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VIA ELECTRONIC SUBMISSION AND HAND DELIVERY

Division of Dockets Management
Food and Drug Administration
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Altria Client Services (“ALCS”), on behalf of Philip Morris USA Inc. (“PM USA”), John Middleton Company (“JMC”), and Sherman Group Holdings LLC and its subsidiaries (“Nat Sherman”), submits these comments to the Food and Drug Administration’s (“FDA’s” or the “Agency’s”) Advance Notice of Proposed Rulemaking (“ANPRM”) on a Tobacco Product Standard for Nicotine Level of Certain Tobacco Products.

The ANPRM comes within the context of an industry in the midst of transformative change. Cigarette smoking is at historically low levels and continues to decline. At the same time, a new market is emerging in innovative noncombustible tobacco products that are potentially less harmful than cigarettes.

There is now a scientific consensus that noncombustible products, like e-vapor, are substantially less risky than conventional cigarettes. It is smoke, and not nicotine, that causes most tobacco-related harm. And adult smokers are increasingly expressing interest in switching from cigarettes to less risky alternatives.

We agree that a nicotine product standard of some sort may make sense in a future regulatory system, but this requires the pre-existence of a marketplace with alternative, FDA-authorized, reduced risk products; more information about the relative risks of those products; and a regulatory system that respects the rights of adults to make decisions based on accurate information.

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1 PM USA, JMC, and Nat Sherman 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. 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, and Nat Sherman.
What is not clear at this time, however, is whether substantially reducing the nicotine content in cigarettes is technically achievable on a commercial basis, is necessary, or would lead to reduced smoking. Nicotine is addictive and adult smokers primarily smoke to obtain nicotine. As noncombustible tobacco products improve, and accurate information about them is disseminated, adult smokers may well migrate to these new products without regard to a nicotine ceiling in cigarettes. And to the extent that is not the case, if adult smokers cannot get the experience they want from legally produced tobacco products, they will likely seek it from illegal sources such as the black market.

We support the Commissioner’s overarching goal; however, much work remains ahead in exploring if or how a nicotine reduction standard would work, and under what conditions:

- First, FDA must ensure that adult smokers have greater access to noncombustible product alternatives and accurate information about switching to them. For a nicotine ceiling on cigarettes to work, adult smokers must have satisfying and less harmful alternatives. Innovations aimed at providing adult smokers with more choices have greatly increased, but the current regulatory system imposes too many barriers to bringing these new products to the market and to adults learning the facts about them.

- Second, any nicotine product standard must conform to the law. Among other things, FDA may not adopt nicotine standards that are technically unachievable, that ban cigarettes, or that reduce nicotine effectively to zero.

- Third, there must be a strong scientific basis to conclude that a mandatory reduction in nicotine levels would be successful, given the scope, scale, and potential risks of this proposal. Among other things, the science needs to demonstrate that reducing nicotine will make cigarettes less addictive and that adult smokers faced with these alterations to the product will not change their behavior in a way that ultimately hurts public health.

- Fourth, a nicotine product standard must take into account adult consumer choice to avoid serious countervailing effects like the emergence of a new black market. Previous attempts to market cigarettes with very low levels of nicotine – though much higher than the 0.3 – 0.5 mg/g under consideration – have failed in the marketplace. Adults deprived of their preferences – especially without satisfying alternatives – are likely to create demand that will fuel illicit trade. As with Prohibition, black markets impose serious costs on society, including harms to public health resulting from consumer demand being met with products manufactured, distributed, and sold entirely outside the regulated system.

- Finally, in addition to evaluating whether to force reductions in nicotine, FDA must carefully weigh how any such reductions would be implemented. Sudden or severe reductions in nicotine are far more likely to result in an outbreak of black market activities to meet adult smoker demand, in comparison to more moderated or gradual steps that would allow the Agency to monitor how adults are responding to them.

We will actively engage in the regulatory process.
EXECUTIVE SUMMARY

This submission responds to the ANPRM on developing a product standard to set a maximum nicotine level for cigarettes. The ANPRM asks more than 80 detailed questions covering multiple categories on diverse topics ranging from addiction science to downstream economic impacts.

We organized our submission to respond to the categories of information in which FDA expressed interest. As detailed below, we provide this information to assist the Agency in understanding the scientific and other evidence it should consider and further evaluate before it proposes a product standard for nicotine levels in cigarettes.

This information demonstrates that:

- a marketplace of FDA-authorized, noncombustible, nicotine-containing products with accompanying modified risk claims must exist before implementing a product standard on the maximum nicotine level in combustible cigarettes;
- a product standard of 0.3-0.5 mg nicotine per gram in tobacco – or any nicotine ceiling even remotely close to that ceiling – is not technically achievable;
- a product standard of 0.3-0.5 mg nicotine per gram in tobacco – or any nicotine ceiling even remotely close to that ceiling – constitutes a threshold level that is not adequately supported by science and evidence;
- a product standard of 0.3-0.5 mg nicotine per gram in tobacco – or any nicotine ceiling even remotely close to that ceiling – will have an enormous economic impact and countervailing effects; and
- a product standard of 0.3-0.5 mg nicotine per gram in tobacco – or any nicotine ceiling even remotely close to that ceiling – will likely create a substantial illicit market.

To guide the Agency in the materials that follow, we provide an overview of the topics listed above:

A Marketplace of FDA-authorized, Noncombustible, Nicotine-Containing Products with Accompanying Modified Risk Claims Must Exist Before Implementing a Product Standard on the Maximum Nicotine Level in Combustible Cigarettes

Since the Family Smoking Prevention and Tobacco Control Act (“FSPTCA,” “TCA” or “the Act”) went into effect nearly nine years ago, a strong public health consensus has formed that there is a continuum of risk among tobacco products. We have urged FDA to acknowledge and regulate along the continuum of risk since the passage of the Act and believe the Agency should focus resources on a comprehensive plan to reduce harm through proven strategies to prevent initiation, encourage cessation, and foster the development of reduced risk alternatives. There

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2 We include a chart that cross-references questions posed in the ANPRM with our responses in the Appendix at Attachment 2.
are currently approximately 44 million adult cigarette smokers in the U.S. According to recent PATH data, more than half of these adult smokers are interested in satisfying, less harmful alternatives to cigarettes. Even more may be persuaded to switch to products lower on the continuum of risk when FDA provides accurate relative risk information.

We were encouraged by Commissioner Gottlieb’s acknowledgement of the risk continuum in his announcement of the Agency’s Comprehensive Plan, which detailed a multi-year roadmap meant to strike “an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes.” Although FDA may view a nicotine product standard as an important component of the Agency’s Comprehensive Plan, it is unlikely to be successful if promulgated before (1) there is a diverse market of FDA-authorized, noncombustible products with accompanying modified risk claims and (2) FDA finalizes a clear set of achievable requirements for new and modified risk tobacco product applications.

**A Product Standard of 0.3-0.5 mg Nicotine per gram in Tobacco – or Any Nicotine Ceiling Even Remotely Close to That Ceiling – Is Not Technically Achievable**

The ANPRM states that FDA “is particularly interested in comments about the merits of nicotine levels like 0.3, 0.4, and 0.5 mg nicotine/g of tobacco filler” and “the technical achievability of [such] a maximum nicotine level.” A product standard imposing a limit on nicotine content to these or similar levels is not technically achievable and would accordingly violate both Section 907 and the Administrative Procedure Act (“APA”).

The Agency states that extremely low levels of nicotine, like those listed in the ANPRM, might be achievable through practices and technologies that include: (1) agronomic practices such as “controlled growing conditions, fertilization, [and] harvest” and “cross-breeding plants;” (2) tobacco blending; (3) “nicotine extraction;” and (4) “genetic engineering.”

We examined each of these approaches and conclude that, with respect to achieving such low levels of nicotine/g of tobacco filler:

- the proposed standard is not technically achievable by existing tobacco and agronomic practices;
- nicotine extraction techniques are not a technically achievable solution;
- current/existing biotechnology and genetic engineering do not provide a technically achievable solution;
- crop variability would make consistent production of very low nicotine content (“VLNC”) tobacco extremely difficult, if not impossible;
- manufacturing variability would further complicate efforts to produce VLNC cigarettes on a commercial scale;
- extracted or bioengineered tobacco might increase the delivery of harmful or potentially harmful constituents; and

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4 2014-2015 PATH data analysis.
5 Gottlieb, Protecting American Families.
7 Id. at 11,831.
current research cigarettes do not solve the problems associated with commercially producing VLNC cigarettes.

Based on the wide-range of unresolved issues listed above, it is not technically achievable to produce VLNC cigarettes on a commercial scale that would meet the nicotine levels suggested in the ANPRM.

In addition, huge challenges exist to make VLNC cigarettes that are sensorially acceptable to adult consumers and/or do not create additional health risks. Experiments with nicotine reduction methods – ranging from water extraction to steam distillation – failed to produce a VLNC cigarette acceptable to consumers. Moreover, members of the public health community declared that Next, a low nicotine content cigarette produced by PM USA in the late 1980s and early 1990s, was dangerous because (1) consumers might misperceive it as “safer” and (2) it may encourage nonsmokers to initiate due to a lack concern over addiction.

If, however, FDA were to promulgate a VLNC standard through formal rulemaking, the implementation schedule should, at a minimum, use a tiered approach. The only deadline set in the first tier would pertain to submission of substantial equivalence reports, premarket tobacco applications (PMTAs), or submissions under a yet-to-be established alternative premarket or certification process (See infra at Section VI, B). Only after these submissions are reviewed, and any Agency and judicial appeals are final, would FDA promulgate a deadline for compliance with a VLNC standard. Using these staggered deadlines would ensure FDA has time to review all applications, allow parties to invest resources to produce VLNC cigarettes commercially once marketing orders for these cigarettes have been issued, and avoid the kind of market disruption that Section 907(d)(2) instructs FDA to avoid.

A Product Standard of 0.3-0.5 mg Nicotine per gram in Tobacco – or Any Nicotine Ceiling Even Remotely Close to That Ceiling – is Not Adequately Supported by Science and Evidence

More research is needed before a VLNC product standard at the levels discussed by FDA has sufficient scientific support. Indeed, the ANPRM calls the contemplated standard a “hypothesis,” acknowledges that “questions remain” and states that “additional data”[9] are needed across multiple dimensions. These observations are correct: the existing science and evidence leaves many critical questions unanswered.

No country in the world has a nicotine ceiling even remotely close to the levels under consideration by FDA, so the Agency will not be able to draw on any real world experiences to better understand the potentially significant unintended consequences. Before any standard is implemented, additional research concerning a number of issues is necessary both to comply with applicable statutes and as a matter of sound policy and basic fairness.

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8 We include a chart that cross-references questions posed in the ANPRM with our responses in the Appendix at Attachment 2.
9 Id. at 11,838, 11,818, and 11,828.
We reviewed the existing science and evidence and conclude that:

- existing science does not support a threshold for addiction within the VLNC levels being considered by FDA;
- there are no consensus criteria for diagnosing nicotine addiction;
- existing science suggests discernible behavioral changes at levels substantially higher than 0.5 mg/g;
- the initial estimate of a threshold for nicotine addiction of 0.5 mg/g in tobacco is arbitrary, conservative, and based on incorrect assumptions;
- the four “study types” identified by FDA do not support a 0.5 mg/g maximum nicotine standard;
- adult smokers may perceive VLNC cigarettes at the levels described in the ANPRM as less harmful, which may lead to increased consumption at the individual and population levels;
- existing science is inadequate to determine the impact of VLNC cigarettes on initiation and cessation;
- the model FDA cites does not accurately reflect the impact of VLNC cigarettes at the levels described in the ANPRM on population harm;
- existing science is inadequate to evaluate the impact of VLNC on youth smoking behavior;
- current evidence is inadequate to determine the degree of compensation that might occur for adult consumers using VLNC cigarettes;
- current evidence is inadequate to determine the impact of technology and processes that might be used to produce VLNC cigarettes on public health; and
- symptoms of nicotine withdrawal may be greater at the population level than described by the ANPRM.

The credibility of the rulemaking process rests, in part, on adherence to principles of sound science and evidence. Here, the Agency is contemplating regulatory action based on inadequate science that cannot be replicated by third parties. This is so for two reasons: (1) FDA’s data is not publicly available and has not been critically reviewed by all stakeholders and (2) FDA’s test cigarettes are not available to the public. As a result of these two factors, the science FDA relies on is virtually unreviewable, not subject to notice and comment, and violates virtually every foundational principle of administrative law. FDA should make publicly available all the underlying scientific data it is considering as part of the ANPRM process and also make available the test cigarettes being used by FDA or its limited number of researchers. The Agency should also provide stakeholders with adequate time to review, analyze and respond to that data and have time to test, authenticate, and attempt to reproduce scientific findings such as those discussed in the ANPRM.

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10 We requested underlying study data from Dr. E. Donny and Dr. D. Hatsukami on June 11, 2018 and June 8, 2018 respectively, but have not yet received copies for review. We began making requests for research cigarettes to NIDA in December, 2012. Our most recent request was sent on June 4, 2018. (See supra at Section III, A, 2, b).
A Product Standard of 0.3-0.5 mg Nicotine per gram in Tobacco – or Any Nicotine Ceiling Even Remotely Close to That Ceiling – Will Have a Significant Negative Economic Impact and Countervailing Effects

The implementation of a VLNC standard will create a significant and devastating economic impact. In the absence of conventional nicotine content cigarettes, the resulting depression of volume will significantly affect stakeholders along the tobacco product value chain. Tobacco growers and retailers will be hardest hit, with those in tobacco growing states like North Carolina and Kentucky facing potentially devastating consequences. Tobacco growers, due to the decrease in contracts and demand for tobacco, will have little choice but to grow other, less profitable crops; slash prices to compete for export contracts; or exit farming altogether. Most tobacco retailers, especially convenience stores, will struggle as consumers turn to other, potentially illicit, markets to purchase conventional nicotine content cigarettes. Worse yet, many tobacco retailers will be unable to recover the lost profits by selling alternative tobacco products and will have no choice but to close. The subsequent loss of billions of dollars from volume-based payments, excise taxes, and sales taxes, in addition to corporate and personal income tax losses, will create massive budget holes for federal, state, and local governments. FDA must consider the enormous economic impact resulting from the loss of up to 951,000 jobs, 45,000 businesses and billions of dollars, as it contemplates a VLNC standard.

A Product Standard of 0.3-0.5 mg Nicotine per gram in Tobacco – or Any Nicotine Ceiling Even Remotely Close to That Ceiling – Will Likely Create a Substantial Illicit Market

We believe that a nicotine reduction standard will likely create a substantial illicit market with numerous unintended consequences. The Agency must address each of these unintended consequences or risk promulgating a standard that would subvert its very purpose – undermining smoking cessation and other public health goals.

We address these unintended consequences in our response to FDA’s docket titled, “Concept Paper: Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard” (“Concept Paper”)\(^\text{11}\) (Appendix Attachment 4).

In our response to the Concept Paper, we conclude that:

- a nicotine reduction standard at the levels contemplated by FDA will create a black market that cannot be mitigated by alternative products under current conditions;
- the current black market in the U.S. represents between 8.5% and 21% of cigarette sales and excise tax losses of $3 billion, while the global black market captures 10% of all cigarettes consumed with governments globally losing between $40 and $50 billion in taxes annually;
- mitigating a significant black market through law enforcement will be extremely expensive and difficult; and
- numerous additional blind spots may exist with respect to black markets that could result from the contemplated standard.

The importance of considering countervailing effects cannot be underestimated prior to decision-making and implementation. There is much we know about the unintended and harmful consequences of FDA’s contemplated nicotine reduction standard. The consequences of such a standard are severe and broad in scope – impacting the population (smokers and non-smokers) and government alike. Perhaps even more troubling, however, is what we do not yet know. Prior to rulemaking, 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.
I. A Nicotine Reduction Standard, if Pursued at All, Must be Part of a Comprehensive Plan that Promotes Authorized, Noncombustible, Reduced-Risk Products

A public health consensus now recognizes that there is a continuum of risk among tobacco products, and that products lower in risk have an important role to play in reducing harm for consumers. We have urged FDA to acknowledge and regulate along the continuum of risk since 2009, when Congress first granted FDA regulatory authority over tobacco products.

There are approximately 44 million adult cigarette smokers in the U.S. according to data from FDA’s PATH study. More than half of these smokers are interested in satisfying, less harmful alternatives to cigarettes. Even more may be persuaded to switch to products lower on the continuum of risk by making available appropriate relative risk communications and corresponding product offerings.

Under the direction of Commissioner Gottlieb, FDA announced a new Comprehensive Plan for the regulation of tobacco products, described as a “multi-year roadmap” driven, for the first time, by a “greater awareness” of the “continuum of risk” presented by different forms of nicotine-containing products. The Comprehensive Plan seeks “to strike an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes.”

We applaud the Agency for adopting this regulatory approach, which can yield substantial benefits for the public health and individual smokers by encouraging the development of noncombustible tobacco products that can reduce the harm associated with smoking. As Commissioner Gottlieb stated, the Comprehensive Plan should be used as a vehicle to “move addicted smokers down that continuum of risk to these less harmful products.”

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12 We include a chart that cross-references questions posed in the ANPRM with our responses in the Appendix at Attachment 2.
18 Gottlieb, Protecting American Families.
19 Id. (“[T]he nicotine in cigarettes is not directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year . . . it’s the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire, that directly and primarily cause the illness and death, not the nicotine.”).
20 Id.
To accomplish that important goal, however, there must be products lower on the risk continuum that are available to adult smokers. Unless a market of FDA-authorized noncombustible tobacco products is established before any nicotine product standard goes into effect, adult smokers would have limited choices for reduced risk products, threatening the viability of the Comprehensive Plan. Simply put, if adult smokers do not understand the benefits of reduced harm products and have access to such products, they will instead turn to other combustible products higher on the risk continuum, or seek out illegal black market cigarettes with conventional nicotine yields. This means that, before promulgating any nicotine product standard, FDA should take several key steps consistent with the Comprehensive Plan.

*First,* FDA should recognize that rushing to promulgate a nicotine reduction product standard could be counter-productive and could have the effect of driving smokers to use other combustible products. FDA should allow the market for noncombustible products to stabilize in light of new regulatory requirements bringing additional products under FDA’s regulatory authority. In particular, under FDA’s current compliance policy, substantial equivalence reports and premarket tobacco applications (PMTAs) for newly regulated noncombustible tobacco products are not due until August 8, 2022. Before promulgating a nicotine product standard for cigarettes, FDA should allow an appropriate time following that deadline to allow for completion of the Agency’s review of premarket submissions. Only in this way can FDA ensure that an established market of noncombustible products, lower on the continuum of risk than cigarettes, will be available to smokers if and when a nicotine product standard is promulgated.

*Second,* FDA should take steps to fulfill Commissioner Gottlieb’s direction for “striking an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes.” Commissioner Gottlieb recognized that FDA’s “approach to nicotine must be accompanied by a firm foundation of rules and standards for newly-regulated products” and that “all of these steps must be done in concert and not in isolation” in order for them to be successful. FDA should accordingly finalize a clear set of achievable requirements for all premarket applications, including substantial equivalence (SE), PMTAs, and modified risk tobacco products (MRTP). The absence of foundational rules for bringing new and potentially reduced harm products to market has created uncertainty and hindered the progress of developing innovative products. At the same time, FDA should streamline the premarket review process. For example, the substantial equivalence process has become unnecessarily lengthy and burdensome, and a massive backlog of products awaiting review existed prior to the Agency’s April 5, 2018 *Update on Provisional Substantial Equivalence Review Process.* FDA should usher reports for noncombustible products through the SE process and center its analysis on the harm reduction potential of these products, which represent an important step for moving adult smokers to use products lower on the continuum of risk.

23 *Id.*
Third, FDA should actively provide consumers with information about the continuum of risk—an effort FDA has never undertaken. FDA has authority to “conduct [...] educational and public information programs” related to tobacco use. FDA has acted under this authority for years, and just recently engaged in a public education campaign regarding youth e-vapor usage. FDA should now engage in a long-term public education campaign to ensure that adult smokers understand the continuum of risk and the harm reduction potential of noncombustible products. For FDA’s new Comprehensive Plan to be effective, adult smokers must have access to reduced harm products and the information that actually promotes their ability to make educated choices about tobacco products lower on the risk continuum.

In short, consistent with the Comprehensive Plan, the Agency should make any nicotine product standard part of a truly comprehensive approach that coordinates all of FDA’s regulatory authority to ensure that smokers are encouraged to use products lower on the risk continuum.

II. **A Product Standard of 0.3-0.5 mg Nicotine per gram in Tobacco – or Any Nicotine Ceiling Even Remotely Close to That Ceiling – Is Not Technically Achievable**

The ANPRM states that FDA “is particularly interested in comments about the merits of nicotine levels like 0.3, 0.4, and 0.5 mg nicotine/g of tobacco filler” and “the technical achievability of [such] a maximum nicotine level.” FDA posits that these extremely low levels of nicotine might be achievable through practices and technologies that include: (1) agronomic practices such as “controlled growing conditions, fertilization, [and] harvest” and “cross-breeding plants;” (2) tobacco blending; (3) “nicotine extraction;” and (4) “genetic engineering.”

Manufacturers and the growing community, including state universities, have researched these technologies and practices for decades and, at times, have attempted to employ many of them on a small scale. These prior efforts demonstrate that trying to use these practices to produce commercial cigarettes with VLNC tobacco would raise insurmountable difficulties. Accordingly, a product standard imposing a limit on nicotine content to these levels is not technically achievable and would violate both Section 907 and the APA.

A. FDA Can Only Adopt A VLNC Standard Under Which Production of Commercial Cigarettes Would Be Broadly Technically Achievable

1. FDA’s Product Standards Cannot Ban Cigarettes or Reduce Nicotine Yields to Zero

Any VLNC standard promulgated by FDA must satisfy FSPTCA provisions. Taken as a whole, these provisions reflect a foundational compromise that Congress struck in the FSPTCA: ensuring the continuation of the cigarette industry for adult consumers who choose to smoke.
while allowing substantial FDA regulation. Promulgating a nicotine standard that makes it impossible for manufacturers to market sensorially acceptable cigarettes containing functional levels of nicotine would undermine this compromise, an outcome that Congress did not want and never intended.

Congress specifically reserved to itself the power to make two critically important decisions about cigarettes by expressly prohibiting FDA from (1) banning cigarettes and (2) reducing nicotine yields to zero. The plain language of these provisions forbids FDA from imposing a product standard that bans cigarettes directly. Likewise, construed in the context of Section 907 and the statute as a whole, these provisions also forbid FDA from banning cigarettes indirectly – either by reducing nicotine yield to a nonfunctional level or by rendering cigarettes incapable of being sensorially acceptable to adult smokers. The Supreme Court has made clear that courts must look to the substance and practical effect of a regulation, not merely its form, in determining whether it constitutes an illegal ban.

The cigarette-specific provisions of the FSPTCA confirm that Congress intended to provide for the continued availability of nicotine-containing cigarettes with familiar sensory attributes. Much of the statute focuses on actions FDA can or must take to reduce the morbidity and mortality associated with tobacco product use notwithstanding the continued availability of cigarettes. Provisions of the legislation intended to ensure that consumers receive accurate information about cigarette smoke constituents likewise would be unnecessary without the continued sale of cigarettes. The continued availability of traditional cigarettes is therefore an undeniable feature of the FSPTCA statutory scheme and cannot be effectively erased through a regulatory product standard.

Moreover, to be a “cigarette,” as defined by the FSPTCA, the tobacco in the cigarette must be “functional in the product.” Cigarette tobacco functions in multiple ways, but its two primary

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30 See, e.g., Lawrence O. Gostin, FDA Regulation of Tobacco: Politics, Law, and the Public's Health, 302 J.A.M.A. 1459 (2009) (“The FSPTCA certainly ensures the industry’s survival, as Congress expressly withheld from FDA the power to ban tobacco products or eliminate nicotine, its addictive ingredient . . . .”).

31 Courts have recognized the importance of interpreting statutes to honor compromises. See, e.g., Thomasson v. Perry, 80 F.3d 915 (4th Cir. 1996) (noting that codification of the “Don’t Ask, Don’t Tell” military policy was a careful compromise); Mohasco Corp. v. Silver, 447 U.S. 807, 820 (1980) (90-day statute of limitations may have “represented a necessary sacrifice of the rights of some victims of discrimination in order that a civil rights bill could be enacted”); In re Islamic Repub. of Iran Terrorism Litig., 659 F. Supp. 2d 31 (D.D.C. 2009) (“[T]he Court fully appreciates first and foremost the delicate nature of the political compromise the FSIA terrorism exception embodies.”).


33 Id. § 907(d)(3)(B).

34 For example, in Granholm v. Heald, 544 U.S. 460, 474 (2005), the Court compared a New York law that required out-of-state wineries to establish a distribution operation in New York in order to ship directly to New York consumers, to a Michigan law that expressly banned out-of-state wineries from shipping directly to Michigan consumers. The Court found that New York’s law, while not an express ban, was just an “indirect way” of achieving the same result by increasing the out-of-state wineries costs to make it impossible to compete. The Court thus found that both laws violated the dormant Commerce Clause.


36 See, e.g., id. § 904(e).

37 See also id. § 3(7) (purposes of statute include “to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers”).

38 Id. § 900(3)(B).
functions are to provide a sensorial experience, including taste and aroma, and to provide nicotine at a level that is acceptable to an adult smoker. If a product standard renders tobacco non-functional in the product, by degrading its sensorial properties to the point of being unacceptable to adult smokers, then products that conform to the standard would no longer be “cigarettes” under the statute. A product standard that reduces important taste, sensory, and functional components of tobacco, such as nicotine, to extremely low levels could have that effect.

Such a standard would be a de facto ban of all cigarettes, in violation of the FSPTCA. The standard would make the cigarette one that is no longer functional and would be tantamount to reducing nicotine yields to zero. A regulation that so fundamentally changes the nature of a product, with the intent of destroying consumer demand for it, is a “ban” by any rational definition of the term.

2. Technical Achievability Requires More Than Possibility

FDA must consider whether manufacturers can comply with any standard. In particular, Section 907(b)(1) requires FDA to consider “information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.” The statute does not define the phrase “technical achievability of compliance,” but the plain language meaning of these words reflects Congress’s intent. “Technical” means “[r]elating to a particular subject, art, or craft, or its techniques.” “Achievable” means “[a]ble to be brought about or reached successfully.” The phrase thus refers to a result that can be accomplished.

The most frequent descriptors of nicotine’s sensory effects as reported by smokers include “sharp” and “pungent,” with pleasant ratings on a hedonic scale. N. Thuerauf, et al., Specific sensory detection, discrimination, and hedonic estimation of nicotine enantiomers in smokers and nonsmokers: are there limitations in replacing the sensory components of nicotine? 472-78, J. Clin. Psychopharmacol. (2000).


Alternatively, reading the TCA as allowing FDA to institute a de facto ban or force manufacturers to sell cigarettes that consumers would not purchase would constitute an unconstitutional delegation of legislative power. See e.g., Mistretta v. U.S., 88 U.S. 361, 371-72 (1989); Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 675-76 (1980).


See, e.g., FDIC v. Meyer, 510 U.S. 471, 476 (1994) (In the absence of a statutory definition, “we construe a statutory term in accordance with its ordinary or natural meaning.”).


Id.
successfully – and on an industry wide basis – not merely something that is a theoretical or scientific possibility. This interpretation is further supported by the phrase “of compliance” that qualifies “technical achievability.” This phrase also indicates that technical achievability should include broader considerations – i.e., whether industry-wide “compliance” is technically achievable – and not only whether a small number of cigarettes can be produced meeting a product standard.

The legislative history of Section 907(b)(1) confirms this interpretation. At various times, Congress contemplated language that would have FDA to consider “technological feasibility,” before it instead adopted the “technical achievability” requirement.\textsuperscript{47} “Technological” is a substantially narrower term than “technical,” meaning “[t]echnological” is a substantially narrower term than “technical,” meaning “[r]elating to or using technology.”\textsuperscript{48} A modification that is scientifically possible in a laboratory, described in a research paper or patented might be considered “technologically feasible.” But it would not be “technically achievable” if it were so speculative or impractical that it could not be “achieved” on an industry-wide basis because of practical problems, such as prohibitive cost or lack of consumer acceptability.

Technical achievability also requires sensorial acceptability. If products cannot be commercially produced that comply with both a product standard and are sensorially acceptable to adult smokers, then manufacturers will not be able to sell their products, causing economic loss and disruption of trade. Moreover, before enacting a standard, FDA must consider “all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard . . . such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this subchapter and the significance of such demand.”\textsuperscript{49} This confirms the importance of consumer acceptability, since a cigarette rejected by the general public would create “a significant demand for contraband.”

In addition, the effective date for any standard must “minimize, consistent with public health, economic loss to, and disruption or dislocation of, domestic and international trade.”\textsuperscript{50} FDA must also consider “information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard.”\textsuperscript{51} Furthermore, technical achievability entails an assessment of both the practical and legal limitations on manufacturers, tobacco growers, and other industry stakeholders. For example, FDA must consider “whether meeting the standard would require manufacturers to demand substantial changes to the methods used by domestic farmers to grow the tobacco used by manufacturers.”\textsuperscript{52} These provisions further reflect the importance of factors other than mere scientific possibility when determining technical achievability.

\textsuperscript{47} The technical achievability concept derives from a predecessor bill to the FSPTCA and several alternative proposals. See National Tobacco Policy and Youth Smoking Reduction Act, S. 1415, 105th Cong. (1997); The Universal Tobacco Settlement Act, S. 1530, 105th Cong. (1997).

\textsuperscript{48} Oxford English Dictionary (2nd ed. 1989).

\textsuperscript{49} FSPTCA § 907(b)(2).

\textsuperscript{50} Id. § 907(b)(2).

\textsuperscript{51} Id. § 907(d)(2).

\textsuperscript{52} Id.
Finally, independent of the technical achievability requirement for product standards prescribed by Section 907, the APA precludes FDA from imposing regulatory requirements that are impossible to meet. The APA bars agencies from promulgating regulations that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” and courts have long recognized that unachievable standards are the epitome of arbitrary and capricious regulation. Any product standard that renders products unsellable—by causing them to be sensorially unacceptable, for example—would be arbitrary and capricious. Compliance would be impossible because it is inherently unreasonable to expect manufacturers to produce and sell a product that no one will buy.

B. Existing Farming, Curing and Blending Practices Do Not Provide a Technically Achievable Solution in Isolation or in Combination

The levels of nicotine discussed in the ANPRM would require a drastic reduction in nicotine of up to 98% or greater relative to those levels found naturally in tobacco. American Blend cigarettes use three different types of tobacco ranging in nicotine content: (1) Flue-cured tobacco with leaf ranging from 15 to 45 mg/g and stem from 3 to 7 mg/g, (2) Burley tobacco with leaf ranging from 15 to 50 mg/g and stem from 3 to 7 mg/g, and (3) Oriental tobacco with leaf ranging from 5 to 20 mg/g (this type is not stemmed). Given these ranges and common blending approaches, the nicotine content in most American Blend cigarettes ranges from 14 to 27 mg/g. The ANPRM, by contrast, discusses the possibility of drastically reducing nicotine content to levels ranging from 0.3 to 0.5 mg/g.

The ANPRM observes that agricultural, curing, and blending practices have been used to decrease nicotine content. But FDA fails to recognize that these practices have, at most, lowered nicotine during small-scale production and resulted in only modest reductions in nicotine. Any nicotine reductions that could be achieved with such practices—whether in isolation or together—would not come close to the upper limit of the levels discussed by FDA. Moreover, these practices often have undesirable consequences, such as harming crop yield or leaf quality, or increasing costs, which further reduces their ability to produce large-scale, commercialized VLNC tobacco. And even if sufficient reduction could be achieved, variability

55 Unless otherwise stated, “mg/g” refers to “milligrams of nicotine per gram of tobacco.”
56 When blending the different materials (leaf and stem) to produce cut rag or cigarette filler, manufacturers use these materials in proportions that are closely aligned with the generation ratios of each material in the plant. For example, leaf (of all types) will make up approximately 75% of the weight of the cigarette filler, with the corresponding 25% being stem or reconstituted stem and leaf.
57 The impact on the nicotine yield that smokers actually receive would be even more severe. For example, the ANPRM indicates that the SPECTRUM cigarette with the lowest nicotine content (0.4 mg/g) has a nicotine yield of less than 0.04 mg/cig (ISO). At most, smokers would receive only a miniscule amount of nicotine when smoking cigarettes containing VLNC tobacco. Forcing manufacturers to produce cigarettes that barely, if at all, provide nicotine to smokers would violate the TCA’s requirement that nicotine yields not be reduced to zero (see § 907(d)(3)(B)).
58 83 Fed. Reg. 11,831-11,832.
occurring both in the field and during the manufacturing process would make compliance with
the nicotine limits discussed by FDA extraordinarily difficult, if not impossible.

1. Agronomic Practices Are Inadequate to Yield the Nicotine Levels FDA Desires

The ANPRM identifies the use of existing “agricultural practices” as a strategy for meeting the
levels of nicotine discussed by FDA.59 These “growing and harvesting practices” include
“controlled growing conditions, fertilization, [and] harvest.”60 But the mere fact that
manufacturers, universities and others have assessed the impact of certain agricultural practices
does not mean such practices can achieve the drastic reduction necessary to produce VLNC
tobacco with nicotine content of 0.3-0.5 mg/g. To the contrary, all of the research conducted to
date—including the studies cited in the ANPRM—demonstrates the opposite: these practices
cannot yield crops that come close to such levels.

Variety selection and adjustment of growing techniques would not achieve the reduction
considered in the ANPRM. For example, studies conducted on flue-cured tobacco show that
increasing plant populations can reduce nicotine content.61 But these practices reduced nicotine
content only by 33%, not the 95.8 to 98.9%62 reduction that FDA is proposing.63 Likewise,
Oriental tobacco, which is lower in nicotine than other tobacco types, is produced using several
practices shown to impact nicotine content, such as use of low-fertility regimes on poor soils,
growing in hot and dry conditions, and not topping plants.64 The nicotine content in Oriental
tobacco, however, still does not come close to the levels discussed in the ANPRM.

