. Simultaneously, the percentage of packs with out-of-state tax stamps rose from 18.3% to 66.3%.”¹³⁴ The bottom line is that after the amended tax law, the supply of black market cigarettes “quickly shifted from one lower-priced jurisdiction [(Native American reservations)] to another [(low-tax states)],” demonstrating the adaptability of the black market.¹³⁵

SECTION II: ESTABLISHING A LOW MAXIMUM NICOTINE LEVEL AND BANNING FLAVORS WOULD SIGNIFICANTLY EXPAND THE CURRENT BLACK MARKET FOR TOBACCO PRODUCTS AND CREATE NEW BLACK MARKETS.

The FDA is considering a prohibition on all conventional cigarettes, and potentially other combustible tobacco products, with nicotine content over a certain amount—a limit of .3, .4 or .5 mg of nicotine per gram of tobacco filler, any one of which would result in a de facto ban on products subject to this standard.¹³⁶ This means that cigarettes, and to the extent the standard is applied to cigars and any other combustible products, at current nicotine levels would effectively be banned. Entire categories of products consumed by millions of people could be taken away. In addition, the FDA also is considering a prohibition on certain flavors used in both combustible and non-combustible tobacco products.¹³⁷

As the FDA acknowledged in its Illicit Trade Paper, many factors could help inform its understanding of the potential demand for black market cigarettes following implementation of a tobacco standard. We analyze below a range of factors currently available to inform the FDA’s analysis and conclude that the low nicotine standards the FDA is considering would create the

¹³³ Martin Kurti et al., *The Intended and Unintended Consequences of a Legal Measure to Cut the Flow of Illegal Cigarettes Into New York City: The Case of the South Bronx*, 105 AM. J. OF PUB. HEALTH 750, 750 (Apr. 2015).

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ See Nicotine ANPRM at 9. In response to the FDA’s nicotine ANPRM, ALCS filed comments today that describe in detail how these contemplated nicotine ceilings are effective product bans, which are unlawful under the TCA.

¹³⁷ See generally Flavor ANPRM.

most expansive black market in cigarettes this country has seen. Applying nicotine standards to other tobacco products and implementing flavor bans across certain tobacco products would further create new black markets. Several analyses support these conclusions. First, economic modeling funded by the FDA indicates that a low nicotine standard would effectively function as a price increase on legitimate cigarettes (similar to taxation) and result in a black market for cigarettes at current nicotine levels.¹³⁸ This is supported by additional economic modeling, which indicates that a nicotine ban alone will result in virtually all combustible cigarettes coming from the black market.¹³⁹ All indicators show that a flavor ban would exacerbate that problem.¹⁴⁰ Second, survey research reveals that many smokers readily admit they will seek out banned products on the black market—an attitude and intention supported by prior examples of consumer actions in response to tax increases. Third, there are notable current and historic examples of consumers seeking banned product in black markets—opioids, cannabis, and alcohol—and it would be naïve to think that a similar response would not result here, particularly given the broad scope of the bans being considered, the lack of acceptable legal alternative products, and the current limited resources available to address the issue.

In light of these factors, it is clear the FDA’s product standards, as currently contemplated, would result in an expansion of the current black market and the creation of new black markets. The actual scope of that problem is less clear, and will obviously depend on numerous factors, including the specific product standards ultimately proposed and the timing of their implementation. The FDA cannot adequately understand the impact of the contemplated regulations on the black market, however, without significant additional research and analysis.

A. The Current Tobacco Black Market Would Expand and New Black Markets Would Emerge Because Low Nicotine and Banned Flavors Are Equivalent to Increases in Price—a Known Driver of Black Markets.

At their core, certain contemplated product standards are prohibitions. By setting a maximum level of nicotine to lower levels, the FDA would effectively ban all current nicotine level cigarettes, and potentially cigars, roll-your-own and other combustible products, which constitute the overwhelming majority of tobacco products currently on the market. One of the logical potential consequences of banning a legal product is the creation or expansion of a black market for that product. The FDA commissioned a study in 2014 to consider the behavioral effects in response to a mandated reduction of nicotine in cigarettes. The authors concluded that reduction in nicotine may be thought of as an increase in the price. Indeed, this correlation between reduction in nicotine and increase in price already has motivated some states to tax e-vapor products based on nicotine levels in an attempt to effectively ban those products.

With respect to flavors, the FDA is considering banning certain flavors not only in combustible tobacco products, but also in the non-combustible products to which smokers might otherwise migrate in response to the nicotine ban or otherwise in the future. Accordingly, the emergence of new black markets also is expected for flavored alternative reduced-harm products.

¹³⁸ Smith et al., *supra* note 11, at 24.

¹³⁹ ALCS comments to Nicotine ANPRM at Section VI.

¹⁴⁰ *Id.*; see also ALCS comments to Flavor ANPRM.

1. A reduction in nicotine has the same effect as a price increase; a reality recognized by an FDA-funded study and a concept already used by states in an attempt to effectively ban certain nicotine products by taxation.

In 2014, researchers from the University of Pittsburgh and the University of Minnesota published a paper entitled “Nicotine reduction as an increase in the unit price of cigarettes: A behavioral economics approach.”¹⁴¹ The paper was supported by the National Institute on Drug Abuse and the FDA Center for Tobacco Products.¹⁴² As the title suggests, the authors looked to apply principles from the field of behavioral economics to the issue of a reduction in nicotine content of cigarettes. One classic tenet of behavioral economics is that taxation drives down consumption of the taxed product.¹⁴³ The authors state that because nicotine is the primary reason people smoke (*i.e.*, a “reinforcer”), “a reduction in nicotine content may be thought of as an increase in the unit price of nicotine.”¹⁴⁴ Accordingly, the authors conclude that a reduction in nicotine content might have the same effect as a price increase, namely, a reduction in smoking.¹⁴⁵ The authors also recognize, however, that given that low nicotine functions like a price increase, “[i]f a nicotine reduction policy is implemented, a black market for nicotine-containing cigarettes is likely to be a concern.”¹⁴⁶

Like the authors in the FDA-funded paper, states across the country also have recognized the connection between nicotine and price. Several states have attempted to tax by nicotine level, as opposed to the overall level of e-liquid or e-juice.

- Oregon lawmakers last year proposed several measures relating to taxation of vapor products. Another bill, H.B. 2056, was introduced which sought to tax by nicotine level—\$.05 per milligram per milliliter of nicotine—as opposed to volume of e-liquid.¹⁴⁷ At the end of the day, the measure failed.
- In Montana, the state legislature considered a bill in 2015, which based the tax on vapor products on the weight of nicotine per milliliter of fluid.¹⁴⁸ The bill would have placed a tax of \$0.0173 per milligram of nicotine on vapor products. The measure ultimately failed.
- The state legislature in Indiana likewise considered imposing a tax on electronic cigarettes at a rate of \$0.0083 per milligram of nicotine in 2015, which also failed.¹⁴⁹

¹⁴¹ Smith et al., *supra* note 11.

¹⁴² *Id.* at 27.

¹⁴³ *Id.* at 23.

¹⁴⁴ *Id.* at 24. Later in the article the authors acknowledge other research suggesting that there are other “reinforcers” besides nicotine, such as cues or conditioning. *Id.* at 26-27.

¹⁴⁵ *Id.* at 27.

¹⁴⁶ *Id.*

¹⁴⁷ H.B. 2056, 79th Leg. Assemb., Reg. Sess. (Or. 2017).

¹⁴⁸ H.B. 579, 64th Leg., Reg. Sess. (Mont. 2015).

¹⁴⁹ S.B. 384, 119th Gen. Assemb., 1st Reg. Sess. (Ind. 2015).

- New Mexico’s legislature considered a \$.04 per milligram of nicotine in vapor product tax in 2015, which did not pass.¹⁵⁰
- North Carolina’s legislature unsuccessfully attempted to levy a tax on vapor products at the rate of \$.03 multiplied by the percent of nicotine concentration in the consumable product and by the volume of the consumable product in milliliters, rounded down to the nearest whole cent.¹⁵¹

For purposes of contemplating the possible unintended consequences surrounding illicit markets, states across the country recognize, as has the FDA, that nicotine is a proxy for price. This is consistent with other experts who have indicated that “state and local levies have grown so onerous in some parts of the country that they almost could be called ‘prohibition by price.’”¹⁵² Such measures taken by states that increase the price of tobacco products will exacerbate the black market consequences of any actions taken by the FDA and undermine the FDA’s efforts to stave off a black market.

2. Because a nicotine ban is equivalent to a price increase, adoption of such a standard would expand the already significant cigarette black market.

There is little dispute that an increase in a tax on cigarettes leads to an increase in illegal trafficking in the black market.¹⁵³ Experts who have studied the issue both domestically and abroad tend to agree. For example, European Union data from 1999 to 2013 demonstrates that “raising prices in any one country would, on average, lead to substantial increases in the expected illicit market share and volume in that country.”¹⁵⁴ Furthermore, tax increases resulting in tax disparities among the states and cities in the United States have repeatedly confirmed that such taxes and disparities create and/or expand black markets in those areas. Raising prices on cigarettes expands the black market for that product. Similarly, a nicotine standard that effectively raises prices on cigarettes will, accordingly, expand the cigarette black market.

Notably, however, the authors of the FDA-funded 2014 behavioral study did not try to quantify how black markets would undermine the very goal of a nicotine reduction strategy. Rather, the researchers left that question to be answered by others.¹⁵⁵ The FDA, however, must answer this question before implementing a nicotine reduction standard.¹⁵⁶

As a starting point, the FDA should consider the economic modeling described in detail in ALCS’ comments to the Nicotine ANPRM. That modeling indicates that, in keeping with the

¹⁵⁰ S.B. 65, 52nd Leg., 1st Sess. (N.M. 2015).

¹⁵¹ S.B. 407, Gen. Assemb., Reg. Sess. (N.C. 2015).

¹⁵² LaFaive et al., *supra* note 96.

¹⁵³ See, e.g., Schultz, *supra* note 91.

¹⁵⁴ Prieger et al., *supra* note 92, at Abstract.

¹⁵⁵ *Id.* at 3-7, 11-12, 32-33.

¹⁵⁶ Scott Gottlieb & Mitchell Zeller, Perspective, *A Nicotine-Focused Framework for Public Health*, J. OF MED. (Sept. 21, 2017), <https://www.nejm.org/doi/full/10.1056/NEJMp1707409>; see also 21 U.S.C. § 387g(b)(2) (2009).

concerns raised by the researchers in the FDA-funded study, a nicotine ban alone will result in virtually all combustible cigarettes coming from the black market.¹⁵⁷

Based on the experience and research cited here, if implemented, the nicotine standards being contemplated by the FDA, coupled with already high federal, state and municipal taxation, would drive significantly more consumers to the black market where they could find cheaper tobacco products with the characteristics they want. These problems would be exacerbated to the extent alternative choices are delayed, restricted, unappealing, and/or prohibited.

3. In addition to an expansion of the cigarette black market, the FDA should expect an expansion of the black market in cigars and other combustible products, and the emergence of a black market for flavored alternative reduced-harm nicotine products.

If the FDA extends its nicotine standard to cigars, roll your own tobacco, and other combustible products,¹⁵⁸ the same analysis would apply, and therefore, black markets likely would emerge for those products as well. Indeed, there is already a black market in certain banned cigars, *e.g.*, Cubans, as well as a black market in roll your own tobacco and other tobacco products; ensuring that any black market would face few barriers to entry.¹⁵⁹ Similarly, the emergence of new black markets also can be expected for flavored alternative reduced harm products if they too were unavailable in the legal marketplace.

B. Survey Research and Other Evidence Indicate that Consumers Have Easy Access to Black Market Tobacco Products, and Would Seek and Obtain Them on the Black Market.

The conclusions from the 2014 behavioral FDA-funded study are supported by actual survey responses about future intended behavior; providing an independent basis for concluding that the contemplated product standards would expand existing, and create new, black markets.

A very-low nicotine content product standard, as contemplated by the FDA and applied to combustible tobacco products, would present smokers with the following options:

- Smoking legal very-low-nicotine content (“VLNC”) combustible products (as a long-term practice or as a transition away from smoking);
- Buying VLNC combustible products and “spiking” them with nicotine in an attempt to create near-substitutes for conventional combustible products;

¹⁵⁷ ALCS’ comments to Nicotine ANPRM at Section VI.

¹⁵⁸ See Nicotine ANPRM.

¹⁵⁹ See, *e.g.*, Jack Kimball, *Cuba’s Cigars: A Black Market Tale of Survival*, REUTERS (Dec. 15, 2011) <https://www.reuters.com/article/us-cuba-cigars/cubas-cigars-a-black-market-tale-of-survival-idUSTRE7BE1N220111215>; see also FDA Illicit Trade Paper at 7 (“RYO cigarettes, while not in widespread use relative to factory-made cigarettes, are easy to make, and instructions for beginners are available on the internet.”).

- Using other nicotine-containing tobacco products such as: e-cigarettes (cig-alikes or tank systems); smokeless tobacco (chewing tobacco, moist smokeless tobacco (“dip”), snus) or oral tobacco-derived nicotine products;
- Using pharmaceutical nicotine replacement therapies (known as “NRTs”) (patches, lozenges, gums, strips, inhalers and nasal sprays);
- Buying black market tobacco products that are imported (genuine branded product, counterfeit, “cheap whites”) or domestic (illegally manufactured, including on reservations); and
- Quitting nicotine use entirely.

More research is needed to predict how many people would pursue each of these options—especially where past experience has been in a world where continued use of tobacco products not subject to the contemplated bans has remained a legal option. Survey research and other evidence, however, suggest a significant number of consumers would turn to the cigarette black market and the black market in other combustible products, as well as create demand for a new black market for non-combustible tobacco products.

For instance, data from a recent survey from smokers in California reveals some details concerning the extent to which smokers will go to obtain the products to which they have become accustomed.¹⁶⁰ The smokers were informed of the date and amount of the planned tax increase on cigarettes in California, and then asked a number of questions about how they planned to respond.¹⁶¹ Almost one-third of the smokers planned to “find ways to get less expensive cigarettes” and over 29% planned to “stock up on cigarettes before the tax goes up.”¹⁶² Indeed, almost half of the smokers surveyed reported that they intended to act in ways that undermine the public health rationale for raising tobacco taxes.¹⁶³ In fact, significant portions of the smoking population indicated that they already engaged in some measure of avoidance and evasion (e.g., buying out of state, buying from sellers who did not pay required taxes) before the new tax increase was even instituted because the current tax rate already rendered the product unaffordable, and acted as a de facto product ban.¹⁶⁴ This survey is consistent with actions taken in 1988 after California raised cigarette taxes by 250%. Although legal cigarette sales dropped by 33%, actual consumption decreased by less than 5%, suggesting that nearly 30% of cigarette volume had migrated to the black market.¹⁶⁵

¹⁶⁰ James E. Prieger & Jonathan Kulick, *Tax Evasion and Illicit Cigarettes in California, Part I – Survey Evidence on Current Behavior*, May 19, 2018 [hereinafter *California Survey Part I*], available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3181586; James E. Prieger & Jonathan Kulick, *Tax Evasion and Illicit Cigarettes in California, Part II – Smokers’ Intended Responses to a Tax Increase*, May 19, 2018 [hereinafter *California Survey Part II*], available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3181617.

¹⁶¹ *California Survey Part II*, *supra* note 160, at 14.

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *California Survey Part I*, *supra* note 160, at 9-13.

¹⁶⁵ Michael D. LaFaive et al., *Cigarette Taxes and Smuggling: A Statistical Analysis and Historical Review* 61 (Mackinac Ctr. for Pub. Pol’y, 2008), <https://www.mackinac.org/archives/2008/s2008-12.pdf>.

Consumers will be further incentivized to resort to the black market where the legal alternatives are undesirable. For example, as further described in ALCS' comments to the Nicotine ANPRM, multiple studies of VLNC cigarettes show that they are not sensorially acceptable to smokers. The VLNC cigarettes were "extremely disliked" and study participants reported that they were "very unlikely" to use such products in the future.¹⁶⁶ In one study, up to 77% of the participants reported that they would "never" switch to VLNC cigarettes.¹⁶⁷ Actual industry experience mirrors the study results. In the late 1980s, PM USA extensively researched and tested a VLNC cigarette it ultimately marketed as "*Next*." Test groups, as large as 4,000 smokers, reported that they preferred their regular brands and would not continue to smoke *Next* cigarettes.¹⁶⁸ The product performed poorly in the marketplace, even after improvements to the product formula and promotional efforts, and was ultimately discontinued.¹⁶⁹ The lack of acceptable alternatives will further fuel the demand for black market cigarettes.

C. History Teaches that This Type of Intervention Inevitably Results in the Expansion and Creation of New Black Markets.

When anticipating the consequences of the FDA's contemplated product bans, it is instructive to look at what in fact happened as a consequence of various levels of government intervention with respect to other products that consumers want. The experience with opioids provides a good example of what happens when the government fails to take into account, and plan for, the unintended consequences of altering a product. While the requirement that opioid manufacturers reformulate their drugs appeared to be a reasonable one, some of the unintended consequences may have been preventable with advanced consideration and planning, or other options may have been more effective in the long run. The experience with cannabis provides an example of the consequences of criminalizing a product in common use. Finally, the experience with Prohibition provides a good example of the unintended consequences of a total ban on a product that millions of people previously consumed legally as part of their lifestyle.

1. Opioids.

The explosive and deadly illegal opioid market provides a recent example of unintended consequences of government intervention that added fuel to an already existing illegal trade. As the FDA and the public are well-aware, the last several years have seen a startling rise in drug overdose deaths involving opioids. In 2016, more than 63,000 people died from drug overdoses, and approximately 66% of those deaths involved an opioid.¹⁷⁰ Indeed, opioids are the main cause of drug overdose deaths.¹⁷¹ Researchers found that the current opioid problem has been made worse by the introduction, in 2010, of an abuse-deterrent formulation of OxyContin that

¹⁶⁶ ALCS' comments to Nicotine ANPRM.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DRUG OVERDOSE DEATHS CONTINUE TO RISE; INCREASE FUELED BY SYNTHETIC OPIOIDS (Mar. 29, 2018) (press release), <https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html>.

¹⁷¹ LISA N. SACCO & ERIN BAGALMAN, CONG. RESEARCH SERV., R44987, THE OPIOID EPIDEMIC AND FEDERAL EFFORTS TO ADDRESS IT: FREQUENTLY ASKED QUESTIONS 8 (2017).

made this prescription drug harder to crush and abuse. The FDA approved the reformulation in 2012.¹⁷² Unfortunately, in response to these agency actions, experts in the field noted a subsequent rise in heroin supply and use.¹⁷³

The new formula made OxyContin pills significantly more difficult to crush and they also dissolved more slowly. According to principal investigator Theodore J. Cicero, PhD, a professor of neuropharmacology in psychiatry, “[t]he idea . . . was to make the drug less attractive to illicit users who wanted to experience an immediate high.”¹⁷⁴ He stated: “‘Our data show that OxyContin use by inhalation or intravenous administration has dropped significantly since that abuse-deterrent formulation came onto the market In that sense, the new formulation was very successful.’”¹⁷⁵ However, “‘[t]he most unexpected, and probably detrimental, effect of the abuse-deterrent formulation was that it contributed to a huge surge in the use of heroin, which is like [the original version of] OxyContin in that it also is inhaled or injected We’re now seeing reports from across the country of large quantities of heroin appearing in suburbs and rural areas. Unable to use OxyContin easily, which was a very popular drug in suburban and rural areas, drug abusers who prefer snorting or IV drug administration now have shifted either to more potent opioids, if they can find them, or to heroin.’”¹⁷⁶ “‘Heroin is a very dangerous drug, and dealers always “cut” the drug with something, with the result that some users will overdose.’”¹⁷⁷

Drug users were surveyed before and after the FDA’s approved reformulation of OxyContin. When users answered a question about which opioid they used to get high “in the past 30 days at least once,” OxyContin fell from 47.4 percent of respondents before the government intervention, to 30 percent.¹⁷⁸ During the same time period, reported use of heroin nearly doubled. In addition to answering a confidential questionnaire when admitted to a drug treatment program, more than 100 of the study subjects also agreed to longer interviews during which they discussed their drug use and the impact of the new OxyContin formulation on their individual choices.¹⁷⁹ Indeed, OxyContin was associated with a 36% decrease in the use of that medicine with a corresponding 42% increase in the use of heroin over the same time frame.¹⁸⁰ Therefore, while this reformulation of a widely abused opioid may have succeeded in reducing its abuse, there clearly were important unintended consequences from such new technologies that were not, but should have been, taken into account prior to governmental action.¹⁸¹

¹⁷² *Id.* at 6.

¹⁷³ *Id.* at 6-7.

¹⁷⁴ Jim Dryden, *OxyContin Formula Change Has Many Abusers Switching to Heroin*, THE SOURCE, WASH. UNIV., ST. LOUIS (July 11, 2012); *see also* Theodore J. Cicero et al., *Effect of Abuse-Deterrent Formulation of OxyContin*, 367 NEW ENGLAND J. OF MED. 187 (July 12, 2012).

¹⁷⁵ Dryden, *supra* note 174 (quoting Cicero).

¹⁷⁶ *Id.* (quoting Cicero).

¹⁷⁷ *Id.* (quoting Cicero).

¹⁷⁸ Cicero, *supra* note 174.

¹⁷⁹ *Id.*

¹⁸⁰ Michael E. Schatman & Beth D. Darnall, *A Practical and Ethical Solution to the Opioid Scheduling Conundrum*, 7 J. OF PAIN RES. 1, 1-3 (2014).

¹⁸¹ *Id.*

“These findings may explain why so many law enforcement officials around the country are reporting increases in heroin use, Cicero says.”¹⁸² Cicero “compares attempts to limit illegal drug use to a levee holding back floodwaters. Where the new formulation of OxyContin may have made it harder for abusers to use that particular drug, the ‘water’ of illicit drug use simply has sought out other weak spots in the ‘levee’ of drug policy.”¹⁸³

Furthermore, while *prescription* opioids historically have been the most common drug involved in overdose deaths, *synthetic* opioids—primarily black market fentanyl—are now the number one killer in opioid-related deaths.¹⁸⁴ A recent report in the Journal of the American Medical Association found that approximately 46% of the 42,249 opioid-related overdose deaths in 2016 involved synthetic opioids such as fentanyl.¹⁸⁵ Significantly, this is more than a three-fold increase from 2010, when synthetic opioids were involved in about 14% of opioid-overdose deaths.¹⁸⁶ Christopher Jones, Director of the National Mental Health and Substance Use Policy Laboratory at the Substance Abuse and Mental Health Services Administration and a lead author of the report, states such figures “track[] very closely with the increased availability of illicit synthetic opioids that are coming into the US.”¹⁸⁷ The vast majority of fentanyl overdose cases are thought to be the result of illicit production and distribution. A senior staff attorney for the nonprofit Drug Policy Alliance commented, “[a]lmost all of the increases in overdose deaths are attributed to illicitly manufactured fentanyl, not pharmaceutical fentanyl that has been misused or diverted. And we know that because the number of prescriptions for pharmaceutical fentanyl has remained relatively stable over the past decade, whereas seizures of illicitly manufactured fentanyl have skyrocketed.”¹⁸⁸ The biggest reason behind this increased use of synthetic fentanyl is cost. Synthetic fentanyl can be produced easily in laboratories in bulk at little cost, and is made almost exclusively in China. Black market fentanyl is typically shipped to Mexico and then enters the United States.¹⁸⁹

Most concerning, fentanyl is increasingly found in counterfeit opioid pills, according to the DEA.¹⁹⁰ This highlights the adaptability of black markets to feed consumer demand. These counterfeit opioids purport to be cheap versions of brand-name prescription opioids, while actually being dangerous and lethal counterfeit products.

¹⁸² Dryden, *supra* note 174.

¹⁸³ *Id.*

¹⁸⁴ Christopher M. Jones et al., *Changes in Synthetic Opioid Involvement in Drug Overdose Deaths in the United States, 2010-2016*, 319 JAMA 1819, 1819 (2018).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ Mark Lieber, *Synthetics now killing more people than prescription opioids, report says*, CNN ONLINE (May 1, 2018) (quoting Christopher Jones), <https://www.cnn.com/2018/05/01/health/fentanyl-opioid-overdose-study/index.html> (last visited Jun. 18, 2018).

¹⁸⁸ *Id.* (quoting Lindsay LaSalle).

¹⁸⁹ *Id.*

¹⁹⁰ DRUG ENFORCEMENT ADMIN., INTELLIGENCE BRIEF, COUNTERFEIT PRESCRIPTION PILLS CONTAINING FENTANYL: A GLOBAL THREAT 2-9 (2016).

2. Cannabis.

The current market in cannabis (marijuana) illustrates the difficulty of containing an illicit market that has a large number of consumers. An estimated 37.5 million people self-report past-year cannabis use, and 24 million of them past-month use. This compares to 61 million past-year cigarette smokers of whom 51 million reported past-month smoking. The most recent official estimate of the size of the cannabis market put it at about half the size of the cigarette market.¹⁹¹

The cannabis market—measured in terms of the amount consumed of the primary psychoactive agent in cannabis, delta-9 tetrahydrocannabinol (known as “THC”)—has multiplied several fold over the past quarter-century. The size of the market has grown both because more cannabis is being consumed and because its potency in terms of THC is rising.¹⁹² Even as effective prices have fallen (due to rising THC content) the dollar volume in the market has roughly quadrupled, making cannabis by far the largest of the illicit drug markets.

One reason for market growth has been changing attitudes toward cannabis, reflected in increasing prevalence of cannabis use, a loosening of legal controls through reduced enforcement activity, and the growth of state-legal marijuana.¹⁹³ Drug enforcement agencies assign cannabis cases a lower priority in part because of the relatively low level of violence associated with these sales compared to sales of other illicit drugs.¹⁹⁴ Another reason for the low enforcement priority is the inability of enforcement to make much difference in the market. Even in times of relatively large—but not necessarily well targeted—expenditures on enforcement, such as the onset of the War on Drugs in the 1980s (when marijuana accounted for about 40% of federal expenditure on drug enforcement), enforcement efforts “did not significantly affect the industry’s ability to deliver its illicit product to consumers.”¹⁹⁵ Finally, over the past decade, due to limits on enforcement resources, concerns about high levels of arrest and incarceration of otherwise law-abiding citizens and about racial disproportion in arrests, there has been less enforcement against the cannabis black market. This lack of enforcement undermines respect for the law and any policy objectives underlying the law.

¹⁹¹ CTR. FOR BEHAV. HEALTH STATS. & QUALITY, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., RESULTS FROM THE 2016 NATIONAL SURVEY ON DRUG USE AND HEALTH: DETAILED TABLES (2017) (marijuana prevalence and frequency: Table 6.1A; tobacco prevalence and frequency: Table 2.1A), <https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf>. For cigarettes, there are 45 million current smokers, of whom 80% (36 million) smoke daily; of those in turn, 75% (27 million) use at least 10 cigarettes per day. *Id.* at Tables 6.7A, 6.7D & 6.7P.