Changing the production practices of individual plants also would be insufficient. One common
practice when growing Flue-cured and Burley tobacco is “topping,” which involves removing
the apical meristem during the early stages of flowering.65 Although topping can increase the
nicotine content of the remaining tobacco plant, research demonstrates that eliminating this
practice would not result in lowered nicotine content anywhere close to the levels discussed by
FDA.66 For example, topping studies performed on Flue-cured tobacco showed that plants that
were not topped averaged only 37% less nicotine than plants that had been topped.67 Once again,
this does not come close to meeting the 95.8 to 98.9% reduction that FDA is proposing in the
ANPRM. Eliminating topping also would have other consequences, including lower crop yields,
decreasing tobacco quality, and lessening the sales value of the tobacco.68 Indeed, the same

59 Id. at 11,831.
60 Id.
“Principles of Tobacco Production”].
62 Principles of Tobacco Production 189 (Results from Table 51 shows that the controls (topped and suckered) had
2.8% nicotine whereas not topped plants and suckered with 1.76% nicotine levels.).
63 Id.
64 D. Layten Davis & Mark T. Nielsen, Tobacco: Production, Chemistry and Technology chs. 5c, 8, & 11 (1999)
[hereinafter “Tobacco Production”].
65 T.C. Tso, Production, Physiology and Biochemistry of Tobacco Plant 438 (1990).
(July 29, 1958), available at http://legacy.library.ucsf.edu/tid/eaz75f00 (research finding topped and suckered,
3.30% nicotine; topped not suckered, 2.89%; not topped or suckered 2.37%); Principles of Tobacco Production at
195, Table 54 (finding nicotine content of plants that were not topped was 1.49%, topped at a height of 20 leaves
was 1.61%, and topped at a height of 10 leaves was 2.64%).
67 Principles of Tobacco Production at 189.
68 Id. at 186 (“[f]or maximum yield and dollar return, the plants should be topped.”).
study also found a 23% reduction in farmer yield and a 25% reduction in gross income per acre for the non-topped crop.\textsuperscript{69}

Likewise, modified leaf selection techniques would be inadequate. FDA states that “tobacco leaves located near the top of the plant can contain higher concentrations of nicotine” and, based on this research, raises the possibility of “substituting leaves found lower on the plants [to] reduce the nicotine content of tobacco products.”\textsuperscript{70} Studies on this practice, however, have reported that the amount of nicotine in leaves at the bottom of the plant is only two to three times less than the nicotine content in the leaves at the top of the plant.\textsuperscript{71} Again, this would not come close to the levels discussed in the ANPRM. This practice also would be incredibly wasteful, since the top of the plant presumably would be discarded, and could have significant economic implications for farmers who would be required to discard approximately 70% of their crops.

Nor can “chemical agents . . . reduce nicotine content” to those levels.\textsuperscript{72} The studies cited by FDA make this clear. In one such study, nicotine content was reduced from 2.72% to 2.42% (27.2 to 24.2 mg/g) after certain chemicals were added to the plant.\textsuperscript{73} The second study reported only a “9% reduction in the nicotine content of the leaf.”\textsuperscript{74} And, although the third study found an approximately 25% reduction in nicotine for an experimental group treated with a chemical,\textsuperscript{75} researchers noted that “different locations of growth [between the control and experimental groups]” – as opposed to the treatment itself – “are likely responsible for the different levels of alkaloids found in the control.”\textsuperscript{76}

Studies not cited by FDA confirm the inability of chemical agents to reduce nicotine enough to approach the levels discussed in the ANPRM. Moreover, chemicals can have adverse and unintended consequences on leaf quality and crop yields. And even if these results justified the widespread use of chemical agents, farmers would need to obtain necessary permits and approvals from regulatory authorities, before such chemicals could be used in the field, presenting further obstacles to this approach. (\textit{See infra} at Section II, C, 2).

Biologics also cannot be used to reduce nicotine to the levels discussed in the ANPRM. FDA references research concerning “microbial bacteria that actively degraded nicotine while leaving other components of the leaf intact.”\textsuperscript{77} Nowhere did these studies conclude that bacteria could be used to reduce nicotine content in tobacco, let alone reduce it to the range being discussed by FDA.\textsuperscript{78} Moreover, although FDA refers to “[c]onsumer product testing” on tobacco with

\begin{itemize}
  \item \textsuperscript{69} \textit{Id.} at 189.
  \item \textsuperscript{70} 83 Fed. Reg. at 11,831 (citing Reference 131).
  \item \textsuperscript{71} \textit{See, e.g.}, \textit{Principles of Tobacco Production} at 286.
  \item \textsuperscript{72} 83 Fed. Reg. at 11,832 (citing references 163-165).
  \item \textsuperscript{73} \textit{Imperial Tobacco Co., Report Regarding Test on Quality of Final Flue-Cured Product} (Apr. 24, 1969), \textit{available at} \url{http://legacy.library.ucsf.edu/tid/mn94a99} (Ref. 163 in ANPRM).
  \item \textsuperscript{74} M. Passey, \textit{Canadian Sucker Control Studies 630000 Crop}, \textit{Imperial Tobacco Co.} (Dec. 18, 1964), \textit{available at} \url{http://legacy.library.ucsf.edu/tid/bjx60f00} (Ref. 164 in ANPRM).
  \item \textsuperscript{75} The results noted that the experimental groups had 2.88% and 3.02% total alkaloids versus 3.80% in the control group.
  \item \textsuperscript{76} 800000 D.R.S. \textit{Ridomil Experiment} (1980), \textit{available at} \url{http://legacy.library.ucsf.edu/tid/ueg52i00} (Ref. 165 in ANPRM).
  \item \textsuperscript{77} \textit{See V.L. Geiss}, \textit{Bw Process I: Reductions of Tobacco Nicotine Using Selected Bacteria} (Dec. 29, 1972), \textit{available at} \url{http://legacy.library.ucsf.edu/tid/jlw84a99} (Ref. 168 in ANPRM); \textit{V.L. Geiss}, \textit{Bw Process VI: Metabolism of
reduced nicotine that supposedly showed the ‘‘product acceptability’ of that tobacco was equal to that of untreated tobacco,’’ the nicotine content in that tobacco was only reduced “by 50%” not the extent necessary to meet the levels discussed by FDA. Finally, although FDA cites a patent that was issued for “a salivary excretion produced by a caterpillar,” the patent description defies that which is known regarding nicotine biosynthesis and transport within the plant and there is no further indication that this technology could be used in the field to produce tobacco that could be used to produce commercial cigarettes. (See infra at Section II, D, 2 - discussing problems that must be overcome to replicate research under actual growing conditions sufficient to produce commercial cigarettes).

2. Curing Practices Are Inadequate to Yield the Nicotine Levels FDA Desires

The ANPRM identifies curing as a possible avenue for lowering nicotine content. As an initial matter, the suggestion that curing can impact the nicotine content of leaves is overly simplistic and assumes that all tobaccos can be cured in the same manner. This is not the case. Current curing practices commercially used to cure the tobacco types used in American Blend cigarettes are flue-curing, air-curing and sun-curing. Flue-cured tobacco is cured under controlled conditions managing heat and moisture over a 7-10 day period, Burley tobacco is air cured in ambient conditions in a process taking several months, and Oriental tobacco is sun-cured.

Moreover, research demonstrates that any reduction that could be achieved by changing curing practices would be marginal at best and most likely within the normal variability seen in nicotine levels of field-grown tobacco plants. In addition, changing curing practices would result in other problems. Alternative curing practices are not practical or commercially feasible to meet the leaf quality required for current commercial products. The curing process imparts the flavor and sensory attributes that adult consumers have come to expect, and significant changes to curing would result in a totally different product that may not be acceptable to consumers, resulting in the very kind of de facto ban Congress prohibited.

The research cited in the ANPRM confirms this point. FDA cites an internal company document when stating that “researchers observed that the properties of tobacco, including nicotine content, could be altered without the need for nontobacco additives by modifying curing practices.” But this document did not remotely suggest that curing could be used to make significant reductions in nicotine. Rather, it notes generally that “[t]heoretically, it should be possible to modify cured tobacco properties beyond the present distinctions into air- and Flue-cured” and that unspecified “enzyme inhibitors could be added to block individual reactions during curing.”

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80 Id. at 11,832.
81 Id.
82 Tobacco Production at ch. 5.
83 Id. at 32.
84 Id. at chs. 5c, 8 & 11.
86 Id.
FDA also asserts that “one manufacturer has explored efforts to speed up the process of aging tobacco, in part to alter or limit the changes in chemistry that naturally occur.”\textsuperscript{87} This research, however, did not conclude that curing practices could produce significant reductions in nicotine content. As an initial matter, “aging” is not the same thing as “curing.” Where “normal aging” was used, the tobacco was stored for supply chain security and any change in nicotine content during the storage period was insignificant.\textsuperscript{88} When tobacco was subject to “forced aging,” the decrease in nicotine content of one sample from 1.56\% to 1.55\% (15.6 to 15.5 mg/g) was not statistically significant; the nicotine content of the second sample increased from 2.47\% to 2.53\% (24.7 to 25.3 mg/g).\textsuperscript{89}

3. Blending Is Inadequate to Yield the Nicotine Levels FDA Desires

The ANPRM proposes that nicotine levels can be reduced through blending techniques such as “replac[ing] more commonly used nicotine-rich varieties like \textit{Nicotiana rustica} with lower nicotine varieties.”\textsuperscript{90} \textit{Nicotiana rustica} is not used in most U.S. commercial cigarettes.\textsuperscript{91} Additionally, \textit{Nicotiana rustica} is a different species of plant than the \textit{Nicotiana tabaccum} that is grown and used in the U.S. Rather, varieties of \textit{Nicotiana tabaccum} containing less nicotine than \textit{Nicotiana rustica} have routinely been used in U.S. cigarettes for decades.\textsuperscript{92} These varieties of \textit{Nicotiana tabaccum}, however, do not come close to meeting the nicotine levels discussed by FDA.

For example, FDA recognizes that “Oriental Turkish-type cigarettes . . . deliver substantially less nicotine than cigarettes that contain air-cured Burley tobacco . . .”\textsuperscript{93} But, even though the amount of nicotine in Oriental tobacco is lower than in Flue-cured and Burley tobacco, it is still 5 to 20 mg/g on average.\textsuperscript{94} Accordingly, even if manufacturers increase the amount of Oriental tobacco they use, the resulting blend would be far from VLNC levels discussed in the ANPRM. In addition, Oriental tobacco is not grown in the United States and cannot be produced in the same environments in which Burley and Flue-cured tobacco are grown. A shift to Oriental tobacco would therefore be disastrous for domestic tobacco farming.\textsuperscript{95}

Any attempt to impose a rule requiring certain types of tobacco would also ignore that Congress expressly denied FDA the authority to directly regulate tobacco growers. In particular, the statute does not apply to “tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers.”\textsuperscript{96} In a similar vein, FDA is not authorized “to promulgate regulations on any matter that involves the production of

\textsuperscript{87} Id.
\textsuperscript{88} Table XIII, Summary of Flue-Cured Aging Study, Forced Aging (Dec. 31, 1991), available at http://legacy.library.ucsf.edu/tid/uvu54f00. (Ref. 166 in ANPRM).
\textsuperscript{89} Id.
\textsuperscript{90} 83 Fed. Reg. at 11,831.
\textsuperscript{91} Tobacco Production at 1.
\textsuperscript{92} Id.
\textsuperscript{93} 83 Fed. Reg. at 11,831.
\textsuperscript{94} Tobacco Production at 350.
\textsuperscript{95} See, e.g., id. at 154 (“The best quality Oriental leaf is produced in rocky, poor, somewhat infertile soil containing minimal amounts of nitrogen and organic matter. The most suitable terrains are mountainside locations with good drainage and ample direct sun.”).
\textsuperscript{96} FSPTCA § 901(c)(2).
tobacco leaf or a producer thereof . . .”97 In light of these constraints, FDA cannot call for specific agricultural practices, demand changes to how tobacco leaf is prepared for the manufacturer, or likewise establish a standard that can only be met through one of these means. This is in line with the language of Section 907(d)(2) that demonstrates that Congress intended for manufacturers to specify and drive such changes.

Moreover, manufacturers cannot simply substitute one variety of tobacco for another without drastic consequences to the cigarette. For example, Oriental tobacco has different sensorial qualities that prevent simply substituting it in blends for other varieties of tobacco.98 Just as changing the kind of grape in a blended wine would change the taste, flavor, and consumer acceptability for a glass of that wine, changing the type of tobacco in a cigarette blend (e.g., from Burley or Flue-cured to Oriental) would fundamentally alter the flavor profile and other aspects of the cigarette.99 Moreover, it is well-established that tobacco type and blend can affect quantities of harmful and potential harmful constituents (“HPHCs”) in cigarettes.100 In fact, FDA acknowledged this connection during its review of substantial equivalence reports, and routinely requires manufacturers to submit additional data regarding the effects of tobacco blend changes.101 FDA does not suggest in the ANPRM that there is an adequate scientific basis for understanding the potential effects on HPHC levels of various unspecified blends aimed at reducing nicotine levels. For this reason, even if FDA were correct that “[b]lend differences can produce significant variations in nicotine concentration in the tobacco rod,”102 these differences would not necessarily provide a technically achievable way to reduce nicotine to the levels discussed by FDA.103

The documents cited in the ANPRM confirm this stance. FDA cites a 2012 Health Canada Report (Ref. 128) that did not find, or even suggest, that reductions in nicotine content achieved by blending would come close to the levels discussed by FDA. In fact, the studies cited in that report indicate otherwise.104 FDA also cites a 2004 article (Ref. 133) for the proposition that “manufacturers could select specific tobacco seedlings that are low in nicotine and plant only those low nicotine seedlings” as a strategy for nicotine reduction.105 Not only did that article not report reductions anywhere close to those discussed in the ANPRM, but the authors of that

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97 Id. § 901(c)(2).
98 See, e.g., Tobacco Production at 157 (“The highly acidic nature of Izmir is important in blended cigarettes as it helps to smooth the smoke by neutralizing the base characteristics of burley.”).
99 Id. at chs. 5c & 11.
100 See, e.g., G. Jaccard, Comparative Assessment of HPHC Yields in the Tobacco Heating System THS2.2 and Commercial Cigarettes, 90 Regulatory Toxicology and Pharmacology 1, 2 (2017) (stating “[t]he impact of the tobacco type and blend is well established. . . .”).
103 In addition, substituting one tobacco type for another would require some type of premarket review by or certification to FDA. (See infra at Section VIII).
104 For example, one study found that nicotine content of bright tobacco ranged from 2 to 2.5% and nicotine content of Burley tobacco ranged from 2.5% to 3.5%. Another study found that bright leaf contained 1.87% nicotine and Burley leaf had 2.5% tobacco. G.F. Wayne, Tobacco Industry Research on Modification of Nicotine Content in Tobacco (1960-1980), Final Report, Prepared for Health Canada, Table 1 (Dec. 21, 2012) (Ref. 128 in ANPRM).
article were clear that they were not evaluating “the technological feasibility and implications of tobacco denicotinisation processes.”\(^{106}\) FDA also refers to “internal tobacco industry documents” that supposedly “describe the use of leaf blending and tobacco selection to control the nicotine content of cigarettes.”\(^{107}\) These documents likewise do not indicate that blending or tobacco selection can produce the extremely low levels in nicotine discussed by FDA. One was a 1966 report that compared the amount of nicotine in certain cigarettes and only indicated generally that less nicotine in smoke would be produced if there was less nicotine in tobacco.\(^{108}\) The other document reported on a 1984 study of toxicity in rats that did not address this issue.\(^{109}\)

4. There Is No Evidence That Agricultural, Curing and Blending Practices Could Be Combined to Produce VLNC Tobacco

There is no evidence that using two or more of these agronomic, curing, and blending practices together would reduce amount of nicotine in tobacco to the levels discussed in the ANPRM. Most of these technologies produce modest reductions. To reduce nicotine content to 0.3 to 0.5 mg/g, however, existing nicotine levels naturally found in tobacco would need to be reduced by more than 98%. There are no published studies combining these production practices. Even if the reduction produced by each of these technologies could be replicated in a single crop, the hypothetical total of these reductions still would fall well short of this amount.

A simple, yet extreme and unrealistic (for U.S. growers) example illustrates this. Assume a manufacturer decided to produce a cigarette using only Oriental tobacco, because Oriental has less nicotine than other varieties of tobacco. Under normal growing conditions for Oriental tobacco, the average nicotine content in leaf begins at 10.5 mg/g. Such plants are not topped, but a farmer growing this tobacco might use only bottom leaves to try to get lower nicotine content. Assuming this could reduce nicotine content by 50%, the nicotine content in these leaves still would exceed 5 mg/g. The farmer then might try to change curing practices and use chemical agents and biologics. Assuming these practices could reduce nicotine content by another 50% (which would exceed the amount of reduction found in the research discussed above), the average nicotine content still would exceed 2.5 mg/g – an amount five times higher than even the outer limit of the range discussed in the ANPRM.

There are other practical problems presented by making such changes. Using different techniques to try to reduce nicotine content might have a bigger impact on crop yield and profitability for the grower. Indeed, in the above example, the single greatest reduction in nicotine content was achieved by discarding over half the plant. This example would also be devastating for domestic tobacco farmers because Oriental tobacco is not produced in the United States. Moreover, this approach assumes that all of the practices discussed by FDA could be used on a single crop of tobacco. But certain practices that would reduce nicotine in one variety

\(^{107}\) 83 Fed. Reg. at 11,831 (citing References 135 and 136).
of tobacco might not work with another variety. For example, curing practices and chemicals might not produce the same reduction in nicotine content when Oriental tobacco is used because the plants are grown under different conditions. Furthermore, as discussed above, changing curing practices would necessarily impact the taste, flavor profiles, constituents and other facts in the tobacco and might make cigarettes produced using that tobacco unacceptable to consumers. And, as discussed below, this approach would still entail significant problems with crop and manufacturing variability.

For all of these reasons, changing agronomic practices, curing, or blending techniques would not make VLNC tobacco technically achievable. It therefore appears that the VLNC levels discussed by FDA could be met only if some form of nicotine extraction or biotechnology solution were developed. As discussed below, despite decades of research and development on these two strategies, neither provides a technically achievable way to meet a VLNC standard.

C. Nicotine Extraction Techniques Are Not a Technically Achievable Solution

The ANPRM identifies nicotine extraction as a way to lower nicotine content. As FDA recognizes, this concept is not new. Since the 1950s, PM USA has extensively researched the use of solvents to extract nicotine from tobacco. Despite committing massive amounts of resources, effort, and time to testing nicotine extraction methods, PM USA determined not only that it is extremely difficult and costly to achieve nicotine reductions using this technology, but also that adult smokers overwhelmingly reject cigarettes made with chemically extracted tobacco. PM USA’s research on nicotine extraction confirmed the conclusions of the National Cancer Institute that removing nicotine can result in bad taste and negatively affect consumer acceptability.

1. Decades of Testing Show That Nicotine Extraction Methods Do Not Provide a Technically Achievable Solution for a VLNC Standard

In the 1950s, PM USA began researching and testing chemical and mechanical extraction methods for reducing nicotine in cigarettes. These efforts demonstrated the limits of nicotine extraction as a pathway for commercializing VLNC cigarettes.

a. Early efforts at chemical and mechanical extraction resulted in inadequate nicotine reduction and unacceptable product quality

Water extraction. In the mid-1950s, PM USA tested water-based extraction methods on Burley tobacco. Initial tests in which Burley tobacco was dipped in water for a short period of time removed about 22% of nicotine from the tobacco and indicated that a higher percentage could be

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111 Bates numbers in the citations throughout this section refer to archived documents available on the University of California San Francisco Industry Documents Library: https://www.industrydocumentslibrary.ucsf.edu/tobacco.
112 Smoking and Health Program, National Cancer Institute, June 1976 Status Report (1003107637/7908) at pp. 19, 53 (“Nicotine has been found to be a major contributor to cigarette flavor acceptability. No matter how ‘safe’ a less hazardous cigarette might be, smokers can be expected to continue smoking more hazardous cigarettes, if the less hazardous cigarette ‘tastes lousy.’”).
removed if the Burley was dipped for a longer time period.\textsuperscript{113} PM USA scientists were concerned, however, that the process would affect the smoking quality of the tobacco.\textsuperscript{114} A subsequent project used the water dip method, followed by wringing out the tobacco and drying it in an oven.\textsuperscript{115} Although PM USA was able to extract up to 95\% of nicotine using this process,\textsuperscript{116} the cigarettes made from this tobacco had poor smoking characteristics, including flat, tasteless smoke.\textsuperscript{117} The process also failed to yield tobacco with nicotine levels that would meet the nicotine levels discussed by FDA.

PM USA continued researching and evaluating the potential of water extraction as a nicotine reduction technique for multiple decades. PM USA ultimately rejected water as a viable extraction solvent because of continued problems with taste, increases in toxic compounds, and the loss in the weight of tobacco that occurred (soluble loss).\textsuperscript{118} The references FDA cites in the ANPRM acknowledge these limitations of water extraction tests, although the ANPRM does not address them.\textsuperscript{119}

**Alcohol, ketones, and other solvents.** From the 1960s to the 1980s, PM USA continued to research whether various solvents—including alcohol, ketones, aldehydes, acids, chlorinated solvents, and other chemical compounds—could be used to produce cigarettes with lowered nicotine levels.\textsuperscript{120} For example, PM USA studied a process that employed methyl ethyl ketone (“MEK”) to extract nicotine from tobacco.\textsuperscript{121} Brine was then used to separate the nicotine from the MEK and return certain constituents to the tobacco.\textsuperscript{122} Although this process showed the ability to remove 80-90\% of nicotine, the tobacco presented significant sensorial problems, including significant flavor and impact issues.\textsuperscript{123} In tests, for example, it was often described as “dry” and “bitter.”\textsuperscript{124} Participants in one test “preferred” an ordinary cigarette, saying it “had

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\textsuperscript{113} See Monthly Progress Report for the Period Ending July 31, 1954, Project 2-007F Part II – Extraction of Nicotine from Burley Tobacco (2022216962/965).

\textsuperscript{114} Id. at 2022216965.

\textsuperscript{115} Monthly Progress Report for the Period Ending April 30, 1955, Project 2-012, Reduction of Nicotine in Tobacco (1001900597/598).

\textsuperscript{116} See id. at 1001900597; see also Monthly Progress Report for the Period Ending October 31, 1955, Project 2-012, Reduction of Nicotine in Tobacco (1001900604/605).

\textsuperscript{117} See id. at 1001900597; see also Monthly Progress Report for the Period Ending October 31, 1955, Project 2-012, Reduction of Nicotine in Tobacco (1001900604/605).

\textsuperscript{118} See C. Lilly, Project ART Richmond Meeting (Nov. 11, 1986) (2021559550/557); Nicotine Control as Related to Cigarette Acceptability, Project 0302 Summary (Apr. 24, 1963) (1001900069/070).

\textsuperscript{119} See 81 Fed. Reg. at 11,831 (citing Ref. 128 in ANPRM).


more tobacco flavor” and “was more satisfying.” And again, the nicotine reductions were not as dramatic as those discussed by FDA in the ANPRM.

Another project sought to develop an economically practical low-tar, low-nicotine delivery cigarette through the use of filler modifications. But PM USA continued to experience problems with the smoking characteristics of nicotine-extracted tobacco, which was described as more irritating and bad-tasting compared to tobacco manufactured through typical methods. The more severe the extraction of nicotine, the more detrimental the effect on flavor. It is likely that volatile compounds that impart flavor are also extracted by this chemical process. These efforts likewise did not produce tobacco with nicotine levels that would meet a VLNC standard.

Steam distillation. In the 1970s, PM USA explored the viability of steam distillation for reducing nicotine levels. In the steam distillation process, tobacco was steamed and ammonia was used as a vehicle to help drive out nicotine. PM USA researchers hypothesized that this process might avoid the problems of solvent extraction because the tobacco was not dipped in a solvent. While steam distillation lowered nicotine levels, it was less effective at reducing nicotine than solvent extraction, and did not approach reductions in the range of interest in the ANPRM. In addition, steam distillation left behind higher levels of ammonia in the smoke, which negatively affected taste. PM USA eventually abandoned steam distillation because of these taste problems and the low level of nicotine extraction achieved.

MEK, at 2042215860/861 (smoke of cigarettes treated with methyl ethyl ketone “tended to have a drying effect in the smoker’s mouth . . . and tended to have a taste that was described as bitter”); Nicotine Control as Related to Cigarette Acceptability (Feb. 22, 1963) (1001900065/0066) at 1001900066 (“the control had more tobacco flavor, was more satisfying and was preferred over the low nicotine cigarette”); Final Report – Low Nicotine, at 2042215860/861.

125 Nicotine Control as Related to Cigarette Acceptability (Feb. 22, 1963) (1001900065/0066) at 1001900066 (“the control had more tobacco flavor, was more satisfying and was preferred over the low nicotine cigarette”).

126 See Project 36-0300 at 1000858470.

127 Id. at 1000858479; see also Mem. from E.J. Gray to Mr. J.E. Lincoln re: Final Report – Low Nicotine, MEK, Parliament (Project 225 – Standard Parliament vs. 226, MEK Preliminary issued 2-28-62) (Mar. 20, 1962) (2042215860/861) (smoke of cigarettes treated with methyl ethyl ketone “tended to have a drying effect in the smoker’s mouth . . . and tended to have a taste that was described as bitter”).

128 See Reduction of Smoke Tar & Nicotine at 2021642054.

129 See Project ART Richmond Meeting, at 2021559552; C. Lilly, Revised Board Talk (July 9, 1987) (2020153270/3287) at 2020153271; Mem. from Betty M. Handy to H.B. Merritt re: Removal of Nicotine from Tobacco by Steam Distillation (Oct. 18, 1971) (2062952228/238); Mem. from G. Gellatly to R.A. Tamol re: Alkaloid Reduction in the ADT Drier (Jan. 23, 1973) (1000717407); Mem. from G. Gellatly to W.L. Dunn re: Evaluation of Human Response to Low Nicotine Cigarettes (July 16, 1973) (1000727531); Mem. from F.V. Utsch to K. S. Burns re: P.M. R&D Alkaloid Reduction Trials Using Steam/Ammonia Treatment (Feb. 14, 1977) (1000729759/763).

130 For an explanation of how the ammoniation and steam stripping process worked, see “The Denicotinized Tobacco Story” (1994) (2073355480/550) at 2073355496.

131 See Mem. from R. B. Seligman to Mr. F. E. Resnik re: Nicotine Free Cigarettes (2022252839) (July 27, 1983) (steam distillation achieved only 80-90% of nicotine removal); see also Evaluation of Human Response to Low Nicotine Cigarettes, at 1000727531.

132 Internal ref. by C. Lilly to Board Talk, Low Nicotine Project (project ART), July 9, 1987 (2031437047-2031437065).

SCFE. In the late 1970s, PM USA began researching the possibility of using SCFE—one of the technologies specifically referenced in the ANPRM—to remove nicotine from tobacco.134 SCFE uses gas in its “supercritical” state as a solvent. PM USA used carbon dioxide gas (CO2) compressed under high pressure and at a low temperature until it became a liquid. The SCFE process allowed for significant reductions of nicotine. But like prior nicotine extraction processes, this technology also failed to produce tobacco that could be used to produce sensorially acceptable cigarettes.135 Nor did it produce tobacco with sufficient reductions in nicotine to meet the levels described in the ANPRM. In September 1979, PM USA determined that because of the “very high pressures and very long cycle times” that produced relatively small amounts of de-nicotinized tobacco, SCFE using CO2 was not economically feasible.136

b. PM USA’s efforts to market VLNC cigarettes produced using SCFE illustrate the inherent problems with this approach

In December 1985, PM USA began a project focused on alkaloid reduced tobacco (the Project), with the objective of producing commercially acceptable cigarettes with low nicotine. The Project contemplated several methods for extracting nicotine: (1) SCFE; (2) low alkaloid cultivars; (3) genetically engineered low alkaloid tobacco; and (4) other extraction methods.137 However, SCFE was the focus of the project and was viewed as the technology of choice for removing nicotine from tobacco in the short-term. The Project took into account the results of past efforts at nicotine extraction that showed soluble loss and poor taste posed significant obstacles.138

In the fall of 1986, PM USA internally tested de-nicotinized blends (both low tar and full flavor) in six subjective taste categories. Although SCFE was efficient at removing nicotine, the resulting tobacco had very poor flavor. SCFE removed important taste compounds in addition to the nicotine, including oils, waxes, and other flavorful compounds.139 The Project’s blends rated worse than the control blends in all six categories.140 Rather than showing that smokers acclimated to the drastic change in taste, testing showed that cigarettes made from the Project’s tobacco became progressively worse in taste as they were smoked and gave smokers “stinging, numbing sensations, mouth coating, thinness, and lingering aftertaste.”141

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135 Internal ref. by C. Lilly to Board Talk, Low Nicotine Project (project ART) (1987) (2031437047).
136 Mem. from F.V. Utsch to K.S. Burns re: Supercritical CO2 Extraction of Nicotine (Sept. 28, 1979) (1003391090/1092).
137 The “other extraction methods” included (1) water extraction using methylene chloride reconstitution, a method abandoned because solvent residue remained in the tobacco at an unacceptably high level; (2) water extraction with salt casing addition, a method abandoned because it produced bad tasting tobacco; and (3) nicotine extraction through vapor phase transfer, a method also abandoned because only 70% of the nicotine was extracted.
138 Project Art, Presentation by Cliff Lilly (Nov. 11, 1986) (2021559550/9572). The presentation also explained that water extraction was not a viable approach to nicotine removal. Id. at 2021559554. PM USA’s prior extraction efforts, in addition to nicotine, removed “sugars and other flavor contributors,” and resulted in “hotter smoke, more harshness and washed out taste,” such that “the more severe the extraction, the more detrimental the effect on smoke flavor.” Reduction of Smoke Tar and Nicotine at 2021642046/2065.
141 Id. at 205184633.
PM USA tried to replace the tobacco derivatives (other than nicotine) removed by extraction to restore taste and structure, but had no success. Even when these derivatives were combined back with treated tobacco, they did not have the same chemical impact on the cigarette, and the cigarette continued to have structural and taste problems.\(^{142}\)

The problems of nicotine extraction were reflected in the poor performance of PM USA’s “Next” project with adult smokers, a proposed commercial cigarette product developed through the Project in light of decades of research on nicotine extraction. Next built upon the testing PM USA conducted in 1986, which had recorded extensive taste and flavor problems in the tobacco.\(^{143}\) In 1988 and 1989, PM USA conducted a series of consumer research tests on Next, with test groups ranging in size from the low-hundreds to up to 4,000 adult smokers.\(^{144}\) This research showed that while most smokers were interested in the concept of a VLNC or de-nicotinized cigarette, they preferred their regular brands and would not continue to smoke Next.\(^{145}\) In one particular survey, 92% of the smokers liked the idea of a de-nicotinized cigarette generally, but only about 17% liked and wanted to continue smoking Next cigarettes.\(^{146}\) Specific complaints about Next cigarettes included bad taste, bad aftertaste, and lack of strength.

The poor response to Next in consumer testing was matched by the product’s poor commercial performance in the marketplace. PM USA concluded that the initial formulation of Next had limited potential after the product achieved unacceptably low share performances in 1989 test markets, with only 0.3% of market share.\(^{147}\) PM USA sold Next in different lead markets in 1990, after making improvements to the product formula, packaging, advertising, and promotional plans.\(^{148}\) PM USA also began marketing Merit\(^\text{TM}\) De-Nic in Spokane, Washington.\(^{149}\) The Merit\(^\text{TM}\) cigarettes were identical to the Next cigarettes except for the packaging. These cigarettes continued to show poor market performance, with consumers lodging a series of complaints about the product, including that “it’s like smoking a lettuce leaf” and “it makes my throat sore.”\(^{150}\) PM USA also extended its test marketing to Phoenix, Arizona

\(^{142}\) Id.

\(^{143}\) See Subjective Internal Testing of ART Project Flavor at 2057044459; Project ART Nicotine Add-Back Test Questionnaire (Dec. 1986) (2031436956); OC Walk-In Test of Pilot Plant ART AB, Pilot Plant ART AB with Nicotine Added Back, and an Unextracted Control (Dec. 22, 1987) (2057044472/474).


\(^{146}\) POL ART Extended Testing at 2023159987, 2023159991.


\(^{148}\) See Mem. from Marketing Information and Analysis/Deborah Potter to Peter Henriques re: Next De-Nic Market Check (June 27, 1990) (2056140809/811) [hereinafter Next De-Nic Market Check].

\(^{149}\) Unless otherwise noted, references to Next in this White Paper are intended to include Next, Merit De-Nic and Benson & Hedges De-Nic.

\(^{150}\) See Next De-Nic Market Check at 2056140810.
in October 1990 with a Benson & Hedges™ brand extension. In a tracking study performed several months after the Phoenix market opened, it became clear that the Benson & Hedges™ extension was faring no better in the Phoenix market than others.

During this time, members of the public health community severely criticized these brands. For example, the director of the U.S. Office on Smoking and Health (“OSH”) told the Wall Street Journal that Next “shouldn’t be considered safe at all” since it contained carcinogens. The OSH even held a meeting in 1989 with members of the public health community at which the group discussed Next and going to war against similar “safer” designs. Likewise, a coalition made up of the American Cancer Society, the American Heart Association, and the American Lung Association wanted to put a halt to cigarettes promoted as “de-nicotined,” citing concerns that consumers could mistakenly believe that these products were safer, healthier and less addictive. They expressed concern that Next would encourage non-smokers to begin smoking (since they would not fear becoming addicted) and would lull addicted smokers who would otherwise quit into continuing to smoke. They also expressed concerns that consumers would compensate for the low nicotine level in the cigarettes by smoking more often, exposing them to more carcinogens, leading the coalition’s staff director to say the product was “the most hazardous tobacco product put on the market in the last 10 years.”

Ultimately, Next was never able to capture and hold more than 0.2% of the market, and stores started refusing to carry Next because of the lack of sales. Between June 1990 and April 1992, each of the test markets was discontinued, and in January 1993, the commercial production facility was closed. Like earlier research efforts, the failure of Next, and the Project as a whole, demonstrated that nicotine extraction is not a viable solution.

PM USA ultimately concluded that “extracting the nicotine from cigarettes decreases strength, satisfaction, and increases off-notes such as mouthcoating, unusual flavor, and nontobacco taste.” PM USA was never able to fully overcome the negative taste effects of nicotine extraction so as to make nicotine extraction a technically achievable process for reducing

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153 Id.
nicotine content in commercialized cigarettes.158 Furthermore, the tobacco produced during the Project did not even meet the 0.3-0.5 mg limit discussed in the ANPRM.159

2. Using Extracted Tobacco on a Commercial Scale Would Have Adverse Economic and Environmental Impacts

Even if a nicotine extraction method could be developed to produce sensorially acceptable cigarettes meeting a VLNC standard, new industrial facilities would be needed to support nicotine extraction on the scale necessary to treat the volume of tobacco used in the production of commercial cigarettes for the entire domestic market. Accordingly, any product standard requiring extraction to meet it would force manufacturers to commit a massive amount of resources to these projects. For example, the facility that PM USA built when researching and developing the Next brand cost more than $250 million in the 1980s and had a capacity of eight billion cigarettes per year. Accordingly, constructing a facility today that would be large enough to process sufficient tobacco to meet PM USA’s volumes and share likely would exceed one billion dollars just to begin commercial production.