¹⁹² The average THC potency has risen from around 0.7-2% in the 1970s to over 12% in 2012, with some samples testing as high as 36%. PROCON.ORG, *Average Marijuana Potency by Year, 1975-2003* (2009), <https://medicalmarijuana.procon.org/view.additional-resource.php?resourceID=000191> (reporting data from National Institute on Drug Abuse); William Brangham, *Is pot getting more potent?*, PBS NewsHour (Apr. 2, 2014) <https://www.pbs.org/newshour/nation/pot-getting-potent>.

¹⁹³ William A. Galston & E.J. Dionne, *The New Politics of Marijuana Legalization: Why Opinion is Changing* (Brookings, May 29, 2013); Abigail Geiger, *Support for Marijuana Legalization Continues to Rise* (Pew Res. Ctr., Oct. 12, 2016).

¹⁹⁴ See, e.g., LISA N. SACCO & KRISTIN FINKLEA, CONG. RESEARCH SERV., R43164, STATE MARIJUANA LEGALIZATION INITIATIVES: IMPLICATIONS FOR FEDERAL LAW ENFORCEMENT 7 (2014) (stating “[f]ederal law enforcement has generally tailored its efforts to target criminal networks rather than individual criminals; its stance regarding drug (particularly marijuana) offenders appears consistent with this position”).

¹⁹⁵ MARK A.R. KLEIMAN, MARIJUANA: COSTS OF ABUSE, COSTS OF CONTROL 85 (1989).

3. Prohibition.

The Prohibition era provides perhaps the classic example of the vast expansion of black markets in the face of a government ban. When the Eighteenth Amendment went into effect, many believed that the liquor problem that had plagued the nation for decades would disappear. The reality, however, was that “[t]he liquor industry wasn’t dead, of course; a new version, this one illegal, underground, and nearly ubiquitous would emerge with the birth of the dry utopia.”¹⁹⁶ For example, “[i]n the first seven months of the first dry-but-wet year, 900,000 cases of liquor found their way from Canadian distilleries to the border city of Windsor, Ontario. This worked out to roughly 215 bottles of booze for every man, woman, and child in the area.”¹⁹⁷ According to one prominent Prohibition scholar:

The greatest unintended consequence of Prohibition[,] however, was the plainest to see. For over a decade, the law that was meant to foster temperance instead fostered intemperance and excess. The solution the United States devised to address the problem of alcohol abuse had instead made the problem even worse. The statistics of the period are notoriously unreliable, but it is very clear that in many parts of the United States more people were drinking, and people were drinking more.¹⁹⁸

The expansion of the black market during Prohibition was astounding and created “criminal operations of a size and sophistication Americans had never known.”¹⁹⁹ And “the criminal activity that had blossomed at Prohibition’s dawn—largely local, infrequently violent—multiplied in scale and in carnage.”²⁰⁰ In retrospect, this expansion was not surprising given, among other things, the demand for the product and the potential profits to be made in supplying that product.

The money to be made during Prohibition “by violating the Eighteenth Amendment’s proscriptions against the sale, manufacture, and transport of intoxicating liquors was spectacular.”²⁰¹ Emory Buckner, the great trial lawyer and U.S. Attorney during the middle of Prohibition, “believed annual sales of bootleg liquor had reached \$3.6 billion nationally by 1926,”²⁰² which is almost \$51 billion in today’s dollars.²⁰³ At a Senate Judiciary Committee subcommittee hearing in April 1926, Senator William Cabell Bruce of Maryland opened the hearings by addressing the massive tax revenues that had been lost as a result of Prohibition.²⁰⁴ But not only was this tax revenue being lost by the government, “most of the \$443,839,544.98 in liquor tax revenues the federal government had collected in the last fully wet year [over \$5.5

¹⁹⁶ DANIEL OKRENT, *LAST CALL: THE RISE AND FALL OF PROHIBITION* 118 (2010).

¹⁹⁷ *Id.* at 124.

¹⁹⁸ Michael Lerner, *Unintended Consequences*, KUED7 (2011), <http://www.pbs.org/kenburns/prohibition/unintended-consequences/>.

¹⁹⁹ OKRENT, *supra* note 196, at 271-72.

²⁰⁰ *Id.* at 271.

²⁰¹ *Id.* at 274.

²⁰² *Id.*

²⁰³ U.S. Inflation Calculator, <http://www.usinflationcalculator.com> (last checked June 16, 2018).

²⁰⁴ OKRENT, *supra* note 196, at 268.

billion in today's dollars²⁰⁵], he said, was now going into 'the pockets of foreign and domestic lawbreakers.'"²⁰⁶

With the enactment of Prohibition came an avalanche of unintended consequences, including: the expansion of organized crime; increased violence; drastically decreased government tax revenues; eroded respect for the law; overburdened judicial system; and dangerous products, just to name a few. Author and scholar Daniel Okrent concluded:

In almost every respect imaginable, Prohibition was a failure. It encouraged criminality and institutionalized hypocrisy. It deprived the government of revenue, stripped the gears of the political system, and imposed profound limitations on individual rights. It fostered a culture of bribery, blackmail, and official corruption. It also maimed and murdered, its excesses apparent in deaths by poison, by the brutality of ill-trained, improperly supervised enforcement officers, and by unfortunate proximity to mob gun battles.²⁰⁷

The lessons learned from Prohibition undoubtedly influenced the drafters of the TCA, motivating them to include a specific requirement for the FDA to consider the "countervailing effects" of any regulation, "such as the creation of a significant demand for contraband" and other harm from illegal trade in tobacco products.²⁰⁸

The cigarette smuggling infrastructure and operations between the U.S. and Canada, Mexico and the Native American reservations, previously discussed, should be of particular concern because they are already in place and ready to expand. Similar trade routes were used during Prohibition as alcohol flowed from Canada to the United States in such volume that the famous Bronfman family, alone, was believed to have earned nearly \$400,000 (Canadian) a month for its liquor business in Saskatchewan,²⁰⁹ which translates to almost \$4.5 million in today's U.S. dollars.²¹⁰ Prohibition-era smugglers also utilized the maritime limit of the United States to create the infamous "rum row" along the Atlantic coast to supply contraband to Americans. Alarming, and unlike the cigarette black market, prior to the enactment of Prohibition, the smuggling

²⁰⁵ U.S. Inflation Calculator, *supra* note 203.

²⁰⁶ OKRENT, *supra* note 196, at 268; *see also* Extension of Morning Business, 111th Cong., 155 CONG. REC. S6405, S6406 (2009) (Statement of Sen. Durbin, original co-sponsor, commenting prospectively on TCA: "People often say to me: Well, why don't we just ban this product? If I thought that would end smoking in America, I might consider it. But we know better. With 43 million Americans currently addicted, they are not going to quit cold turkey tomorrow. A black market would emerge, and then the next thing you know the underground economy would be sustaining tobacco. That would not be the result we are looking for.").

²⁰⁷ OKRENT, *supra* note 196, at 373; *see also* Mark Thornton, *Alcohol Prohibition Was a Failure* (Cato Inst., July 17, 1991) (concluding that decrease in alcohol consumption was not very significant; consumption rose steadily after an initial drop; resources devoted to enforce Prohibition increased along with consumption; and overall social consequences of Prohibition negated the few benefits).

²⁰⁸ 21 U.S.C. § 387g(b)(2) (2009); *see, e.g., supra* note 206 (original Senate co-sponsor of TCA noting tobacco product ban would create black market and undermine goals of TCA).

²⁰⁹ OKRENT, *supra* note 196, at 150-53.

²¹⁰ Based on the Bank of Canada inflation and currency calculators, available respectively at <https://www.bankofcanada.ca/rates/related/inflation-calculator> (last checked June 16, 2018) and <https://www.bankofcanada.ca/rates/exchange/currency-converter> (last checked June 16, 2018).

infrastructure and operations that would be eventually employed to satisfy America's thirst for alcohol were largely non-existent.

SECTION III: A LARGE BLACK MARKET IN CIGARETTES WOULD BE DETRIMENTAL TO THE PUBLIC HEALTH.

If, as expected, nicotine and flavor product standards expand the existing tobacco black market, they would bring with them a host of negative consequences. As the illegal tobacco trade gets larger, so will the attendant problems. This section catalogues the unintended consequences that would flow from an increase in the black market in tobacco products. In short, an increase in black markets is detrimental to the public health—the expanded black market will: undermine product standards; weaken public health efforts to curb smoking; expose more youth to illegal tobacco products; lead to more criminal activity and violence; expose more youth to black market activities and dangers, and reduce federal and state tax revenues.²¹¹

A. Comprehensive Regulation of All Tobacco Products Sold in the U.S. Undermined, Leading to Additional Risk.

All lawfully sold tobacco products in the United States are subject to regulation by the FDA under the TCA. These requirements include, among other things: premarket review of new or modified products; compliance with any product standards; reporting of ingredients and harmful and potentially harmful constituents; inspections of manufacturing facilities to ensure sanitary conditions; labeling requirements, and marketing restrictions. Federal and state laws impose other requirements, such as state fire safety requirements for cigarettes. Tobacco products on the black market, however, have no such regulatory oversight.

Illegally manufactured cigarettes, for instance, could be designed or manufactured in such a way to present risks that regulated products do not. Indeed, ATF has warned that “[c]ounterfeit cigarettes pose a greater health risk to consumers for these reasons.”²¹² Some sources report finding insect eggs, dead flies, mold, and human feces in counterfeit cigarettes.²¹³ “Furthermore, many contain contaminants[] such as sand and other packaging materials, including bits of plastic.”²¹⁴

By their very nature, tobacco products that are unregulated could present unknown and unknowable risks to consumers. Criminals engaged in counterfeiting have little incentive to

²¹¹ ALCS' comments in response to the Nicotine ANPRM also address some of these and other economic impacts from the product standards being contemplated by the FDA. *See, e.g.*, ALCS' comments to Nicotine ANPRM at Section VI.

²¹² PUB. AFFAIRS DIV., BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES, FACT SHEET: TOBACCO ENFORCEMENT 2 (May 2014).

²¹³ Scott Drenkard, *Tobacco Taxation and Unintended Consequences*, Hearing on Tobacco: Taxes Owed, Avoided, and Evaded, before the U.S. Senate Committee on Finance 5 (Tax Found., July 29, 2014) (written submission); Te-Ping Chen, The Center for Pub. Integrity, *China's Marlboro Country: A Massive Underground Industry Makes China the World Leader in Counterfeit Cigarettes* 3 (June 28, 2009); W. Edryd Stephens et al., *Source and Health Implications of High Toxic Metal Concentrations in Illicit Tobacco Products*, 39 ENVTL. SCI. & TECH. 479 (2005); *see also* Barbara Booth, *The Added Danger of Counterfeit Cigarettes*, 39 ENVTL. SCI. & TECH. 34A (2005).

²¹⁴ FACT SHEET, *supra* note 212, at 2.

consider the health and safety of consumers.²¹⁵ As the House Committee on Energy and Commerce recognized in considering the TCA, “the sudden removal of a legal source for such a product without the type of consideration and review that FDA will be able to conduct might unnecessarily increase the illegal black market risk, which could also pose a health hazard to users.”²¹⁶ In connection with any potential regulatory ban, the FDA must consider “information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products.”²¹⁷

B. Cessation Efforts Thwarted.

The availability of inexpensive, unregulated tobacco products undermines smoking cessation efforts in particular. “[B]y targeting smokers with cheap cigarettes, health authorities fear the counterfeit influx diminishes incentives to quit.”²¹⁸ As an example, in one study, the percentage of smokers who made quit attempts over a seven-month period was lower, by up to half as much, among those buying low- or no-tax cigarettes from Native American reservations than those buying full-priced cigarettes.²¹⁹ “The availability of low-taxed or untaxed cigarettes may inhibit motivation to attempt to quit smoking, thus undermining the public health benefit of higher cigarette excise taxes.”²²⁰ In other words, whether cigarettes are effectively banned by price or by other regulatory efforts, the continued availability of untaxed or unregulated cigarettes undermines quit attempts and subverts the FDA’s public health goals.

C. Increased Youth Access.

Expanding tobacco black markets pose a number of dangers to young people, including increased smoking initiation and continuation. Researchers have noted that “the illicit market may increase underage smoking, and thus contribute to public health costs, through several mechanisms.”²²¹ Because “unlicensed sellers are operating outside the law, they are unlikely to be scrupulous about checking the identification of buyers, hence providing youth[] with a way around the minimum-age restrictions.”²²² Further, “to the extent that the illicit trade creates low-price options for smokers, or lowers prices generally, youth[] (like adults) will smoke more.”²²³ Lowering barriers to youth initiation of smoking is contrary to the FDA’s stated policy goals of reducing underage tobacco use. Additional research is needed to fully understand the dangers

²¹⁵ See *id.*; see also U.S. ATT’Y’S OFFICE, DISTRICT OF N.J., U.S. DEP’T OF JUST., TWENTY-NINE CHARGED IN NEW JERSEY FOR RELATED, INTERNATIONAL SCHEMES TO IMPORT COUNTERFEIT GOODS AND DRUGS, LAUNDER PROFITS 3 (March 2, 2012) (press release) (When asked whether counterfeit products would be harmful to consumers, one indicted individual said, “[a]ll I care about is to make money, other things do not matter.” In response to a statement that business should be done with a clear conscience, he replied “[t]hen go be a monk.”).

²¹⁶ H.R. Rep. No. 111-58, pt. 1, at 38 (2009).

²¹⁷ 21 U.S.C. § 387g(b)(2) (2009).

²¹⁸ Chen, *supra* note 213, at 3.

²¹⁹ Andrew Hyland et al., *Access to Low-Taxed Cigarettes Deters Smoking Cessation Attempts*, 95 AM. J. OF PUB. HEALTH 994, 994 (June 2005).

²²⁰ *Id.* at 995.

²²¹ NRC *Illicit Trade Paper* *supra* note 15, at 73.

²²² *Id.*

²²³ *Id.* (citation omitted).

that product bans would have for youth access. Given the stated goal of combating youth access to tobacco underlying the FDA's regulatory efforts, this fact alone militates against imposing product bans before the resulting unintended consequences on youth initiation are fully understood.

D. Additional Organized Criminal Activity and Violence.

Other predictable, unintended negative consequences of a larger black market include increased criminal activity and violence. It is axiomatic that "[o]rganized crime is more likely to emerge . . . in conditions under which either the State is weak or when the State effectively cedes control by, for example, prohibiting certain activities that are then picked up by organized crime."²²⁴

This is certainly true with respect to cigarettes. The ATF has explicitly stated that, "[l]ike all black market cigarettes, counterfeit cigarettes are used by many organized crime organizations because of the substantial profits that are generated through tobacco diversion. Much of these profits are used by these organizations to fund their other criminal activities, to include international money laundering and possibly terrorism."²²⁵ "While the illegal trade is oftentimes carried out by individuals trying to save money by buying illegal tobacco for personal use, it is carried out on a large scale commercial level and has been linked to organized crime. Criminals are willing to work in the illegal tobacco market because the potential economic benefits have, under current laws, far exceeded the associated risks of getting caught."²²⁶

Indeed, law enforcement nationally has observed that organized crime has moved into the business of cigarette trafficking.²²⁷ "As organized crime turns to Virginia for its supplies of cigarettes, there is an increase in attendant crimes: identity theft/credit card fraud; money laundering; burglaries and robberies of other criminals."²²⁸ The Virginia State Crime Commission concluded that "[i]llegal cigarette trafficking is not a 'cigarette issue.' IT IS AN ORGANIZED CRIME ISSUE."²²⁹

The tobacco black market is "a significant source of income for all levels of organized crime[;] income that is often reinvested to support other criminal activities."²³⁰ James T. Hayes Jr., Special Agent in Charge, Office of Homeland Security, observed that the proceeds from an

²²⁴ Kumar, *supra* note 24, at 2.

²²⁵ PUB. AFFAIRS DIV., BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES, FACT SHEET: AT THE FRONTLINE AGAINST VIOLENT CRIME (March 2010).

²²⁶ COMMISSION ON ILLEGAL TOBACCO, COMMONWEALTH OF MASS., REPORT OF COMMISSION ON ILLEGAL TOBACCO 12 (March 1, 2014), <https://www.mass.gov/files/documents/2018/03/21/dor-other-reports-commission-report-on-illegal-tobacco.pdf>.

²²⁷ VA. ST. CRIME COMMISSION, SJR 21: ILLEGAL CIGARETTE TRAFFICKING 12 (Nov. 13, 2012) (PowerPoint presentation), http://vscc.virginia.gov/FINAL_Cigarette%20trafficking%20November%20presentation.pdf.

²²⁸ *Id.*

²²⁹ *Id.* at 14 (emphasis in original).

²³⁰ ROYAL CANADIAN MOUNTED POLICE, CONTRABAND TOBACCO ENFORCEMENT STRATEGY 5 (2008).

alleged smuggling ring “can be used to fund a host of other criminal acts that threaten national security and public safety of Americans at home and abroad.”²³¹

In addition to funding other illegal activity, black markets have been shown to lead to outbreaks of violence. For example, studies have shown that “[i]llicit drug markets have proven to be particularly susceptible to violence.”²³² Without the ability to use the legal system to settle conflicts, and given the high value of the illegal goods traded, participants in the black markets may resort to violence to enforce discipline in the market. Violence may deter enforcement agencies and potential informants.²³³ Furthermore, the cash nature of black markets lends itself to robbery and other violent crime. Robberies of drug dealers (which may lead to retributive violent response) “are triggered by expectations that dealers carry large amounts of cash or valuable product on their person.”²³⁴ “By definition, black markets are supplied by criminals, and with criminal activity comes the potential for other associated crimes and violence, though to an extent that varies widely by product, area, and period. Illegal drug markets seem particularly prone to violence”²³⁵ The level of violence in a given black market is difficult to predict. As discussed below, it can depend on how profitable the market is and the level of enforcement against the market.

The cigarette black market is no exception to the above phenomena. In 2015, for example, robbers in Virginia accosted two cigarette traffickers loading cigarettes into a vehicle at gunpoint and escaped with \$90,000 worth of cigarettes and \$25,000 in cash.²³⁶ Likewise, in Canada, organized crime has become increasingly involved with the illegal cigarette trade, and crimes associated with tobacco have been increasing—particularly crimes of violence. For example, convenience stores in large metropolitan areas, as well as truck drivers are experiencing break-ins and armed robberies related to tobacco products.²³⁷

In addition to the violence inherent in black markets, the groups involved in the tobacco black markets are increasingly diversifying their criminal conduct. These same groups also are involved in the movement of drugs, weapons, counterfeit cash and money laundering operations, and human smuggling.²³⁸

²³¹ OFFICE OF THE ATT’Y GEN., STATE OF N.Y., A.G. SCHNEIDERMAN & NYPD COMMISSIONER KELLY ANNOUNCE TAKE DOWN OF MASSIVE EASTER SEABOARD UNSTAMPED CIGARETTE TRAFFICKING ENTERPRISE (May 16, 2013) (press release).

²³² Kulick et al., *supra* note 17, at 4.

²³³ Jonathan D. Kulick, James E. Prieger & Mark A.R. Kleiman, *Unintended Consequences of Cigarette Prohibition, Regulation, and Taxation*, 46 INT’L J. OF L. CRIME & JUST. 69, 72 (Sept. 2016).

²³⁴ *Id.* at 74.

²³⁵ *Id.* at 72.

²³⁶ Frank Green, *Cigarette Trafficking Spawning Other Crimes and Possibly Violence*, RICHMOND TIMES-DISPATCH (March 28, 2015), http://www.richmond.com/news/local/crime/cigarette-trafficking-spawning-other-crimes-and-possibly-violence/article_e101477f-1c3d-5117-bcce-f8839f52485c.html.

²³⁷ ROYAL CANADIAN MOUNTED POLICE, *supra* note 230, at 18.

²³⁸ *Id.*

E. More Youth Exposure to Criminal Activity.

Among the effects of the black market in tobacco, the Royal Canadian Mounted Police have concluded that young people are taking up smoking through unrestricted access to cheap, illegal cigarettes.²³⁹ Moreover, “[y]outh are being lured into contraband tobacco activities by the appeal of easy money. Local police have seen the results of youth being involved in organized crime, namely an increase in violent behavior and general disrespect for their community as well as for others. A number of youth, predominantly in Ontario and Quebec, are being exploited by organized crime via the contraband tobacco trade, which can be a gateway to involvement in other criminal activity.”²⁴⁰ Researchers in Canada found that “[t]he use of contraband cigarettes in this age group [14-18 years] is striking.”²⁴¹ “[A]s cigarette distribution moves out of normal outlets and into criminal channels, controls on cigarette purchases by minors erode. Not only does this potentially increase smoking by teen-agers, but it brings more of them into contact with dealers pushing stronger drugs.”²⁴²

F. Significant Reduction in Federal and State Tax Revenues.

Time and again, and as illustrated above, the illegal trade in tobacco has been shown to cause significant reductions in federal and state tax revenues and, indeed, around the world. “Illicit tobacco undermines the effectiveness of tax policies, leads to over []\$40 billion in lost revenue globally, and increases the availability of cheap cigarettes thus increasing consumption and tobacco related deaths in the future.”²⁴³ It is estimated that the illegal trade of cigarettes cost \$5 billion in lost state and federal tax revenues in 2010 and \$7 to \$10 billion in 2014.²⁴⁴ As a percentage, “the total amount of tax revenue lost to the illicit tobacco market is roughly 10 percent of the total tobacco tax due.”²⁴⁵ In fact, “[t]he growth of cigarette smuggling is a key reason why cigarette tax revenues are not keeping pace with tax increases. Between 1992 and 2000, the average state cigarette tax rate increased 64 percent while gross state tax revenues rose only 35 percent. . . . The apparent fall in smoking rates over this period was not nearly enough to account for the revenue shortfall. This suggests that states expecting higher revenues from

²³⁹ *Id.* at 26.

²⁴⁰ *Id.*

²⁴¹ Russell C. Callaghan et al., *Use of Contraband Cigarettes Among Adolescent Daily Smokers in Canada*, 181 CMAJ 384, 385 (2009).

²⁴² Bruce Bartlett, *Cigarette Smuggling* (Nat’l Ctr. for Pol’y Analysis, Oct. 30, 2002), <http://www.ncpathinktank.org/pub/ba423>.

²⁴³ Luk Joossens & Martin Raw, *From Cigarette Smuggling to Illicit Tobacco Trade*, 21 TOBACCO CONTROL 230 (2012).

²⁴⁴ Mark Niquette & Esmé E. Deprez, *Cigarette Smuggling Increase Prompts Crackdown by States*, BLOOMBERG (March 24, 2014), bloomberg.com/news/articles/2014-03-25/cigarette-smuggling-increase-prompts-crackdown-by-states; see also Mark Kleiman, James Prieger & Jonathan Kulick, *Illicit Trade as a Countervailing Effect: What the FDA Would Have to Know to Evaluate Tobacco Regulations*, J. OF DRUG POL’Y ANALYSIS (2016); Kulick et al., *supra* note 233, at 72 (stating “[t]he U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) (2009) estimates that tobacco diversion among states costs over \$5 billion in revenue from unpaid excise taxes annually in the United States”).

²⁴⁵ NRC *Illicit Trade Paper*, *supra* note 15, at 104.

recent cigarette tax increases may never see them.”²⁴⁶ An expansion of the black market for cigarettes will further reduce tax revenues from the sale of legal products.

**SECTION IV: UNDER CURRENT CONDITIONS, THE STANDARDS
CONTEMPLATED BY THE FDA WILL CREATE A BLACK MARKET
THAT CANNOT BE MITIGATED BY ALTERNATIVE PRODUCTS.**

The FDA has suggested that one of the reasons to impose nicotine and/or flavor product standards on combustible products is to migrate smokers to less harmful non-combustible nicotine products. But for that to be a viable goal, smokers must have acceptable, legal alternatives available to them, and truthful information about the reduced harm associated with those alternatives relative to cigarettes. Without such alternatives and information, black markets will surely fill the void. Yet far from being encouraged, the availability of acceptable legal alternatives is in jeopardy at the federal, state and local levels.

As stated in the Nicotine and Flavor ANPRM comments submitted by ALCS, the availability of alternative, non-combustible, sensorially acceptable nicotine products will play an important role in whether consumers would begin using those products instead of cigarettes.²⁴⁷ If consumers have not adopted these products over cigarettes, then they would likely go to the highly adaptable black market for familiar products, *i.e.*, current nicotine level cigarettes.

The FDA, however, has to receive applications for, and authorize, these alternative nicotine products—the products on the market now are only there temporarily until that happens. This process could be significantly delayed given that the FDA has a number of other tobacco products currently under review. Add to that pipeline the applications for other newly deemed tobacco products, such as cigars and pipe tobacco, and the backlog of applications for the FDA to review is bound to be significant. Compounding the problem will be the separate applications for modified risk claims that will need to be filed, and which are essential to educate cigarette smokers and encourage them to migrate to reduced-risk products. The FDA has yet to authorize any of the pending applications for modified risk claims. Consequently, even if alternative non-combustible products could serve a role in mitigating the migration of tobacco users to the black market, those alternatives are a long way from being a permanent fixture in the legitimate market; making it difficult for smokers to rely on them as a transition away from cigarettes.

Not only are we a long way from a stable market of acceptable alternative non-combustible products, but such a market is under threat of being diminished, not expanded. At the same time the FDA is considering nicotine standards and flavor bans on combustible cigarettes, it is also contemplating flavor bans on alternative non-combustible products, which lowers their acceptability as alternatives.

Furthermore, state and local governments are independently taxing the very alternative products to which the FDA theoretically wants consumers to migrate, making them less accessible to consumers. Indeed, approximately half of the states in the country have considered the issue of taxes on e-vapor products, with eight states having already passed legislation enacting such

²⁴⁶ Bartlett, *supra* note 242.

²⁴⁷ See ALCS comments to Nicotine ANPRM and Flavor ANPRM.

taxes. At present, the following states tax e-vapor products: California,²⁴⁸ Delaware,²⁴⁹ Kansas,²⁵⁰ Louisiana,²⁵¹ Minnesota,²⁵² North Carolina,²⁵³ Pennsylvania,²⁵⁴ and West Virginia.²⁵⁵ Moreover, Washington, D.C.²⁵⁶ and Puerto Rico²⁵⁷ also have decided to tax e-vapor products.

Minnesota was the first state to begin taxing e-vapor products. On October 22, 2012, Minnesota's Department of Revenue issued a revenue notice stating that electronic cigarettes, as a "product containing, made, or derived from tobacco" and intended for human consumption, fell under the definition of "tobacco products."²⁵⁸ As a result, e-vapor products are now taxed at the rate of 95% of their wholesale price in Minnesota. In 2017, Minnesota considered imposing a 30 cent per milliliter tax on e-liquids which could have doubled the cost of e-vapor products, *i.e.*, consumers who chose e-vapor products could have paid double for e-liquid if the proposed bill had passed.²⁵⁹ The proposal ultimately failed.