Even if existing facilities could integrate newly developed processes, the Clean Air Act and Clean Water Act (and their state equivalents) require manufacturers to first obtain pre-construction environmental permits and approvals for (a) new or modified air emissions sources (e.g., New Source Review or “NSR” permitting, Prevention of Significant Deterioration or “PSD” permitting, etc.) and (b) new or modified wastewater discharges (e.g., National Pollutant Discharge Elimination System or “NPDES” permits). The preparation of such permit applications cannot begin until the applicant has completed the final design of the new facility, equipment and processes. Then the applicant needs to perform engineering and environmental evaluations and compile detailed information regarding the design and operation of the facility, materials, air emissions, wastewater discharge, impacted media, processing equipment and pollution control equipment. The preparation of such permit applications would likely take at least twelve (12) months to complete. Thereafter, acquiring necessary federal and state permits for the facility would require an additional significant time investment. Regulatory agencies commonly require 12 to 18 months for processing such permits, including time necessary for the agencies to conduct the required analysis, assessment, and record of decision. A key variable here is that the “agency time clock” can be restarted when an agency has questions or requires supplemental submissions from an applicant. In such instances, the permit processing period can extend well beyond 18 months.

More generally, manufacturers would need to conduct, in advance of construction, a full assessment of the operations, chemical inventories, and outputs and their potential to affect all federal and state regulatory requirements. At a minimum, most nicotine extraction processes

158 Id. The two documents cited in the ANPRM do not address these conclusions and do not suggest that SCFE is a technically achievable pathway for reducing nicotine content. One study (Ref. 140) focuses on optimal conditions for removing solanesol, not nicotine, from tobacco, and neither study (Refs. 140 and 141) address the effects SCFE may have on tobacco or smoke constituents, smoking characteristics of the tobacco, or the implications for the commercial uses for tobacco that has undergone an SCFE process.
159 The ANPRM cites patent number 5,018,540 (May 28, 1991) for the proposition that the patented process reduced nicotine levels by 96 % “while achieving a product that ‘was subjectively rated as average in nicotine characteristics.’” 83 Fed. Reg. at 11,826. The cited patent, however, addressed early techniques tested on a small scale that did not yield successful tests in the marketplace.
require an assessment of internal operations and an expanded Environmental Management System and Safety Management System. New compliance processes would be required (e.g., OSHA Process Safety Management standards, Environmental Protection Agency (“EPA”) Risk Management Plan requirements, etc.) prior to the start of operations. Significant time would be needed to pre-plan, build processes, systems, and train workers in order to operate safely. These compliance obligations would need to be in place even before any “tune & test” of a new facility operation. Furthermore, the manufacturer would need to comply with any applicable hazardous waste requirements associated with the new manufacturing process.

D. Biotechnology and Genetic Engineering Do Not Provide a Technically Achievable Solution

The ANPRM seeks comments on the technical achievability of genetic engineering or biotechnology to meet the nicotine levels discussed by FDA. Despite 50-plus years of research by leading scientists, bioengineered or genetically modified seeds that produce Flue-cured, Burley, and Oriental tobacco in the field that would meet the nicotine levels discussed by FDA do not currently exist. It is possible that some form of biotechnology might be developed in the future to produce tobacco that could be used in cigarettes meeting the nicotine levels discussed by FDA. But it cannot be over-emphasized that developing a way to produce such VLNC tobacco using biotechnology would be a time-consuming, resource-intensive, and unpredictable process.

The first step in this process is to identify commercially viable technologies, engineer these technologies into desired types and varieties, and then develop seeds that produce tobacco containing sufficiently low amounts of nicotine under controlled, experimental conditions. This significant scientific challenge would only be the beginning. The next step would be to understand the increased disease and pest pressure resulting from reduced nicotine levels in the plant and then develop adequate solutions including, but not limited to, protection from insects, pests, mold and other threats. It then would be necessary to ensure that this variety of tobacco fully matured under normal growing conditions and produced leaves that could be cured and used in cigarettes. Thereafter, researchers would need to develop agronomic and curing practices for producing this tobacco and then this knowledge would have to be successfully transferred to farmers in order to grow sufficient quantities to meet domestic demand while maintaining sufficient profitability. Growers would also need to ensure complete segregation of domestically grown VLNC tobacco and traditional tobacco for export such that domestically grown VLNC tobacco does not mix with tobacco for export as the VLNC tobacco would not be accepted or have any value outside of the United States.

1. Challenges Presented by Developing VLNC Seeds with Biotechnology

Developing VLNC seeds through biotechnology requires researchers to identify specific genes and pathways within the tobacco genome that might affect nicotine biosynthesis and then attempt to alter the expression of those genes or pathways in a way that results in a tobacco plant with

161 Ramsey S. Lewis, Potential Mandated Lowering of Nicotine Levels in Cigarettes: A Plant Perspective 1-5, Nicotine & Tobacco Research (Feb. 1, 2018).
very low nicotine content. This research is extremely complicated, particularly given the complexity of the tobacco genome.\textsuperscript{162}

For decades, tobacco product manufacturers, state universities and others have researched the possibility of using biotechnology to reduce nicotine in tobacco. As a result of this research, scientific articles and patent literature have addressed certain genes and pathways that are believed to impact nicotine production.\textsuperscript{163} It should be noted that the mere fact that a specific technology is “patented” does not mean it is technically achievable, including in the sense of Section 907. United States patent law requires that a patent application enable one of ordinary skill in the art to practice the invention, but United States patent law does not impose a commercial viability requirement\textsuperscript{164} or require that “the invention accomplish all its intended functions.”\textsuperscript{165} Indeed, the U.S. Patent Office’s Manual states that “lack of working examples or lack of evidence that the claimed invention works as described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement.”\textsuperscript{166} Moreover, a patent may include technically inaccurate statements or describe inoperative embodiments.\textsuperscript{167}

Developing VLNC tobacco requires far more than simply identifying a gene or pathway as related to the production of nicotine. Researchers must determine how altering the expression of genes will actually affect the production of nicotine and the tobacco plant generally. Given biological system redundancies and relationships between genes in the complex tobacco genome,\textsuperscript{168} changing the expression of one gene can affect the expression of other genes, and it is

\begin{footnotesize}
\textsuperscript{162} See, e.g., T. Shoji, et al., \textit{Clustered Transcription Factor Genes Regulate Nicotine Biosynthesis in Tobacco} 3390-3409, 3390, \textit{The Plant Cell} (2010) (“Overexpression, suppression, and dominant repression experiments using transgenic tobacco roots showed both functional redundancy and divergence among the NIC2-locus ERF genes;” “In the tobacco NIC2 locus, there exist two levels of redundancy: one caused by local gene duplications in a chromosomal region and the other originating from the allotetraploid history of the tobacco genome.”).


\textsuperscript{164} See, e.g., \textit{CFMT, INC. v. Yieldsup Int’l Corp.}, 349 F.3d 1333, 1338 (Fed. Cir. 2003) (“Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.”); \textit{see also} U.S. Patent Office, Manual of Patent Examining Procedure (“MPEP”) § 2164 (“[T]o comply with 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, it is not necessary to ‘enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.’”). 35 U.S.C. § 112(a) requires that the “specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.”

\textsuperscript{165} See, e.g., \textit{E.I. du Pont de Nemours & Co. v. Berkley & Co., Inc.}, 620 F.2d 1247, 1260 n.17 (8thCir. 1980).

\textsuperscript{166} MPEP § 2164.02.

\textsuperscript{167} See, e.g., \textit{Atlas Powder Co. v. E.I. du Pont De Nemours & Co.}, 750 F.2d 1569, 1576 (Fed. Cir. 1984) (“Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid.”); MPEP § 2107.02 (“regardless of the category of invention that is claimed (e.g., product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not ‘credible,’ do not render the claimed invention lacking in utility.”).

\textsuperscript{168} See, e.g., T. Shoji, et al., \textit{Clustered Transcription Factor Genes Regulate Nicotine Biosynthesis in Tobacco} 3390-3409, 3390, \textit{The Plant Cell} (2010) (“Overexpression, suppression, and dominant repression experiments using transgenic tobacco roots showed both functional redundancy and divergence among the NIC2-locus ERF genes;” “In the tobacco NIC2 locus, there exist two levels of redundancy: one caused by local gene duplications in a chromosomal region and the other originating from the allotetraploid history of the tobacco genome.”).
\end{footnotesize}
exceedingly difficult to predict how those genes will respond or react when another gene or pathway is activated or altered.\textsuperscript{169}

The ANPRM references low nicotine tobacco developed in the 1960s and 1970s in Kentucky.\textsuperscript{170} This decades-old technology does not demonstrate that tobacco can be produced with sufficiently lowered levels of nicotine to meet the levels discussed by FDA. To the contrary, the nicotine levels in this tobacco exceeded the VLNC levels discussed in the ANPRM.\textsuperscript{171}

Likewise, the ANPRM cites a 2004 article that addressed PM USA’s biotechnology efforts in the 1980s and 1990s, but does not acknowledge that “the research programme” only “achieved tobacco with an 80% reduction in nicotine.”\textsuperscript{172} In addition, research on biotechnology produced to date typically finds even smaller reductions in nicotine than reported in this study.\textsuperscript{173} And, although the ANPRM cites a study that reported a nicotine reduction between 93 and 95%; based on the content of nicotine in tobacco at that time, even this reduction would not meet the levels FDA discusses.\textsuperscript{174} Nor, to our knowledge, has this tobacco been produced outside of small scale research plots.

The more recent bioengineered tobacco products referenced in the ANPRM also do not demonstrate that cigarettes with VLNC at the levels discussed by FDA are achievable. For example, the ANPRM states that Vector Tobacco’s “Quest” cigarette was “produced from genetically modified tobacco and contain[ing] only trace amounts of nicotine.”\textsuperscript{175} But even the lowest level of Quest, Quest 3, had 1.0 mg/g and thus would not have met the VLNC levels

\textsuperscript{169} See, e.g., L. Buczini & L.R. Goldman, Starlink Corn: a Risk Analysis, 110 Environmental Health Perspectives 4-13, 4 & 11 (2002) (discussing genetic engineering more generally not noting that “uncertainties still surround genomic alternations due to the insertion site of the DNA (which is random) and metabolic changes due to the new proteins expressed (which are difficult to predict)").

\textsuperscript{170} 83 Fed. Reg. at 11,832.

\textsuperscript{171} J.F. Chaplin & W.W. Weeks, Ass’n Between Percent Total Alkaloids and Other Traits in Flue-cured Tobacco 16(3):416-418, Crop Science (1976).

\textsuperscript{172} J. Dunsby & L. Bero, A Nicotine Delivery Device Without the Nicotine? Tobacco Industry Development of Low Nicotine Cigarettes 13(4):362-369, Tobacco Control (2004) (Ref. 133 in ANPRM). The ANPRM also cites other historical company documents that discuss research projects involving low nicotine tobacco or cigarettes, but the reductions in nicotine described in this research also falls well short of what would be necessary to produce cigarettes meeting the levels discussed in the ANPRM. See, e.g., Nicotine Reduction Program (Apr. 24, 1989), available at https://legacy.library.ucsf.edu/tid/srm73d00;jsessionid=FB8DABDE8C48ECC41CA7589B1E4A842E (Ref. 123 in ANPRM) (stating that RJR was capable of only obtaining a 50% reduction in nicotine yields in existing products using the low nicotine that it had available); E.H. Harwood, Monthly Project Development Report (May 20, 1996), available at http://legacy.library.ucsf.edu/tid/aqu29d00 (Ref. 129 in ANPRM) (discussing reduction of 61.9%). Moreover, that companies have had intentions of trying to reduce nicotine content and pursued such research for decades confirms that such research is complex and time consuming.

\textsuperscript{173} Ramsey S. Lewis, Potential Mandated Lowering of Nicotine Levels in Cigarettes: A Plant Perspective 1-5, Nicotine & Tobacco Research (Feb. 1, 2018).

\textsuperscript{174} T.E. Smith, Report Number 72-18 Tobacco and Smoke Characteristics of Low Nicotine Strains of Burley (June 28, 1972), available at http://legacy.library.ucsf.edu/tid/gqg00f00 (Ref. 155 in ANPRM). The ANPRM also notes that “Canadian researchers examined low nicotine strains of tobacco.” 83 Fed. Reg. at 11,832. But the mere fact this research was conducted does not establish that VLNC tobacco—whether used in this experiment or elsewhere—can be used to produce commercial cigarettes.

\textsuperscript{175} 83 Fed. Reg. at 11,832. Quest 3 was made “in large majority if not exclusively” by genetically-modified tobacco; and Quest 2 and Quest 1 contained about ½ and ¼ respectively of the genetically-modified tobacco contained in Quest 3. E-mail from Ferruccio Gadani, “GMO Testing Quest cigarettes: 1st analytical results,” (Apr. 3, 2003) (3062211591/1592); E-mail from Mary Ellen Counts, “GMO Testing Quest cigarettes: 2nd set of analytical results,” (Oct. 24, 2004) (3009307201/7203).
discussed in the ANPRM. In any event, rather than serving as a success story, Quest cigarettes illustrate the market’s rejection of low nicotine cigarettes using genetically modified tobacco. According to Vector’s Annual Reports, sales dropped each year Quest was in the market, from approximately $26 million in 2003 to $1.5 million in 2009. Sales continued to fall, and Vector ultimately discontinued the product. In 2006, Vector decided to discontinue its genetics operation and not to pursue FDA approval of Quest as a smoking cessation aid given the projected time and expense involved in seeking FDA approval.

Likewise, there is no evidence that the research cigarettes made by 22nd Century could be used to produce commercial cigarettes in sufficient volume that are sensorially acceptable. To the contrary, as discussed in Section II, A, any effort to do so would run into numerous problems that appear to lack a technically achievable solution.

2. Producing VLNC Tobacco on a Commercial Scale Presents Different Challenges Than Growing VLNC Tobacco for Research

Assuming that VLNC varieties could be developed that produce plants under experimental conditions, prior research demonstrates that several additional challenges may prevent that tobacco from being grown in the field. These issues are discussed below.

Nicotine levels. Achieving a certain level of nicotine in controlled, laboratory environments or small, tightly monitored field plots does not mean that the same levels would be produced when these varieties are planted commercially in the field. To the contrary, “alkaloid levels in laboratory greenhouse-grown, or small plot plants are not representative of those observed in large scale field-grown plants.” Additionally, “ultimate observed concentrations are highly influenced by weather, soil fertility, and production practices” In light of these issues, the results of research involving tobacco with VLNC would need to be replicated under normal growing conditions at several locations over multiple years to validate the feasibility of commercial production before planting an entire crop of VLNC tobacco.

Leaf maturity and quality. Researchers also must evaluate the quality of VLNC tobacco leaf grown in the field. Indeed, the low nicotine tobacco produced to date using biotechnology and breeding techniques has had extremely poor agronomic profiles. This tobacco has an abnormal metabolism resulting in an excessive production of green tobacco leaves that are difficult to cure. Furthermore, “low alkaloid plants tend to be lower yielding and have lower grade

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176 D.K. Hatsukami, et al., Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation 105(2): 343-55, Addiction (Feb. 2010); M. Mercincavage, et al., A Randomized Controlled Trial of Progressively Reduced Nicotine Content Cigarettes on Smoking Behaviors, Biomarkers of Exposure, and Subjective Ratings 25(7): 1125-33, Cancer Epidemiology, Biomarkers & Prevention (2016).
177 Vector Group Ltd., Form 10-K for the Period Ending 12/31/08 (filed 3/2/09), at 36.
179 Id.
180 J.F. Chaplin & W.W. Weeks, Association Between Percent Total Alkaloids and Other Traits in Flue-cured Tobacco, 16 Crop Science 416-418 (May-June 1976) (“The high chlorophyll content in the low alkaloid lines reflected the greener color of these leaves at the time of harvest. The leaves on the low alkaloid plants stayed green longer and generally did not ripen.”). Even the documents cited by FDA notes that this tobacco “has amounts of
indexes,” which are used to “indicate[] the physical appearance of the cured leaf based on standard U.S. government grades.”

Insect and pest resistance. Because nicotine is a natural insecticide, low-nicotine tobacco is far more prone to attack by insects and other pests. In fact, without sufficient protection and deterrence against pests, low-nicotine tobacco can become the preferred refuge and food source for insects, as illustrated in the photographs below:

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182 See, e.g., A. Steppuhn, et al., *Nicotine's Defensive Function in Nature*, 2 PLOS Biology 8 (Aug. 17, 2004) (“These results provide direct evidence for the defensive value of nicotine. In a field trial, we established that a native tobacco, which produces large amounts of nicotine, is better defended against its natural herbivores than are nicotine-deficient transformants of the same genetic background.”).
VLNC tobacco may also lack characteristics that make conventional tobacco plants resistant to certain fungi and mold. Further, it appears that the plant protection properties lost when nicotine is removed from the plant cannot be replaced through traditional breeding processes.

As a result, new insecticides, fungicides, and other forms of pesticides (collectively “pesticides”) may need to be developed to produce VLNC tobacco. 183 This would be a challenging and time-consuming task in itself.184 Because tobacco is not grown in the U.S. on the scale of major crops such as corn or soybeans, U.S. pesticide manufacturers lack sufficient economic incentive to develop new pesticides for use on tobacco.185 Moreover, even as new pesticides are developed, their use would need to be approved by EPA and state regulatory authorities for each state in which the pesticide would be used. This process, at a minimum, would incur cost and delay.186 Among the numerous data requirements which must be fulfilled prior to submitting an application to EPA for registration for a new pesticide, or approval for its use on a new crop, are data concerning the potential health and environmental effects of the pesticide, as well as data addressing whether the product might leave a chemical residue on or in treated crops. It can take years and many millions of dollars to generate and compile the necessary data to apply for the federal registration of a new pesticide.187 Once the necessary data are gathered and formatted for submission to EPA, the registration of a new pesticide active ingredient can require two full years to obtain after EPA has received the application and determined the documentation is complete.188

In addition, each state imposes its own pesticide registration requirements and will not accept an application to register a pesticide without an EPA registration. The only exceptions to these registration requirements are emergencies, such as the introduction or spread of a harmful invasive species or a pest that poses a significant threat to human health.189

Disease resistance. If researchers were successful in developing a variety of tobacco that achieved VLNC standards in the laboratory and in the field, as noted above, that variety also could lack sufficient disease resistance to be commercially viable. For example, VLNC varieties developed in the 1960s and 1970s lacked adequate disease resistance traits required today to meet the growers’ disease challenges.190 Imparting disease resistance to a new variety intended

183 FSPTCA §907(a)(1)(b) prohibits a tobacco manufacturer from using tobacco “that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law.”
185 For example, in 2017, there were approximately 320,000 acres of tobacco grown in the United States in as compared to 82,700,000 acres of corn and 89,500,000 acres of soybean production. U.S. Dep’t of Agriculture, Crop Production 2017 Summary (Jan. 2018).
186 Likewise, EPA regulations generally require that the Agency also must authorize any “new use” of an existing pesticide which previously may have been registered for use on another crop. 40 CFR § 152.44.
187 EPA has estimated the applicant’s costs to generate the data needed to obtain a registration for a new pesticide that will be used on a food or feed crop to be nearly $10 M. See EPA, Estimating the Data Generation Costs for Registration of a New Conventional Pesticide Active Ingredient, https://archive.epa.gov/pesticides/ppdc/web/pdf/new-conventional.pdf.
188 EPA also requires the submission of a registration fee which, for an entirely new active ingredient, will be in the hundreds of thousands of dollars. See EPA’s “Fee Category Table at https://www.epa.gov/pria-fees/pria-fee-category-table-registration-division-new-active-ingredients. Additional “maintenance fees” must be paid to EPA to sustain a registration on an annual basis.
189 See 40 C.F.R. Pt. 166.
190 Use the tobacco production guides as references.
for domestic tobacco production might be achieved through genetic modifications or potentially selective breeding techniques, but this too would be a time consuming and costly process. For example, EPA requires that modified plants include transgenic materials to provide disease or insect resistant properties be specifically authorized by that Agency. Thus, EPA has promulgated separate data and application fee requirements for such Plant-Incorporated Protectants (“PIPs”).

Additional approvals for GMOs. The use of genetic modifications to produce VLNC would also contain GMO technology requiring USDA deregulation before that tobacco can be tested in the field and subsequently grown for commercial purposes. Technologies such as traditional Ethyl Methanesulfonate (EMS) mutations or newer gene editing technologies (e.g., CRISPR) do not require USDA deregulation, although their GMO classification is still in debate in markets such as the European Union. Initial testing of GMO plants is generally undertaken on a small scale and is typically subject to federal permitting, which can often only be performed in greenhouses or in small research scale field trials where “containment” can be assured. This process to move from the research and development phases, through federal approvals and ultimately commercial introduction could take many years. Numerous states also oversee the experimental and commercial introduction of genetically modified plants. Section 904(a)(1) of the Tobacco Control Act also requires tobacco product manufacturers to submit to FDA a listing of all ingredients for tobacco products. This includes the type of tobacco (e.g., Burley, Flue-cured, and Oriental), the variety, the curing method and heat source, as well as “any DNA recombinant technology used to engineer the tobacco.”

Curing. As discussed above, the manner in which tobacco is cured impacts the nicotine level and sensorial quality of tobacco. To date, no VLNC tobacco has been cured in a way that provides the leaf quality necessary to create and market commercial cigarettes in the USA, and there is little information available on how to cure the different varieties of VLNC tobacco needed for cigarettes—Flue-cured, Burley and Oriental—each of which presently has very different curing practices from the other two. This research would therefore need to be conducted before cigarettes using VLNC tobacco were manufactured.

3. VLNC Cigarettes Using Biotechnology Would Not Be Sensorially Acceptable

As noted, technical achievability also requires sensorial acceptability. This presents an additional obstacle to using VLNC tobacco produced using biotechnology. Indeed, existing evidence from a variety of disciplines strongly suggests that reducing nicotine content to such low levels degrades the sensory properties of a cigarette to such an extent that it is unacceptable to adult smokers. For example, one study published by Benowitz et al. reported that “[VLNC cigarettes] were rated as poor quality…there was a high non-completion rate…primarily related

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191 See generally, 40 CFR Pt. 174.
193 See, e.g., EPA regulations at 40 CFR § 172.45 and APHIS regulations at 7 CFR § 340.3(c).
194 Ramsey S. Lewis, Potential Mandated Lowering of Nicotine Levels in Cigarettes: A Plant Perspective 1-5 at 4, Nicotine & Tobacco Research (Feb. 1, 2018).
195 See, e.g., Virginia Biotechnology Research Act § 2.2-5500.
196 FORM FDA 3742, “Listing of Ingredients in Tobacco Products.”

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to dissatisfaction with the research cigarettes.” \(^{197}\) Another study including low nicotine cigarettes that specifically evaluated sensory acceptability demonstrated that these cigarettes were “extremely disliked” and participants indicated that they were “very unlikely” to use these products in the future (up to 77% of participants said they would never switch to these cigarettes). \(^{198}\) Recent randomized trials using Quest or SPECTRUM cigarettes \(^{199}\) do not include measures of sensory acceptability, but one study reports that “poor taste ratings of SPECTRUM research cigarettes negatively influence hypothetical and real smoking behaviors.” \(^{200}\)

4. Challenges Presented by Producing VLNC Tobacco Commercially

Even if VLNC tobacco could be grown in the field with adequate disease resistance, sufficient insect and pest protection and acceptable sensory characteristics, additional research and regulatory approvals would be necessary before these varieties could be produced in sufficient quality and quantity to make commercial cigarettes.

**Agronomic practices.** The development of agronomic practices for new varieties of tobacco is typically conducted by university researchers at land grant universities such as the University of Kentucky and North Carolina State University. \(^{201}\) These practices are then provided to the farmers who will grow the tobacco. University researchers would need to address several variables to determine how to grow a particular variety of VLNC tobacco in a manner that produces a sufficient crop yield and returns a profit for farmers. These include input recommendations, such as fertility levels and pesticide use, and other practices necessary to maximize farmer profit, such as transplanting time, planting space, topping height, and harvesting time.

Each of these variables would need to be studied to determine how a new VLNC variety should be grown. Simply put, there is virtually no research on the agricultural practices best suited for VLNC tobacco. And, since universities usually do not receive funding from USDA to support tobacco research and there has been no demand for VLNC tobacco, few people even have knowledge in this particular field.

In addition, once agronomic practices are developed to produce VLNC tobacco at a level that is profitable and sustainable, growers would need training to use those practices on their farms. This cannot be done until after practices are developed and published in tobacco production guides, requiring additional time.

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\(^{198}\) D.L. McKinney, et al., *Cigarettes with different nicotine levels affect sensory perception and levels of biomarkers of exposure in adult smokers* 16(7): 948-60, Nicotine Tobacco Research (2014).


Moreover, the use of biotechnology to meet the standards being considered by FDA would create a market with multiple proprietary, patented and licensed varieties that differ from one another. This would further compound the research needed, as universities would have to conduct separate research for each of these varieties to determine best agronomic practices.

**Segregation.** Many farmers grow tobacco for both domestic use and exportation. Countries of export do not impose the same standards as the United States, and many countries have different standards for GMOs or prohibit their import altogether. In addition, cigarette manufacturers in foreign countries that are not subject to a VLNC standard would not want to purchase VLNC tobacco, particularly where it was genetically modified. Accordingly, even if agronomic practices for VLNC tobacco were established, growers would need to segregate domestic and export tobacco seeds and plants entirely throughout the time it was grown, cured and delivered for sale.

Failing to segregate VLNC tobacco and conventional tobacco presents a serious risk to international trade, as illustrated by other crops with genetically modified organisms that were inadvertently released into commerce. For example, when genetically modified rice not approved for human consumption was found in the commercial rice supply, one company “burned and buried enough rice to feed 20 million people” and “farmers and seed companies . . . lost hundreds of millions of dollars as a result of the contamination.” Likewise, in 2001, genetically modified corn approved only for animal feed was inadvertently released into the human food supply, resulting in significant disruptions in the food supply and residual harm to U.S. corn exports.

Tobacco farmers in the United States, as well as foreign growers in countries such as Brazil, Malawi, or Turkey, would therefore need to keep tobacco segregated throughout the time that it was grown, cured and delivered for sale. Leaf merchants also would need to segregate domestic tobacco and export tobacco during processing to prevent mixing tobaccos destined for different markets. In some instances, however, on-farm segregation might not even be a realistic solution. For example, in some Oriental tobacco leaf markets where farmers retain their own seed, cross-pollination and seed supply contamination could put entire markets at risk. Moreover, the extra burden and cost of on-farm segregation would favor larger, more sophisticated farms and disadvantage smaller growers. These issues are critical and must be carefully addressed to avoid putting the sizeable United States export business in jeopardy. Indeed, collapse of the export

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204 For example, British American Tobacco states on their website that they prohibit the use of GMO tobacco in their commercial products: “We respect consumer concerns that have been expressed about genetic modification of crops. Our current policy is that we do not use genetically modified (GM) tobacco in any of our products and we take all reasonable precautions to avoid the purchase of any.” British American Tobacco, *Leaf Research: Finding better ways to grow*, http://www.bat.com/group/sites/UK_9D9KCY.nsf/vwPagesWebLive/DO9EBGLP.


A VLNC standard would create other challenges as well. Domestic cigarette manufacturers rely in part on foreign-grown tobacco. Indeed, 100% of Oriental tobaccos are grown offshore given the unique agronomic requirements of the crop. (See supra at Section II, B, 3). Off-shore growers also produce Flue-cured and Burley tobacco for import to the United States. If a VLNC standard were promulgated, these companies might need to export VLNC tobacco seeds to farmers in foreign countries, which might be difficult based on that country’s laws. Moreover, in the current market, tobacco grown in the United States can be sold at a premium price because it has a higher quality and taste. If a VLNC standard is adopted, however, the difference between domestic and offshore tobacco is likely to fall and, with it, any premium that could be charged. Domestic manufacturers thus may opt to purchase cheaper, off-shore leaf at the expense of American farmers.

Certification of seed. VLNC seed also require certification for large-scale production under state law, which could include minimum standards and other certification paths. For example, programs in North Carolina and Kentucky establish nicotine ranges (upper/lower) for manufacturer usability.

E. Crop Variability Would Make Consistent Production of VLNC Tobacco Extremely Difficult, If Not Impossible

Regardless of the specific farming practices used, farmers attempting to grow VLNC tobacco would face significant challenges related to crop variability. Tobacco naturally varies – even on the same farm – from crop to crop, plant to plant, and even from one position to another on the stalk of the same tobacco plant. Tobacco chemistry also changes as a function of growing conditions, such as weather patterns, insects and disease, weed control, and the location where it is planted. These changes significantly affect the chemical composition and flavor of tobacco, including the nicotine content. For example, data from the North Carolina Variety Test for a popular Flue-cured variety conducted over a 10 year period at multiple locations found the amount of total alkaloids varied widely from 1.75% to 3.3% (17.5 to 33.0 mg/g). In light of

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207 Ramsey S. Lewis, Potential Mandated Lowering of Nicotine Levels in Cigarettes: A Plant Perspective 1-5 at 2, Nicotine & Tobacco Research (Feb. 1, 2018) (“As a plant natural product, observed nicotine levels can vary significantly for identical tobacco varieties grown in different years or locations.”); T.C. Tso, Production, Physiology and Biochemistry of Tobacco Plant 431 (1990) (“In fact, every step in tobacco production that affects plant metabolism will influence the level of alkaloid content to a certain degree.”).

208 See, e.g., C.L. Gaworski, et al., Insights from a Multi-Year Program Designed to Test the Impact of Ingredients on Mainstream Cigarette Smoke Toxicity, 23 Inhalation Toxicology 172 (2011); P.F. Bernasek, et al., Sugar/Nicotine Study, R.J. Reynolds Records (July 29, 1992), available at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=sljb0079 (“The chemical composition of leaf tobacco varies with genetic makeup, environmental conditions, stalk position, and curing practices.”).


210 Ramsey S. Lewis, Potential Mandated Lowering of Nicotine Levels in Cigarettes: A Plant Perspective Figure 1, Nicotine & Tobacco Research (Feb. 1, 2018); see also, e.g., SW Purkis, et al, A Review of Current Smoke Constituent Measurement Activities and Aspects of Yield Variability, 62 Regulatory Toxicology Pharmacology 202, 204 (2012).
this variability, tobacco crops cannot be produced uniformly at any single point in time, much less from year-to-year. The ANPRM does not account for this crop variability, which would make compliance with any VLNC standard difficult, if not impossible.211

Moreover, in light of variability, growers would need to test each crop to determine whether it is compliant. Due to the large number of plants to be tested, this testing would be extremely difficult, if not impossible. There is no way to know whether tobacco would be suitable for use as VLNC until after it is grown, because testing seeds or seedlings for nicotine concentrations before planting is not indicative of what the levels will be at maturity. No technology currently exists to measure nicotine in plants in the field at a low enough levels to determine if they are below the amounts discussed in the ANPRM. This is no small problem. It would be catastrophic to a grower to produce a crop of tobacco that exceeds a VLNC standard. Such a crop could not be used domestically and would not be purchased to produce VLNC cigarettes. There would also be no alternative market for this tobacco. Manufacturers in other countries would not want it, because they would not be subject to a VLNC standard. This is particularly true where genetically modified organisms have been used, since many “Europeans and Asian consumers simply don't want genetically engineered food.”212 Simply put, the challenges and risks presented by crop variability and inability to test for VLNC levels would be immense and the bulk of the risks associated with such a standard would be borne by U.S. farmers growing such a crop.

F. Manufacturing Variability Would Further Complicate Efforts to Produce VLNC Cigarettes on a Commercial Scale

Currently, there are no commercially available VLNC products in the U.S. Nor have analytical test methods for nicotine been standardized or well characterized at such low concentrations. Therefore, the variability that would apply to VLNC products can only be approximated using the variability associated with current commercial cigarette products. The year-to-year variation of filler nicotine measured in current commercial cigarette products tested over several years suggests that manufacturers would have to try to produce cigarettes with an average nicotine concentration 25% or more below any maximum set by FDA to avoid exceeding any limit, due to the inherent variability of an agronomic product with manufacturing and analytical testing variation.

Allowing for such variation would be further complicated by the challenges necessary to analyze the amount of nicotine in cigarettes being manufactured. Adequate equipment for measuring the extremely low levels of nicotine at sufficient resolution to assure compliance or control blending processes are not available in a manufacturing setting. Likewise, sensors cannot appropriately

211 FDA cites the written direct testimony of William Farone, who frequently testifies on behalf of plaintiffs in smoking and health litigation. 28 Fed. Reg. 11,831 (citing, as Ref. 127, United States’ Written Direct Examination of William A. Farone, Ph.D. Submitted Pursuant to Order #471, United States v. Philip Morris USA Inc., Civil Action No. 99-2496(GK) (D.D.C.)). Far from disputing the impact of crop variability, however, Dr. Farone acknowledges that manufacturers “blend not only across types of tobacco, but also across years, in order to compensate for the year-to-year variations in the tobacco crop.” United States’ Written Direct Examination of William A. Farone, Ph.D. Submitted Pursuant to Order #471, United States v. Philip Morris USA Inc., Civil Action No. 99-2496(GK) (D.D.C.) (Ref. 127 in ANPRM).

212 M. Gunther, Attack of the Mutant Rice, Fortune (July 2, 2007).
measure to control manufacturing processes and we are not aware of any commercially available technology for on-farm testing at very low levels.

G. Extracted or Bioengineered Tobacco Might Increase the Delivery of Harmful Constituents

The potential health effects of reducing nicotine cannot be evaluated in a vacuum. Using extraction, biotechnology, or other processes to reduce the nicotine content of tobacco is likely to impact other constituents. These consequences must be considered not only when evaluating technical achievability but also to ensure that any product standard is “appropriate for the protection of the public health.”  

Combustible cigarettes, including those manufactured with VLNC tobacco, produce thousands of chemicals and carcinogens. Lowering nicotine would not reduce these other constituents. Rather, as the WHO International Agency for Research on Cancer (“IARC”) observed when comparing smoke from conventional and de-nicotinized cigarettes, “despite being de-nicotinized, the commercial brand still contained amounts of preformed carcinogenic NNK in the tobacco comparable to five other commercial cigarettes [that contain conventional amounts nicotine].” IARC thus recognized that “manipulation of tobacco composition, such as removing a single compound or group of compounds from tobacco, would not necessarily reduce the overall toxicity of the product.”

The same is true here: the mere fact that nicotine content is reduced does not ensure that overall risk is reduced. For example, as discussed above, nicotine extraction often results in a loss in tobacco weight. This requires more tobacco to be used in the manufacturing process, which not only makes extraction more costly, but also might increase potential risks due to increases in harmful or potentially harmful constituents. In addition, using extracted tobacco might require the addition of flavors or other additives to ensure that the products are sufficiently acceptable to consumers so as to avoid creating a de facto ban or prompting consumers to resort to contraband. Thus, the potential health impact of such additives should also be considered.

Moreover, research “has demonstrated that levels of many of the chemical constituents in the tobacco leaf are under genetic control,” and that “induced unnatural variation in alkaloid or metabolic profiles could affect the accumulation of alternative harmful constituents or moderate

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217 For example, FDA cites Monograph 7, which stated generally that “[a]lthough most additives that are used as flavor-enhancing agents are sprayed onto tobacco in milligram amounts and may therefore generate at most microgram amounts of toxic or tumorigenic agents in the smoke, it is nevertheless important to document the fate of such compounds when they are added to cigarettes, cigars, or pipe tobacco.” National Cancer Institute, The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Smoking and Tobacco Control Monograph 7, 29 (Ref. 126 in ANPRM).
218 J.F. Chaplin, Genetic Influence on Chemical Constituents of Tobacco Leaf and Smoke, Beiträge zur Tabakforschung (Dec. 1975).
the impact of mandated nicotine reductions by reinforcement of nicotine addictive properties.”

Despite the potential impact of genetic engineering, however, there is little information about whether this tobacco presents any specific health risks and whether any impacts could be mitigated by other design changes. Accordingly, at a minimum, additional time would be necessary to study the possible risks raised by using VLNC tobacco before such tobacco is used in commercial cigarettes.

H. The Research Cigarettes Produced By 22nd Century Do Not Solve the Problems Associated with Commercially Producing VLNC Cigarettes

The ANPRM observes that 22nd Century developed experimental cigarettes “that are similar in many sensory characteristics to conventional cigarettes but with extremely low nicotine levels.”

To date, 22nd Century has been unwilling to share its cigarettes for research purposes. As a result, it is impossible to confirm the results of this research, let alone identify all of the problems that attempting to produce these cigarettes on a commercial basis might raise. But even based on the limited evidence that is available, there are numerous reasons why SPECTRUM cigarettes would not provide a technically achievable way to meet a VLNC standard.

The ANPRM correctly describes these cigarettes as “research cigarettes” and notes that they are “not currently commercially available.” Nor is there any indication that the VLNC tobacco used in these “research cigarettes” could be produced on a commercial scale. It is one thing to produce a small amount of VLNC tobacco under carefully controlled research conditions. However, doing so does not mean the same tobacco could be grown in larger quantities under actual field conditions. To the contrary, many issues would need to be addressed before that could be done. This includes developing agronomic practices that allow leaves to mature completely and plants to grow in sufficient quantities, and ensuring adequate and appropriate insect, pest and disease protection. Likewise, to the extent that this tobacco uses genetically modified tobacco, additional regulatory approvals would be necessary. There is no evidence that 22nd Century has addressed any of these complex issues.

Moreover, before 22nd Century or another company could use this tobacco to produce American Blend cigarettes, it would need to use this technology to produce Flue-cured, Burley, and Oriental tobacco. There is no indication that this can be done. Furthermore, such tobacco would also need to be processed and cured for commercial use. Again, PM USA is not aware of anything showing that these critical steps could be accomplished.


222 Id.
In addition, there is no indication that cigarettes using VLNC tobacco produced by 22nd Century would be sensorially acceptable to consumers. Indeed, available research indicates the opposite: “poor taste ratings of SPECTRUM research cigarettes negatively influence hypothetical and real smoking behaviors.” Likewise, although studies attempting to measure the amount of certain constituents in 22nd Century’s SPECTRUM cigarettes recognize that “it is important to monitor levels of chemicals of public health concern and regulatory interest as technologies emerge to reduce levels of nicotine or other targeted chemicals in tobacco products,” sufficient research does not currently exist to evaluate the risks of constituents produced by these cigarettes.

Finally, even if researchers could develop adequate agronomic and curing practices to produce this tobacco for use in commercial cigarettes this knowledge would need to be provided to growers. (See supra at Section II, D, 4). And these growers would then need to ensure complete segregation of this tobacco from conventional tobacco for export. The research cited in the ANPRM concerning 22nd Century does not begin to solve any of these problems.

III. A Product Standard of 0.3-0.5 mg Nicotine per g Tobacco – or Any Nicotine Ceiling Even Remotely Close to That Ceiling – Is Not Adequately Supported by Science and Evidence

More research would be needed before any VLNC product standard would have sufficient scientific support. Indeed, the ANPRM calls the contemplated standard a “hypothesis,” acknowledges that “questions remain,” and states that “additional data” are needed across multiple dimensions. These observations are correct: the existing science leaves many critical questions unanswered. It also does not support the VLNC levels discussed in the ANPRM. Accordingly, adopting a standard based on this science and without additional research would not comply with applicable statutes and be contrary to sound policy and basic fairness.

A. FDA Cannot Adopt A VLNC Standard Without Adequate Scientific Support

1. Section 907 and the APA Require That Any VLNC Standard Be Based on Science and Evidence

225 We include a chart that cross-references questions posed in the ANPRM with our responses in the Appendix at Attachment 2.
FDA can adopt a product standard for VLNC tobacco only if the standard is based on adequate scientific support. Section 907 requires FDA to establish that a proposed tobacco product standard is “appropriate for the protection of public health” based on “scientific evidence.” When determining whether a tobacco product standard is appropriate for the protection of public health, FDA must consider: (1) “the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;” (2) “the increased or decreased likelihood that existing users of tobacco products will stop using such products;” and (3) “the increased or decreased likelihood that those who do not use tobacco products will start using such products.” The statute further requires FDA to 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.” Each of these considerations must be based on science and evidence.

Indeed, the requirements in Section 907 supplement the basic requirement under the APA that agency action be based on a rational connection to the record and adequately explained. An agency acts in an arbitrary and capricious manner when it “entirely fail[s] to consider an important aspect of the problem.” Under this standard, a court considers whether the agency used the correct analytical methodology, applied the proper criteria, considered the relevant factors, and “pointed to adequate support in the record for material empirical propositions.” Courts take a “hard look” at the record when reviewing a regulation, and to meet that standard, FDA would need to identify its assumptions, explain inconsistencies, disclose methodologies, rebut contradictory evidence, eliminate guesswork, ensure record references are solidly grounded, and support its conclusions in a “manner capable of judicial understanding.”

227 FDA, Section 907 of the FDCA - Tobacco Product Standards (2009), available at https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm263053.htm; FSPTCA § 907(a)(3)(A), (B)(i). The statute further provides for interested parties to “provide for the Secretary’s consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.” Id. § 907(a)(3)(B)(ii).
228 Id. § 907(a)(3)(B)(i).
229 Id. § 907 (b)(2).
230 Motor Vehicle Mfrs. Assoc. of the U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (an agency must articulate a "satisfactory explanation for its action including a rational connection between the facts found and the choice made"); Natural Res. Def. Council v. EPA, 902 F.2d 962, 968 (D.C. Cir. 1990) (internal quotation marks omitted) (Courts must “review the record to ascertain that the agency has made a reasoned decision based on reasonable extrapolations from some reliable evidence.”).
A proposed product standard therefore must be supported by scientific evidence that shows the standard is capable of achieving its intended purpose and would be appropriate for the protection of public health. If the potential countervailing effects of a product standard outweigh its projected benefits, then FDA should not propose it.\textsuperscript{234} Thus, for example, if FDA cannot gather sufficient science and evidence showing that a nicotine product standard will reduce tobacco initiation and addiction, without countervailing effects that negate any prospective gains, the resulting product standard would be inherently arbitrary and capricious.\textsuperscript{235}

The impact of a product standard requiring VLNC levels amplifies the need for adequate scientific support and a “hard look” at that evidence. Unprecedented in its complexity and scale, a VLNC standard would fundamentally change the design and function of cigarettes, modify the choices and behaviors of more than 44 million\textsuperscript{236} adult smokers in the United States, and transform a market that currently supplies approximately 250 billion cigarettes each year and has far-reaching impacts across the economy. It is therefore crucial that scientific evidence support every element of a VLNC standard. For example, the maximum nicotine level imposed by a product standard should be supported by well-controlled experiments with the appropriate level of statistical power. Different implementation options should be studied to understand how best to employ a product standard that improves public health while avoiding economic disruption. And record evidence should support every statutory consideration related to the standard, such as the impact on individual risk, the effect on population harm, whether VLNC cigarettes are sensorially acceptable, and countervailing effects. In short, FDA should not adopt a product standard where important and relevant questions remain unanswered.

2. The ANPRM’s Reliance Upon Limited, Non-Public Research as “Best Available Science” Is Legally and Scientifically Inadequate

a. The best “available” science is not necessarily adequate to support regulatory action

In the ANPRM, FDA repeatedly states that any VLNC standard would be based on the “best available science.”\textsuperscript{237} On its face, “best available” is not enough. It does not satisfy the standard to support regulatory action. Nor does “best available science” ensure that a VLNC standard will protect public health or serve the public’s interest. To the contrary, “best available science” is necessarily limited to the evidence that is currently available.

Here, the “best available science” is neither well-developed nor sufficient to support regulatory action. As noted, the ANPRM itself describes a VLNC nicotine standard as a “hypothesis” and observes that “questions remain” and “additional data” are needed.\textsuperscript{238} This language alone indicates that the scientific evidence that exists today is inadequate under Section 907 to support a product standard mandating the nicotine levels discussed in the ANPRM.

\textsuperscript{234} See Fox Television Stations, Inc. v. FCC, 280 F.3d 1027, 1043-44 (D.C. Cir. 2002) (holding agency decision arbitrary and capricious because it offered neither support that the rule was “necessary to the public interest, nor an “adequate basis” that the purpose “would be accomplished”).

\textsuperscript{235} FDA recognizes a number of potential countervailing effects in the ANPRM. See 83 Fed. Reg. at 11,820.


\textsuperscript{238} Id. at 11,818, 11,828, and 11,838.
Moreover, the ANPRM’s discussion of maximum nicotine levels and addiction thresholds focuses on a limited number of FDA-funded studies, executed by a small group of researchers, for which the studies and underlying data have not been available to stakeholders or the public.\textsuperscript{239} Many of FDA’s assumptions concerning thresholds for nicotine addiction, for example, are based on research using “low-nicotine cigarettes . . . produced and distributed for research purposes by Research Triangle Institute (RTI), under a contract for the NIDA’s Drug Supply Program . . . that contain 0.4 mg nicotine/gram (g) of tobacco filler.”\textsuperscript{240}

As discussed below, this research does not support the adoption of a VLNC standard. But more fundamentally, FDA’s approach is insufficient and improper given the enormous complexity of the scientific issues raised in the ANPRM and the many variables implicated by these subjects. As an initial matter, the findings of this small pool of government-funded research cannot be extrapolated to larger scale commercial contexts. Moreover, given the massive implications of any proposed standard, the scientific conclusions underlying such a standard should be drawn from a wide range of sources and not from a small number of studies based on limited data sets, from studies executed by a single set of researchers, such as the recent research involving 22nd Century, or from studies conducted by only those select researchers who to date have been granted access to VLNC test cigarettes.

b. FDA should not base regulatory action on science that is not publicly available and has not been critically reviewed by all stakeholders

The problems with FDA’s approach are compounded here, because the ANPRM relies heavily upon studies for which the underlying data are non-public and unavailable to stakeholders. FDA’s reliance on non-public data and information violates the FSPTCA, the APA, the right of all stakeholders to fair notice and a meaningful opportunity to be heard, principles of good governance, and due process.

“Under APA notice and comment requirements, among the information that must be revealed for public evaluation are the technical studies and data upon which the agency relies [in its rulemaking].”\textsuperscript{241} Thus, “[a]n agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.”\textsuperscript{242} Moreover, due process requires that agencies provide full disclosure of the basis for, and expectations of, any proposed rule, as well as “fair warning of the conduct a regulation prohibits or requires.”\textsuperscript{243}

Recognizing the significance of such issues, EPA recently issued a proposed rule that would strengthen the requirements where scientific research is the basis for regulations.\textsuperscript{244} The rule is

\begin{footnotesize}
\begin{enumerate}
\item Id. at 11,827-28.
\item Id. at 11,827.
\item Am. Radio Relay League, Inc. v. F.C.C., 524 F.3d 227, 236 (D.C. Cir. 2008) (citation and quotation omitted).
\end{enumerate}
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designed to ensure that, “for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis.” As noted by EPA’s leadership in announcing the proposed rule, “[t]he ability to test, authenticate, and reproduce scientific findings is vital for the integrity of the rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives.” EPA’s proposed rule is also consistent with Executive Order 13777, which provides that regulatory reform efforts shall attempt to identify “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility.”

The same principles apply here with even more force because the TCA expressly requires FDA to make data underlying an ANPRM available for public inspection and comment, stating that “[e]ach notice of proposed rulemaking...shall set forth...the manner in which interested persons may examine data and other information on which the notice or findings is based.” Congress took this requirement verbatim from the Medical Device Amendments to the FDCA “to provide a rulemaking procedure...in which all participants would have a full opportunity to present their views and analyses of the data underlying the proposed regulation.” This statutory command is more specific than the disclosure requirements under the APA, which FDA likewise has not satisfied here.

FDA should immediately make the data underlying the research cited by FDA in its ANPRM available to the public. For example, FDA should release the data underlying the research in the 2015 New England Journal of Medicine publication entitled “Randomized Trial of Reduced-Nicotine Standards for Cigarettes.” The same is true for other studies referenced in the ANPRM, particularly those using SPECTRUM research cigarettes. PM USA asked FDA to make this data available, so that PM USA could address it in these comments, but FDA has so far ignored that request (see letter from J. Murillo to FDA, Dkt. No. FDA-2017-N-6189 submitted on May 2, 2018).

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245 83 Fed. Reg. at 18,769.
248 FSPTCA § 906(b)(1).
249 21 U.S.C. § 360j(d); see also Becton, Dickinson and Co. v. Food and Drug Administration, 589 F.2d 1175, 1181 (2d Cir. 1978).
250 Ref. 85 in ANPRM.
252 Ltr. from J. Murillo to FDA available at: https://www.regulations.gov/docketBrowser?pp=25&so=DESC&sb=commentDueDate&po=0&D=FDA-2017-N-6189
FDA likewise should make current data available, even if not yet formally published, where the Agency is funding the underlying research. This is illustrated by a presentation given at the Vermont Center on Behavioral Health-Tobacco Regulatory Science Conference (VCBH) in 2017 that shared pharmacokinetic data on SPECTRUM cigarettes, which were supported by funding from NIH and FDA.\(^\text{253}\) This presentation sought to highlight potential “challenges” to research conducted in support of a standard for VLNC cigarettes—a subject that is of obvious import here.\(^\text{254}\) These findings, however, have yet to be published in peer-reviewed literature.

In addition, access to the test cigarettes used in these FDA-funded studies is critical to assessing information in the ANPRM that is directly related to the fundamental requirements of Section 907, such as dependence, potential compensatory behavior, and technical achievability. The ANPRM notes that “22nd Century, acting as vendor for RTI’s contract with NIDA, has developed cigarettes, not currently commercially available, that are similar in many sensory characteristics to conventional cigarettes but with extremely low nicotine levels (Refs. 54, 124, and 125).”\(^\text{255}\)

But neither RTI or 22nd Century currently publicly offers these research cigarettes to any entity other than NIDA. PM USA has repeatedly requested samples of these VLNC cigarettes from NIDA and other information, including most recently on June 4, 2018.\(^\text{256}\) NIDA previously denied our requests.\(^\text{257}\) Without access to these test cigarettes, other researchers, including those funded by regulated entities, are not able to conduct scientific studies to assess the information in the ANPRM or upon which FDA might rely when pursuing a product standard. Again, adopting a VLNC standard under these circumstances or resolving important policy questions based on undisclosed information would violate the APA and principles of due process.

In short, the credibility of the rulemaking process rests, in part, on adherence to principles of sound regulatory science. FDA should make publicly available all the underlying scientific data it is considering as part of the ANPRM process and also make available the test cigarettes being used by FDA or its researchers. Further, FDA must ensure that stakeholders have adequate time to review, analyze and respond to that data and have time to test, authenticate, and attempt to reproduce scientific findings such as those discussed in the ANPRM. In any potential rulemaking – particularly one with as far-reaching implications as this one – it is essential for FDA’s scientific conclusions to be transparent and reliable, in both substance and appearance. FDA should disclose all evidence, data, and methodologies from studies funded by FDA to ensure that every stakeholder, including scientific experts not affiliated with FDA, has an opportunity to evaluate the scientific basis for any product standard and provide comments as part of the rulemaking process well before any standard might be implemented.

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254 *Id.*


256 June 4, 2018 email from Willie McKinney, Ph.D., D.A.B.T., Vice President, Regulatory Sciences, ALCS, to Hari H. Singh, Ph.D., Program Director, Drug Supply & Analytical Sciences, Chemistry & Physiological Systems Research Branch, Division of Basic Neuroscience & Behavior Research, National Institute on Drug Abuse, National Institutes of Health (“Dr. Singh”).

257 There were multiple email requests for research cigarettes from Marc Fariss, Ph.D., Principal Scientist, ALCS, to Dr. Singh from December 21, 2012, through August 7, 2013. Our requests were ultimately denied on August 7, 2013.
B. The Current Science Does Not Support a Threshold for Nicotine Addiction Within the VLNC Levels Being Considered By FDA

The ANPRM states that any VLNC standard “could merit consideration only if there were a threshold nicotine exposure level below which the nicotine did not produce significant reinforcing effects or sustain addiction in the majority of the population.”\textsuperscript{258} It further states that it will be “important,” in connection with any potential nicotine product standard, to consider “how the threshold of nicotine addiction should be measured.”\textsuperscript{259} Below, we explain why current science does not provide answers to these questions and why the nicotine levels discussed in the ANPRM are refuted, rather than supported, by the existing research.

As an initial matter, there is no scientific consensus on the criteria for nicotine addiction. Moreover, the research cited and discussed by FDA does not support a maximum nicotine standard at the VLNC levels discussed in the ANPRM. The available studies rarely find discernible behavior change when comparing cigarettes with 0.4 mg/g and cigarettes with 2.4 mg/g. To the contrary, research most frequently suggests discernable differences at levels higher than 2.4 mg/g.

1. There Are No Consensus Criteria for Diagnosing Nicotine Addiction

Defining the criteria for nicotine addiction would be necessary before identifying a nicotine addiction threshold for adult cigarette smokers. Consensus criteria for diagnosing nicotine addiction, however, have not been established. As the Surgeon General stated in 2010, “[t]he crux of understanding the pathophysiology of tobacco addiction and its measurement . . . continues to evolve, and significant gaps in research are evident.”\textsuperscript{260} As a result, “[t]here is no established consensus on criteria for diagnosing nicotine addiction.”\textsuperscript{261} The gaps identified by the Surgeon General’s report have still not been filled.

In the absence of consensus criteria, investigators have relied upon multiple, sometimes divergent, tools to study nicotine addiction in smokers. For example, researchers have assessed dependence levels through quantitative measurements such as the number of cigarettes smoked per day (CPD) during a study,\textsuperscript{262} and behavior assessment criteria such as those specified in the Fagerström Test for Nicotine Dependence and the Diagnostic and Statistical Manual of Mental Disorders. In addition, researchers have used methods in animal models such as nicotine self-administration and dose discrimination, and more recently have adapted these methods to human studies. Furthermore, some researchers have relied upon subjective reports from participants about relief from negative effects, such as withdrawal symptoms.

Currently, it is unclear, at best, whether one or more of these approaches could provide definitive criteria for nicotine addiction in smokers. The problem is further complicated by “the weak

\textsuperscript{258} 83 Fed. Reg. at 11,827.
\textsuperscript{259} Id.
\textsuperscript{261} Id.
\textsuperscript{262} D.K. Hatsukami, et al., Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation 105(2): 343-55, Addiction (Feb. 2010).
relationship between nicotine addiction and actual rates of tobacco use." Moreover, given the wide variety of measurement tools, studies evaluating nicotine dependence and addiction are difficult to correlate and confirm. It will likely be necessary to integrate information from multiple validated and predictive study types to identify the threshold of nicotine addiction, if it exists.

The ANPRM does not offer a solution to these problems – nor could it, given the state of the science. Instead, FDA identifies a list of variables that have no current parameters or limits. FDA concedes that it must “consider . . . how the threshold of nicotine addiction should be measured,” without directing how that measurement should be determined. FDA posits it may “set a maximum nicotine level in cigarettes so that they are minimally addictive or nonaddictive,” without defining the threshold of “addiction” or defining what “minimally addictive” could mean. And FDA states that it “envision[s] the potential circumstance where nicotine levels in cigarettes do not spur or sustain addiction for some portion of potential smokers,” without discussing how it would put appropriate quantitative measures on this “portion” of smokers.

In other words, the ANPRM identifies significant gaps in the science, without acknowledging that these gaps must be filled before FDA can consider proposing a product standard. Researchers must first establish a consistent and science-based definition for nicotine addiction to allow for the proper study of a possible nicotine addiction threshold.

2. The Weight of the Available Evidence Demonstrates That Discernible Behavior Change Occurs at Nicotine Levels Much Higher than 0.5 mg/g

FDA must have a science-based foundation for identifying the “maximum nicotine level” below which cigarettes would be rendered “minimally addictive or nonaddictive.” Identifying the lowest concentration of nicotine in cigarettes that reinforces tobacco use in humans might be one step toward identifying a threshold for nicotine addiction. Existing scientific literature, however, does not support the proposition that this level would be at or around 0.5 mg/g. Rather, research on VLNC cigarettes finds that discernible behavior changes take place at nicotine levels that are much higher.

a. The literature suggests discernible behavior changes above 2.4 mg/g

The majority of studies on VLNC cigarettes indicate that discernible behavior change related to these cigarettes occurs at a nicotine content level significantly higher than 0.5 mg/g and do not find meaningful differences when comparing 0.4 and 2.4 mg/g cigarettes. This evidence contradicts any assumption that a threshold for nicotine addiction is at or below 0.5 mg/g.

265 Id. at 11,821.
266 Id. at 11,818.
267 Id. at 11,826.
To summarize this recent data, we conducted a comprehensive analysis of all of the available VLNC cigarette studies that used SPECTRUM VLNC cigarettes – eight different studies.269 When conducting this analysis, we determined whether the study investigators found statistically significant differences between the test cigarettes and conventional nicotine content cigarettes for various endpoints measured in these studies. The studies measured several specific endpoints, including the number of cigarettes smoked per day, non-study cigarette use, quit attempts and cigarettes per day at a 30-day follow-up, urinary total NE, urinary NNAL, expired CO at week 6, CO boost, perceived nicotine level, subjective self-report measures such as the Questionnaire of Smoking Urges-Brief (“QSU”) and the Minnesota Nicotine Withdrawal Scale (“MNWS”), the Fagerstrom criteria, and nicotine discrimination.

The results of this analysis are presented in Figure 1. The non-color-coded columns on the left side of the table identify each study and the specific endpoint being tested. The remaining columns indicate whether there was a statistically significant difference for each endpoint when a specific SPECTRUM test cigarette with nicotine content levels of 0.4, 1.3, 2.4, or 5.2 mg/g was compared with a conventional nicotine content cigarette (NRC600). Orange cells indicate results that are not statistically different from NRC600, green cells indicate results that are statistically different from NRC600, and grey cells indicate cigarettes not included in the study. For consistency, the same nicotine content numbers described in Donny et al.270 are used in this figure.

Figure 1: Graphical summary of results from published studies using SPECTRUM VLNC cigarettes

<table>
<thead>
<tr>
<th>Study</th>
<th>Measure</th>
<th>Area</th>
<th>Nicotine content (mg/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donny 2015</td>
<td>Total CPD at week 6</td>
<td>CPD</td>
<td>0.4</td>
</tr>
<tr>
<td>Donny 2015</td>
<td>Total CPD at week 6 - menthol</td>
<td>CPD</td>
<td>1.3</td>
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<tr>
<td>Donny 2015</td>
<td>Total CPD at week 6 - non-menthol</td>
<td>CPD</td>
<td>2.4</td>
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<tr>
<td>Donny 2015</td>
<td>Study Cig CPD at week 6</td>
<td>CPD</td>
<td>5.2</td>
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<tr>
<td>Donny 2015</td>
<td>Nonstudy cig use</td>
<td></td>
<td>15.8</td>
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<tr>
<td>Donny 2015</td>
<td>Quit attempt 30 day follow-up</td>
<td>Quit</td>
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<tr>
<td>Donny 2015</td>
<td>CPD 30 day follow-up</td>
<td>CPD</td>
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<table>
<thead>
<tr>
<th>Study</th>
<th>Measure</th>
<th>Area</th>
<th>NRC102</th>
<th>NRC200</th>
<th>NRC300</th>
<th>NRC400</th>
<th>NRC600</th>
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<tbody>
<tr>
<td>Donny 2015</td>
<td>Urinary total NE Exposure</td>
<td></td>
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<td>Donny 2015</td>
<td>Urinary NNAL Exposure</td>
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<td>Donny 2015</td>
<td>Expired CO at week 6 Exposure</td>
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<tr>
<td>Donny 2015</td>
<td>CO boost after 1 cigarette Exposure</td>
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<td>Donny 2015</td>
<td>Total puff volume Topography</td>
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<td>Donny 2015</td>
<td>Perceived nicotine level Subjective</td>
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<tr>
<td>Donny 2015</td>
<td>CPD at $6/pack Behavior</td>
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<tr>
<td>Donny 2015</td>
<td>WISDM – week 6 Dependence</td>
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<td>Donny 2015</td>
<td>Fagerstrom – week 6 Dependence</td>
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<td>MNWS – week 6 (total &amp; max) Dependence</td>
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<td>Donny 2015</td>
<td>QSU (total)--wk 6 Dependence</td>
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<td>Donny 2015</td>
<td>QSU (total)--wk 6 - abstinence Dependence</td>
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<td>Donny 2015</td>
<td>QSU(factor 1)--wk 6 - abstinence Dependence</td>
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<tr>
<td>Smith 2017</td>
<td>Estimated CPD at $4, $10/pack Behavior</td>
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<td>Smith 2017</td>
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<td>Smith 2017</td>
<td>Smoke 0 CPD at &gt;$50/pack Behavior</td>
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<td>Smith 2017</td>
<td>Quit in 1 year if only product option Behavior</td>
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<td>Smith 2017</td>
<td>Omax (max $/day will spend) Behavior</td>
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<td>Smith 2017</td>
<td>Intensity (CPD if free) Behavior</td>
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<td>Smith 2017</td>
<td>Breakpoint (lowest price to 0 CPD) Behavior</td>
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<td>Smith 2017</td>
<td>Breakpoint after 24h abstinence Behavior</td>
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<td>Rupprecht 2017</td>
<td>Weight gain-wk 6, compliant subjects</td>
<td>Weight</td>
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<td>Perkins 2016</td>
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<td>Nicotine discrimination - Menthol Threshold</td>
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<td>Higgins 2017</td>
<td>MNWS (Total) Dependence</td>
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<td>Higgins 2017</td>
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<td>Faulkner 2017</td>
<td>Craving and withdrawal reduction Dependence</td>
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<td>Faulkner 2017</td>
<td>Positive or negative affect Dependence</td>
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<td>Faulkner 2017</td>
<td>Sustained attention Performance</td>
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<td>Faulkner 2017</td>
<td>Liking Dependence</td>
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Even a cursory review of this chart demonstrates that cigarettes with nicotine content of 1.3 and 2.4 mg/g frequently produce comparable outcomes to 0.4 mg/g cigarettes. In particular, for the majority of endpoints evaluated in studies using SPECTRUM cigarettes, researchers found statistically significant differences when a cigarette with 0.4, 1.3, and 2.4 mg/g was compared with a conventional nicotine content cigarette (NRC600). By contrast, only a small number of endpoints showed statistically significant differences for a 0.4 mg/g cigarette but not a 1.3 or 2.4 mg/g cigarette.

Other researchers have acknowledged the observation evident in the chart above. For example, in the following figures by Donny et al.271 (see Figure 2 below) there is a marked decrease in the number of cigarettes smoked—whether study cigarettes (Panel B) or total cigarettes (Panel A) – above 2.4 mg/g.

Figure 2 - Reproduced from Donny et al. (2015) showing that the number of cigarettes smoked per day significantly decreased between 5.2 mg/g and 2.4 mg/g nicotine in tobacco.
Considering this data, a subsequent study reinforces the point that the cigarette models “clearly naturally clustered into two groups” – one comprising cigarettes at 0.4, 1.3 and 2.4 mg/g, and the other comprising the 15.8 mg/g cigarettes and the participants’ usual brand. The authors “excluded the 5.2 mg/g group from [their] analyses because the effects of this dose on smoking behavior were unclear.” Based on an investigation of nicotine discrimination thresholds using the SPECTRUM VLNC cigarettes, another study reported that the median nicotine threshold was even higher, at 11 mg/g.

Finally, a 2017 presentation at the Vermont Center on Behavioral Health-Tobacco Regulatory Science Conference shared pharmacokinetic data on SPECTRUM cigarettes. These data, which were supported by funding from NIH and FDA, have yet to be published in peer-reviewed literature. As shown in Figure 3 below, the research analyzed three different nicotine content SPECTRUM cigarettes and the resulting plasma nicotine concentrations to evaluate the physiological impact from different cigarettes. While the figure lacks error bars and specificity as to which SPECTRUM cigarette models were tested, and details of the study methodology were not provided in the presentation, once again, there appears to be a distinct difference between the “high” and “usual brand” models and the “medium” and “low” models. In fact, the “low” model does not appear to provide any discernible increase in plasma nicotine concentration at all. This suggests that the “low” model reduces nicotine yield to the practical or functional equivalent of zero, in contravention of the statute. (See supra at Section II, A, 1). The same may also be true for the “medium” model, although it is not possible to say with certainty, for either cigarette, until more complete data are made publicly available. Other FDA-funded authors have concluded the lowest nicotine content SPECTRUM cigarette, 0.4 mg/g, “results in a nicotine yield of ~0.04 mg, which is effectively denicotinized.” FDA should make these and other current data available, even if not yet formally published, where the Agency is funding the underlying research, as stated above.

272 J.D. Robinson, et al., Cigarette Nicotine Content as a Moderator of the Relationship Between Negative Affect and Smoking, Nicotine Tobacco Research 19(9), 1080-1086 (2017) 19(9).
Figure 3. Pharmacokinetic curve on SPECTRUM cigarettes presented by Foulds in a presentation titled: “An FDA-mandated product Standard for Reduced nicotine Content Cigarettes: How might our research be challenged?”.

These results are consistent with research using VLNC cigarettes other than SPECTRUM. For example, Quest cigarettes were available at 1.0, 6.4, and 12.5 mg/g. Results from human studies using Quest cigarettes suggest discernible behavior changes between 1.0 mg/g and 6.4 mg/g. Moreover, each of these studies found relief of withdrawal symptoms regardless of the nicotine content of the cigarettes. This finding is consistent with earlier work showing substantial withdrawal relief from cigarettes regardless of nicotine content, and further suggest a nicotine threshold significantly higher than 0.5 mg/g.

Accordingly, although there is no consensus on a nicotine addiction threshold, the totality of the scientific evidence suggests that—if such a threshold exists—it exists a level greater than 2.4 mg/g. At a minimum, the existing evidence underscores the need for further research before any product standard presenting insurmountable technical achievability issues is implemented.

275 D.K. Hatsukami, et al., Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation 105(2): 343-55, Addiction (Feb. 2010); M. Mercincavage, et al., A Randomized Controlled Trial of Progressively Reduced Nicotine Content Cigarettes on Smoking Behaviors, Biomarkers of Exposure, and Subjective Ratings 25(7): 1125-33, Cancer Epidemiology, Biomarkers & Prevention (2016).


277 Id.
b. The methodology used to reach the original threshold proposal of 0.5 mg/g, corrected to apply more science-based assumptions, predicts a much higher estimated threshold.

The initial estimate for minimizing the addictiveness of cigarettes and limiting nicotine content to 0.5 mg/g originated in a policy proposal published in 1994 by Benowitz and Henningfield. To calculate this estimate, the authors relied on a series of assumptions about the average number of cigarettes smokers consumed per day and the bioavailability (i.e., yield) of nicotine. These assumptions were not only arbitrary and conservative when made, they are inconsistent with today’s scientific evidence. Substituting more accurate assumptions suggests that the estimate Benowitz and Henningfield sought to calculate in fact should be much higher.

In particular, the 1994 estimate assumed that smokers consume 30 cigarettes per day ("CPD")

The Centers for Disease Control and Prevention ("CDC"), however, recently published a report showing that the average cigarette consumption is 14.1 CPD – less than half the rate underlying the 0.5 mg/g estimate. In addition, when estimating the transfer efficiency of nicotine from tobacco to smoke, the 1994 estimate assumed a maximum “nicotine yield” of 40%. In more recent clinical studies (such as those cited in the ANPRM, including by Dr. Benowitz), researchers have relied on a more likely maximum nicotine yield of 20%. This 20% value also is more in line with measured Canadian Intense nicotine yields of 14-19% for SPECTRUM cigarettes.

Using the same methodology as the 1994 estimate, but applying the more scientifically substantiated assumptions of 15 CPD and a 20% nicotine yield, produces an estimate substantially higher than the earlier hypothesized 0.5 mg/g level threshold and the range discussed in the ANPRM. Indeed, as presented in Table 1 below, these results indicate an estimated threshold of 2.8 mg/g tobacco filler.

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279 Id.
282 N.L. Benowitz, et al., Nicotine and carcigen exposure with smoking of progressively reduced nicotine content cigarette 16(11), 2479-2485, Cancer Epidemiology Biomarkers Prev. (2007), http://cebp.aacrjournals.org/content/16/11/2479; N.L. Benowitz, et al., Smoking behavior and exposure to tobacco toxicants during 6 months of smoking progressively reduced nicotine content cigarettes 21(5), 761-769, Cancer Epidemiology, Biomarkers & Prevention (2012).
This recalculation shows that the methodology used to reach the 1994 estimate, when corrected to apply more science-based assumptions, predicts an estimated threshold much higher than 0.5 mg/g. Of course, neither the original estimate, the recalculated estimate, nor the methodology used to calculate them are capable of establishing that a nicotine addiction threshold exists, let alone what the level of that threshold might be. Answering those questions will require substantially more research than exists today.