Similarly, California currently taxes e-vapor products at 65.08% of the wholesale price,²⁶⁰ Pennsylvania at 40%,²⁶¹ and Washington, D.C. at 60%.²⁶² Taxing e-vapor products at such a high amount has the effect of pricing such products far higher than even combustible cigarettes, and therefore discourages smokers from switching to e-vapor. North Carolina was the second state to tax e-vapor products and did so in 2014, taking a different approach by opting to tax e-vapor product by liquid volume; specifically, at a rate of 5 cents per milliliter of nicotine fluid.²⁶³ In 2015, Kansas and Louisiana followed North Carolina's approach taxing by volume at the same rate. Delaware,²⁶⁴ West Virginia²⁶⁵ and Puerto Rico later followed suit.²⁶⁶ Such taxation

²⁴⁸ CAL. REV. & TAX CODE § 30130.51(b) (2016); CAL. BD. OF EQUALIZATION, SPECIAL NOTICE: NEW TAX RATE ON OTHER TOBACCO PRODUCTS, EFFECTIVE JULY 1, 2017 THROUGH JUNE 30, 2018 (2017).

²⁴⁹ DEL. CODE ANN. tit. 30 § 5305(c)(2) (2017).

²⁵⁰ KAN. STAT. ANN. § 79-3399 (2017).

²⁵¹ LA. STAT. ANN. § 47:841(F) (2016).

²⁵² MINN. STAT. ANN. § 297F.05(3)(2017) & MINN. DEP'T OF REVENUE, REVENUE NOTICE #12-10: TOBACCO PRODUCTS TAX—TAXABILITY—E-CIGARETTES (2012).

²⁵³ N.C. GEN. STAT. § 105-113.35(a1) (2017).

²⁵⁴ 72 PA. STAT. AND CONS. STAT. ANN. § 8202-A(a.1) (2016).

²⁵⁵ W.VA. CODE ANN. § 11-17-4b(b)(1) (West 2016).

²⁵⁶ D.C. CODE ANN. §§ 47-2401(5A), -2402.01(a)(1)(C) (West 2015).

²⁵⁷ P.R. LAWS ANN. tit. 13 § 31635(b) (2017).

²⁵⁸ MINN. DEP'T OF REVENUE, REVENUE NOTICE #12-10: TOBACCO PRODUCTS TAX—TAXABILITY—E-CIGARETTES (2012).

²⁵⁹ Susan Du, *Minnesota Sen. David Senjem's bill would double prices for e-cigarette smokers*, CITY PAGES (Mar. 10, 2017), <http://www.citypages.com/news/minnesota-sen-david-senjem-s-bill-would-double-prices-for-e-cigarette-smokers/415802183>.

²⁶⁰ CAL. REV. & TAX CODE § 30130.51(b) (2016); CAL. BD. OF EQUALIZATION, SPECIAL NOTICE: NEW TAX RATE ON OTHER TOBACCO PRODUCTS, EFFECTIVE JULY 1, 2017 THROUGH JUNE 30, 2018 (2017).

²⁶¹ 72 PA. STAT. AND CONS. STAT. ANN. § 8202-A(a.1) (2016).

²⁶² D.C. CODE ANN. § 47-2401(5A) (West 2015); D.C. OFFICE OF TAX & REVENUE, OTR NOTICE 2017-03: TOBACCO AND VAPOR PRODUCTS WHOLESALERS (2017).

²⁶³ Scott Drenkard, *North Carolina's E-Cigarette Tax Proposal*, TAX FOUND. (May 27, 2014), <https://taxfoundation.org/blog/north-carolina-s-e-cigarette-tax-proposal>.

²⁶⁴ DEL. CODE ANN. tit. 30 § 5305(c)(2) (2017).

²⁶⁵ W.VA. CODE ANN. § 11-17-4b(b)(1) (West 2016). West Virginia taxes vapor products at 7.5 cents per milliliter of nicotine fluid. *Id.*

²⁶⁶ P.R. LAWS ANN. tit. 13 § 31635(b) (2017). Notably, Puerto Rico also taxes at \$3.00 per e-cigarette and \$6.00 per vaporizer. *Id.*

results in an approximately 45 to 65 cent per device tax; making e-vapor products significantly less affordable to the consumer.

Notably, various cities and counties also have imposed taxes on e-vapor products. For example, two years ago, Chicago, Illinois adopted a “Liquid Nicotine Product Tax” at 80 cents per product unit, plus an additional .55 cents per milliliter.²⁶⁷ Similarly, Cook County, Illinois taxes e-liquids at a rate of 20 cents per milliliter, if the product contains nicotine.²⁶⁸ Montgomery County, Maryland imposes a 30 percent tax on distributors of e-vapor products.²⁶⁹ These are de facto bans based on taxation.

Still other cities and counties have instituted outright bans of these products. In California, Sonoma was the first city in the United States to ban flavors in 2015.²⁷⁰ San Francisco has passed an ordinance banning sales of flavored tobacco, which includes e-vapor and smokeless tobacco products.²⁷¹ Notably, some harm-reduction scholars have stated, “[s]uch draconian regulation makes San Francisco a prime location for the development of a thriving black market of tobacco products, as the city is surrounded by water on three sides and borders a city and counties that already have fairly strict tobacco sales ordinances in place.”²⁷²

Furthermore, Oakland, California approved a flavor ban for e-cigarettes on September 19, 2017.²⁷³ The ban prohibits flavored tobacco products in convenience stores, grocery stores, gas stations and nearly all other stores that sell tobacco products.²⁷⁴ Other cities and counties in California have passed various flavor bans including: El Cerrito,²⁷⁵ San Leandro,²⁷⁶ Los Gatos,²⁷⁷ Manhattan Beach,²⁷⁸ Palo Alto,²⁷⁹ Yolo County²⁸⁰ and Santa Clara County.²⁸¹

In Massachusetts, nearly one hundred cities and towns have passed measures to ban the sale of flavored products at establishments without an age restriction to enter, like convenience and

²⁶⁷ CHICAGO, ILL., CODE ch. 3-47 (2017).

²⁶⁸ COOK COUNTY, ILL., ORDINANCES § 74-433(e) (May 2016).

²⁶⁹ MONTGOMERY COUNTY, MD., CODE §§ 52-95 to -100 (2015).

²⁷⁰ SONOMA, CAL., ORDINANCES § 7.25.020(H) (June 2015).

²⁷¹ SAN FRANCISCO, CAL., BOARD OF SUPERVISORS ORDINANCES no. 140-17 (June 2017); SAN FRANCISCO, CAL., HEALTH CODE § 19H.2. (2015).

²⁷² Carrie Wade & Steven Greenhut, *Bay Area Flavored Tobacco Bans Undermine Harm Reduction*, at 4 (R Street, Nov. 2017), <https://2o9ub0417chl2lg6m43em6psi2i-wpengine.netdna-ssl.com/wp-content/uploads/2018/04/119-1.pdf>.

²⁷³ OAKLAND, CAL., ORDINANCES 13452, §§ 5.91.010, 5.91.030(C) (Sept. 19, 2017).

²⁷⁴ *Id.*

²⁷⁵ EL CERRITO, CAL., ORDINANCES 2015-08, art. 2, § 6.100.160 (Sept. 15, 2015).

²⁷⁶ SAN LEANDRO, CAL., ORDINANCES 2017-017 (Oct. 16, 2017).

²⁷⁷ LOS GATOS, CAL., CODE § 18.60.020(c)(8) (2017).

²⁷⁸ MANHATTAN BEACH, CAL., CODE § 4.118.030(H) (2017).

²⁷⁹ PALO ALTO, CAL., CODE § 4.64.030(h)(1) (2017).

²⁸⁰ YOLO COUNTY, CAL., CODE § 6-15.10(e)(1) (2016).

²⁸¹ SANTA CLARA COUNTY, CAL., ORDINANCES no. NS-300.903, § A18-369(i)(1) (Oct. 18, 2016).

retail stores.²⁸² Such cities include Boston,²⁸³ Cambridge,²⁸⁴ Northampton, Chelsea, Gardner, West Boylston and Salem.²⁸⁵

Other cities, including Central Falls, Rhode Island,²⁸⁶ Providence, Rhode Island,²⁸⁷ St. Paul, Minnesota,²⁸⁸ Shoreview, Minnesota²⁸⁹ and Minneapolis, Minnesota,²⁹⁰ also have implemented bans of certain flavors for e-vapor products.

Given the growing trend among states, cities and counties to heavily tax or outright ban alternative nicotine products, including those with flavors, and the FDA's contemplated flavor ban on these products, smokers are unlikely to view non-combustible products as alternatives to the black market.

SECTION V: MITIGATING A SIGNIFICANT BLACK MARKET THROUGH LAW ENFORCEMENT WILL BE EXTREMELY EXPENSIVE AND DIFFICULT.

Given the current existence of a dynamic cigarette black market in the United States and the high likelihood that the FDA's contemplated product bans would fuel demand for black market products, it would be extremely expensive and difficult to mitigate the expected increase in the black market and the resulting negative consequences. This is particularly true in the absence of permanently available consumer-acceptable substitutes, and truthful information about them. Current regulatory and law enforcement efforts are underfunded, not focused on tobacco black markets (as opposed to other ills such as the opioid crisis) and are not coordinated with one another in a way that can contain even the existing tobacco black market. Any increase in the size and scope of the tobacco black market in response to the product bans would quickly overwhelm these already limited resources; particularly as the FDA has made no realistic effort to address or plan for enforcement of the bans and to overcome the lack of priority in tobacco-related enforcement. Given that an entire product category could be banned by a nicotine standard, as applied to cigarettes alone, the black market in current nicotine level cigarettes would render the problem virtually uncontrollable, even with every effort at enforcement. Combined with a ban on other combustible products, and bans on other non-combustible alternative products, the black market in tobacco products could be insurmountable.

²⁸² Bill Shaner, *Updated: City holds firm on proposed flavored tobacco ban despite Chamber pushback*, WORCESTER MAGAZINE (Apr. 19, 2018), <https://worcestermag.com/2018/04/19/chamber-blasts-flavored-tobacco-ban-in-letter-to-board-of-health/58985>.

²⁸³ BOSTON PUB. HEALTH COMM'N, YOUTH ACCESS REGULATION § III(E)(1)(Jan. 28, 2016).

²⁸⁴ CAMBRIDGE, MASS., CODE § 8.28.030(K)(2017).

²⁸⁵ Donald J. Wilson, Municipal Tobacco Control Technical Assistance Program, *Local Policies Restricting Flavored "Other Tobacco Products" (OTP) to Adult-Only Retailers* (Apr. 21, 2017), <https://static1.squarespace.com/static/528681f8e4b021ccf6d3c997/t/5903c670cd0f68a2400c03ab/1493419633486/muni+list+Flavored+OTP+Restriction+.pdf>.

²⁸⁶ CENTRAL FALLS, R.I., CODE § 12-421(e)(2017).

²⁸⁷ PROVIDENCE, R.I., CODE § 14-309 (2016).

²⁸⁸ ST. PAUL, MINN. CODE § 324.07(f) (2017).

²⁸⁹ SHOREVIEW, MINN., ORDINANCES no. 946 (Nov. 21, 2016).

²⁹⁰ MINNEAPOLIS, MINN., CODE § 281.45(f) (2017).

Importantly, any attempt at large-scale enforcement against a product that millions of people use would lead to additional unintended and seriously harmful consequences.

This section discusses the FDA's assumption that it can "prevent or curtail" black markets through the regulatory control provided in the TCA and enforcement by other agencies. It further discusses the inability of law enforcement to control the expansion of the black markets that would result from the contemplated product bans, including the costs and consequences of those efforts, in a way that is compatible with the American ethos. The FDA clearly does not have the enforcement resources, tools, or authority to enforce its contemplated bans. The FDA will need to rely on a network of federal and state law enforcement agencies, with whom the FDA should carefully consult, before it contemplates any bans, to understand whether these agencies have the means to assist.

A. The FDA's Assumption that It Can Control the Black Markets Through Simple Regulatory Action Is Misplaced.

The FDA Illicit Trade Paper assumes that the FDA can control the black markets resulting from any product bans through simple regulatory enforcement of lawful manufacturers, wholesalers and retailers. That assumption is flatly incompatible with the data, with all that is known about how black markets generally operate, and with how the cigarette black market operates in particular. Regulatory enforcement of otherwise lawful enterprises is distinct from enforcement against criminal enterprises in black markets, which implicates federal and state criminal law enforcement authorities and agencies.

While regulatory enforcement can be effective as to people and businesses operating within the legitimate supply chain—using, for example, the warning letters mentioned in the FDA Illicit Trade Paper—that same type of enforcement is completely ineffective against criminal enterprises. Unlike legitimate enterprises that conduct their business in the open, are likely to be deterred by the loss of a license that allows their business to operate, and for which there are significant regulatory barriers to entry (at least in the tobacco context), criminal enterprises have no such limitations. Criminal enterprises operate covertly, by definition do not comply with (or care about) regulatory requirements, and the barriers to entry may be very low. Thus, removing one actor from the black market simply creates an opportunity for a new enterprise to emerge or an existing enterprise to add "market share."²⁹¹ Enforcement against these criminal enterprises generally requires investigation and prosecution by federal and state criminal law enforcement agencies, and such efforts obviously require substantial investments of both time and money.

In contrast to these likely enforcement problems against real-world black markets in tobacco, the FDA's Illicit Trade Paper concentrates on merely identifying which agency would have regulatory jurisdiction over violations of various types. Such a focus fails to reflect the realities of enforcement efforts against black markets.

²⁹¹ See, e.g., *supra* Section I.

B. No Amount of Enforcement Is Likely to Adequately Mitigate the Resulting Black Market.

Existing enforcement efforts are insufficient to enforce even current tobacco policies and regulations, and will remain so in the future as the black market expands in response to the product bans should they be implemented. Current federal and state expenditures for policing black market cigarettes are constrained by budget limitations and are not a priority as compared to other crimes.²⁹² Further, there is limited coordination among applicable federal and state enforcement agencies.²⁹³ The costs to fund the enforcement efforts (based on the unrealistic assumption that the black markets can be controlled) are extraordinary, and such efforts to police the black markets will usher in their own negative consequences. Lastly, reliance on purported “track and trace programs” will not solve or stem the black market problem. Each of these topics is discussed below.

1. Enforcement in the face of the growing cigarette black market is not a priority now and will not be a priority in the future.

The growth of the current cigarette black market is outpacing enforcement efforts, as has the willingness of consumers to buy goods from the black market. According to the National Academies, the share of smuggled cigarettes increased by more than 150% from 1992 through 2011.²⁹⁴ A growing black market becomes harder and harder to enforce against, further reducing the risks to traffickers and inviting still more growth.²⁹⁵ The alcohol market in the last few years of Prohibition and the cannabis market over the past two decades illustrate that sort of “black market spiral.” This spiral will continue as the primary responsibility for enforcement falls to the states, enforcement remains a low federal priority, and there remains a lack of coordination among government enforcement agencies.

- a. Primary responsibility for enforcement falls to the states, which are underfunded and do not prioritize tobacco enforcement over more serious crimes.*

Federal and state governments have not made a priority of combating the black market in tobacco. The substantial black market in the United States consists primarily of cigarettes legally produced domestically then smuggled across state borders, making this smuggling

²⁹² See, e.g., Memorandum from Ronald B. Turk, Assistant Director (Field Operations), Bureau of Alcohol, Tobacco, Firearms and Explosives, to All Special Agents in Charge (July 30, 2012), <https://www.scribd.com/document/186352280/Atf-Memo> (requiring all new tobacco investigations to have a nexus to violent crime, except in rare occasions for instances of large scale fraud perpetrated by organized criminal enterprises).

²⁹³ Michael DeFeo & Mark A.R. Kleiman, *Organizing the Federal Enforcement Effort Against Illicit Traffic in Tobacco Products: An Agenda for a New Administration* 2-6 (Feb. 25, 2017), <http://www.illicittobaccoinfo.com/wp-content/uploads/2017/03/Organizing-the-Federal-Enforcement-Effort-Against-Illicit-Traffic-in-Tobacco-Products-An-Agenda-for-a-New-Administration.pdf>.

²⁹⁴ NRC *Illicit Trade Paper*, *supra* note 15, at 97-99.

²⁹⁵ Mark Kleiman & Beau Kilmer, *The Dynamics of Deterrence* (Aug. 25, 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2732889/>.

primarily a state and local enforcement issue.²⁹⁶ Thus, most enforcement efforts require local resources; the black market activity resulting from the contemplated product bans would therefore increase the workload of state and local law enforcement.²⁹⁷ Those agencies, however, already have their hands full dealing with violent and property crimes, and their budgets have not been growing in the face of state and local fiscal stringency, so no additional resources are readily available.²⁹⁸

“State and local enforcement is limited by the perception of ITTP [(Illicit Trade in Tobacco Products)] as a low-priority crime.”²⁹⁹ And although “New York City and other areas with a high incidence of ITTP occasionally conduct sweeps of retail outlets likely to sell illicit tobacco, and law-enforcement agencies in sourcing states such as Virginia occasionally investigate suppliers of illicit product[,] [f]ew states have entire units dedicated to combating ITTP.”³⁰⁰ “The legal system often perceives illicit tobacco cases not as serious as the possession of other illicit products, such as drugs or weapons, especially if the trade remains nonviolent . . . [T]he illicit tobacco trade is usually a low priority for criminal prosecutions.”³⁰¹ That in turn further discourages police from investigating crimes that they know may not be vigorously prosecuted. Police departments focused on reducing rates of predatory crimes will not happily accept the invitation to divert their attention to tobacco control; especially as evidence indicates that, in general, arrests for illicit substance violations do not reduce violent crime.³⁰² Moreover, local enforcement is limited by the tolerance of the citizenry for arrest and incarceration. That tolerance has been shrinking; particularly in high-crime neighborhoods where the existing black market tobacco trade is concentrated.

This low priority of enforcing against tobacco black markets is evident in a stark example from Virginia. It is estimated that “less than one-sixth of 1 percent (0.16 percent) of the total number of cigarette packs being smuggled out of Virginia are intercepted by Virginia state authorities.”³⁰³ And there is a corresponding lack of coordination among enforcement efforts within the various states. For example, in Massachusetts, “there is no formal multi-agency taskforce combating the illegal tobacco market in the Commonwealth.”³⁰⁴ Given the states’

²⁹⁶ Kleiman et al., *supra* note 244, at §§ 2.2.2.1, 2.2.3.1.

²⁹⁷ *Id.*

²⁹⁸ Since 2010, the trend in combined state and local direct spending on police and corrections has been declining or flat in constant-dollar terms. *Police and Corrections Expenditures* (Urban Institute), <https://www.urban.org/policy-centers/cross-center-initiatives/state-local-finance-initiative/state-and-local-backgrounders/police-and-corrections-expenditures> (citing figures from U.S. BUREAU OF THE CENSUS, SURVEY OF STATE AND LOCAL GOVERNMENT FINANCE, 2015).

²⁹⁹ Kulick et al., *supra* note 17, at 7.

³⁰⁰ *Id.*

³⁰¹ *Id.* (quoting Hana Ross, *Measures to Control Illicit Tobacco Trade*, TOBACCONOMICS 4 (June 14, 2015), https://tobacconomics.org/wp-content/uploads/2015/08/Ross_Available_Measures_8.10.15.pdf).

³⁰² For example, an econometric study of New York State found no significant negative relationship between drug arrests and violent or non-violent crime, and instead found positive associations between drug arrests and certain types of crime. Edward M. Shepard & Paul R. Blackley, *Drug Enforcement and Crime: Recent Evidence from New York State*, 86 SOC. SCIENCE Q. 323, 323-342 (June 2005).

³⁰³ NRC Illicit Trade Paper, *supra* note 15, at 148.

³⁰⁴ COMMISSION ON ILLEGAL TOBACCO, COMMONWEALTH OF MASS., REPORT OF COMMISSION ON ILLEGAL TOBACCO 4 (March 1, 2014), <https://www.mass.gov/files/documents/2018/03/21/dor-other-reports-commission-report-on-illegal-tobacco.pdf>.

current limitations on addressing the cigarette black market, additional demands created by the contemplated product bans would exacerbate the existing resource shortfall.

- b. *Black market tobacco is not a current priority and will not be a priority for federal law enforcement.*

At the federal level, “[c]urrent enforcement efforts against ITTP appear to be . . . sporadic Apart from the occasional high-profile sting operation (U.S. State Dept., 2015), often only when ties to terrorism are involved, federal enforcement of tobacco laws is [minimal]. Primary criminal responsibility is in the ATF, which spends less than 2% of its budget on fighting tobacco diversion (DOJ OIG, 2009). Primary responsibility for federal excise tax compliance is in the [TTB], a Treasury Department agency that lacks the power to make arrests. TTB completed about 400 revenue investigations of alcohol and tobacco diversions, but these contributed to the identification of additional excise tax revenue of only \$57 million (TTB, 2016). This amount, which includes alcohol taxes, is a pittance of the value of tax revenue due on all ITTP.”³⁰⁵ Investigations and prosecutions of traffickers in black market tobacco products are arduous, require long-term commitments, and require a significant investment of resources.³⁰⁶

Further restricting federal resources devoted to addressing this problem, “[l]imitations were imposed on investigations in July 2012 by an internal memorandum from ATF’s assistant director of field operations: it stated that all new tobacco investigations ‘need a nexus to violent crime’ and only on ‘rare occasions’ will investigations be authorized if they do not involve a violent crime component but still involve ‘large-scale fraud perpetrated by organized criminal enterprises and results in a significant loss of federal or state tax revenue.’”³⁰⁷ And since that policy was implemented, “the number of tobacco investigations initiated by [ATF] has fallen significantly, from 100 initiated in 2011 to just 11 in 2013.”³⁰⁸ As indicated above, “the modern A.T.F. has focused its stagnant budget on violent crime and bombings, while tobacco smuggling—a little-known crime that costs the government billions in lost taxes each year—goes largely unenforced.”³⁰⁹ “Alcohol and tobacco enforcement is now regarded by many [ATF] agents as a backwater.”³¹⁰

Currently, the “Trump administration has drafted plans to strip key authorities from the [ATF], . . . an acknowledgment that the agency has all but abandoned its legacy of fighting liquor and tobacco smugglers.”³¹¹ Under the administration’s plan, the Treasury Department would inherit

³⁰⁵ Kulick et al. *supra* note 17, at 7.

³⁰⁶ U.S. ATT’Y FOR THE E.D. OF CAL., U.S. DEP’T OF JUST., 15 CHARGED WITH EVASION OF TENS OF MILLIONS OF DOLLARS IN STATE TOBACCO PRODUCTS EXCISE TAX (Aug. 9, 2010).

³⁰⁷ NRC Illicit Trade Paper, *supra* note 15, at 141 (quoting Memorandum from Ronald B. Turk, Assistant Director (Field Operations), Bureau of Alcohol, Tobacco, Firearms and Explosives, to All Special Agents in Charge (July 30, 2012), <https://blog.timesunion.com/capitol/archives/200087/atf-document-shows-why-investigators-are-laying-off-tobacco-investigations-in-ny/>).

³⁰⁸ *Id.*

³⁰⁹ Ali Watkins & Matt Apuzzo, *Trump Envisions an A.T.F. without the A or T*, N.Y. TIMES (Jan. 19, 2018), <https://www.nytimes.com/2018/01/19/us/politics/atf-authorities-tobacco-liquor-smuggling.html?smid=pl-share>.

³¹⁰ *Id.*

³¹¹ *Id.*

the authority to investigate tobacco and alcohol smuggling. The proposed “plan envisions hiring roughly two dozen Treasury agents, plus auditors and support staff.”³¹² (By comparison, the Drug Enforcement Administration employs 4,000 criminal investigators.) While Congress would have to pass a law to effect the proposed reorganization, this development is further evidence that combating the black market trade in tobacco is not a priority for the federal government.

c. There is little coordination between and among the various levels of government.

A variety of federal, state and local agencies have overlapping authority to enforce laws governing tobacco and the illicit tobacco trade. “The enforcement of the [TCA and related federal laws that address the illegal tobacco trade and product diversion] is largely the responsibility of the Bureau of Alcohol, Tobacco, Firearms and Explosives in the U.S. Department of Justice, the Immigration and Customs Enforcement and Customs and Border Protection agencies in the U.S. Department of Homeland Security, and the Alcohol and Tobacco Tax and Trade Bureau in the U.S. Department of the Treasury.”³¹³ “In addition[], states and localities can enact and enforce laws that govern the illicit tobacco trade. For example, every state has laws with civil and criminal consequences for possessing, transporting, or selling illicit cigarettes. The agencies that enforce these laws are also varied and range from public health and tax and revenue departments to sheriff’s offices and local tax boards.”³¹⁴

There is no standing organization to coordinate the activities of these various agencies representing different jurisdictions and levels of government.³¹⁵ This lack of communication and coordination further prejudices the ability of government to curtail the unintended consequences of the FDA’s contemplated bans; particularly if these agencies operate at cross-purposes.

2. The costs and consequences of the FDA’s unrealistic assumption that the black markets can be controlled.

Enforcement activity at the same level presently used to fight the current cocaine and opiate/opioid black markets would have budgetary costs and side-effects officials and taxpayers might be unwilling to bear. On the other hand, limited enforcement, as in the case of the cannabis black market, will not stop the proliferation of such a market. Instead, using either approach, as was the case with opioids and cannabis, the tobacco black market will flourish.

a. Increased enforcement costs.

As noted above, the FDA’s contemplated product bans would present the existing population of cigarette smokers—more than 40 million individuals—with a reduced set of options, no longer

³¹² *Id.*

³¹³ NRC Illicit Trade Paper, *supra* note 15, at 19-20.

³¹⁴ *Id.* at 20-21.

³¹⁵ Mark A.R. Kleiman & Michael DeFeo, *Enforcing the Law against Illicit Traffic in Tobacco Products: Organizational Problems and Potential Solutions* 1-5 (Aug. 23, 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3025138.

including the continued use of legal current nicotine level cigarettes among them. Even if only 20% of those smokers accessed the black market, that would mean about 8 million tobacco black market customers.³¹⁶ That is about twice the currently estimated number of non-medical users of opiates and opioids, and an even larger multiple of the estimated number of cocaine or methamphetamine users.³¹⁷

Euromonitor International statistics estimate about \$2,700 in cigarette revenue per smoker in the United States for 2018.³¹⁸ That figure times the 8 million smokers seeking black market cigarettes approaches \$22 billion. The need for law enforcement agency and prosecutorial personnel to even attempt to enforce against the cigarette black markets at the same level as marshalled against the black markets for drugs would be overwhelming. Moreover, there is no reason to think that black market cigarettes would be purchased exclusively by current smokers; black market traffickers would presumably be more willing than legal retailers to sell to minors. As a result, the cigarette black market might sustain itself indefinitely. And this is without consideration of the additional black markets to be created if there is a prohibition on certain flavors, let alone nicotine in all combustible tobacco products.