3. Existing Science Does Not Support a Nicotine Addiction Threshold of 0.3-0.5 mg/g

a. The 2013 survey paper cited by the ANPRM does not support a nicotine threshold at or below 0.5 mg/g

The ANPRM requests comments on a paper published in 2013 by Benowitz and Henningfield.284 That paper refers back to the authors’ original 1994 estimate for reductions in nicotine content to 0.5 mg/g, and states that “more recent analysis suggests that the maximum allowable nicotine content per cigarette that minimizes the risk of central nervous system effects contributing to addiction may be lower.”285

As an initial matter, this statement and this article are contrary to and refuted by the more recent research described above that has found discernable behavioral change occurs above 2.4 mg/g and has not found differences between 0.5 and 2.4 mg/g cigarettes. Moreover, the 2013 paper does not offer any data to support its assertion that a nicotine addiction threshold “may be lower” than 0.5 mg/g. To the contrary, the only “more recent analysis” that the paper appears to mention is a 2010 article published by Hatsukami et al.286 But this 2010 article also did not attempt to identify a nicotine threshold. To the contrary, it merely expressed optimism that a threshold level “will eventually be identified.”287 At the same time, it recognized that “developing practical, scientifically supported recommendations about nicotine levels in tobacco products involves filling gaps in knowledge in diverse areas including tobacco product design, content, and emissions; biomarkers of exposure; addiction; sensory perception; motivational factors; withdrawal and craving; animal studies; human clinical research; genetics; physiology,

Table 1: Recalculated Nicotine Threshold Based on Current Scientific Evidence Regarding CPD and Nicotine Bioavailability

<table>
<thead>
<tr>
<th>Assumed CPD</th>
<th>Assumed Nicotine Yield</th>
<th>Estimated Nicotine Threshold (mg/g tobacco filler)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benowitz &amp; Henningfield</td>
<td>30</td>
<td>40%</td>
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<tr>
<td>Recalculation</td>
<td>15</td>
<td>20%</td>
</tr>
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</table>

285 83 Fed. Reg. at 11,819 (citing Ref. 2 in ANPRM).
287 Id. at 12.
pharmacokinetics and metabolism; population studies; economics; and communications and messaging.”

In short, the 2013 survey paper does not support the conclusion that there is a nicotine addiction threshold at or below 0.5 mg/g and does not provide any basis for a product standard at the levels discussed in the ANPRM.

b. The nicotine intravenous (“IV”) infusion study cited by the ANPRM does not establish a 0.3-0.5 mg/g threshold

The ANPRM suggests that the results of a nicotine IV infusion study published by Sofuoglu et al. could provide corroborating evidence for the 0.5 mg/g threshold initially estimated in 1994 by Benowitz and Henningfield. This study used a choice procedure in which smokers were able to choose between 0.1, 0.4, or 0.7 mg IV nicotine doses or saline. The two higher doses, but not the lowest dose, were self-administered more than placebo, which led the researchers to suggest a nicotine threshold between 0.1 and 0.4 mg per injection. The ANPRM states “the lowest dose in the study overlaps with the upper limit of an addiction threshold estimated by the 1994 study” and concludes “despite the study limitations of both these estimates, they help to provide a range on which to potentially base a nicotine level threshold.”

FDA’s cursory discussion does not disclose how its conclusion accounts for the considerable difference in route of exposure (i.e., IV versus inhalation), the significant differences in the pharmacokinetics and pharmacodynamics that result from this difference, or the fact that only a maximum of 20% of the 0.4 mg nicotine per gram tobacco would transfer from the tobacco to cigarette smoke. IV administration has significant limitations for estimating a potential nicotine threshold in the context of cigarette smoking. As the ANPRM notes, “[IV] delivery does not mimic inhalation, administration of nicotine alone omits other psychoactive constituents in tobacco smoke, and other factors such as age, sex, and genetic variations may influence nicotine’s reinforcing properties.” Likewise, IV delivery removes non-nicotine aspects of cigarette smoking, including the sensory cues associated with smoking such as smell, taste, and respiratory tract irritation, which have been shown to have potent reinforcing effects. In addition, although IV nicotine can produce nicotine blood levels similar to cigarette smoking, it does not reproduce peripheral effects in the lung. For this reason alone, the results of these studies have limited application.

Moreover, because the 0.1 mg dose in this study “was chosen to be approximately half the amount of nicotine inhaled from one puff of a cigarette,” a multiplier accounting for the number of puffs per cigarette would have to be applied before making a comparison to a per cigarette

288 Id. at 13 (emphasis added).
290 Id.
291 Id.
293 Id.
295 Id.
nicotine threshold. An average cigarette provides eight puffs, so said multiplier, on average, would be 16 giving a dose of 1.6 mg instead of 0.1 mg. This would be equivalent to 8 mg nicotine per cigarette (or 11 mg/g) once a nicotine in smoke yield of 20% is considered – which is significantly higher than 0.4 mg/g as discussed in the ANPRM. In addition, published IV nicotine studies do not demonstrate consistent satiating effects on subsequent nicotine seeking behavior.

Other research using IV nicotine administration further confirms that such research cannot be used to determine a maximum nicotine threshold. In one recent study, there was no preference for nicotine over a placebo at any dose condition and there was a negative relationship between self-administration in males, who self-administered nicotine more often when receiving 0.1 mg and 0.2 mg doses than 0.4 mg doses. In another study, subjects self-administered more puffs of de-nicotinized smoke than any other alternative, including IV nicotine, and denicotinized cigarettes were found to alleviate withdrawal symptoms where IV nicotine did not. Results from IV studies are therefore inconsistent and point only to complex interactions among nicotine doses and outcome measures. They do not support a 0.5 mg/g threshold.

c. The four “study types” identified by FDA do not support a 0.3-0.5 mg/g maximum nicotine standard

The ANPRM identifies four additional “study types” that it claims “speak to the level of nicotine in tobacco that could significantly reduce product addictiveness.” None of these study types establish a threshold for nicotine addiction. Assuming that such a threshold exists – and can be discerned based on current and future studies – its identification will likely require a weight of evidence analysis using multiple validated and predictive study types. FDA’s evaluation of the evidence should not place inordinate weight on any one study type.

i. Indirect estimates of an addiction threshold

The ANPRM cites “indirect estimates” of an addiction threshold, including studies on intermittent smokers (i.e., “chippers”) and research concerning intravenous nicotine delivery. These do not provide a reliable way to determine whether a nicotine threshold exists for an entire population or at what level.

The ANPRM relies on a 1994 paper by Benowitz and Henningfield that reviewed a study on intermittent smokers (“chippers”). The authors assumed that the smoking behaviors of

297 Here, we use 8 puffs per cigarette as an illustration. We previously submitted puff count per cigarette data for all of our cigarette brands in 2012, in connection with HPHC testing further to Section 904(a). The average for king size products was 7.62 puffs per cigarette (SD = 0.52) ISO and 9.23 puffs per cigarette (SD = 0.75) CI.
298 Reinforcing effects of nicotine.
300 Reinforcing effects of nicotine.
chippers translate to the general smoking population. Findings in a population of intermittent smokers, however, are not representative of the smoking population as a whole. Research has found that there is a clear difference between regular smokers and chippers, who de-emphasize pharmacological motives for smoking. Accordingly, the conclusions in this article concerning chippers do not generalize to the overall population of smokers. Moreover, the estimate offered in this 1994 article was based on arbitrary, unfounded, and incorrect assumptions and, once corrected, the methodology used in this paper suggests that any nicotine threshold would be significantly higher.

The ANPRM also relies on two studies “using intravenous nicotine administration” as providing an “indirect estimate” of a nicotine addiction threshold. This research did not establish such a threshold. One of the two studies (Ref. 84) found a wide range of possible thresholds: “between 1.5 to 6.0 micrograms/kg in humans and 3 to 10 micrograms/kg in rats.” The second study – a 2008 study in which nicotine was delivered intravenously – also does not provide support for a 0.5 mg/g threshold. To the contrary, such a contention ignores the route of exposure (intravenous versus inhalation) and differences in pharmacokinetics and pharmacodynamics that accompany each route. Moreover, a multiplier accounting for the number of puffs per cigarette would have to be applied before making any comparison on a per cigarette basis, and other research involving nicotine administration has reached inconsistent results. These “limitations” severely undermine the ANPRM’s reliance on this research.

ii. Findings of increased cessation for VLNC cigarettes

The ANPRM also discusses research evaluating the relationship between VLNC cigarettes and cessation rates. The ANPRM, however, concedes that “no large-scale clinical trials of reduced nicotine cigarettes have been conducted” and “little is known about the dose-related effects of reduced nicotine.” At most, this research suggests generally that, “if nicotine content is adequately reduced, smokers may benefit by smoking fewer cigarettes and experiencing less nicotine dependence, with few negative consequences.” It does not identify a threshold for nicotine addiction or even suggest one is possible.

The import of this research is questionable for other reasons. “One limitation of these studies is that they were conducted in an unregulated environment in which smokers continued to have


307 Id.

308 Id. (citing Ref. 84 in ANPRM).


access to the normal nicotine content (NNC) cigarettes.”\textsuperscript{312} Given the availability of the study participants own brand and other NNC cigarettes, the occurrence of “non-compliance” (in which participants supplement test cigarettes with NNC cigarettes) is a significant confounding variable in these studies. For example, one study cited by FDA as finding a decrease in the number of cigarettes smoked per day had a non-compliance rate between 22.9% and 40.8%\textsuperscript{313}. And another study cited by FDA\textsuperscript{314} reported a reduction in cigarettes per day had a non-compliance rate between 57% to 81\%\textsuperscript{315}

Further undermining the research discussed by FDA is its reliance on participant self-reports for measurement of non-compliance. Such measurements are most likely underestimated because study participants may be reticent to admit using non-study products and violating study protocols. Indeed, “biochemical assessments detect many more cases of non-compliance than self-report, and non-compliance with smoking VLNCs is observed in the majority of participants.”\textsuperscript{316} Furthermore, not all research in this area has found a reduction in the number of CPD when participants smoked VLNC cigarettes.\textsuperscript{317} For example, the ANPRM relies on a study that progressively reduced the nicotine content of experimental cigarettes (down to 0.5 mg/g).\textsuperscript{318} At the end of a follow-up period 12 months after the intervention period, however, the authors noted that quit rates were low and concluded that “lengthy exposure to [VLNC cigarettes] does not result in the extinction of nicotine dependence, as might be seen in loss of smoking urges, reduction in CPD or increased quitting.”\textsuperscript{319} Accordingly, these studies do not support a nicotine threshold at the levels discussed in the ANPRM.

iii. Subjective effects and relief of withdrawal symptoms associated with VLNC cigarettes

The ANPRM also refers to research comparing the subjective responses of participants when smoking VLNC and NNC cigarettes. Based on this research, the ANPRM observes that “[i]ndividuals who smoke VLNC cigarettes experience some of the same subjective effects as those individuals who smoke traditional, NNC cigarettes . . . but do not experience other symptoms associated with full nicotine cigarettes.”\textsuperscript{320} This research does not suggest that there is a threshold for nicotine addiction, let alone what that threshold might be. If anything, this research confirms the complexity of these questions and the inability to answer them using currently available science.

\textsuperscript{312} Id.
\textsuperscript{313} Dorothy K. Hatsukami, et al., Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation 105(2): 343-55, Addiction (Feb. 2010).
\textsuperscript{316} Id.
\textsuperscript{317} N.L. Benowitz, et al., Effect of reducing the nicotine content of cigarettes on cigarette smoking behavior and tobacco smoke toxicant exposure: 2-year follow up 110(10): 1667-75, Addiction (Oct. 2015).
\textsuperscript{318} Id.
\textsuperscript{319} Id.
\textsuperscript{320} 83 Fed. Reg. at 11,828.
Indeed, “dependence to cigarette smoking is a multifaceted and broad dependence.” The sensory stimuli associated with smoking and the mechanics of the habit itself are extremely potent drivers of cigarette use and dependence, and factors other than nicotine intake are important for relief of withdrawal symptoms. As a result, the effects typically associated with nicotine, such as craving and withdrawal, are difficult to disentangle from non-nicotine effects of cigarette smoking, such as conditioned cues and environmental/situational effects. For this reason also, research comparing subjective responses to VLNC and other cigarettes cannot establish whether there is a threshold for nicotine addiction.

iv. Lower nAChR occupancy and cerebral response from the use of VLNC cigarettes

Finally, the ANPRM references studies showing “lower nAChR occupancy and cerebral response in individuals smoking VLNC.” Like the first three study types, this research does not establish an addiction threshold for nicotine. Rather, this research suggests only that “VLNC cigarettes may not produce the full range of subjective responses . . . observed following use of NNC cigarettes.” Thus, the ANPRM posits, this research “supports the hypothesis that many subjective and physiological effects observed following exposure to smoke from VLNC cigarettes could be due to repeated pairing of nicotine with sensory and conditioned cues or to other psychoactive chemicals.” Even if this hypothesis were eventually shown to be true, it would fall well short of demonstrating that a threshold for nicotine addiction exists and can be identified.

d. Currently available animal models do not establish an addiction threshold for nicotine

The ANPRM cites certain animal studies, but these models are incapable of determining a threshold for nicotine addiction in human cigarette smokers. Researchers, including FDA-funded scientists, have identified multiple deficiencies with these models.

One recent review, for example, identified gaps in animal research on nicotine reduction and concluded that the existing animal model cannot account for the sensory aspects of smoking. This is a critical deficiency because sensory and environmental cues that are paired with nicotine

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325 Id.
326 Id.
327 Id. at 11,829.

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have the potential to reinforce smoking behavior.\textsuperscript{329} This study also observed that animal models cannot predict changes in human smoking topography (e.g., changes in cigarettes smoked per day or compensatory smoking changes within the cigarette).\textsuperscript{330}

Animal research also has produced inconsistent data regarding the threshold for nicotine reinforcement and the role of nicotine metabolism.\textsuperscript{331} For example, research using rodents has demonstrated low reinforcement thresholds because they metabolize nicotine quickly.\textsuperscript{332} Humans, by contrast, metabolize nicotine more slowly and demonstrate higher reinforcement thresholds.\textsuperscript{333} If a threshold for nicotine addiction exists in animals, it has not been determined in any animal model.

In addition, evidence from animal models does not encompass the choices that adult smokers have in the marketplace among tobacco products. Animal models would need to incorporate “the choice that smokers have between VLNC cigarettes and alternative tobacco products by providing rats with more than one choice in the self-administration paradigm.”\textsuperscript{334} Moreover, researchers typically use a nicotine self-administration model (“NSA”) in experiments with animals. But NSA does not assess cognitive function, avoidance of withdrawal, or self-medication of psychiatric symptoms. These are critical problems that undermine the relevance of animal studies for evaluating human addiction thresholds.

\section*{C. The Current Science is Inadequate to Determine the Public Health Consequences of Cigarettes with 0.3-0.5 mg/g}

\subsection*{1. Consumers May Perceive VLNC Cigarettes as Less Harmful}

Existing science cannot predict how consumer perceptions and beliefs about VLNC cigarettes might affect behavior or disease outcomes, but it does reveal that many consumers have deeply-entrenched misperceptions about the role of nicotine in smoking-related disease. Research published by FDA demonstrates that adult smokers believe VLNC cigarettes present less risk than regular cigarettes. One recent study funded by NCI and FDA, for example, found “47.1\% of smokers . . . believ[ed] that VLNC cigarettes are less likely to cause cancer than current


cigarettes.” Another FDA-funded study reported that “[i]ndependent of true nicotine content, when smokers were told a cigarette had low nicotine levels, they reported it was less harmful than a cigarette with an average amount of nicotine.”

Such beliefs could have unintended consequences such as reducing cessation efforts, increasing cigarette consumption, increasing the likelihood to return to smoking by former smokers or initiation by new smokers and discouraging use of less risky nicotine products for smoking cessation, the other goal of FDA’s new approach. Before moving forward, FDA should study perceptions and beliefs about the risks of VLNC cigarettes and their potential impact.

2. Existing Science Is Inadequate to Determine the Impact of VLNC Cigarettes on Initiation, Cessation and Dependence

Scientific research on VLNC cigarettes is still in its infancy. The FDA recognizes “the inherent limitations of the available research on changes in smoking as a function of VLNC cigarette use.” That observation is well-founded. Among other things, the current evidence is inadequate to evaluate the impact of VLNC cigarettes on initiation, cessation and dependence in individuals, the population as whole, and population subgroups of particular interest such as youth.

   a. Existing research is inadequate to evaluate the impact of VLNC cigarettes on smoking initiation in youth or adults

Assuming sensorially acceptable VLNC cigarettes could be produced for commercial sale, additional information would be necessary to evaluate the impact of those cigarettes on initiation rates. We are not aware of any studies that have investigated this issue.

There is, however, reason to believe that producing only VLNC cigarettes, without an appropriate market of noncombustible products, would not prevent smoking initiation. Social factors, rather than nicotine, are believed to play the dominant role in smoking initiation, particularly among youth. “Because the non-pharmaceutical factors noted above are most

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340 Tobacco Product Standard for Nicotine Level of Combusted Cigarettes.

prominent in initiation, taking the nicotine out of cigarettes alone is not likely to eliminate the initiation of social cigarette smoking.\textsuperscript{342}

In addition, available evidence suggests no difference in the dependence potential of cigarettes at varying nicotine levels among current youth smokers. One study examined the reinforcing value of various nicotine content cigarettes (15.8, 5.2, 1.3, and 0.4 mg/g) and usual brand cigarettes among adolescent daily cigarette smokers.\textsuperscript{343} Adolescents completed a hypothetical cigarette purchase task after smoking each research cigarette type. The results showed significantly higher demand (intensity of demand, maximum expenditure, breakpoint, and essential value) for usual brand cigarettes but no differences in demand of SPECTRUM cigarettes based on nicotine level. These findings suggest that nicotine content might not impact the reinforcing efficacy of VLNC cigarettes among adolescents.

FDA should address these implications when evaluating a possible product standard. Indeed, this is one of many reasons why FDA should pursue a product standard only in the context of its Comprehensive Plan.

b. Existing research is inadequate to evaluate the impact of VLNC cigarettes on smoking cessation in youth or adults

The impact of VLNC cigarettes on smoking cessation has been evaluated primarily in short-term studies. These studies are inadequate to determine if VLNC cigarettes facilitate smoking cessation. In these studies, participants smoked as little as a few puffs over a one-or two-hour laboratory session, and then were asked to rate the products on subjective attributes. Participants therefore did not smoke the test cigarettes in the way regular smokers use cigarettes or for an extended period of time, and they do not have an opportunity to acclimate to the test cigarette products. And any relationship between subjective attributes and cessation under these conditions is tenuous at best.

The few available longer-term studies have had, at most, mixed results, and do not establish that a VLNC standard would lead to increased cessation. For example, a study that followed smokers using reduced nicotine cigarettes for almost two years found no difference in quit rates between those who used their usual brand during that time and the group that received low nicotine


\textsuperscript{343} R.N. Cassidy, (Paper presented at the SRNT 2018).
cigarettes. Likewise, a study that evaluated participants at a 12 month follow-up concluded “lengthy exposure to [VLNC cigarettes] does not result in the extinction of nicotine dependence, as might be seen in loss of smoking urges, reduction in CPD or increased quitting.” A six week study of SPECTRUM VLNC cigarettes cited by the ANPRM that did not specifically assess cessation or abstinence rates, found at a 30-day follow-up that approximately 90% of participants reported current smoking, and the percentage of current smokers was the same in the experimental groups and in the usual brand group.

By contrast, some studies suggest that VLNC cigarettes may be minimally effective for smokers who are planning to quit, at least when combined with other forms of therapy. Results of one clinical trial conducted in New Zealand, for example, suggested that the addition of VLNC cigarettes to standard quitting support (behavioral support and NRTs) modestly improved smoking cessation outcomes at six months (28% vs. 33% among the study participants). Two other clinical trials examined the effects of reduced nicotine cigarettes with yields of 0.3 and 0.05 mg/cigarette and 0.05 to 0.09 mg/cigarette. The results of these studies suggest that cigarettes with nicotine yields of 0.05 to 0.09 mg resulted in modestly reduced cigarette consumption. It is unclear from the studies, however, whether the reduction in consumption resulted from lower nicotine-mediated reinforcing effects or from the participants’ aversion to these cigarettes.

In addition, studies suggesting that increased quit attempts could be associated with VLNC cigarettes are mixed and may be subject to measurement error. For example, one study reported that a greater percentage of participants in a group using a 0.4 mg/g cigarette made a quit attempt than did participants in the 15.8 mg/g group after completing the study. But the data also showed that the percentage making a quit attempt in the 0.4 mg/g group did not differ from the usual brand condition. The fact that quit attempts did not increase relative to usual brand smokers indicates that factors other than nicotine content drive consumer quit attempts.

c. The model cited by FDA does not accurately reflect the impact of cigarettes with 0.3-0.5 mg/g tobacco on population harm

Modeling can be a useful tool for predicting the potential impact of harm reduction strategies on a population. The only population harm model cited by FDA, however, uses arbitrary model

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345 Id.
347 N. Walker, et al., The combined effect of very low nicotine content cigarettes, used as an adjunct to usual Quitline care (nicotine replacement therapy and behavioural support), on smoking cessation: a randomized controlled trial 107(10), 1857-1867, Addiction (2012), doi:10.1111/j.1360-0443.2012.03906.x
349 D.K. Hatsukami, et al., Reduced nicotine content cigarettes and nicotine patch 22(6), 1015-1024, Cancer Epidemiology, Biomarkers & Prevention (2013), doi:10.1158/1055-9965.epi-12-1439.
inputs and is therefore biased.351 Indeed, the input parameters for cessation and initiation, product switching, dual use, and initiation of non-combusted products were not based on data, but estimated by a panel of eight “experts,” who were “asked to provide estimates of the anticipated effects of a hypothetical policy” requiring VLNC usage.352

Moreover, because of the assumptions presented to this panel, the model was preordained to produce a net population benefit. First, the panel assumed that the nicotine standard would be fully and effectively implemented, because no data exist to serve as a basis for model inputs.353 Second, the panel was told to assume that the nicotine standard applied to other smokeable products that are likely to serve as substitutes for cigarettes, such as roll-your-own tobacco, pipe tobacco, and non-premium cigars.354 Third, the panel assumed, unrealistically, that contraband cigarettes would not be available and completely disregarded other unintended consequences, such as consumers continuing to smoke cigarettes compliant with the standard while augmenting their nicotine intake by other means.

In addition to these flawed inputs, the cessation estimates produced by individual experts varied dramatically, ranging from 4.5% to 80%. The divergence in these estimates is further evidence that the model does not provide an adequate basis for regulatory decision-making. This is confirmed by the disconnect between the model’s findings and the data available in the VLNC cigarette literature. For example, one study reported that VLNC cigarettes resulted in greater cessation at day 7 of a 6-week follow-up (after a 6-week intervention period), but no differences remained at week 4 of the same 6-week follow up period.355 Many studies, however, fail to observe any differences in cessation whatsoever between VLNC cigarettes and conventional cigarettes.356 And although one study found a 25% cessation rate, it qualified those results: “because the number of subjects in the study was small and the study was not controlled, no definitive conclusion about quitting can be made.”357

Accordingly, the lone model cited in the ANPRM therefore does not provide reliable or adequate data on the impact of VLNC cigarettes on cessation rates.

352 Id.
353 See id.
354 Id.
357 N.L. Benowitz, et al., Nicotine and carcinogen exposure with smoking of progressively reduced nicotine content cigarette 16(11), 2479-2485, Cancer Epidemiology Biomarkers Prev. (2007), http://cebp.aacrjournals.org/content/16/11/2479.
d. Existing research is inadequate to evaluate the impact of a nicotine standard on youth smoking behavior

One recent survey showed that past 30-day use of cigarettes among 8th, 10th, and 12th graders has declined from a peak of 28.3% in 1997 to 5.4% in 2017. This represents both a historical low and an 81% decline in youth smoking prevalence over the last two decades. FDA should carefully consider the potential impacts of a nicotine reduction standard to ensure that it does not slow or reverse the decline in youth smoking. To our knowledge, no studies have addressed this issue.

As noted, youth might incorrectly believe that VLNC cigarettes are less harmful or easier to quit because they contain less nicotine. (See supra at Section III, C, 1). Moreover, adults who influence youth behaviors, like parents and teachers, might be less concerned about youth smoking if they misperceive VLNC cigarettes as less harmful. In addition, youth might find VLNC cigarettes more enjoyable or pleasant than traditional cigarettes because they do not produce, or produce at lower levels, the aversive effects associated with the initial use of nicotine, such as nausea, dizziness, headache, and vomiting. None of the outcomes described above are acceptable and underscore the need for FDA to further study and address these issues before a VLNC standard is implemented.

3. The Current Evidence Is Inadequate to Determine the Degree of Compensation that Might Occur with the Use of VLNC Cigarettes

Like conventional cigarettes, VLNC cigarettes deliver toxic substances to the smoker in addition to nicotine. The delivery of such substances raises the question of whether and to what extent consumers alter their smoking behavior to compensate for the lower nicotine in VLNC cigarettes—for example, by smoking more cigarettes, smoking individual cigarettes more intensely, or by using VLNC cigarettes in combination with other sources of nicotine. Such behaviors could reduce the presumed benefit of a VLNC standard on individual risk and population harm by allowing smokers to maintain substantial levels of exposure to harmful and potentially harmful smoke constituents in combusted tobacco. As noted, the public health community attacked Next cigarettes marketed as having significantly lowered nicotine as “the most hazardous tobacco product put on the market in the last 10 years” based on concerns that smokers would compensate when smoking them.

Studies measuring exposure to toxicants from VLNC cigarettes will be important when considering the extent to which smokers compensate when smoking these cigarettes. Studies measuring puffing topography and carbon monoxide exposure while smoking a single VLNC cigarette have yielded mixed results. One study showed increases in puff number, while

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359 Id.


showing no differences in puff volume. Other researchers have found no differences in number of puffs or puff volume. In addition, several studies have reported increases in CO exposure in trials with VLNC cigarettes, while others reported decreases in CO exposure with VLNC cigarettes.

Drawing conclusions from existing studies is also complicated by non-compliance with VLNC cigarette use. Non-compliance is often widespread in studies of VLNC cigarettes. Such non-compliance is particularly problematic when evaluating the degree of compensation. As one study observed, having “[s]ome participants [who] were not fully compliant with smoking


366 See, e.g., N. Nardone, et al., Estimations and predictors of non-compliance in switchers to reduced nicotine content cigarettes 111(12), 2208-2216, Addiction (2016), https://onlinelibrary.wiley.com/doi/abs/10.1111/add.13519 (“In the present study, non-compliance was 76-78% using biochemical assessment and 39% by self-report.”); D.K. Hatsukami, et al., Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation 105(2): 343-55, Addiction (Feb. 2010) (“[U]se of nonstudy cigarettes was common, which probably attenuated the reduction in nicotine exposure relative to nicotine content and may have minimized the effects of nicotine reduction.”); M. Mercincavage, et al., A Randomized Controlled Trial of Progressively Reduced Nicotine Content Cigarettes on Smoking Behaviors, Biomarkers of Exposure, and Subjective Ratings 25(7): 1125-33, Cancer Epidemiology, Biomarkers & Prevention (2016) (“We also could not verify noncompliance with the RNC cigarettes beyond participants’ self-report and spent filter discrepancies, and thus cannot determine the impact of other cigarette use on study outcomes.”); N.L. Benowitz, et al., Effect of reducing the nicotine content of cigarettes on cigarette smoking behavior and tobacco smoke toxicant exposure: 2-year follow up 110(10): 1667-75, Addiction (Oct. 2015) (“A number of subjects (30% at 6 months and 43% at 12 months) reported that they supplemented their reduced nicotine content cigarettes with some conventional cigarettes.”); N.L. Benowitz, et al., Nicotine and carcinogen exposure with smoking of progressively reduced nicotine content cigarette 16(11), 2479-2485, Cancer Epidemiology Biomarkers Prev. (2007), http://cebp.aacrjournals.org/content/16/11/2479 (“Compliance with smoking only the research nicotine cigarettes could not be tested.”); D.K. Hatsukami, et al., Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation 105(2): 343-55, Addiction (Feb. 2010) (“Another limitation was the inability to determine if smokers were compliant with the study procedures (i.e., that they used the assigned products solely)”).

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reduced nicotine content cigarettes and smoked some conventional cigarettes . . . might lead to an underestimation of the occurrence of compensatory smoking.\textsuperscript{367}

Accordingly, additional research is needed to determine the potential prevalence, extent, and methods of compensation that may occur in response to a VLNC standard.

4. The Current Evidence Is Inadequate to Determine the Impact of Technology and Processes that Might Be Used to Produce VLNC on Potential Health Effects

As discussed above, biotechnology, extraction and other processes that might reduce the nicotine content of tobacco are likely to raise questions concerning the potential health effects of those techniques. (See supra at Section III, G). For example, reducing the amount of nicotine in cigarettes through biotechnology or extraction can lead to other changes within the tobacco that increase other constituents.\textsuperscript{368} In addition, the use of VLNC tobacco might necessitate the use of flavors or other additives to ensure that products are sufficiently acceptable to consumers, which might impact the potential health effects of the final product. Currently, little science is available to evaluate these risks. Any standard requiring VLNC tobacco should not be implemented before these questions are addressed.

5. Symptoms of Nicotine Withdrawal May Be Significant on a Population Level

Early abstinence from nicotine can result in a wide range of clinical symptoms, including irritability, anxiety, emotional distress, sleep problems, dysphoria, aggressive behaviors, drug craving,\textsuperscript{369} anger, frustration, desire to smoke, difficulty concentrating, increased appetite, hunger and weight gain.\textsuperscript{370} Smokers with high levels of hostility may use cigarettes to cope with anger-provoking situations\textsuperscript{371} and withdrawal-related negative mood.\textsuperscript{372} There is a high comorbidity between smoking and mental and emotional disabilities and mood disorders.\textsuperscript{373} Negative affect, related to withdrawal symptoms is also associated with non-nicotine substance abuse risk.\textsuperscript{374}


Certain segments of the population may be at higher risk for the negative impacts of nicotine withdrawal. For instance, lower socioeconomic status (SES) smokers have a harder time quitting\textsuperscript{375} and are more susceptible to relapse due to a lack of social support, increased craving, increased stress and negative affect, decreased positive affect and motivation.\textsuperscript{376} Moreover, due to healthcare inequities, people within lower SES groups also are less likely to have access to the nicotine replacement therapies (NRT). And even with equal access to the NRT treatment, studies have shown that people in low SES groups have a harder time quitting.\textsuperscript{377} Furthermore, a nicotine standard may disproportionately affect other “at risk” populations, such as the mentally ill, who may be more vulnerable to the negative impacts of nicotine withdrawal.

FDA should study and understand these issues before setting a VLNC standard.

IV. \textbf{A Product Standard of 0.3-0.5 mg/g – or Any Nicotine Ceiling Even Remotely Close to That Ceiling – Will Have a Significant Negative Economic Impact and Countervailing Effects}\textsuperscript{378}

Implementing a VLNC standard even remotely close to the levels discussed in the ANPRM\textsuperscript{379} will have an enormous economic impact and countervailing effects. FDA must consider each of these consequences and how they affect tobacco stakeholders, state and local governments, and the overall economy before implementing a VLNC standard for combustible cigarettes. Indeed, the Agency recognizes the potential for these consequences and requests “comments, data, research and results regarding economic impacts.”\textsuperscript{380} The economic impact will be significant and devastating.

FDA is required to consider the economic impacts of any proposed rule. Executive Orders 12866 and 13563\textsuperscript{381} require FDA to submit “significant regulatory actions” (like this one) to the Office of Information & Regulatory Affairs within the Office of Management and Budget for

\begin{itemize}
\item \textsuperscript{376} M.S. Businelle, \textit{et al.}, \textit{Mechanisms linking socioeconomic status to smoking cessation: a structural equation modeling approach} 29(3), 262-273, Health Psychology (2010), doi:10.1037/a0019285.
\item \textsuperscript{378} We include a chart that cross-references questions posed in the ANPRM with our responses in the Appendix at Attachment 2.
\item \textsuperscript{379} For purposes of this section, we assume that the hypothetical VLNC standard applies to all combustible tobacco products, namely, cigarettes, cigars, roll-your-own tobacco, cigarette tobacco, and pipe tobacco. Given relative market shares, we use data for these categories to predict various economic impacts.
\item \textsuperscript{380} 83 Fed. Reg. at 11,820. “Considerations – FDA also recognizes that, if FDA were to proceed to the stage of proposing a rule in this area, potential costs and benefits from a possible nicotine tobacco product standard would be estimated and considered in an accompanying preliminary impact analysis, including the potential impacts on growers of tobacco and current users of potentially regulated products. Thus FDA is also seeking comments, data, research results, and other information regarding economic impacts of a potential nicotine tobacco product standard.”
\item \textsuperscript{381} Exec. Order 12866, Regulatory Planning and Review, 58 Fed. Reg. 51,735 (Oct. 4, 1993); Exec. Order 13563, Improving Regulation and Regulatory Review (Jan. 18, 2011) (“reaffirm[ing] the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866”); \textit{see also} Exec. Order 13771, Reducing Regulation and Controlling Regulatory Costs, 82 Fed. Reg. 9339 (Jan. 30, 2017) (requiring any new incremental costs associated with new regulations . . . [to] be offset by the elimination of existing costs associated with at least two prior regulations”).
\end{itemize}
review and clearance, including cost-benefit analysis. To have meaning, that review must be based on a good faith preliminary estimate of the economic costs that would result from a product standard. In addition, the Regulatory Flexibility Act requires FDA to address “the steps the agency has taken to minimize the significant economic impact on small entities….” These requirements supplement those imposed by the APA and basic due process rights, which likewise require FDA to carefully evaluate the economic impact of any proposed rule as part of notice and comment rulemaking. Congress confirmed its concern with a product standard’s potential economic impacts in Section 907(d)(2), which specifies that the effective dates for a product standard “shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.” Consistent with that concern beyond the timing of any effective date, Section 907(b)(2) requires FDA to “consider all other information submitted in connection with a proposed standard”—a requirement that extends to economic ramifications. Indeed, Congress’s ongoing concern about the adverse economic effects of regulations can be seen in its increased willingness to exercise authority under the Congressional Review Act.

In this section, we provide insights into how a hypothetical VLNC standard at the levels contemplated in the ANPRM will affect tobacco growers, retailers, and other key tobacco product stakeholders. A standard of this magnitude will undoubtedly affect each of these stakeholders in numerous ways; however, our comments predominantly focus on the standard’s impact to jobs, government budgets and other key economic factors.

To evaluate these key economic factors, we first examine the impact of a hypothetical VLNC standard on tobacco product volume by modeling volume shifts. Next, we analyze how this shift in volume affects businesses and jobs, specifically tobacco growers and retailers. In the final section we study how the shifts in volume, and the resulting business and job losses, create implications for federal, state, and local budgets, which all receive tobacco revenue.
A. Tobacco Product Volume Implications

If FDA implements a VLNC standard at the levels described in the ANPRM, it will force adult smokers to consider other options beyond continuing to smoke lawful combustible products now meeting the VLNC standard or quitting all tobacco products, such as: smoking VLNC combustible products; moving down the continuum of risk to products like e-vapor or smokeless tobacco; or obtaining conventional nicotine content combustible products from the illicit market.