The existing black markets for drugs provide an example of the consuming costs in money and personnel to even attempt to control such markets. Consumers spend approximately \$100 billion per year on illegal drugs (estimated as of 2010).³¹⁹ Government is estimated to spend over \$50 billion per year on its drug enforcement efforts.³²⁰ Thus, government spends roughly \$1 on enforcement for every \$2 spent on illegal drugs. Government spending on drug enforcement efforts represents about 21% of the estimated \$265 billion government spends on *all* criminal-justice operations.³²¹ If the proportion of work-hours roughly reflects the proportion of these expenditures, then drug enforcement would consume the efforts of some 500,000 of the

³¹⁶ There is no experimental evidence on the success of forced cigarette cessation, but voluntary quit attempts have success rates no better than 25%, even among the self-selected half of cigarette smokers who make a serious quit attempt in the course of a year. Even assuming an incredible and overly optimistic success rate of 80% would leave about 8 million smokers of the current 40 million in search of black market cigarettes.

³¹⁷ In 2016, about 0.5 million people aged 12 or older in the U.S. were estimated to be current heroin users, and another 3.3 million people 12 or older were current misusers of pain relievers. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2016 NATIONAL SURVEY ON DRUG USE AND HEALTH 16, 18 (Sept. 2017), <https://store.samhsa.gov/shin/content/SMA17-5044/SMA17-5044.pdf>. In 2016, the same source estimated that about 1.9 million people aged 12 or older were current users of cocaine and 0.7 million were current users of methamphetamines. *Id.* at 17, 20.

³¹⁸ Euromonitor International, Passport Database.

³¹⁹ Beau Kilmer et al., *What America's Users Spend on Illegal Drugs: 2000-2010*, at 103 (RAND Corp., Feb. 2014), https://obamawhitehouse.archives.gov/sites/default/files/ondcp/policy-and-research/wausid_results_report.pdf.

³²⁰ Drug Policy Alliance, *Drug War Statistics*, <http://www.drugpolicy.org/issues/drug-war-statistics> (last visited June 14, 2018). Federal drug enforcement efforts cost in excess of \$30 billion per year. See WHITE HOUSE OFFICE OF NAT'L DRUG CONTROL POL'Y, NATIONAL DRUG CONTROL BUDGET FY2017: FUNDING HIGHLIGHTS 2 (Feb. 2016). State and local governments are estimated to spend in excess of \$25 billion on the drug war every year. Jeffrey A Miron & Katherine Waldoock, *The Budgetary Impact of Ending Drug Prohibition* 5 (Cato Inst., 2010).

³²¹ The Hamilton Project, *Corrections Spending per Capita* (Brookings, Oct. 21, 2016), hamiltonproject.org/charts/corrections_spending_per_capita.

estimated 2.4 million people employed by criminal justice agencies at all levels of government.³²²

Assume an enforcement effort against the tobacco black market proportional in size to the current effort against illegal drugs—in other words, an estimate of the level of enforcement and incarceration necessary to put as much pressure on the tobacco black market as is currently applied to the black market for drugs. A \$22 billion per year tobacco black market would be approximately 20% the dollar size of the illegal drug black market. A comparable level of effort would then require annual enforcement expenditures of approximately \$11 billion and approximately 100,000 full-time equivalent criminal justice personnel.

Additionally, there are approximately 1.5 million arrests per year in the illegal drug black markets and approximately 500,000 people behind bars at any one time for drug offenses (more than 90% for the “hard” drugs: heroin and other opiates and opioids, cocaine, and methamphetamine).³²³ Scaled to the tobacco black market, this would equate to 300,000 arrests per year, and keeping 100,000 black market tobacco traffickers behind bars.³²⁴

Thus, the effort to even attempt to address the growth of the black market that would be created by the contemplated bans is remarkable—and law enforcement already has its hands full with enforcement and the associated costs in connection with the more recent and still-growing opioid epidemic.³²⁵ As noted previously, none of the above estimates considers the impact of the additional bans under consideration by the FDA, which will further strain limited resources.

b. Black market proliferation versus aggressive over-enforcement.

Presuming an all-out enforcement effort would be desirable or could possibly be effective, it might not be feasible. The decision about whether to mount such an effort would be outside the control not only of the FDA, but of the federal government altogether, given that about 90% of

³²² TRACY KYCKELHAHN, BUREAU OF JUST. STATS., U.S. DEP’T OF JUST., JUSTICE EXPENDITURE AND EMPLOYMENT EXTRACTS, 2012 –PRELIMINARY (Feb. 26, 2015), <https://www.bjs.gov/index.cfm?ty=pbdetail&iid=5239>.

³²³ FED. BUREAU OF INVESTIGATION, DEP’T OF JUST., CRIME IN THE UNITED STATES, Table 18 (2016), <https://ucr.fbi.gov/crime-in-the-u.s/2016/crime-in-the-u.s.-2016/topic-pages/tables/table-18>.

³²⁴ The illegal drug markets provide a warning about the futility of such increased efforts in any event: increasing the number of drug dealers behind bars approximately thirtyfold (from about 15,000 to about 500,000) did not prevent price decreases and volume increases in the markets for cannabis, heroin, and cocaine. Jonathan P. Caulkins & Peter Reuter, *How Drug Enforcement Affects Drug Prices*, 39 CRIME & JUST. 213 (2010).

³²⁵ Altarum, *Economic Toll of Opioid Crisis in U.S. Exceeded \$1 Trillion Since 2001* (Feb. 13, 2018), <https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-s-exceeded-1-trillion-since-2001>. According to Altarum, a nonprofit group that studies health and the economy, the opioid epidemic has cost the U.S. more than a trillion dollars from 2001 to 2017, and may exceed another \$500 billion over the next three years. *Id.* Among these costs, federal, state and local governments are losing tax revenue and expending resources on health care, social services, education and criminal justice. *Id.*; see also Greg Allen, *Cost of U.S. Opioid Epidemic Since 2001 Is \$1 Trillion and Climbing*, NAT’L PUB. RADIO (Feb. 13, 2018), <https://www.npr.org/sections/health-shots/2018/02/13/585199746/cost-of-u-s-opioid-epidemic-since-2001-is-1-trillion-and-climbing>. Congress is proposing a \$6 billion spend over the next two years to address the opioid crisis, and President Trump has proposed \$13 billion in new spending related to opioids. *Id.*

the nation's law enforcement capacity is controlled by state and local governments.³²⁶ Moreover, efforts to criminalize the purchase or possession of cigarettes from the black markets, that is, to pursue the buyers, would turn potentially tens of millions of otherwise law-abiding citizens into criminals. The efforts to police the conduct of that many citizens would similarly be socially problematic.

As an example, the cannabis enforcement effort is far less vigorous than the efforts against "hard" drugs—while cannabis represents more than one-third of illicit-drug revenues, incarceration for cannabis dealing represents less than 6% of all drug-related incarceration.³²⁷ Partly as a result, cannabis is now available virtually nationwide. The widespread and open use of cannabis leads to a very large volume of buyer arrests—at over 500,000 per year, cannabis possession is the third-most-frequent arrest charge nationally—with important negative effects on police-community relations in high-crime neighborhoods.³²⁸ If the FDA's contemplated product bans were enforced against sellers but not against buyers, some enforcement costs would be avoided but at the cost of allowing flagrant disrespect for the law and foregoing an important deterrent to black market tobacco purchases.

If a more rigorous enforcement approach is taken, it too would likely be ineffective and actually lead to more violence. For example, removing a drug lord in an area can renew competition, and violence can result as sellers jostle for turf and market share, as has happened in recent years in Mexican drug markets.³²⁹ Enforcement also can lead to more violence through its economic impacts. Enforcement against black markets is typically oriented toward importers, distributors and sellers—the supply side—which can drive up prices and revenues in the market. But higher

³²⁶ According to the Census Bureau's Annual Survey of Public Employment and Payroll, in 2008 there were 692,887 federal, state, and local civilian government employees who were sworn law enforcement officers. Of these, 625,668 were in local police departments and sheriffs' offices, which is 90.3% of the total. DUREN BANKS ET AL., BUREAU OF JUST. STATS., U.S. DEP'T OF JUST., NATIONAL SOURCES OF LAW ENFORCEMENT EMPLOYMENT DATA Tables 3 & 9 (Rev. Oct. 2016), <https://www.bjs.gov/content/pub/pdf/nslead.pdf>.

³²⁷ In 2010, the RAND Corporation estimated that the approximately \$40B spend on cannabis represented about 37% of all consumer expenditure on marijuana, cocaine, methamphetamines, and heroin in the U.S. Kilmer et al., *supra* note 319, at 30-38, 55-62, 103, https://obamawhitehouse.archives.gov/sites/default/files/ondcp/policy-and-research/wausid_results_report.pdf (figures cited are based on "middle estimates" in report). For the proportion of drug-related incarceration for cannabis dealing, see JONATHAN P. CAULKINS, BEAU KILMER & MARK A.R. KLEIMAN, MARIJUANA LEGALIZATION: WHAT EVERYONE NEEDS TO KNOW 99 (2016), stating that less than 3% of all state and federal inmates have a "controlling conviction" for marijuana, and that most of those are for dealing (not possession). Because about half of state and federal inmates are convicted for drug offenses, this statistic implies the 6% stated in the text above.

³²⁸ In 2015, estimates based on data from the FBI indicate that there were about 575,000 arrests in the U.S. for possession of marijuana, composing over 45% of all drug possession arrests. Drug War Facts, *Estimated Annual Number of Arrests for Drug Offenses in the US By Type of Offense*, <http://www.drugwarfacts.org/node/3705#overlay=table/annual-drug-arrests>. If so, then marijuana possession arrests would follow only larceny-theft and DUI arrests. See FED. BUREAU OF INVESTIGATION, DEP'T OF JUST., CRIME IN THE UNITED STATES Table 29 (2015), <https://ucr.fbi.gov/crime-in-the-u.s/2015/crime-in-the-u.s.-2015/tables/table-29>.

³²⁹ Peter Reuter, *Systemic Violence in Drug Markets*, 52 CRIME, L. & SOC. CHANGE 275 (Sept. 2009); Melissa Dell, *Trafficking Networks and the Mexican Drug War*, 105 AM. ECON. REV. 1738 (2015); Matthew Dickenson, *The Impact of Leadership Removal on Mexican Drug Trafficking Organizations*, 30 J. QUANTITATIVE CRIMINOLOGY 651 (Dec. 2014); Viridiana Rios, *Why did Mexico become so violent? A self-reinforcing violent equilibrium caused by competition and enforcement*, 16 TRENDS IN ORGANIZED CRIME 138 (June 2013).

black market revenue can lead to more violence, as higher profit margins become worth fighting over and more valuable caches of drugs become more worth stealing and more in need of defending. The literature overwhelmingly finds positive links between increased enforcement and violence.³³⁰

Therefore, as a result of the development of a massive black market for the products that are the subject of the FDA's contemplated bans, policy-makers would face a series of high-stakes, no-win decisions. Cracking down on the market the wrong way could lead to violence (as illustrated by the cocaine market in the 1980s), while failing to curb the black market could lead to the kind of out-of-control growth that has recently characterized the cannabis market.

c. No matter the enforcement level, a black market will still exist.

Experience with increased drug law enforcement and incarceration in the period after 1980 (sometimes called “the War on Drugs”) shows that even extreme efforts are inadequate to extinguish an established black market, or even to prevent its growth. Because a post-ban cigarette black market would start with a very large base of potential consumers, a successful effort to control such a market is not feasible.³³¹ Even with extraordinary effort, there is no assurance that the tobacco black market would not grow to meet the new black market demand. And, as with cannabis, reversing such growth will prove impossible.

The estimates above represent projections based on reasonable but unverified assumptions. There can be no assurance that the cigarette black market will not be even larger than that hypothesized here. In order to include a precise quantitative estimate of black market volumes and costs in its rulemaking—which are required to satisfy the statutory requirement to take into account countervailing effects—the FDA would have to develop a way to refine those projections, or at least to place a reasonable upper bound on them. That would require both empirical measurements that have not been made, and substantial theoretical advances in the economics of black markets.

3. Reliance on an undefined and unworkable “track and trace” program will not solve the problem of expanding black markets.

Despite the FDA's contention to the contrary in its Illicit Trade Paper, so-called “tracking and tracing tobacco products through the supply chain”³³² will not prevent or ameliorate an expansion of the cigarette black market. Track and trace programs use technology to attempt to *track* the movement of tobacco products from the start of production, through the supply chain, to the point of sale, and allow enforcement authorities to *trace* where such products were diverted into illegal channels.³³³ A track and trace system, however, tracks only legitimately

³³⁰ See the literature surveys by Dan Werb et al., *Effect of Drug Law Enforcement on Drug Market Violence: A Systematic Review*, 22 INT'L J. OF DRUG POL'Y 87 (March 2011), and Kulick et al., *supra* note 233.

³³¹ Jonathan P. Caulkins & Mark A.R. Kleiman, *Lessons to Be Drawn from U.S. Drug Control Policies*, 24 EUR. J. ON CRIM. POL'Y & RES. 125 (June 2018).

³³² FDA Illicit Trade Paper at 22.

³³³ FRANK J. CHALOUKKA, OFFICE ON SMOKING & HEALTH, CTRS. FOR DISEASE CONTROL, PREVENTING AND REDUCING ILLICIT TOBACCO TRADE IN THE UNITED STATES 25 (Dec. 2015), <https://www.cdc.gov/tobacco/stateandcommunity/pdfs/illicit-trade-report-121815-508tagged.pdf>.

manufactured products and depends on the willingness of the manufacturers and distributors to participate in the system. Illicit manufacturers and distributors will, of course, avoid any track and trace system so that their illegal products can remain covert from the point of manufacture through final sale to the consumer.