Modeling the economic impacts of a hypothetical standard is challenging due to the number of unknowns. These unknowns include critical factors, such as: the potential scope of the hypothetical VLNC standard; a volume baseline for VLNC combustible products; and whether or not numerous alternative, nicotine-containing products will remain in the marketplace following the PMTA submission deadline in 2022.

We include a detailed description of our methodology and assumptions for this model in the Appendix at Attachment 1, but note that the economic impacts of a hypothetical VLNC standard may vary from those described below depending on unknown factors like those described above.

**VLNC cigarette and cigar purchases.** Our tobacco volume flow model estimates that after implementation of a VLNC standard, VLNC cigarettes and cigars would hypothetically represent 0.4 percent of tobacco purchases.

Our volume assumption is based on our prior experience with PM USA’s “Next” cigarette introduction, which initially captured 0.2 percent market share. (See supra at Section II, C, b). In addition, given the growth of alternative, nicotine-containing noncombustible products such as e-vapor, adult smokers may use other tobacco products instead of or in addition to VLNC cigarettes and cigars. According to PATH data, approximately 19 percent of adult smokers consume smokeless tobacco products and e-vapor products in addition to smoking conventional nicotine content cigarettes.

**E-vapor purchases.** Adult smokers did not find previous low nicotine cigarettes acceptable and these cigarettes would not meet the VLNC levels suggested in the ANPRM. (See supra at Section II, C, 1, b). Therefore, adult smokers who do not switch to VLNC cigarettes may switch to e-vapor products. Following implementation of a VLNC standard, we estimate that e-vapor would hypothetically represent 20 percent of tobacco product purchases (legal and illicit.

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385 We use PATH data, internal ALCS STARS data, and IRI, Data on combustible cigarette, cigar, and smokeless tobacco products (pulled May 9, 2018) in our model to demonstrate the direction and possible impacts flowing from a hypothetical VLNC standard. To the extent other sources of data become available and prove more reliable (e.g., forthcoming Wave 3 PATH data), the resulting model outputs would change. Using our inputs and assumptions, Charles River Associates (CRA) applied an empirical methodology to estimate the potential composition of the tobacco marketplace following implementation of a VLNC standard at the levels described in the ANPRM. The methodology relies on the approach developed in Becker, Murphy, and Grossman’s 2006 *Journal of Political Economy* paper on “The Market for Illegal Goods: The Case of Drugs,” which observed that enforcement efforts are equivalent in their impact on demand to price changes.

386 This is based on behaviors studied of adult smokers and market data of previously introduced low nicotine cigarettes.

387 See Appendix at Attachment 1 for details on PATH data and assumptions.

purchases) compared to the current marketplace. A National Cancer Institute (NCI) and National Institutes of Health (NIH) supported study found that adults trying to quit smoking cigarettes were more prone to try e-vapor products than other products. Euromonitor market data and analyst reports expect strong e-vapor revenue growth over the next year relative to mostly flat or declining performances among other tobacco products.

Smokeless tobacco purchases. Although smokeless tobacco use is significantly lower than e-vapor products, adult smokers might also switch to these products in the event of a VLNC standard. We estimate that smokeless tobacco products would hypothetically represent 12 percent of tobacco product purchases (legal and illicit purchases) as compared to the current marketplace. PATH data shows that adult cigarette smokers’ dual use of smokeless tobacco is significantly lower than dual use of e-vapor products. Euromonitor estimates a one percent growth in smokeless tobacco sales over the next year.

Diminished volume of legal sales. The economic impact of a hypothetical VLNC standard is driven by the decrease in lawful sales of legal combustible products and is offset by the increase in lawful sales of other legal tobacco products such as e-vapor and smokeless tobacco products. While some adult smokers will quit all tobacco products, this decrease is primarily driven by adult smokers who do not find VLNC combustible products, e-vapor products, or smokeless tobacco products satisfying and turn to the illicit market to purchase combustible products with conventional nicotine levels.

We estimate that the decrease in lawful sales of legal combustible products would hypothetically account for approximately two thirds (67 percent) of the tobacco marketplace following implementation of a hypothetical VLNC standard. Currently, numerous states are already experiencing large illicit markets driven by price differences, such as: New York (56.9 percent); Arizona (51.5 percent); New Mexico (48.1 percent); Washington (48.0 percent); and Wisconsin (34.6 percent).

Our above estimates predict an impact of up to 99 percent of legal combustible product volume – in short, a de facto ban – as adult smokers find cigarettes and cigars meeting a hypothetical VLNC standard unacceptable and unpalatable.

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392 Euromonitor data and research by Bonnie Herzog – Wells Fargo research analyst covering tobacco

393 2014-2015 PATH data.


B. Thousands of Businesses and Hundreds of Thousands of Jobs in the Combustible Cigarette and Cigar Value Chain will be Negatively Affected by a VLNC Standard

Federal, state, and local governments have much to lose because conventional nicotine content cigarettes and cigars account for 83 percent of total tobacco product sales.\textsuperscript{396} Tobacco products sales support at least 180,000 businesses, 2.3 million jobs, and over $60 billion of federal, state, and local budgets. Moreover, $700 million of revenue from tobacco export contracts (representing 60 percent of U.S. tobacco production) will be at risk if some types of newly developed Genetically Modified Organism (GMO) tobaccos must be grown domestically to meet a VLNC standard.\textsuperscript{397}

Figure 4 below shows that the tobacco value chain includes 180,000 businesses across eight key stakeholder groups.

Figure 4 – Breakdown of total tobacco value chain businesses and jobs

\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|}
\hline
 & Number of businesses & Jobs generated \\
\hline
Growers & 8,000 & 20,000 \\
Leaf Merchants & 5 & 4,000 \\
Direct Material & 100 & 3,000 \\
Transportation & 60 & 700 \\
Warehousing & 30 & 1,400 \\
Manufacturers & 250 & 17,000 \\
Wholesalers & 450 & 39,000 \\
Retailers & 169,000 & 2,200,000 \\
\hline
Total & & 2,285,100 \\
\hline
\end{tabular}
\end{table}

In 2017, 12.4 billion packs of conventional nicotine content cigarettes were sold in the U.S., representing 76 percent of total tobacco volume sold.\textsuperscript{398} Producing, distributing, and selling conventional nicotine content cigarettes at this volume requires hundreds of thousands of employees across various industries. Figure 5 below describes the role of each stakeholder in this process and is similar for other tobacco products.

\textsuperscript{396} See Appendix Attachment 1 at p. 115.
\textsuperscript{397} GMO includes technologies and breeding techniques deemed to be GMO by certain countries.
\textsuperscript{398} See Appendix Attachment 1 at p. 115.
C. VLNC Standard Implementation Includes the Loss of Thousands of Businesses and Jobs

Stakeholder impact in the tobacco chain will be significant. The direct and indirect impact includes the loss of up to 45,000 businesses and up to 951,000 jobs, causing an increase in unemployment from 3.9 percent to 4.5 percent. Up to 634,000 Americans could lose their jobs under a VLNC standard. (See infra at Section IV, D). The Bureau of Economic Analysis estimates that every job loss impacts another half of a job, so the indirect impact to the economy could include an additional 317,000 American jobs lost.

There will be significant effects to virtually every stakeholder in the growing, manufacturing, sale and distribution of cigarettes and cigars. We focus our analysis on tobacco growers and retailers because of the particularly devastating impact on these businesses.

1. Tobacco Grower Impact
   a. Tobacco grower landscape

Cigarettes use three main types of tobacco: Flue-cured, Burley, and Oriental. Approximately 80 percent of combustible tobacco products manufactured in the U.S. contain tobacco grown domestically because of higher quality and specific taste requirements.

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399 Our response considers tobacco stakeholders from growers to retailers. Other tobacco stakeholders preceding growers in the value chain will also be impacted. These stakeholders include university and extension personnel, as well as companies supplying tobacco growers with essential farming products like equipment, fertilizer, and seeds.
400 According to BLS, current unemployment rate is 3.9% and number of unemployed in the US is 6.3 million people https://www.deptofnumbers.com/unemployment/us/.
402 Note: Considers volume from Altria and RJ Reynolds using Euromonitor data for overall share.
In the U.S., tobacco growers produce over 700 million total pounds of tobacco (including dark tobacco, which is not used in conventional American Blend cigarettes).\textsuperscript{403} Although there are more Burley tobacco growers, most of the tobacco grown is Flue-cured, as Figure 6 shows. Seven states, primarily in the Appalachian and Southeastern regions of the U.S., grow tobacco, and most tobacco is grown in just two states – North Carolina and Kentucky (See Figure 7 for detailed breakdown of where tobacco is grown).

Figure 6: Number of tobacco growers by tobacco type and total production

![Figure 6](image)

Figure 7: Distribution of production by tobacco type by state\textsuperscript{404}

![Figure 7](image)

Domestic and international markets purchase U.S.-grown tobacco due to its high quality and unique taste characteristics, as shown in Figure 8 below.


Tobacco generates the most revenue and profit as compared to any other crop, and growers rely on this tobacco income. As Figures 9 and 10 show, tobacco generates up to two to three times more revenue per acre and two to ten times more profit per acre, respectively.

Tobacco growers depend on tobacco as their primary source of income. As Figure 11 shows below, over half of tobacco growers indicate that they derive more than 50 percent of their income from farming and nearly three quarters consider tobacco growing to be their primary occupation. In contrast, less than half of all growers (not just tobacco growers) far as their primary occupation and only 22 percent derive more than half their income from farming.

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405 All or a subset of the listed crops are planted by tobacco growers either at the same time or rotated with tobacco.
Figure 11: Percent of tobacco growers who derive income primarily from farming and percent that consider farming a primary occupation\textsuperscript{406}

![Bar chart showing percentage of income from farming and consideration of farming as a primary occupation for all growers and tobacco growers.]

The importance of tobacco profits varies based on the mix and size of a tobacco grower’s total farm. The definition of a small, medium, or large farm depends on the type of tobacco grown, total gross income of the farm, and acres of tobacco grown.\textsuperscript{407} As shown in Figure 12 below, 74 percent of tobacco growers are small.

Figure 12 – Distribution of small, medium, and large tobacco growers

![Pie chart showing distribution of small, medium, and large tobacco growers.]


\textsuperscript{407} See Appendix Attachment 1 at p. 116 for details on Small/Medium/Large farms. Note: This represents the distribution for Flue-cured and Burley farms since data is only available for these tobacco types.
Operating profits for small Flue-cured farms are far more dependent on tobacco revenue than large farms because they allocate the majority of their land to growing tobacco. (See Table 2 above).

Tobacco growers also support a significant number of jobs. Harvesting tobacco is considerably more labor intensive than other crops. For example, Flue-cured tobacco production (including pre-harvest, harvest, and post-harvest) requires an average of 75 hours of labor per acre as compared to corn, which is more automated and requires only one of labor hour per acre. This explains why U.S. production of Flue-cured and Burley tobacco involves an estimated 20,000 workers annually. The majority of these workers are concentrated in the two largest, Flue-cured and Burley tobacco producing states: North Carolina and Kentucky.

b. Tobacco growers face challenges under a VLNC standard

Manufacturing commercial VLNC cigarettes at the levels described in the ANPRM is not technically achievable. (See supra at Section II). However, we describe the impact a VLNC standard at these levels would have on tobacco growers for illustrative purposes in Table 3 below:

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408 Modeled based on economic budgets from NC State and combined with estimate of small, medium, and/or large farms.
Table 3 – Scenarios illustrating the effect of a VLNC standard on tobacco growers

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Grow VLNC tobacco using non-GMO seeds</strong></td>
<td>Tobacco growers continue farming current tobacco types for export and new VLNC tobacco for domestic contracts. Reduced demand for VLNC tobacco requires tobacco growers to adjust land allocation (e.g. utilizing unused acreage to grow another crop). Additionally, new agricultural practices will need to be developed by universities and adopted by growers, which include the segregation of VLNC tobacco.</td>
</tr>
<tr>
<td>2. <strong>Import VLNC tobacco grown from non-GMO seeds</strong></td>
<td>U.S.-grown tobacco commands a premium price due to its quality and taste. <em>(See supra at Section II, D, 4).</em> This advantage over foreign-grown tobacco will likely diminish if a VLNC standard at the levels proposed in the ANPRM is implemented. Consequently, domestic manufacturers may opt to purchase cheaper, off-shore leaf at the expense of American growers. In this scenario, we assume growers will no longer farm tobacco for domestic contracts and will instead use the land for other crops.</td>
</tr>
<tr>
<td>3. <strong>Grow VLNC tobacco using GMO seeds</strong></td>
<td>Growing GMO tobacco will severely limit the market for exported leaf. Countries have different standards for GMO crops and many prohibit their import altogether. Even if tobacco growers segregate crops for domestic and export contracts, there is a high likelihood that GMO VLNC tobacco will contaminate export supply. <em>(See supra at Section II, D, 4).</em> In this scenario, we assume that export contracts will be eliminated and tobacco growers will use the land for other crops.</td>
</tr>
</tbody>
</table>

Tobacco growers face significant negative economic impacts in each of the scenarios described above. However, these scenarios will affect growers differently.

For example, Burley tobacco growers will face the most significant impact in Scenarios One and Two. Even though Burley tobacco growers typically allocate a smaller portion of their land to tobacco and operate with net tobacco profits only half those of Flue-cured tobacco growers, they will be disproportionally hurt by decreased demand since 65 percent of their contracts are for the domestic market. By contrast, 70 percent of Flue-cured growers’ contracts are for export.

We focus the remainder of our analysis below on the most devastating of these scenarios, Scenario Three. In this scenario, the hypothetical VLNC standard is met using GMO seeds. This has the potential to affect up to 2,400 tobacco growers (24 percent of all tobacco growers) and 11,000 farm-related jobs (approximately half of total tobacco-related farm jobs).
Flue-cured tobacco growers – particularly those operating small or medium-sized farms – face the biggest impact from growing GMO tobacco due to their heavy reliance on export contracts. We assume that export contracts will likely be eliminated in this scenario due to the concerns raised in Table 3 above. As a result, Flue-cured tobacco growers operating medium-sized farms would see a potential 68 percent decrease in profits even if they increase production of other crops to offset tobacco-related losses. (See Figure 13 below).

Figure 13: VLNC standard impact on Flue-cured tobacco growers operating medium-sized farms

Flue-cured tobacco growers operating medium-sized farms could remain profitable following implementation of a VLNC standard. However, given the significant decrease in profitability and the fact that our calculations do not include tobacco growers’ salaries, it is plausible to assume that many of these tobacco growers will exit tobacco farming or even farming altogether. This assumption is further substantiated when considering the challenges and costs (e.g., obtaining new contracts, obtaining financing or purchasing equipment) confronting tobacco growers attempting to transition away from tobacco and adjust their crop portfolio. Valee Taylor, a former tobacco grower who converted tobacco farmland, stated that:

“It took me four years just to get my financing. That’s the hardest thing when you’re trying to transition, educating the USDA. I had to put up 150% collateral to get it”

- Valee Taylor – third generation tobacco grower

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Figure 14 – Average operating profit for small, medium, and large Flue-cured tobacco growers today and after implementation of a VLNC standard.

Flue-cured tobacco growers operating small farms will be impacted even more than those operating medium-sized farms due to the percentage of land dedicated to tobacco. Although Flue-cured tobacco growers operating large farms will see a significant decrease in profitability, it may still be sufficient to keep the farm operating. (See Figure 14 above). Therefore, in total, 1,700 to 2,400 tobacco growers will be impacted by a VLNC standard, which results in an initial loss of 3,800 to 5,300 farm-related jobs. An additional 6,000 farm-related jobs are likely to be lost if growers shift to less labor-intensive crops – resulting in a potential total loss of over 11,000 farm-related jobs.

Impact to North Carolina Flue-cured tobacco growers. Numerous states will suffer economic harm if the Agency implements a VLNC standard at the levels discussed in the ANPRM. We provide North Carolina as an example of this economic impact since it is the largest producer of Flue-cured tobacco; approximately 80 percent of all Flue-cured tobacco grown in the U.S. comes from North Carolina.\textsuperscript{411} Flue-cured tobacco growers in North Carolina are mostly concentrated within a 50-mile radius within the Coastal Plain region.\textsuperscript{412} Further, the top 13 of 31 tobacco-growing counties account for approximately 60 percent of North Carolina’s overall Flue-cured tobacco production. (See Table 4 below)

Implementation of a VLNC standard may force nearly 1,500 small and medium-sized Flue-cured farms to shut down – resulting in the loss of approximately 3,300 jobs.

\textsuperscript{412} \textit{Id.}
2. Tobacco Retailer Impact
   a. Current tobacco retailer landscape

Nearly a quarter of a million retail outlets in the United States sell conventional nicotine content cigarettes, cigars, and other tobacco products. Most tobacco products are sold through convenience stores, followed by grocery and drug stores, as Figure 15 shows.

Figure 15 – Number of stores by retail channel and percent of total stores

<table>
<thead>
<tr>
<th>Stores by retail channel</th>
<th>Percent of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convenience store</td>
<td>154,000</td>
</tr>
<tr>
<td></td>
<td>63%</td>
</tr>
<tr>
<td>Tobacco store</td>
<td>11,000</td>
</tr>
<tr>
<td></td>
<td>5%</td>
</tr>
<tr>
<td>Grocery store</td>
<td>47,000</td>
</tr>
<tr>
<td></td>
<td>19%</td>
</tr>
<tr>
<td>Mass merchandise</td>
<td>5,300</td>
</tr>
<tr>
<td></td>
<td>2%</td>
</tr>
<tr>
<td>Drug store</td>
<td>23,650</td>
</tr>
<tr>
<td></td>
<td>9%</td>
</tr>
<tr>
<td>Vape store</td>
<td>3,050</td>
</tr>
<tr>
<td></td>
<td>1%</td>
</tr>
<tr>
<td>Total</td>
<td>244,000</td>
</tr>
</tbody>
</table>

---

In addition to their purchase of tobacco products, adult tobacco consumers’ repeated visits and non-tobacco product purchases represent important segments of convenience store revenue.

Adult smokers contribute to a larger portion of a convenience store’s non-tobacco sales than the average consumer due to the frequency of their visits and ancillary purchases. While non-tobacco consumers average only two visits per month, adult tobacco consumers average nearly 16 visits per month (roughly every other day) and purchase more non-tobacco items per visit than other shoppers. This generates significant revenue for convenience stores – beyond tobacco product sales as adult tobacco consumers purchase snacks, beverages, and other items.

Convenience stores, tobacco stores, and vape stores heavily rely on tobacco product revenue. (See Figure 16 below). Subsequently, these channels drive the largest footprint and employment across the United States, totaling 169,000 stores and 2.2 million jobs. (See Figure 17 below). We exclude grocery, mass merchandise, and drugstores given the fact that tobacco sales only account for less than one percent of total sales.

Figure 16 – Percent of store revenue from conventional nicotine content cigarettes and cigars

<table>
<thead>
<tr>
<th>Store Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convenience store</td>
<td>24%</td>
</tr>
<tr>
<td>Tobacco store</td>
<td>70%</td>
</tr>
<tr>
<td>Grocery store</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Mass merchandise</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Drug store</td>
<td>2%</td>
</tr>
<tr>
<td>Vape store</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

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415 Internal ALCS Retail Survey data.
Convenience stores are an important source of employment and GDP because they employ more than 2.1 million workers and generate $500 billion dollars in revenue annually. Only 17 percent of convenience store workers have a college degree compared to the U.S. average of 23 percent. The convenience store channel is critical to providing jobs to workers that might otherwise have difficulty finding employment.

The operating profit margin of convenience stores averages four percent (see Figure 18 below). This is small when compared to an average of six percent for other general merchandise retailers. Low gross margins and high fixed costs, including employee wages, facility costs, and other costs required to run a convenience store create this landscape. Any loss in revenue affects a convenience store’s ability to stay in business and maintain employment.

Figure 17 – Employees by retail channel

<table>
<thead>
<tr>
<th>Employment by retail channel, Thousands</th>
<th>Percent of total employment, Percent</th>
<th>Average employees per location, Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convenience store</td>
<td>2,128,000</td>
<td>95%</td>
</tr>
<tr>
<td>Tobacco store</td>
<td>84,000</td>
<td>4%</td>
</tr>
<tr>
<td>Vape store</td>
<td>19,500</td>
<td>1%</td>
</tr>
<tr>
<td>Total</td>
<td>2,231,500</td>
<td></td>
</tr>
</tbody>
</table>

Convenience stores are an important source of employment and GDP because they employ more than 2.1 million workers and generate $500 billion dollars in revenue annually. Only 17 percent of convenience store workers have a college degree compared to the U.S. average of 23 percent. The convenience store channel is critical to providing jobs to workers that might otherwise have difficulty finding employment.

The operating profit margin of convenience stores averages four percent (see Figure 18 below). This is small when compared to an average of six percent for other general merchandise retailers. Low gross margins and high fixed costs, including employee wages, facility costs, and other costs required to run a convenience store create this landscape. Any loss in revenue affects a convenience store’s ability to stay in business and maintain employment.

Figure 18 – Gross profit and costs as a percent of convenience store sales

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417 Id.
419 Id.
420 Id. at 14.
b. Impact of a VLNC standard on convenience stores

A VLNC standard as contemplated in the ANPRM could cause up to 42,500 retail stores to close and trigger the loss of approximately 590,000 jobs. Convenience stores represent the majority of a VLNC standard’s retail impact. Of the 244,000 retail outlets selling tobacco products, 169,000 (of which 154,000 are convenience stores) derive over 20 percent of their revenue from conventional nicotine content cigarettes and cigars. In comparison, smokeless tobacco and e-vapor products currently account for less than 10 percent of the revenue in these 169,000 stores. The remaining outlets do not derive a significant portion of their revenue from conventional nicotine content cigarettes and cigars. Further, vape stores and online shops generate almost all of their revenue from e-vapor product sales.

Convenience stores average gross profits of $687,000 annually per store, or 18 percent of total sales. Tobacco purchases represent $102,000, while non-tobacco purchases account for the other $585,000. If FDA implements a VLNC standard, gross profits will decrease as shown in Figure 19 below.

Figure 19 – Annual convenience store gross profit from adult tobacco consumers by basket component

![Figure 19](image)

Millions of adult smokers are likely to obtain conventional nicotine content cigarettes and cigars from illicit markets because convenience stores no longer sell them. Assuming adult smokers decrease the frequency of their visits in line with average non-tobacco consumers, convenience stores will see an 88 percent drop in patronage.

In our modeled scenario, an additional 600,000 adult tobacco consumers will choose to buy smokeless tobacco products in convenience stores. However, this will not offset the millions of adult smokers who shift to illicit markets because adult smokeless tobacco product consumers make 34 percent fewer trips per month and spend 26 percent less than adult smokers who purchase conventional nicotine content cigarettes.

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421 *Id.* at 11.
422 *Id.* at 14. “Basket component” is comprised of tobacco and non-tobacco purchases.
423 Capital IQ at 36.
Reduced annual gross profits will not cover annual fixed costs for 42,500 stores, potentially resulting in closure. According to the National Association of Convenience Stores (NACS), a quarter of stores (38,500 stores) have annual fixed costs of approximately 16 percent of sales ($620,000). Since a convenience store’s annual fixed costs would not change, 38,500 stores with annual gross profits of ($585,000) would no longer be able to cover fixed costs, leading them to shut down.

NACS data also suggests another two to three percent of convenience stores have annual fixed costs of $601,000 (greater than their projected annual gross profit of $585,000). Therefore, approximately 4,000 more stores will close, resulting in a total of 42,500 store closures.

Convenience stores employ an average of 14 people per store. If 38,500 to 42,500 stores shut down, 539,000 to 595,000 convenience store jobs will be lost. E-vapor stores are likely to hire an additional two employees each due to increased demand. This will create a small offset to overall job losses (approximately 6,000 jobs), resulting in a net job loss of approximately 533,000 to 589,000 jobs.

c. Retail case studies

Recent retail industry shifts from brick and mortar to online add context to anticipated job losses. As Amazon expanded its footprint and sales, the jobs lost outnumbered the jobs created. Although Amazon created 146,000 jobs, Amazon displaced 294,000 retailing jobs, resulting in a net loss of 148,000 jobs.

The effect of regulatory changes can hit convenience stores hard. In 2015, Indonesia banned convenience stores, such as 7-Eleven, from selling alcohol. The economic impact of this ban forced all 7-Eleven stores to shut down and exit the market. Alcohol only comprised 10 percent of store sales, while in the U.S., conventional nicotine content cigarettes and cigars comprise nearly two and a half times that (24 percent) of convenience store sales. This implies a similarly significant, if not greater, VLNC standard impact on convenience store closures.

In Mexico, which has a similar landscape of small, independently owned convenience stores, a soda sales tax had results similar to the Indonesian alcohol ban. Soda sales in la tienditas (equivalent to convenience stores) represented a comparable contribution of revenue as tobacco products in U.S. convenience stores. In 2016, following the passage of a 30 percent sugar tax on beverages, 30,000 la tienditas closed (approximately four percent), and 93 percent of the tienditas saw a significant fall in profits.

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424 NACS data suggest 25 percent of convenience stores (38,500 stores) have a fixed cost of 14 percent of revenue. We assume not all of these stores have a fixed cost of 14 percent since it represents an average, and therefore, some stores within this group will have a higher fixed cost. We conservatively assume just 10 percent of these stores have a fixed cost of 15 percent.


426 *Id.* at 14.

**D. Overall Impact to Jobs**

Implementing a VLNC standard has the potential to impact up to 951,000 jobs (including direct and indirect job loss), which would increase unemployment from 3.9 percent to 4.5 percent nationwide. Worse yet, studies showed that only one in three unemployed job-seekers found a job within the two years following the 2007-2009 recession and 50 percent of those who found jobs ended up earning less.\(^{428}\) Therefore, after adjusting for those who will find another job, we still estimate that a VLNC standard could result in up to 634,000 lost jobs. (See Figure 20 below for details).

Figure 20: Range of jobs lost

Indirect costs to the economy must be considered in addition to the direct loss of jobs. For example, unemployment benefits in the U.S. average approximately $4,700 per person, but can range up to $11,700. Even if each of the unemployed workers described above are able to find a job within two years (a very unlikely scenario given past experience), this would still result in up to $22.3 billion in unemployment benefits over the same time.

**E. Federal, State, and Local Budgets Could Lose Billions of Dollars Annually Under a VLNC Standard**

1. The Tobacco Industry is a Significant Source of Revenue for Federal, State, and Local Governments

Over $60 billion is generated annually from Master Settlement Agreement (“MSA”) and Previously Settled State Agreements (“PSS”) payments (see below for explanation on MSA and PSS), excise taxes and sales taxes, as well as taxable corporate and personal income derived from tobacco-related businesses and jobs. Most tobacco-related revenues are tied directly to the unit volume of cigarette sales (see Table 5 below).

---

Table 5 – Overview of 2017 tobacco tax revenue ($ in billions)

<table>
<thead>
<tr>
<th>Tobacco Product</th>
<th>Excise Tax</th>
<th>MSA/PSS Sales Tax</th>
<th>Corporate Income Tax</th>
<th>Personal Income Tax</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarettes</td>
<td>$30.1</td>
<td>$7.2</td>
<td>-</td>
<td>-</td>
<td>$42.5</td>
</tr>
<tr>
<td>Cigars</td>
<td>$1.3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>$1.5</td>
</tr>
<tr>
<td>MST</td>
<td>$1.3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>$1.8</td>
</tr>
<tr>
<td>E-vapor</td>
<td>$0.1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>$0.4</td>
</tr>
<tr>
<td>Corporate Income Tax</td>
<td>-</td>
<td>-</td>
<td>$8.8</td>
<td>-</td>
<td>$8.8</td>
</tr>
<tr>
<td>Personal Income Tax</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>$8.0</td>
<td>$8.0</td>
</tr>
<tr>
<td>Total</td>
<td>$32.8</td>
<td>$7.2</td>
<td>$6.2</td>
<td>$8.8</td>
<td>$63.0</td>
</tr>
</tbody>
</table>

**Excise taxes.** Excise taxes are levied on cigarettes and other tobacco products (e.g., cigars, smokeless tobacco) in all 50 states. For cigarettes, federal, state, and local excise taxes are levied as per-pack dollar amounts.

The federal excise tax on cigarettes ($1.01 per pack) grossed $12.9 billion in 2017, while state cigarette excise taxes (ranging from $0.17 per pack in Missouri to $4.35 per pack in New York) grossed $17.2 billion. Over 600 local municipalities also imposed excise taxes on cigarettes, generating an additional $400 million. On average, federal and state excise taxes account for 42.9 percent of the retail price of cigarettes.\(^{429}\)

**MSA & PSS.** In 1998, PM USA, the other major cigarette companies (at the time, R. J. Reynolds, Brown & Williamson, Lorillard) and certain other cigarette companies entered into the MSA to settle health care cost recovery claims brought by 46 states, the District of Columbia, and certain U.S. territories to recover health care costs allegedly caused by cigarettes. Prior to the MSA, PM USA and the other major cigarette companies entered into similar agreements to settle similar claims brought by Florida, Minnesota, Mississippi and Texas, which are referred to as the Previously Settled State Agreements. The MSA and PSS resulted in perpetual, annual payments from these domestic cigarette manufacturers to the states. Since inception, MSA payments to settling states total $126 billion.\(^{430}\)

Under the MSA, the annual payments are calculated from a base amount of $9 billion (while the base amount in the PSS is $8 billion), with adjustments made for items including, among other things, changes in volume and inflation. After these adjustments were applied, the states received $7.2 billion in payments from the MSA and the PSS in 2017. The 2017 distribution of $7.2 billion was allocated to states based on pre-defined, static rates established in the MSA and the PSS. Cigarettes are the only tobacco product category that is subject to the annual MSA payments.

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Sales taxes. State and local sales taxes, paid by the adult tobacco consumer at the point of purchase, are determined by conventional nicotine content cigarette and cigar volume and retail price, as well as the applicable sales tax rate within the jurisdiction of purchase. In 2017, 12.4 billion packs of cigarettes and 1.2 billion units of cigars were sold across the country. Average conventional nicotine content cigarette retail prices range from $5.31 per pack in Missouri to $10.76 per pack in New York.

Corporate and personal income taxes. Taxes from tobacco-related businesses and jobs are sources of additional, tobacco-related tax revenue. The majority of taxable corporate profits are generated by retailers and manufacturers. Although it is likely that tax revenue from corporate profits and the corresponding impact would be spread across multiple states, for these purposes, we assumed profits from manufacturers are concentrated in states where major manufacturers are headquartered, specifically Virginia and North Carolina. Retail locations, and subsequently, tobacco-related retailer profits, are more evenly dispersed throughout the country and largely mirror the distribution of cigarette sales.

Taxable personal income is produced by the 2.2 million jobs, largely concentrated in retail, that are currently supported by the sale of tobacco products. Overall, 2017 federal and state corporate and personal income taxes stemming from cigarette sales totaled $13.0 billion and $3.9 billion, respectively.

2. Tobacco Revenues Fund Many State Programs

State budgets rely on tobacco revenues, with tobacco taxes and MSA/PSS payments accounting for four percent of total state tax revenues from all sources, on average. For context, state property taxes, insurance premiums sales tax, and motor vehicle licenses each account for two percent to three percent of total state tax revenues. States with the highest state cigarette excise tax rates and cigarette volume sales generate the most tobacco tax revenues (see Table 7).

Table 7 – Largest state recipients of tobacco revenues ($ in billions)

<table>
<thead>
<tr>
<th>State</th>
<th>Tobacco Revenue</th>
<th>Percent of Total Tax Revenue</th>
<th>Top Programs Funded</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>$2.4</td>
<td>1.5%</td>
<td>• Childhood Development</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Debt Service</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>$2.3</td>
<td>6.1%</td>
<td>• Medical Care for Disabled Workers</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Hospital Uncompensated Care</td>
</tr>
<tr>
<td>New York</td>
<td>$2.3</td>
<td>2.9%</td>
<td>• Health Care Reform Act</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Debt Service</td>
</tr>
<tr>
<td>Texas</td>
<td>$2.3</td>
<td>4.2%</td>
<td>• Property Tax Relief</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Children's Health Insurance Program</td>
</tr>
<tr>
<td>Florida</td>
<td>$2.0</td>
<td>5.0%</td>
<td>• Agency for Health Administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Department for Family Services</td>
</tr>
</tbody>
</table>

States use tobacco revenues to fund a variety of programs, ranging from health care to education to infrastructure; however, only a fraction of revenues generated from tobacco taxes are clearly earmarked for tobacco prevention programs (see Table 8).

“Over the past decade, only about 3 percent of [tobacco taxes and legal settlements] have been spent funding tobacco prevention programs.”

- Center for Disease Control and Prevention

The largest uses of tobacco revenues are state general funds (58 percent of tobacco excise tax revenues) and debt repayments (26 percent of MSA revenues), respectively. The noted debt repayments primarily support securitized MSA payments (“tobacco bonds”), while general funds are public sector “catch-all” funds for revenues that are not assigned to a specific purpose, and can cover administrative and operational expenses.

Table 8 – Top state programs funded by excise tax and MSA/PSS revenue ($ in billions)

<table>
<thead>
<tr>
<th>Program Type</th>
<th>Excise Tax Revenue</th>
<th>MSA/PSS Revenue</th>
<th>Top Programs Funded</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>$11.4</td>
<td>$1.2</td>
<td>General Fund</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>General Distribution to the States</td>
</tr>
<tr>
<td>Health Care</td>
<td>$2.6</td>
<td>$1.3</td>
<td>Family Health Plus</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Elderly Pharmaceutical Insurance</td>
</tr>
<tr>
<td>Debt Service</td>
<td>$0.1</td>
<td>$2.1</td>
<td>Securitization Payments</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Debt Service on State Bonds</td>
</tr>
<tr>
<td>Medicaid</td>
<td>$0.6</td>
<td>$1.2</td>
<td>Medicaid Benefit Trust Fund</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Children's Health Insurance Program</td>
</tr>
<tr>
<td>Other</td>
<td>$1.3</td>
<td>$0.3</td>
<td>Property Tax Relief Fund</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Agriculture Enhancement Programs</td>
</tr>
</tbody>
</table>

3. VLNC Standard Would Significantly Impact Overall Tobacco Volumes, Subsequently Eliminating $50 billion of Tax Revenues and Creating Gaps in Federal, State, and Local Budgets

a. Tobacco-related tax loss would lead to budget shortfalls and municipal default risk

Massive tax losses resulting from a VLNC standard would blow gaping holes in federal, state, and local budgets and increase the default risk of municipal “tobacco bonds.”

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First, many federal, state and local programs that rely on funding from tobacco tax revenues would be left underfunded. For example, federal cigarette and cigar excise tax receipts fund the Children's Health Insurance Program (“CHIP”). CHIP is a partnership between the federal government and states that provides health coverage to uninsured children in low income families that do not qualify for Medicaid. In 2016, total CHIP spending of $15.6 billion consisted of a federal contribution of $14.5 billion. Assuming excise tax rates remain constant, a VLNC standard would decrease federal cigarette and cigar excise tax revenues by $13.3 billion, equivalent to 93 percent of the program’s 2016 federal contribution. An increase in e-vapor and smokeless tobacco product sales will not be able to offset this loss. Currently, over 6.4 million individuals are enrolled in CHIP, meaning that coverage for six million beneficiaries would require funding through alternative methods.

Decreased state tobacco revenues could also lead to budget cuts due to increased funding gaps, including pension liabilities. In 2017, 22 states reported a budget shortfall. There were no overarching common characteristics present in these jurisdictions, as states facing shortfalls included energy-dependent states (e.g., Alaska), debt and retirement-burdened states (e.g., Connecticut), and agriculturally-dependent states (e.g., South Dakota). States with the largest dollar budgetary shortfalls are California, New York, and Texas. These three states were also among the four largest dollar recipients of tobacco revenues.

Second, issuers of municipal “tobacco bonds” could potentially default on payments, leaving bondholders with claims to significantly discounted revenue streams. To meet upfront budgetary needs, 17 states and the District of Columbia established special purpose entities to issue debt solely secured by future MSA payments (see Table 12). Of note, the following seven states securitized 100 percent of their tobacco MSA revenues: Alabama; Arkansas; Illinois; Ohio; South Carolina, South Dakota, and West Virginia. New York and California allocated fractions of their MSA payments to underlying municipal entities, many of which have subsequently securitized the allocated tobacco revenue streams. While utilizing special purpose entities generally allowed the settling states to avoid putting their credit ratings at risk, defaults would have significant negative financial implications on investors of municipal bond portfolios within mutual funds or exchange-traded funds.

438 Id. 33.
Table 12 – Tobacco MSA revenues securitized by state (percent of tobacco revenues securitized by state):

In aggregate, outstanding MSA-backed tobacco bonds total $19.8 billion, or 19 percent of total domestic high yield municipal debt revenue debt (see Table 13). Many tobacco bonds issued during the mid-2000s were highly leveraged and require MSA payments driven by cigarette volume declines of less than 4 percent per year to be fully repaid. Since actual cigarette consumption declines have outpaced this anticipated rate, Pacific Investment Management Company (PIMCO) now estimates that “a large portion of these bonds can only withstand around 3 percent to 3.5 percent per year in cigarette consumption declines for full repayment of principal at stated maturity.” Under a default scenario, bondholders would continue to receive any available tobacco settlement funds; however, they would not receive any acceleration of the volume-based payments.
Table 13 – Overview of outstanding high yield U.S. municipal debt

- Tobacco: 19.4%
- Sales tax securitization: 15.5%
- Education: 12.1%
- Development: 9.0%
- Hospital: 7.5%
- Power: 5.7%
- Lease-backed: 4.8%
- Water & Sewer: 4.4%
- Government guaranteed: 3.6%
- Pension obligation: 3.1%
- Appropriated debt: 3.1%
- Other: 2.9%
- Airport: 2.7%
- CCRC: 2.1%
- Highway: 1.8%
- Other tax securitization: 1.5%
- Housing: 0.8%
- Power: 5.7%
- Lease-backed: 4.8%
- Other: 2.9%
- Special tax district: -

b. Impact of decline in tobacco tax revenue on Texas and Virginia

Texas. Texas derived $2.3 billion, or 4.2 percent of its total revenue, from tobacco taxes and settlement payments in 2017. Most tobacco revenues from excise taxes and settlement payments in Texas are earmarked for Medicaid/CHIP, or education programs such as university research and K-12 funding via property tax relief.

Combined, CHIP and Medicaid cover 45 percent of all children in Texas. Under the program, 394,000 Texan children receive health insurance, and 36,000 women receive prenatal care. In Texas, K-12 funding is directly tied to property taxes as local school districts account for 55 percent of property taxes. In 2017, $1.7 billion of state excise taxes were used to fund public schools via property tax relief programs. Without these earmarked tobacco revenues, local school financing would require an increased burden on property taxes or other sources of funds. Property tax rates are already a significant issue in Texas, and Governor Abbott has already proposed a property tax cap.

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441 Texas and Virginia serve as examples because both states have large populations with a substantial percentage of smokers. Additionally, Texas represents a high volume state for cigarette sales and Virginia represents a state benefiting from tobacco-related corporate and personal income taxes (Altria Group, Inc. is headquartered in Richmond, VA).


443 Marissa Evans, Texas has enough federal funds to keep CHIP running through the end of March, Tex. Tribune (Jan. 5, 2018), available at https://www.texastribune.org/2018/01/05/report-texas-now-has-enough-federal-funds-keep-chip-running-through-en/.
“With the skyrocketing rise in property taxes, more and more Texans face the risk of being forced out of the homes they have lived in for decades. Young families who are just starting out are having trouble affording their first home and businesses are unable to grow and hire more workers.”

- Texas Governor Abbott\(^{444}\)

Virginia. Virginia received $1.1 billion, or 5.1 percent of its total revenue from tobacco taxes and MSA payments in 2017.\(^{445}\) Of the state’s tobacco revenues, $0.3 billion was derived from excise taxes and MSA payments. In Virginia, receipts from these two sources are earmarked exclusively for healthcare and debt service on securitized MSA payments (see Table 15). In 2017, 100 percent of the state’s excise tax revenues were directed towards the Virginia Healthcare Fund, which helps uninsured Virginians from underserved communities receive medical, dental, and mental health care.

Most of Virginia’s tobacco tax revenues are generated by personal and corporate income taxes from tobacco-related companies and jobs. Over 8,600 retailers in the state sell tobacco products, while Altria Group and Universal Corporation are both headquartered in Virginia and employ over 5,000 Virginians. Additional sources of impact from the tobacco industry include community investments from corporations, supply chain spending with Virginia-based suppliers, and other forms of associated taxes (e.g., property taxes, franchise taxes).

The tax implications of a VLNC standard would be widespread, as every state and the federal government would see a decline in tobacco revenues that cannot be offset by increased e-vapor and smokeless tobacco product sales. In addition to the immediate impact from lower cigarette and cigar excise taxes and MSA/PSS payments, participants throughout the tobacco value chain would also be affected. Lower taxable income levels caused by the contraction of tobacco-related businesses would be compounded by the impact of increased unemployment benefit requirements and lower personal spending associated with job loss. A VLNC standard would force federal, state and local governments to either cut spending or to leverage other sources of taxes to compensate for lower tobacco revenues.

**F. Conclusions**

The implementation of a VLNC standard will create a significant and devastating economic impact. In the absence of conventional nicotine content cigarettes, the resulting depression of volume will significantly affect stakeholders along the tobacco product value chain – particularly tobacco growers and retailers. Tobacco growers, due to the decrease in contracts and demand for tobacco, will have little choice but to grow other, less profitable crops; slash prices to compete for export contracts; or exit farming altogether. Most tobacco retailers, especially convenience stores, will struggle as consumers turn to other, potentially illicit, markets to purchase conventional nicotine content cigarettes. Worse yet, many tobacco retailers will be unable to


recover the lost profits by selling alternative tobacco products and will have no choice but to close. The subsequent loss of billions of dollars in revenue from volume-based payments, excise taxes and sales taxes, in addition to corporate and personal income tax losses, will create massive holes in federal, state, and local budgets. FDA must consider the enormous economic impact resulting from the loss of up to 951,000 jobs, 45,000 businesses, and billions of dollars as it contemplates a VLNC standard.

V. A Product Standard of 0.3-0.5 mg Nicotine per gram in Tobacco – or Any Nicotine Ceiling Even Remotely Close to That Ceiling – Will Likely Create a Substantial Illicit Market

We believe that a nicotine reduction standard will likely create a substantial illicit market with numerous unintended consequences. The Agency must analyze, research, understand and address each of these unintended consequences or risk promulgating a standard that would subvert its very purpose – undermining smoking cessation and other public health goals.

We address these unintended consequences in our response to FDA’s docket titled, “Concept Paper: Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard.” (Appendix Attachment 4).

VI. Any VLNC Tobacco Product Standard Must Take a Reasonable Approach to Implementation

Based on the wide-range of unresolved issues discussed above, we do not believe it is technically achievable to produce VLNC cigarettes that would meet the nicotine levels suggested in the ANPRM. In addition, huge challenges exist to make cigarettes that are also sensorially acceptable and/or do not create additional health risks. If, however, FDA were to promulgate a VLNC standard through formal rulemaking, the implementation schedule for that rule would need to be carefully structured and provide sufficient time for manufacturers and growers to attempt to meet that standard by changing agricultural and manufacturing practices.

A. FDA Must Consider Whether Any Effective Date Would Be Technically Achievable

In Section 907(d)(2), Congress expressly instructed FDA to consider implementation timing when promulgating a product standard. In particular, the implementation date must “minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.”

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446 We include a chart that cross-references questions posed in the ANPRM with our responses in the Appendix at Attachment 2.
448 We include a chart that cross-references questions posed in the ANPRM with our responses in the Appendix at Attachment 2.
449 FSPTCA § 907(d)(2).
450 Id.
Accordingly, when setting an implementation timeframe for a product standard, FDA is required to consider how to reduce, “to the smallest possible amount or degree,”\(^{451}\) the market ramifications of attempting to comply with that product standard. This means FDA must account for obstacles to compliance and potential sources of market disruption, such as the effects that any mandated changes will have on the businesses of growers and the time needed for developing the necessary technology at multiple stages in the chain of production. Any implementation timetable also must allow sufficient time to produce a post-standard supply of usable tobacco. In order to minimize market disruption and economic impact to growers, this supply must be large enough to produce a volume of cigarettes capable of meeting the pre-standard level of adult consumer demand.\(^{452}\) Moreover, FDA must account for possible effects across the marketplace and, among other things, facilitate the availability of noncombustible alternatives to cigarettes by resolving substantial equivalence reports and PMTAs for products lower on the continuum of risk.

In addition, Section 907(d)(2) expressly requires FDA to consider “information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard.”\(^{453}\) Here, this would require that FDA consider how the existence of patents for extraction, genetic engineering, and other agricultural practices might affect any timeframe for compliance with a potential standard. A product standard should not require that all market participants obtain licenses to use that technology. Patent owners may be unwilling to license technology to manufacturers on commercially reasonable terms, which would require time-consuming development of other technologies that meet the standard but do not infringe these patents. Alternatively, patent licensing negotiations may take a considerable amount of time to reach a successful resolution. Any implementation schedule should take into account and allow sufficient time for these possibilities.

**B. FDA Should Use a Tiered Approach to Implementation That Only Sets a Deadline for Submission of Applications for Products Meeting Any VLNC Standard**

Any implementation schedule should, at a minimum, use a tiered approach. The only deadline set in the first tier would pertain to submission of SEs, PMTAs, or submissions under a yet-to-be established alternative premarket or certification process, such as the one outlined below. Only after these submissions are reviewed, and any Agency and judicial appeals are final, would FDA promulgate a deadline for compliance with a VLNC standard. Using these staggered deadlines would ensure FDA has time to review all applications, save parties from investing resources to produce VLNC cigarettes commercially until after marketing orders for these cigarettes have been issued, and avoid the kind of market disruption that Section 907(d)(2) instructs FDA to avoid.


\(^{452}\) In order to avoid statutorily impermissible results, FDA must treat section 907(d)(2) as requiring sufficient time to implement a new tobacco product standard such that the post-standard supply of usable tobacco is inadequate to meet the pre-standard level of adult consumer demand. Otherwise, FDA could end-run the limitations imposed on its authority by the FSPTCA by banning all cigarettes indirectly. For example, FDA could impose an effective date of one year on a tobacco product standard that requires three years to produce a supply of usable tobacco that complies with the new tobacco product standard and is capable of meeting the pre-standard level of adult consumer demand.

\(^{453}\) FSPTCA § 907(d)(2) (emphasis added).
In addition, the deadline for rule compliance should be at least twelve years after the final rule becomes effective and all Agency and judicial appeals are final. At least twelve years is the absolute minimum amount of time necessary to attempt to address the many issues that must be resolved before VLNC tobaccos could be commercially produced at necessary volumes and cigarettes using those tobaccos could be designed and manufactured to replace currently marketed cigarettes. A final product design is, of course, a necessary prerequisite for any required premarket filing seeking authorization to commercially market the new cigarette meeting any product standard. If biotechnology, agronomic or other industrial extraction techniques are used, certain aspects of VLNC tobacco development could be shorter, but the complexities introduced into the U.S. tobacco market, as well as restrictions associated with patents, state requirements where tobacco is grown, determining whether certain flavors and additives could be used, evaluating any unanticipated and unintended consequences, and FDA product approval requirements may not significantly shorten timelines needed for compliance. Furthermore, this implementation allows for four years after requests for marketing authorizations that have been ruled upon and any appeals from that process that are final before cigarettes would need to meet a standard. This amount of time, at a minimum, would be necessary to produce enough tobacco to meet domestic demand, ensure compliance with the standard and use existing inventories of non-VLNC tobacco leaf. It is important to note that this timeline assumes the standard can be implemented in a single step rather than as a series of smaller reductions.

1. The Implementation Schedule Should Provide a Deadline Only for Submitting Premarket Applications for Products Modified to Meet the Product Standard

Under FDA’s current regime, manufacturers will need to go through a premarket process for cigarettes developed to meet any new VLNC product standard.\textsuperscript{454} For example, the current SE process requires manufacturers to obtain a marketing authorization from FDA for any “new tobacco product,” defined under the FSPTCA as either (A) “any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007,” or (B) “any modification . . . of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.”\textsuperscript{455} The SE process thus would be triggered simply by the changes necessary to manufacture a product with a lower nicotine content, as such a product would constitute a “new tobacco product.” Moreover, the process of producing cigarettes with VLNC tobacco that are sensorially acceptable to consumers is almost certain to require other practices, such as the addition of flavors or additives and use of different blends, that also would trigger SE requirements.

In setting timelines associated with a new product standard, FDA must take into account the time it would take to reach a final determination on SE applications or an alternative pathway to market. The current SE process would increase the amount of time needed to get VLNC products to market. FDA can take over six months to review SE reports that only involve a change to a single ingredient, and FDA has taken multiple years to review other SE reports. If FDA were to adopt a VLNC standard for all cigarettes or combustible tobacco products, the massive number of SE reports likely to be submitted at the same time would make review even

\textsuperscript{454} See 21 U.S.C. § 387e(j); id. § 387j(a)(3).
\textsuperscript{455} Id. § 387j(a)(1).
more difficult. The potential for delay occasioned by the SE process is no mere hypothetical. In 2011, FDA received thousands of SE reports for provisional products, creating a regulatory backlog for over seven years that ended only when FDA announced that it would not review all of these reports and instead would remove 1,500 of 2,500 provisional SE reports from the SE process.

Before a VLNC standard could be imposed, FDA also would need to address how the SE standard could be applied reasonably to products that are changed solely to comply with an agency-mandated standard. The SE process requires manufacturers to show that the new product has either “the same characteristics as the predicate tobacco product” or “different characteristics and . . . the product does not raise different questions of public health.” Products modified to have dramatically lower nicotine levels plainly will not have the same characteristics as predicate products. But in promulgating the product standard, FDA presumably will have concluded that cigarettes modified to comply with the standard were done so for “the protection of the public health.” FDA would need to address this tension, otherwise the Agency could use product standards to foreclose the marketing of cigarettes, which Congress has expressly prohibited.

Given these issues, before FDA imposes a VLNC standard, it should streamline the current SE process for lawfully marketed cigarettes modified solely for the purpose of complying with a VLNC standard and to achieve parity from an adult consumer perspective with the pre-modified products. FDA should issue expedited market orders if a manufacturer demonstrates that other HPHC levels besides nicotine and/or the addition of ingredients/additives are at or below the levels present in cigarettes commercially marketed as of February 15, 2007, in cigarettes subject to a market order, or in provisional cigarette products FDA decided to “remove from [SE] review.”

Even if FDA were to adopt a more streamlined approach, it is uncertain how many SEs would be received and how long it would take to process them. Given that uncertainty, if FDA were to consider a VLNC standard, it should not adopt a deadline to comply with that standard. Rather, it should only set deadlines for submitting SEs or PMTAs for products meeting that standard and should postpone compliance with that standard until after all of those SEs and PMTAs have been reviewed, ruled upon and resolved to a final adjudication.

This approach would ensure that FDA has sufficient time to review carefully all applications. It also would prevent manufacturers from investing the massive resources necessary to produce VLNC cigarettes commercially at risk without pre-market authorization and ensure that no manufacturer is required to sell VLNC cigarettes until every company is on equal footing. Moreover, to the extent that companies attempt to produce VLNC tobacco using biotechnology,

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456 Depending on when any deadline might be set, this review also might be slowed by the number of SE reports likely to be submitted for cigar and e-vapor cigarettes when the compliance periods for deemed products end in 2021 and 2022. See FDA, Guidance for Industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised) (Nov. 2017).
459 Id. § 387g(a)(3)(A).
this approach would allow all domestic tobacco growers to adopt practices and begin producing VLNC tobacco during the same growing season, which would simplify the many issues that growers would need to address when doing so.


   a. Developing VLNC seed, tobacco and cigarettes using this tobacco would take, at an absolute minimum, 12 years

If FDA promulgated a VLNC standard, manufacturers and farmers would need adequate time to develop VLNC tobacco with sufficiently low nicotine content that can be grown in fields under normal conditions in sufficient quantities for commercial use. As discussed above, breeds that can be grown outside of controlled laboratory settings that would meet a VLNC standard are not currently available.

Even assuming this tobacco could be developed, companies would then need to conduct additional research on whether and how this tobacco can be used to produce commercial cigarettes. Past experience with VLNC tobacco demonstrates that this can be a complex, time-consuming and unpredictable process in which results are anything but guaranteed. For these reasons, the mere fact that small quantities of VLNC tobacco have been grown under carefully controlled conditions that might meet the levels discussed in the ANPRM does not mean that commercial cigarettes using that tobacco can be designed.

In light of these issues, FDA should, at a minimum, provide manufacturers at least twelve years before applications for pre-market authorization must be submitted to FDA. This will also allow the industry time to ensure that tobacco seed meets minimum standards under existing state law programs, which would also need to be done before new tobacco could be commercialized.

   b. Growing sufficient tobacco, developing adequate infrastructure and inventories, and using existing inventories would require, at a minimum, four years from the end of the premarket authorization process

FDA should not set a deadline for compliance with any VLNC standard until at least four years after all SE reports have been resolved and adjudicated. This timing is necessary regardless of whether a manufacturer attempts to meet a VLNC standard through biotechnology or extraction.

Assuming biotechnology becomes a commercially viable solution, it would still take at least four years to build VLNC tobacco inventories. One year would be necessary to develop a sufficient amount of tobacco seed, and three more years would be required to produce three crop-years of VLNC tobacco. These three crop years, which is the approach PM USA currently takes, are necessary to address variability between crop years and preserve consistency. If, by contrast, a

461 The ANPRM asks about “methods [that] tobacco product manufacturers [are] currently using to maintain consistency of the nicotine in their products, given the variability of nicotine levels over growing seasons and crop type.” 83 Fed. Reg. at 11,832. PM historically deals with this variability by blending tobacco from at least three crop-years.
possible method of extraction was identified and SE orders granted for products made with such a method, we estimate that it would take three to four years to build the necessary facility and obtain the permits, licenses and raw materials needed to run that facility.

In addition, this three to four year period would be necessary to use existing inventories of conventional tobacco. A significant inventory of tobacco likely would exist even after the deadline for a VLNC standard. In 2017, for example, PM USA had $941 million in tobacco leaf in its inventory. Again, PM USA has historically used this tobacco over a three-year period to maintain product consistency and should be permitted to use this inventory before any VLNC standard takes effect. Any other outcome, among other things, would amount to an improper regulatory taking.

It also would be difficult to address this situation by requiring growers to reduce their production. If growers produce too little conventional tobacco, manufacturers could not produce a sufficient number of conventional nicotine content cigarettes before VLNC standards are mandatory, resulting in disruptions to the domestic market that Congress intended to avoid. (See supra at Section II, A, 1). Conversely, if growers were to produce too much VLNC tobacco, it would flood the market with tobacco during a given year. The likely result in this scenario would be VLNC tobacco sold being at a lower price, which puts growers’ economic viability at risk, and again disrupts the domestic market.

Accordingly, if FDA promulgated a VLNC standard (despite our position that such a standard would not be technically achievable), the implementation schedule for that standard would need to provide sufficient time and flexibility at least to provide an opportunity to attempt to meet that standard.

C. Additional Research Is Necessary to Determine Whether to Phase-in a VLNC Standard Over Time or Impose it Immediately

The ANPRM suggests two alternative approaches for implementing a nicotine reduction standard: a “step-down” approach and a “single target” approach. The “step-down” approach would phase in nicotine reductions gradually over time until reaching the target level. The “single target” approach would immediately reduce nicotine to the target level. The available scientific evidence does not resolve which approach would be most protective of public health.

To date, no published study has directly compared gradual and immediate approaches to nicotine reductions. Some studies have examined one of these approaches in isolation. These studies, however, have significant limitations, including small sample sizes, substantial non-compliance, non-generalizable study subjects and reliance on unpublished data – all of which constrain their usefulness for secondary analyses. Moreover, efforts to compare results across these varied studies are inherently uncertain, due to differences in the underlying methodologies.

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462 See Altria Group, Inc., Form 10-K at Item 8 (2017).
465 Id.
466 Id.
We are also aware of two unpublished studies that compare the gradual and immediate approaches.468 The first was a 20 week study comparing gradual versus immediate nicotine reduction in 858 smokers that was presented by Hatsukami at the Vermont Center on Behavioral Health-Tobacco Regulatory Science conference (VCBH) in 2017.469 In summarizing her work, Hatsukami commented that an immediate reduction is “more likely to cause difficulty for smokers” due to withdrawal symptoms. Thus, although further research is needed, it is possible that withdrawal effects would be more severe with an immediate reduction.470 The second unpublished study was a secondary analysis presented at the Society for Research on Nicotine and Tobacco in 2018.471 This analysis reported significant weight gain over the 20 week period in study participants. The control group gained an average of 0.41 kg, compared to 1.56 kg and 3.35 kg in the gradual and immediate reduction groups, respectively. The lack of cessation outcomes in the study, however, combined with the lack of adequate non-compliance data, makes it difficult to draw any other conclusions.

In short, additional evidence is necessary to determine whether gradual or immediate reduction is appropriate.

D. Existing Analytical Methods Are Inadequate to Support Evaluation and Compliance with a Nicotine Reduction Standard

1. FDA Should Not Implement Any VLNC Standard Without Consensus Standardized Methods to Measure Nicotine at the Levels Required by those Standards

Prior to issuing a nicotine product standard, consensus standardized methods to measure nicotine in tobacco products subject to the standard would need to be developed and tested. We agree with FDA that such a test method should produce comparable results across different accredited testing laboratories and demonstrate a high level of specificity, accuracy, and precision in measuring a range of nicotine levels in a wide variety of blends and tobacco products.472 To meet these criteria, the method must be well characterized and have defined repeatability and reproducibility values for a variety of products with nicotine levels in the range of the proposed product standard. The repeatability and reproducibility values must be determined in collaborative studies involving a range of stakeholders.

The ANPRM notes that the Cooperation Centre for Scientific Research Relative to Tobacco (“CORESTA”) developed a consensus standardized method (CRM 62) for analyzing nicotine in unburned tobacco and tobacco products, CRM 62.473 CRM 62 was validated through round-

468 We describe these unpublished studies below to provide further context in response to the ANPRM. In principle, however, if FDA decides to propose a nicotine reduction standard, it should base its determinations only on evidence, data, and methodologies that have been fully disclosed, so that relevant stakeholders, including experts outside of FDA, can independently evaluate them.
470 id.
473 Id. at 11,830 (citing Ref. 116 in ANPRM).
robin studies in accordance with ISO 5725-1 and ISO 5725-2, but is not fit for the purpose of analyzing VLNC cigarette fillers, because it does not contain defined repeatability and reproducibility values for products with nicotine in the range of 0.3 to 0.5 mg/g. Rather, the repeatability and reproducibility values stated in CRM 62 are for traditional tobaccos and tobacco products containing significantly more nicotine (i.e., in the range of 8.5 to 41.2 mg nicotine/g tobacco).

Similarly, the ANPRM notes that ISO 10315 is a standardized method for analyzing nicotine in smoke. ISO 10315 also was developed within CORESTA and is based upon CRM 7. But ISO 10315 is not fit for the purpose of analyzing smoke from VLNC cigarettes. Rather, the repeatability and reproducibility values stated in ISO 10315 are for traditional cigarettes with ISO mainstream smoke nicotine values in the range of 0.091 to 1.412 mg per cigarette.

FDA therefore would need to ensure that adequate testing methods for VLNC tobacco could be developed before it implements a VLNC standard. Moreover, the lack of adequate consensus methods to measure nicotine in tobacco and smoke at levels reported in VLNC cigarettes highlights uncertainty in any reported measurements of such products. For this reason also, it is imperative that, prior to any VLNC standard being implemented, consensus standard methods be developed.

2. FDA Should Not Implement a VLNC Standard Without Certified VLNC Reference Products and Proficiency Testing

The ANPRM does not address the use of tobacco reference products. Use of reference products, however, should be a part of any testing program. Reference products play an integral role in demonstrating laboratory proficiency. Reference products also allow comparisons between analytical results from a single laboratory over time and across different testing laboratories.

Certified reference products allow testing laboratories to verify the performance of their analytical procedures—a critical component for FDA to obtain representative and comparable data about the commercial products sold on the U.S. market, as well as allow for proficiency testing. Proficiency testing will provide assurance that a laboratory has competency for that analysis and that the data generated by the laboratory are comparable to other laboratories and useful for decision making. Results from proficiency testing can provide FDA confidence in the data and insights into interlaboratory variability. In addition, certified reference products would facilitate the establishment of validated HPHC analytical methods in laboratories.

With one limited exception, the currently available reference products were developed from conventional tobaccos, not VLNC tobaccos. These products are therefore poorly suited for use as reference products for the analysis of VLNC cigarettes. Before any VLNC standard is adopted, FDA should ensure that reference products exist.

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474 Id. at 11,830.
VII. **Scope**

The ANPRM also seeks comments on the “[s]cope of products to be covered” by a potential nicotine product standard. As discussed above, the science and evidence currently does not support a nicotine product standard for any tobacco products, including cigarettes. But if FDA continues to pursue a nicotine product standard, the scope of the standard should be limited to combustible cigarettes.

The ANPRM posits that “[c]igarettes are the tobacco product category that causes the greatest burden of harm to public health given the prevalence of cigarette use . . . and the toxicity and addictiveness of these products . . .” The focus of a product standard thus should not extend beyond cigarettes, to ensure that FDA addresses the product category that it has identified as having the greatest public health impact. Adding other product categories would prove unduly burdensome and needlessly complex.

As FDA suggests, the product standard would have to be “tailored to reflect differences in these products.” Section 907 and the APA would require FDA to develop a science- and evidence-based record that supports establishing VLNC levels in the other combustible products. (See supra at Section III, A, 1). To our knowledge, however, there is no research identifying whether there is an addiction threshold for nicotine in pipes and cigars, let alone what that threshold might be. As a result, there is no scientific basis upon which to impose a VLNC standard for these products.

In addition, there is no evidence that a nicotine reduction in these products would be technically achievable. Many of the same general concerns presented by developing and growing VLNC tobacco and producing VLNC cigarettes would also apply in the context of cigars and pipes. But the specific techniques that might be implemented to address these concerns would be fundamentally different. For example, cigars and pipes use different tobacco types than cigarettes. Different strategies for lowering the nicotine content in these tobacco seeds and plants would therefore be necessary. Cigars and pipe tobacco are also produced through entirely different manufacturing processes, thus raising a different set of considerations for each of those product categories. Furthermore, the public health consequences, potential countervailing effects and economic impact of reducing nicotine in cigars and pipe tobacco would each raise distinct issues that would need to be separately considered before such reductions could be implemented.

Moreover, extending the scope of a potential standard to encompass other products would unnecessarily increase the already substantial complexity of the product standard. As just one example, the ANPRM indicates that extending a standard to include premium cigars would require defining “premium cigars.” But that effort in itself raises a range of challenging issues

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478 We include a chart that cross-references questions posed in the ANPRM with our responses in the Appendix at Attachment 2.
480 Id. at 11,819.
481 Id. at 11,826.
482 Tobacco Production at ch. 13.
483 Id.
484 Id.
that fall within the purview of FDA’s separate ANPRM on cigars.\textsuperscript{485} Linking the nicotine and
cigar ANPRMs is unnecessary and dilutes the focus of each regulatory effort.

Finally, FDA should exclude from any nicotine product standard innovative products that offer
risk reduction opportunities. Specifically, products like IQOS “HeatSticks” should not be
subject to any product standard for nicotine levels in cigarettes. IQOS is an innovative,
electronically heated tobacco product, comprised of a Tobacco Heating Device and a Tobacco
Stick (“Heatstick”) that meets the definition of a “cigarette” under the FDCA.\textsuperscript{486} IQOS heats
tobacco without combustion, producing a nicotine-containing aerosol with significantly reduced
levels of harmful and potentially harmful smoke constituents compared to cigarette smoke.\textsuperscript{487}

As a noncombustible tobacco product, IQOS is not within the scope of the ANPRM, which by
content and title (“Tobacco Product Standard for Nicotine Level of Combusted Cigarettes”) focuses only on combustible products. Even more importantly, IQOS has the potential to reduce
the harm caused by smoking combustible cigarettes and advance the objectives of the
Comprehensive Plan, as part of a diverse marketplace of FDA-authorized, noncombustible
products with accompanying modified risk claims. The IQOS device and Heatsticks are the
subject of Premarket Tobacco Applications and Modified Risk Tobacco Product Applications
currently pending before FDA.\textsuperscript{488} Through its consideration of these applications, FDA will
determine whether to authorize IQOS to be sold in the U.S. and whether to permit any claims of
reduced risk or reduced exposure. Most or all noncombustible heated tobacco products will be
subject to similar premarket review, which will provide FDA the context needed to evaluate each
product on an individual basis to determine its harm reduction potential.

For these reasons, any potential product standard for nicotine levels should be limited to
combustible cigarettes and should not include other combustible products or noncombustible
products like IQOS Heatsticks.

\textbf{VIII. Conclusion}

We appreciate the opportunity to provide our views and look forward to continuing to engage
with FDA. If you have questions, please feel free to contact me. I can be reached at 804-335-2879.

Sincerely,

\[Signature\]

\textsuperscript{486} See, e.g., FDA, \textit{Philip Morris Prods. S.A. Modified Risk Tobacco Product (MRTP)} (last updated June 21, 2018),
available at https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm#1.
\textsuperscript{487} See, e.g., Philip Morris Int’l Mgmt. SA, \textit{Tobacco Meets Technology} (last visited June 26, 2018),
\textsuperscript{488} These PMTAs and MRTPAs were submitted to FDA by Philip Morris Products S.A., a subsidiary of Philip
Morris International Inc. Altria’s companies have an exclusive licensing agreement with PMI to sell this heated
tobacco product in the United States. Should FDA authorize the requested marketing order, Philip Morris USA, an
Altria company, will commercialize the product in the U.S.
APPENDIX
Attachment 1:

Approach to Estimating Economic Impact
To assess and quantify the potential costs and economic impact that could result from a VLNC standard, we modeled (1) a potential scenario for tobacco product volume flow; (2) the impact to stakeholder businesses and jobs; and (3) the subsequent impact to federal, state, and local budgets. Each of these is described below in more detail.

1. Model for a Potential Scenario for Tobacco Product Volume Flow

Overview. Imposing significant restrictions on the amount of nicotine in combustible cigarettes and cigars will not eliminate the demand for such products. If a VLNC standard is implemented, adult smokers will face options. Some adult smokers may use VLNC cigarettes for the experience while others may switch to VLNC cigarettes to help them quit smoking. Other adult smokers may switch to the use of e-vapor products or smokeless tobacco products. The majority of adult smokers are predicted to turn to the illicit market for cigarettes with current nicotine levels. Although it is not possible to predict with certainty how adult smokers will react to a VLNC standard, we can make reasonable assumptions about likely outcomes. Their reaction to the implementation of a VLNC standard depends on the definition and scope of the VLNC standard, the degree to which adult smokers consider VLNC cigarettes and cigars, smokeless tobacco, and e-vapor products to be substitutes for conventional nicotine content cigarettes or cigars, and the cost and availability of illicit cigarettes and cigars with conventional nicotine content levels.

A VLNC standard will affect the quantity and composition of sales of tobacco products by affecting what consumers will pay for conventional nicotine content cigarettes and cigars. To illustrate the potential economic impact of a VLNC standard, we have developed an economic framework to model the possible outcomes and share the results based on the following methodology and assumptions.

Model and Methodology. Our model is comprised of products that are regulated by a hypothetical VLNC standard (e.g., combustible conventional nicotine content cigarettes and cigars) and noncombustible tobacco products not regulated by such a VLNC standard (e.g., smokeless tobacco, e-vapor). We use a log-linear consumer demand model to simulate substitution across tobacco products. With this model, the quantity of the two tobacco product types is assumed to change linearly with the natural logarithm of their price.

Model Inputs. The impact of a VLNC standard on sales of tobacco products is the product of (1) the effective price increase for tobacco products purchased from illicit markets; (2) the consumer price sensitivity of tobacco products (including those purchased from illicit markets); and (3) the market share of tobacco products that would not be regulated by a hypothetical VLNC standard.

Our first input to the analysis is the estimated effective price increase for illicit tobacco products, which includes not only out-of-pocket monetary payments but also production costs, distribution costs and perceived consumer costs such as inconvenience and stigma.

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489 Price is to be understood broadly as not only out-of-pocket monetary payments but also costs of inconvenience, stigma associated with illicit market activity and loss of familiar branding, quality, and taste.
490 For small price changes, this model allows us to approximate how a percent change in price impacts the number of units sold.
Production Costs: We assume that the baseline production costs for illicit cigarettes and cigars are the same as the baseline costs of producing conventional nicotine content cigarettes and cigars.