The experience of foreign countries with various track and trace systems indicates their potential value under a limited set of circumstances, but those circumstances would not be present in a post-product-ban tobacco black market. For example, Turkey has been described as “the first country in the world to adopt and implement a tracking-and-tracing system,” and track and trace advocates point to the 31.5% increase in Turkey’s tobacco tax revenues within the first year of implementing its track and trace system.³³⁴ The new Turkish system, however, did not replace the sort of system now operating in the U.S., where cigarette tax stamps are nearly universal. Turkey did not employ tax stamps of any kind before implementing its track and trace system. Accordingly, it is no surprise that the new system led to increased tax revenues. Simply employing tax stamps—like most states in the U.S. already use—would likely lead to revenue increases because legitimate entities that place the stamps on tobacco products (known as “stamping agents”) pay the government for those stamps. In addition, while some have described Turkey as utilizing a “tracking and tracing system,” the CDC found Turkey’s system to “have limited tracking features.”³³⁵ Thus, generalizing from Turkey’s experience does not support a conclusion that a similar system in the U.S. would result in anything even remotely comparable in terms of tax revenue results. Importantly, the comprehensive multi-year data show that black market trade in Turkey has actually increased to historic levels of approximately 19.0%, as reported by the Director General from the Turkish Ministry of Finance.³³⁶ The CDC reports similar black market trade levels in Turkey of 14.0% to 17.5% in recent years.³³⁷

The experience of Brazil is also instructive. Brazil was once the “poster child” for track and trace advocates in the past. While some tout Brazil as a major success story for track and trace systems,³³⁸ recent experience has shown that trade of black market tobacco products in Brazil has returned to levels higher than existed before its track and trace system was implemented. For example, approximately 20 billion cigarettes produced in Paraguay are being illegally sold in Brazil each year.³³⁹ The latest data reported by Euromonitor indicates that the volume of black market cigarette consumption rose by 8% from 2015 to 2016 alone.³⁴⁰ Strikingly, from 2008,

³³⁴ *Id.* at 27.

³³⁵ *Id.*

³³⁶ See Unal Tayyan, DG of Revenue Policies, Ministry of Finance, *Tobacco Banderol System Application in Turkey* (presentation at meeting of Asia Pacific Association for the Control of Tobacco, Aug. 20, 2013), http://www.apact.jp/presentation_data/pdf/PL3-4.pdf.

³³⁷ CHALOUPKA, *supra* note 333, at 27.

³³⁸ See, e.g., LUK JOOSSENS, INTERAGENCY COMM. ON SMOKING AND HEALTH, CTRS. FOR DISEASE CONTROL, COMBATING ILLICIT TOBACCO TRADE GLOBALLY 14 (Jan. 29, 2013) (summary of presentation); Hanna Ross, *Controlling Illicit Tobacco Trade: International Experience*, UNIV. OF CHICAGO INST. FOR HEALTH RES. & POL’Y 2-7 (June 16, 2015); WORLD HEALTH ORG., WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC, 2015, at 45, 87 (2015).

³³⁹ See Roberto Iglesias, World Bank, *The Brazilian Experience in Combating Illicit Tobacco Trade*, The Economics of Tobacco Control in Southern Africa: The Issues of Taxation and Smuggling, Gaborone, Botswana, June 3-5, 2012 (presentation).

³⁴⁰ *Cigarettes in Brazil – Analysis*, Euromonitor, Passport Database.

when Brazil's track and trace system was implemented, to 2013, the total proportion of black market cigarette consumption increased from 16.6% to 31.1% and from 13.0 to 24.3 billion units, respectively.³⁴¹ Notably, the company that sold Brazil on its track and trace system, SICPA, is under investigation for corruption related to its traceability technology.³⁴²

What is perhaps most ironic about Brazil's purported track and trace system is that even the Framework Convention on Tobacco Control ("FCTC") has found that the SICPA system is not, in fact, a true track and trace system.³⁴³ Rather, it is merely a complex and expensive stamp program. The FCTC's analysis not only highlights over \$90 million in implementation costs,³⁴⁴ but further demonstrates that the SICPA system lacks certain serialization and data exchange standards, and does not track events along the supply chain, among other things.³⁴⁵ Therefore, at the end of the day, similar to Turkey, the SICPA system in Brazil is not a true track and trace regime at all.

Three states in the U.S.—California, Massachusetts and Michigan—use tax stamp systems with coded identifiers on each cigarette pack. These systems only allow partial tracing back to a stamping agent, and do not enter or track movement through the supply chain. These state systems cannot track or trace stamps with another state's tax stamp, which is highly ineffective when it comes to combating the black market. That only three states have adopted so-called "track and trace" systems demonstrates that the costs of these systems do not yield sufficient benefits to be worthwhile for any reason, including staying off the black market.

"Tracking and tracing" is not suited to combat any black market, including the black market in the U.S. Moreover, attempts to "track and trace" have been altogether ineffective in Turkey and Brazil, countries that are touted as having implemented such a program. While track and trace

³⁴¹ See Roberto Magno Iglesias et al., *Estimating the Size of Illicit Tobacco Consumption in Brazil: Findings from the Global Adult Tobacco Survey*, TOBACCO CONTROL (Jan. 21, 2016), <http://dx.doi.org/10.1136/tobaccocontrol-2015-052465>.

³⁴² See James Panichi & Ivo Oliveira, *Top Euro Banknote Security Firm Faces Brazil Probe*, POLITICO (July 16, 2015), <http://www.politico.eu/article/euro-bank-security-greece-faces-brazil-tax-million/>.

³⁴³ See Hana Ross, *Controlling Illicit Tobacco Trade: International Experience*, TOBACCONOMICS 7 (May 28, 2015) ("The system used currently in Brazil is a sophisticated solution for the domestic market, but it does not meet the requirements of an international track and trace regime for tobacco products."), https://tobacconomics.org/wp-content/uploads/2015/08/Ross_Available_Measures_8.10.15.pdf.

³⁴⁴ See Framework Convention Alliance, *The Use of Technology to Combat Illicit Tobacco Trade* (2018), https://www.fctc.org/wp-content/uploads/2008/10/INB-2_Factsheet_Use_of_Technology2.pdf. The paper estimates implementation costs of 1.7 U.S. cents per cigarette pack and domestic production of 5.3 billion packs annually. *Id.*

³⁴⁵ CONVENTION SECRETARIAT, INTERGOVERNMENTAL NEGOTIATING BODY ON A PROTOCOL ON ILLICIT TRADE IN TOBACCO PRODS., WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, *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*, FCTC/COP/INB-IT/4/INF.DOC./1, Annex 8 (Conference of the Parties, 4th Sess., Feb. 22, 2010), http://apps.who.int/iris/bitstream/handle/10665/75715/FCTC_COP_INB_IT4_ID1-en.pdf?sequence=1&isAllowed=y.

may be somewhat useful in defeating tax evasion in the open sale of legally produced cigarettes, track and trace has no applicability to the covert sale of illegally produced cigarettes.³⁴⁶

SECTION VI: THE FDA MUST ASSESS THE RISKS TO THE PUBLIC HEALTH FROM THE BLACK MARKET THAT WILL RESULT FROM ITS CONTEMPLATED PRODUCT STANDARDS.

The FDA's obligation to ensure that it is only imposing product standards that are "appropriate for the protection of the public health" necessarily requires that the FDA study and understand, among other things, the size, scope and adaptability of the black market that will result, as well as the costs and resources associated with combating it. This undertaking is absolutely critical given that the product standards, as currently contemplated, would result in a black market the size of which has not been seen in this country for 100 years. The stakes are simply enormous.

In apparent recognition of the gravity of these issues, the FDA contracted with the National Academy of Sciences to assess the tobacco black market. The result of this project was an over 200-page report addressing the characteristics, participants, size, and other features of the cigarette black market.³⁴⁷ One of the primary conclusions of the paper was that "there is insufficient evidence to draw strong conclusions about how the illicit tobacco market would adapt in response to permanent modifications to tobacco products as the result of any new regulations."³⁴⁸ Accordingly, the authors made numerous recommendations for research and data collection to better understand the nature of the black market. Some of these recommendations include:

- Because youth[] under the age of 18 are of particular concern to policy makers, research is needed about the extent to which they purchase cigarettes in the illicit market and how easily they do so.
- Systematic evaluations should be conducted of existing and future enforcement interventions in the illicit tobacco trade in the United States. State- and local-level efforts, such as the tobacco task force led by the New York City Sheriff's Office, should be evaluated by independent researchers.
- Research is needed on the relationship between the use of e-cigarettes and the use of conventional tobacco products and on the role of e-cigarettes as an alternative to participation in the illicit tobacco market.³⁴⁹

These three recommendations represent only a small fraction of the additional research recommendations made by the National Academy of Sciences. These recommendations appear consistent with the comments in the other FDA-funded study evaluating nicotine reduction as an

³⁴⁶ For additional information and analysis of track and trace systems, see ALCS' *Response to Citizen Petition "Requesting the Implementation of a Track and Trace System to Monitor Manufacturing and the Flow of Tobacco Products from Production Through Distribution to Retail Outlets,"* Docket No. FDA-2013-P-0285 (Sept. 6, 2013).

³⁴⁷ See generally NRC Illicit Trade Paper, *supra* note 15.

³⁴⁸ *Id.* at 9.

³⁴⁹ *Id.* at 9-12.

increase in price, wherein the authors recognized that their paper “has highlighted several important nicotine reduction research questions and described how the behavioral economic framework could be used to address them.”³⁵⁰ Until these critical and acknowledged questions are studied and understood, the FDA cannot fully anticipate, much less appropriately weigh or even prepare to counter, the unintended consequences of the product standards it is considering. Indeed, even the FDA Illicit Trade Paper recognizes that it “represents only an *initial step* toward assessing the potential for demand for illicit tobacco products after an FDA product standard.”³⁵¹ Without this essential information, the FDA cannot fulfill its statutory mandate to take action that is only “appropriate for the protection of the public health,” and evaluate countervailing effects in advance of rulemaking.

CONCLUSION:

The TCA requires the FDA to impose product standards that are “appropriate for the protection of the public health,” and in so doing, consider the countervailing effects of its contemplated nicotine and product flavor bans, including the creation of a significant demand for contraband, in advance of adopting any regulation. Pursuant to this statutory requirement, the FDA has acknowledged that such analysis and research is necessary.³⁵² Promulgating rules of sweeping magnitude and impact without first analyzing, researching, understanding and addressing the unintended consequences would result in rules that subvert their very purpose—not only undermining the FDA’s goal of smoking cessation, but also creating myriad additional consequences adverse to public health and detrimental to society.

The consequences of the FDA’s contemplated regulations would be massive in scope and scale. Through these product bans, the FDA would be impacting tens of millions of consumers, who, history has shown, will continue to look for and find what they want. Indeed, there already exists a robust black market in tobacco, which would only expand as a result of the contemplated bans.

The existing black market in cigarettes is large and growing, and has proven to be adaptable, dynamic and able to rapidly adjust to regulations, in the form of taxation or otherwise, and to consumer desires. Compounding the issue, black markets come in many forms, including smuggling or bootlegging, illegal domestic manufacture, illegal international manufacture and smuggling, gray markets, counterfeiting, and internet sales, each with their unique problems and harmful impacts on consumers, as well as local, state, and federal governments.

Research and experience show that consumers will migrate to the black market in the face of a product ban. Alcohol prohibition is perhaps the paradigmatic example of the unintended and

³⁵⁰ Smith et al., *supra* note 11, at 10.

³⁵¹ FDA Illicit Trade Paper, *supra* note 10, at 24 (emphasis added); *see also id.* (“While this draft paper represents only an initial step toward assessing the potential for demand for illicit tobacco products after an FDA product standard in general terms, understanding the limited research available, the potential price of such products, potential facilitators and consumer buying behavior, and the potential adulteration of legal tobacco products, as well as how illicit trade operates with respect to other products and locations may all help inform understanding of any potential demand that may develop due to a tobacco product standard.”).

³⁵² Gottlieb et al., *supra* note 156; *see also* 21 U.S.C. § 387g(b)(2) (2009).

harmful effects of a governmental ban of a product that millions of consumers use, and the risk that the resulting black market will grow so out of control as to force a reversal of such a ban. The current cannabis market appears to be recapitulating that story. The national opiate crisis further reveals the risks of shutting off the legal supply of a product.

The unintended consequences of the contemplated product bans would include an increase in organized criminal activity and violence. Product bans also would undermine smoking cessation efforts, as illicit tobacco products are cheaper and are not subject to FDA standards. The black market trade in tobacco is particularly harmful to youth, causing an increase in initiation and continuation of smoking, in addition to exposing youth to criminal activity generally. Of course, black markets harm federal and state treasuries by reducing the taxes collected on the manufacture and sale of legal cigarettes. As was observed during the Prohibition era, laws that cannot be enforced are destructive of the public's respect for government and the laws the government does not enforce.

The importance of considering the countervailing effects in the context of doing what is "appropriate for the protection of the public health" cannot be underestimated prior to decision-making and implementation. Even those efforts, however, would still be insufficient to stem the growth of the black markets that would be unleashed as a result of the contemplated product bans, which markets, and all of their unintended consequences, would only grow and become more dangerous.

There is much we know about the unintended and harmful consequences of the FDA's contemplated bans, as presented in this paper. The consequences of such bans would be severe and broad in scope—impacting consumers (smokers and non-smokers) and government alike. Perhaps even more troubling, however, is what we do not yet know. The FDA has shown blind spots with respect to the black markets that would result from its contemplated bans. Prior to rulemaking, the FDA must conduct substantial additional research before it can responsibly impose regulations that have the potential to dramatically increase black market trade, with all of its attendant negative consequences.