Distribution Costs: Enforcement levels can significantly raise the costs of supplying or obtaining illicit products. For example, if federal agencies successfully seize and destroy illicit product, the costs to supply illicit product and what consumers pay for illicit product will both increase. Given existing enforcement resource constraints, we assume limited enforcement of the VLNC standard. Therefore, we do not expect enforcement of a VLNC standard to increase the price of illicit tobacco products as much as the effect that drug enforcement has had on increasing the consumer price of cocaine, illicit opioids, or marijuana.491

Consumer stigma and inconvenience: Cigarettes and cigars can and will be sourced through several different channels (e.g., through importing cigarettes and cigars with current nicotine levels from outside the United States or through online sales). Consumers who purchase such products may acquire them from the channel that, for example, he or she finds least burdensome. Regardless, this will likely be far less convenient that purchasing products from convenience stores or mass merchants today. Studies of the New York market estimate consumer stigma and inconvenience costs to be approximately $2 per pack.492

Effective price of illicit tobacco products: We estimate the effective price of illicit cigarettes and cigars to be approximately 30 percent more than the price of conventional nicotine content cigarettes and cigars at the national level. The effective price is based on no excise taxes paid, an estimated domestic distribution cost of $1 per pack, consumer inconvenience and stigma cost of $2 per pack and an estimated range for the cost of bringing illicit product into the United States (ranging from zero to approximately one third of the estimated cost of crossing the Mexican border with marijuana). Since the effective price does not include excise taxes, proceeds originally paid to support government programs would now fund an illicit market. This estimated 30 percent price increase is conservative compared to other industries. For example,


492 The percentage of the total cigarette market represented by illicit sales in New York is estimated to be near 45 percent, (Nat’l Research Council, Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences102-03 (2015), available at https://doi.org/10.17226/19016). In 2011, the NY state tax was $4.35 per pack, as compared to $0.30 per pack in Virginia; cigarettes bootlegged from Virginia save $4.05 in taxes. However, it is less efficient to deliver consumer products through bootleg operations than through major retailers that enjoy economies of scale and have no risk of having products seized by law enforcement. The retail price differential between legal and illicit cigarettes is therefore between $0 and $4. The consumer on the margin of illicit and legal cigarettes therefore has a stigma and inconvenience cost equal to such retail price difference. We use $2 as an estimate. In addition, evidence from the growth of the illicit market for cigarettes in Canada during the mid-2000s shows that consumers were willing to purchase illicit cigarettes from Reservations in order to save on taxes. See Contraband tobacco ‘out of control’ in Ontario, convenience store lobby says, CBC News (Nov. 15, 2017), available at http://www.cbc.ca/news/canada/hamilton/contraband-cigarettes-hamilton-1.4403220.
during Prohibition, alcohol prices were approximately three times pre-Prohibition prices, and Oxycodone sold in illicit markets today is approximately five times legal prices.

*Our second input* is the demand for tobacco products. The price of illicit cigarette and cigar products following implementation of a VLNC standard will impact the composition of sales (e.g., adult smokers may purchase from illicit markets, switch to other tobacco products, or reduce consumption). The price elasticity of demand for conventional nicotine content cigarettes has been widely studied. These studies show that each 10 percent increase in cigarette prices reduces consumption by three to six percent. We use four percent in our estimation.

Cross-price elasticities between each tobacco product category and cigarettes determine how volume shifts to other tobacco product categories in response to price changes in cigarettes (i.e., shifts towards smokeless tobacco and/or e-vapor as the price of cigarettes increases). Cross-price elasticity is an economic concept that measures the responsiveness in the quantity demanded of one product when the price of another product changes. It is calculated as follows:

\[
\text{Cross price elasticity} = \frac{\% \text{ change in quantity demanded of product } A}{\% \text{ change in price of product } B}
\]

Based on a recent study, we assume the cross-price elasticity with cigarettes or cigars to be 2.5 for e-vapor products. We further assume the cross-price elasticity of smokeless tobacco products with cigarettes is 0.5. This is consistent with PATH data, which shows that adult smokers may be more likely to switch to e-vapor products than smokeless tobacco products. The PATH data shows there are an estimated three times as many e-vapor users as smokeless tobacco (15 percent compared to 3 percent of cigarette adult smoker population).

*Our third input* is the starting point of the modeled scenario and relates to market share. For purposes of assessing market share, we assume an effective date for a VLNC standard to be 2022. Prior to 2022, we assume:

- E-vapor products continue to grow (with a conservative estimate to be 10 percent of total tobacco volume);
- Smokeless tobacco is estimated to be 10 percent of total tobacco product volume;
- Combustible cigarettes account for approximately 76 percent of total tobacco volume; and
- Cigars account for approximately 7 percent of total tobacco volume.

Following implementation of a hypothetical VLNC standard in 2022, the assumptions above indicate that tobacco product volume would hypothetically change to approximately:

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496 2014-2015 PATH data analysis.
497 Due to rounding, shares do not add to 100%.
• 0.4 percent would be VLNC cigarette and cigar purchases;
• 20 percent would be e-vapor purchases;
• 12 percent would be smokeless tobacco purchases; and
• 67 percent would be associated with diminished volume of legal sales.

2. Impact on Stakeholders and Jobs

We developed a model for every stakeholder with the following characteristics based primarily on publicly available information:498

• One common input – tobacco product volume change as described previously;
• Quantifying the current state for operating profit, number of businesses, and number of jobs supported;499 and
• Three consistent outputs—impact to operating profit, number of impacted business closures, and number of jobs lost when tobacco product volume changes.

After the tobacco product volume change is applied to each stakeholder model, the three consistent outputs (operating profit impact, number of business closures, and jobs lost) are captured and aggregated as inputs to estimate the related effect of these impacts to federal, state, and local budgets.

3. Subsequent Impact to Federal, State, and Local Budgets

All settlement and tax payments are calculated and modeled using publicly available data for rates, methodology, and historical payments. Each model utilizes volumes sold of tobacco products today and volumes projected post implementation of a VLNC standard as described above.

The MSA includes 46 states (does not include Mississippi, Minnesota, Florida, and Texas making up PSS), District of Columbia, Puerto Rico, and four U.S. territories. The perpetual, annual MSA payments are calculated starting with a base amount of $9 billion per year that is then adjusted for changes in shipment volume, inflation and the market share of Non-Participating Manufacturers (“NP”)”, which are those cigarette companies that have not signed the MSA. The other four states settled separately and receive payments that are calculated in a

498 Each model utilizes publicly available information, including but not limited to industry publications (e.g., NACS – National Association of Convenience Stores, Capital IQ), government data (e.g., USDA Agriculture Census), and company annual financial reports.

499 Each stakeholder model starts with defining the appropriate stakeholder segments. For example, tobacco growers segment by tobacco type and farm size, and retailers segment by outlet type, such as convenience stores or vape shops. The number of businesses for each stakeholder segment is referenced directly or estimated from publicly available information. Next, a P&L for each stakeholder segment identifies the key drivers of revenue and profitability and quantifies the contribution of tobacco products to a stakeholder segment’s profitability. Each P&L model is built to reflect changes to revenue and profits when volume changes, and the inputs are granular at the product-type level, specifically, cigarettes, cigars, smokeless tobacco, e-vapor products, and other non-tobacco product volume. Finally, we estimate the number of jobs required by each stakeholder through modeling the key drivers for employment. For example, acres harvested per worker partially determines the number of workers required by tobacco growers.
similar manner, starting with a base amount of $8 billion that is subsequently adjusted for changes in shipment volume and inflation. The payments are then allocated to each state. MSA and PSS payments are based, in significant part, on the volume of cigarettes sold domestically, and therefore changes in the number of cigarettes sold affects MSA and PSS payments while changes in sales volume in other tobacco products do not affect MSA and PSS payments.

Excise taxes are calculated and modeled by multiplying the volume sold of each tobacco product with the respective federal, state, and local excise tax rates. Federal and state excise tax rates used in the calculations are sourced from Tax Foundation, and the actual historical excise taxes paid on cigarettes and other tobacco products are validated and sourced from The Tax Burden on Tobacco - Vol 52.

Sales taxes are calculated and modeled by multiplying the current and projected volume sold of each type of tobacco products by each tobacco product’s average selling price and the respective sales tax rates for each state. Actual historical volumes and average unit prices are sourced from The Tax Burden on Tobacco - Vol 52. Current state and local sales tax rates are sourced from Tax Foundation.

Corporate income taxes are modeled by applying state and federal corporate income tax rates to current and projected corporate earnings from tobacco industry stakeholders. Corporate income tax revenue for each state is calculated by allocating stakeholder earnings to states based on each state’s respective share of cigarette volume, sourced from The Tax Burden on Tobacco - Vol 52. Manufacturer corporate earnings are allocated to states based on corporate headquarter locations and historical tax payment data from public filings.

Personal income taxes are modeled by applying state and federal effective income tax rates to current and projected wages earned by jobs generated by each stakeholder. Effective tax rates are derived from public tools. Personal income tax revenue for each state is calculated by allocating the tax revenue to states based on each state’s respective share of cigarette volume, sourced from The Tax Burden on Tobacco - Vol 52.

Log-linear Consumer Demand Model Details

Using the Log-linear Demand System to Simulate Substitution Effects: Our model is comprised of two types of products: products that are subject to a hypothetical VLNC standard (e.g., conventional nicotine content cigarettes), and products that are not (e.g., smokeless tobacco, e-vapor). Let \( p_R \) and \( p_U \) denote their inflation-adjusted prices, respectively. Let \( q_{R} \) and \( q_{U} \) denote their sales volume, respectively. \( p_R \) and \( p_U \) are both normalized to one absent the hypothetical VLNC standard.

As discussed previously, a hypothetical VLNC standard raises \( p_R \) to above one. This price increase raises the sales \( q_U \) of products not subject to a VLNC standard by an amount lower than it reduces the sales of products subject to a hypothetical VLNC standard \( (q_R) \). That is, a hypothetical VLNC standard reduces total smoking to some degree. It is assumed that the quantity of each type of product is linear in the log price and therefore that total smoking is linear in the log price:

\[ \log q_U = \alpha + \beta \log p_U \]
\[ \log q_R = \alpha + \beta \log p_R \]

\[ \alpha > 0, \quad \beta > 0 \]

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\[ q_U = 1 - \omega + \beta \ln p_R \]  \hspace{1cm} (1)

\[ q_U + q_R = 1 - \eta \omega \ln p_R \]  \hspace{1cm} (2)

Where the baseline total amount of smoking is normalized to one and \( \omega \in (0,1) \) reflects the range of products that are not subject to a hypothetical VLNC standard. Because \( p_R > 1 \) and \( \eta > 0 \), a broader range of tobacco products not subject to a hypothetical VLNC standard means more quitting (\( \eta \)). Note that, to the extent that \( q_R > 0 \), there is an illicit market for conventional nicotine content cigarettes and cigars.

In this model, an increase in the price of all products would reduce total smoking according to the elasticity \( \eta \) that has been widely studied and found to be in the range 0.3 to 0.6 (it is estimated that consumption will reduce by 0.3 to 0.6 percent for each one percent increase in price). According to the literature, 0.4 is used.

The cross-price elasticity is related to the slope coefficient \( \beta \), and vice versa, according to:

\[ \text{cross-price elasticity} = \frac{\beta}{\omega + \frac{\beta}{2} \ln p_R} \]  \hspace{1cm} (3)

As discussed previously, cross-price elasticity is assumed to be 2.5 for ENDS.

**Estimation of the Free Parameters:** \( \eta > 0 \) has been estimated many times in the literature on the effect of cigarette prices on the quantity of cigarette sales. Because noncombustible cigarettes and low-nicotine products have existed in the past, \( \omega \) can be estimated as the historical market share of products that are not regulated by a hypothetical VLNC standard, such as e-vapor.

For a VLNC standard, the price \( p_U \) is held constant at one. The simulated value for \( p_R \) is taken as 1.3, according to the prior analysis of how enforcement of the hypothetical VLNC standard would affect the cost of illicit conventional nicotine content cigarettes.

The value of \( \omega \) is the historical market share of conventional nicotine content cigarettes that have nicotine levels in excess of the VLNC standard. The market shares are then read off of the demand functions (1)-(2).

**Translating impacts into dollars and volume of tobacco products:** The simulations described above yield proportional impacts on revenue and units sold. These are translated to absolute dollar and unit impacts by multiplying by baseline expenditure (in dollars) and baseline units sold in each segment.

**State-specific simulations:** We assumed each state has the same extra cost added to conventional nicotine content cigarettes by the hypothetical VLNC standard. But as a proportion of the
baseline retail price, this impact on \( p_R \) varies by state because states have different baseline retail prices for conventional nicotine content cigarettes.

States also differ in the baseline share \( \omega \).

These differences produce different simulation results for each state.

**Smokeless tobacco:** Smokeless tobacco is treated as a separate demand system because it is not inhalable like the other tobacco product categories. We estimated the cross-price elasticity of smokeless tobacco at 0.5. The growth of smokeless tobacco consumption post-regulation is modeled as 2 percentage points, based on an analysis of poly users in PATH data.

**Calculating Percent of Smokeless Tobacco and E-Vapor Consumers from PATH Data**

The pie chart below shows the distribution of exclusive cigarette use and dual use of other tobacco products by adult cigarette smokers today.

![Pie chart showing distribution of exclusive cigarette use and dual use of other tobacco products](image)

PATH shows that there are 44 million adult smokers in Wave 2, which represents the time period of October 2014 to October 2015. 35 million of these adult smokers only smoke cigarettes and 6.4 million adult smokers are dual or poly-use consumers who also use smokeless tobacco, e-vapor, or a combination of both smokeless tobacco and e-vapor products. We assume that following implementation of a hypothetical VLNC standard, these dual or poly-use adult smokers will likely use other, noncombustible products like smokeless tobacco or e-vapor.
Therefore, the distribution of adult smokers with other tobacco products is as follows:\textsuperscript{501}:

<table>
<thead>
<tr>
<th>Adult Tobacco Consumer Type</th>
<th>Number of Adult Tobacco Consumers, Millions</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarette Only</td>
<td>36.2</td>
<td>82%</td>
</tr>
<tr>
<td>Cigarette + Smokeless Tobacco</td>
<td>2.1</td>
<td>5%</td>
</tr>
<tr>
<td>Cigarette + E-Vapor</td>
<td>5.9</td>
<td>13%</td>
</tr>
<tr>
<td>Cigarette + Smokeless Tobacco + E-Vapor</td>
<td>0.2</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>44.4</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

\textsuperscript{501} Due to rounding, shares do not add to 100%.

\textsuperscript{502} Alcohol and Tobacco Tax and Trade Bureau, \textit{Tobacco Statistics for 2017}, available at https://www.ttb.gov/tobacco/tobacco-stats.shtml; This analysis estimates small and large cigar volumes by using total cigar stick volume from TTB, then applying an estimate for the small and large cigars, consistent with Middleton’s stated definition of large cigars (see: Altria for 10-K, February 13, 2017). 2017 e-vapor volume is calculated using 2018 market estimates from: Bonnie Herzog, \textit{Our Evening With blu 4}, Wells Fargo (Mar. 28 2018), available at https://www.wellsfargoresearch.com/Reports/ViewReport/6dd7ce28-1708-4b56-9c05-cd59ca71fb40?source=WFR.COM&ght=bc605b8a-3f2e-4903- and assuming 25% annual growth rates, as seen in Euromonitor, and an average price of $4.20 per unit. This analysis assumes the following equivalency units: 1 pack of cigarettes (20 sticks) = 1 can of smokeless tobacco (avg. of 1.1 oz.) = 1 pack of small cigars (20 sticks) = 1 pack of large cigars (10 sticks) = 1 unit of e-vapor (1 cartridge, or 1 mL e-liquid).
Retail Outlets in the United States

<table>
<thead>
<tr>
<th>Stores</th>
<th>Example</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convenience stores</td>
<td>7-Eleven</td>
<td>Primarily engaged in retailing both gasoline products outside store as well as merchandise and prepared foods at inside store. Located in residential neighborhoods</td>
</tr>
<tr>
<td>Tobacco store</td>
<td>Admiral Discount Tobacco</td>
<td>Specialist retailers of tobacco products including pipes, lighters, cigarettes boxes and other smoking-related equipment</td>
</tr>
<tr>
<td>Grocery store</td>
<td>Safeway</td>
<td>Primarily engaged in retailing food, beverages, and other everyday groceries. Tobacco products sold in selected formats. Includes large format hypermarkets and smaller independent grocers</td>
</tr>
<tr>
<td>Mass merchandise</td>
<td>Walmart</td>
<td>Primarily engaged in selling general merchandise and conveying the perception of a high-volume, fast-turnover, and discount environment. Tobacco products sold in selected formats</td>
</tr>
<tr>
<td>Drug store</td>
<td>Walgreens</td>
<td>Primarily engaged in selling pharmaceuticals, OTC healthcare, cosmetics and toiletries, disposable paper products, household care products and other general merchandise. Tobacco products sold in selected formats</td>
</tr>
<tr>
<td>Vape store &amp; online</td>
<td>Avail</td>
<td>Primarily engaged in retailing electronic cigarettes and vapors, tanks, and personal vaporizers. Also sells cigars and vape products online that ship direct to adult tobacco consumers</td>
</tr>
</tbody>
</table>

Criteria and Number of Tobacco Farms by Size

USDA defines a small farm as a farm with a Gross Cash Farm Income (GFCI) of less than $250,000. Given the high value of tobacco crops and the varying amount of tobacco that’s planted depending on tobacco type, the definition varies slightly for Flue-cured and Burley farms based on varying thresholds for GFCI and acres of tobacco grown.

Flue-cured acres are typically greater than Burley; on average, acres grown of Flue-cured tobacco in North Carolina is 100 acres while in Kentucky average acres grown of Burley is 19. Based on this the GFCI for a Flue-cured farm is almost $500,000 and a Burley farm is $84,000. Therefore, if a small Flue-cured farm is defined as a farm with a GFCI of less than $1 million and less than 100 acres of tobacco, there are 1,082 Flue-cured farms in North Carolina (65 percent of total farms). For Burley, if a small farm is defined as a farm with a GFCI of less than $250,000 and less than 25 acres, there are 2,520 farms in Kentucky (79 percent of total farms). See below tables for details:

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503 Id.

504 North Carolina and Kentucky tables on number of tobacco farms and acres.
Table: Estimated number of North Carolina Flue-cured farms by size

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<tr>
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<th>Small</th>
<th>Medium</th>
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<tbody>
<tr>
<td>GFCI</td>
<td>&lt;$1M</td>
<td>$1-2M</td>
<td>$2M+</td>
</tr>
<tr>
<td>Tobacco acres</td>
<td>0 to 100</td>
<td>100 to 250</td>
<td>250+</td>
</tr>
<tr>
<td>Average total farm acreage(^{505})</td>
<td>79</td>
<td>947</td>
<td>3,363</td>
</tr>
<tr>
<td>Average tobacco acres(^{506})</td>
<td>37</td>
<td>150</td>
<td>407</td>
</tr>
<tr>
<td>Number of farms</td>
<td>1,082</td>
<td>447</td>
<td>146</td>
</tr>
</tbody>
</table>

\(^{505}\) Calculated based on total farm land found in USDA 2012 Ag Census for North Carolina.

\(^{506}\) Calculated based on tobacco farm land found in USDA 2012 Ag Census for North Carolina.

Table: Estimated number of Kentucky Burley farms by size

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<tr>
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<th>Small</th>
<th>Medium</th>
<th>Large</th>
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<tbody>
<tr>
<td>GFCI</td>
<td>&lt;$250K</td>
<td>$250K-1M</td>
<td>$1M+</td>
</tr>
<tr>
<td>Tobacco acres</td>
<td>0 to 25</td>
<td>25 to 75</td>
<td>75+</td>
</tr>
<tr>
<td>Average total farm acreage(^{507})</td>
<td>102</td>
<td>871</td>
<td>3,395</td>
</tr>
<tr>
<td>Average tobacco acres(^{508})</td>
<td>8</td>
<td>39</td>
<td>119</td>
</tr>
<tr>
<td>Number of farms</td>
<td>2,520</td>
<td>495</td>
<td>181</td>
</tr>
</tbody>
</table>

\(^{507}\) Calculated based on total farm land found in USDA 2012 Ag Census for Kentucky.

\(^{508}\) Calculated based on tobacco farm land found in USDA 2012 Ag Census for Kentucky.
Attachment 2:

Cross-reference to Questions Raised in the ANPRM

Cross-reference to Questions Raised in the ANPRM509

509 FDA asks commenters to identify the ANPRM section and question number associated with responsive comments and information. (83. Fed. Reg. 12294, 12298). The chart provided above identifies sections of our
### Questions Raised for Comment in the Nicotine ANPRM

<table>
<thead>
<tr>
<th>A. Scope</th>
<th>Corresponding Comment Section(s)</th>
</tr>
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<tbody>
<tr>
<td>1. If FDA were to propose a product standard setting a maximum nicotine level, should such a standard cover other combusted tobacco products in addition to cigarettes? If so, which other products? If FDA were to propose to include additional categories of combusted tobacco products in a nicotine tobacco product standard, should the standard be tailored to reflect differences in these products? What criteria should be used to determine whether, and which, products should be covered?</td>
<td>Section VII</td>
</tr>
<tr>
<td>2. Some suggest that large cigars and those cigars typically referred to as “premium” cigars should be regulated differently from other cigars, asserting that they are used primarily by adults and their patterns of use are different from those of regular cigars (81 FR 28973 at 29024). FDA requests information and data on whether large and/or so-called premium cigars should be excluded from a possible nicotine tobacco product standard based on asserted different patterns of use, and whether large and/or so-called premium cigars would be migration (or dual use) candidates if FDA were to issue a nicotine tobacco product standard that excluded premium cigars from its scope. FDA also requests data and information on whether and how there is a way that, if FDA were to exclude premium cigars from the scope of a nicotine tobacco product standard, FDA could define “premium cigar” to include only unlikely migration or dual use products and thereby minimize such consequences.</td>
<td>Section VII</td>
</tr>
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</table>

comments that contain information responsive to particular ANPRM questions. This chart, while intended to be helpful, does not and should not substitute for FDA’s thoughtful consideration of our comments as an integrated whole.
1. The Tobacco Control Act prohibits FDA from reducing nicotine yields in any combusted tobacco product to zero (Section 907(d)(3) of the FD&C Act). If FDA were to propose a maximum nicotine level for cigarettes, what should be the maximum level to ensure that the product is minimally addictive or nonaddictive, using the best available science to determine a level that is appropriate for the protection of the public health? Rather than establishing a nicotine target to make products “minimally addictive” or “nonaddictive,” should FDA consider a different threshold (e.g., less addictive than current products on the market)? How should the maximum level be measured (e.g., nicotine yield, nicotine in cigarette filler, something else)? What would be the potential health impacts of requiring a maximum nicotine level such as 0.4 mg nicotine/g of tobacco filler? FDA is interested in public health impacts of requiring different maximum nicotine levels, such as 0.3, 0.4, and 0.5 mg nicotine/gram of tobacco filler, as well as other maximum nicotine levels and solicits comments about the potential health impacts of different maximum levels. 

2. FDA lists four types of studies to estimate the threshold of nicotine addiction (i.e., indirect estimates; findings of increased cessation for VLNC cigarettes; subjective effects, craving, and withdrawal associated with VLNC cigarettes; and lower nAChR occupancy and cerebral response from the use of VLNC cigarettes). Should FDA rely on some or all of these types of studies? Why or why not? Is there a different method that FDA should investigate or use to determine the threshold for nicotine addiction? 

3. In addition to nicotine, minor tobacco alkaloids (including nornicotine, cotinine, anabasine, anatabine, and myosamine) and tobacco smoke aldehydes (such as acetaldehyde) are pharmacologically active and may contribute to addiction (see, e.g., Refs. 98 and 99). Researchers have investigated the abuse potential of nornicotine, cotinine, anabasine, and acetaldehyde in animals (Ref. 100). However, many of these compounds are only present in tobacco smoke at low levels and are likely less potent than nicotine in mediating pharmacological response and, therefore, reinforcement (Refs. 101 and 102). In addition to setting a maximum nicotine level, should the product standard also set maximum levels of other constituents (e.g., nornicotine, acetaldehyde, anabasine) that may have the potential to produce dependence and be addictive? If so, at what levels?
4. If FDA were to finalize a nicotine tobacco product standard, what is the potential that adults and adolescents would perceive these VLNC cigarettes as “safe”--and how could youth and adult risk perceptions of these cigarettes impact initiation, use, and cessation habits of combusted tobacco products?

C. Implementation (Single Target vs. Stepped-Down Approach)

1. What data are available to demonstrate that a single target approach to reach a maximum nicotine level would or would not result in any unintended consequences?

2. In the alternative, what data are available to demonstrate that a stepped-down approach involving a sequence of incremental levels and implementation dates to reach a proposed nicotine level would or would not result in any unintended consequences?

3. If FDA were to select a stepped-down approach for a nicotine tobacco product standard, what scientific evidence exists to support particular interim nicotine levels and the appropriate number of steps that would be needed to reach the target level?

4. Would a single target and a stepped-down approach for implementation result in comparable quit rates or reduced initiation rates?

5. What would be the likely implementation differences, including implementation timelines and transition costs, between a single target approach or a stepped-down approach involving a sequence of incremental levels and implementation dates?

D. Analytical Testing Method

1. If FDA were to issue a product standard, should the Agency require a standard method of product testing to analyze the nicotine levels in products subject to the standard? If so, what method or methods should FDA use?

2. Should the Agency require manufacturers to sample their products in a specific manner to ensure that products do not contain excess levels of nicotine? Should manufacturers be required to test each manufactured batch to ensure compliance with a product standard limiting nicotine levels? What criteria should be used to determine if a batch passes or fails testing?

E. Technical Achievability
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<tr>
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<th>Question</th>
<th>Section(s)</th>
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<tbody>
<tr>
<td>1.</td>
<td>What methods are tobacco product manufacturers currently using to maintain consistency of the nicotine in their products, given the variability of nicotine levels over growing seasons and crop type? How could these methods be adapted to ensure that certain combusted tobacco products meet a potential nicotine tobacco product standard?</td>
<td>Section II; Section VI</td>
</tr>
<tr>
<td>2.</td>
<td>What is the feasibility of using the techniques discussed in this section, or other nicotine reduction techniques, to reduce the nicotine in cigarettes?</td>
<td>Section II</td>
</tr>
<tr>
<td>3.</td>
<td>What is the feasibility of using the techniques discussed in this section, or other nicotine reduction techniques, for non-cigarette combusted tobacco products (e.g., cigarette tobacco, RYO tobacco, little cigars, large cigars, cigarillos, pipe tobacco, and waterpipe tobacco) that FDA is considering covering under a nicotine tobacco product standard?</td>
<td>Section II</td>
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<tr>
<td>4.</td>
<td>If FDA were to propose a tobacco product standard setting a maximum nicotine level, how, if at all, would such a product standard impact tobacco farmers’ growing and/or curing practices? If FDA were to finalize a nicotine tobacco product standard, what would be the costs and benefits for tobacco farmers and tobacco processors, particularly regarding how any such rulemaking might affect them in light of new technologies and business opportunities that are foreseeable, but not now in place? In addition, if FDA were to finalize a nicotine tobacco product standard, what would be the costs for farmers in light of such a standard?</td>
<td>Section II; Section IV</td>
</tr>
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5. Section 907(d)(2) of the FD&C Act provides that a tobacco product standard must set forth the effective date of the standard, which may not be less than 1 year after publication of a final rule unless FDA determines that an earlier effective date is necessary for the protection of the public health (and that such effective date be established “to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade”). This section also provides that the effective date be a minimum of 2 years after publication of a final rule if the tobacco standard can be met only by requiring “substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer.” Therefore, if FDA were to propose a product standard setting a maximum nicotine level, when should this standard become effective? What implementation timeframe would allow adequate time for industry to comply? Should the same timeframe be required for all tobacco product manufacturers, regardless of their number of employees and/or annual revenues? Given the currently available processes to reduce the nicotine in tobacco products (e.g., chemical processes, genetic engineering), what do manufacturers and others with relevant expertise consider an appropriate timeframe to implement a product standard to reduce nicotine? Would a 2-year, 4-year, or 6-year timeframe be appropriate?

6. Should the standard include provisions that would allow manufacturers, distributors, or retailers to sell off existing nonconforming inventory of manufactured combusted tobacco products? If so, what would be a reasonable sell-off period?

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

<table>
<thead>
<tr>
<th>F. Possible Countervailing Effects</th>
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<tbody>
<tr>
<td>Section V; Appendix at Attachment 4, ALCS response to FDA’s docket titled, “Concept Paper: Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard”</td>
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<th>G. Other Considerations</th>
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<tr>
<td>Appendix at Attachment 1</td>
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<td>9.</td>
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**Request for Comments at 11838.**

FDA is seeking data, evidence, and other information that could inform the following five parameter inputs that would be helpful in determining the public health impact of a nicotine product standard:

- Percent of current cigarette smokers who would quit cigarette smoking as a result of standard restricting nicotine to minimally addictive levels.
- Percent of quitters switching to other combusted or noncombusted tobacco products.
- Percent of continuing smokers who become dual product users of cigarettes and noncombusted tobacco products.
- Percent reduction in annual smoking initiation rates
- Percent of dissuaded smoking initiates who initiate noncombusted tobacco product use instead.
Attachment 3:

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Attachment 4:

ALCS Response to Docket No. FDA-2018-N-5029
“Concept Paper: Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard”
Jose Luis Murillo  
Vice President  
Regulatory Affairs

July 16, 2018

VIA ELECTRONIC SUBMISSION AND HAND DELIVERY

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852


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

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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.
Holdings LLC and its subsidiaries ("Nat Sherman"), John Middleton Company ("JMC"), U.S. Smokeless Tobacco Company LLC ("USSTC"), and Nu Mark LLC ("Nu Mark"), 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,

[Signature]

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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. 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. 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.

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

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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, 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,” 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.” 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, even before accounting for the compounding impact of a flavor ban.

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

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. 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.” 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].

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. 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. 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. 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.” The black market has many other names, including: shadow, informal, hidden, underground, gray, clandestine, illegal and parallel economies. 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. 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.
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.

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\(^{25}\) 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).


\(^{28}\) The size and adaptability of the cigarettes black market is addressed *infra* Sections I.C. & I.E.

\(^{29}\) GAO-11-313, *supra* note 19.
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

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\(^{30}\) 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.


\(^{35}\) Id.

\(^{36}\) Id. at 9.

\(^{37}\) Id. at 6.
Diego. 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. 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%.

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. Residents of the Mohawk nation travel freely across this territory—which straddles the Canada-U.S. border—without interference by custom authorities. 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. 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.” The term “large-scale smuggling,” however, does not refer to the scale of the

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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.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.

\textsuperscript{45} \textit{Id.} at 34.
\textsuperscript{46} \textit{Id.} at 35.
\textsuperscript{47} \textit{Id.} at 38.
\textsuperscript{48} The most common brand of illicit whites is “Jin Ling,” which is manufactured in Russia, Ukraine, and Moldova. \textit{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.
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


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. 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.

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 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 cigarettes 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 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.
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

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).
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. 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. “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.” 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. The ATF has noted that the “trade of counterfeit tobacco products is also a rapidly growing global problem.” 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.

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61 Id.
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

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 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 underage 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

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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.
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.²⁷⁴ 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.²⁷⁵ 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.²⁷⁶
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.²⁷⁷ 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.”²⁷⁸

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.²⁷⁹ 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.²⁸⁰

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.”²⁸¹ 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. . . .”²⁸² It
is ready-made for a large scale and uncontrolled market for all manner of black market trade.

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²⁷⁴ Jennifer A. Jensen et al., Availability of Tobacco to Youth Via the Internet, 291 JAMA 1837, 1837 (2004).
²⁷⁵ Id.
²⁷⁶ Id.
²⁷⁷ Id.
²⁷⁸ Id.
²⁸⁰ NRC Illicit Trade Paper, supra note 15, at 191.
²⁸¹ KRISTIN FINKLEA, CONG. RESEARCH SERV., R44101, DARK WEB 3 (2017).
²⁸² Id., Summary.
“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

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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.
<table>
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<th>YEARS</th>
<th>TYPES OF CONTRABAND</th>
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| 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.  
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.  
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. The seizure followed PM USA’s own |  

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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).

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.

<table>
<thead>
<tr>
<th>2010 – present</th>
<th><strong>Tribal manufacturing and state-to-state smuggling</strong> began to increase to take the place of internet sales.</th>
</tr>
</thead>
</table>

|                      | There has been a lack of consistent and vigorous enforcement to combat this type of illicit activity. |

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

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.
and volume in that country.” 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.”

New York also provides a clear example of high cigarette taxes resulting in a black market problem. 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.” 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.” As researchers have recognized:

Like 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.

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.” At that time, the retail prices averaged $7.50–$8.00 per pack. 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, in more recent years, there has been a reported rise in the number of stores that engage in the sale of bootlegged cigarettes. 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

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93 Id.
94 Id.
95 See infra Section II.C.3.
97 Id.
98 Id.
99 Id.
100 Id. at 1483.
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](image)

<table>
<thead>
<tr>
<th>Pack</th>
<th>Carton</th>
<th>Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York City</td>
<td>$6.86</td>
<td>$68.60</td>
</tr>
<tr>
<td>Richmond</td>
<td>1.31</td>
<td>13.10</td>
</tr>
<tr>
<td>Differential</td>
<td>$5.55</td>
<td>$55.50</td>
</tr>
</tbody>
</table>

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

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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,

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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.
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.’”  

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.  

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.


As the FDA is undoubtedly aware, the current cigarette black market in the United States is substantial. 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. 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.” Illicit trade in tobacco products, including cigarettes, is “a large and growing economic activity in the U.S.”  

It is beyond dispute that illicit trade is increasing, and not decreasing.

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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)).  
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.”\textsuperscript{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.”\textsuperscript{125}

On a global scale, “[i]licit 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.”\textsuperscript{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.\textsuperscript{127} Indeed, “[t]he illegal trade in untaxed cigarettes has come to be recognized as a significant problem around the world. According to some estimates, almost one third of the global cigarette exports is funneled into black markets.”\textsuperscript{128}

\textsuperscript{124} GAO-11-313, supra note 19, at 16.
\textsuperscript{125} Id.
\textsuperscript{126} Euromonitor International, Passport Database.
\textsuperscript{127} Id.
\textsuperscript{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).
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.”\textsuperscript{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.\textsuperscript{131}

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

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

\textsuperscript{130} Aziani et al., supra note 38, at Abstract.
\textsuperscript{131} See supra Section I.D.
\textsuperscript{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. 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%.” 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.

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. 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.

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.\textsuperscript{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.\textsuperscript{139} All indicators show that a flavor ban would exacerbate that problem.\textsuperscript{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.

\textbf{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.

\textsuperscript{138} Smith et al., \textit{supra} note 11, at 24.
\textsuperscript{139} ALCS comments to Nicotine ANPRM at Section VI.
\textsuperscript{140} \textit{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

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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.
148 H.B. 579, 64th Leg., Reg. Sess. (Mont. 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).
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.
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.\textsuperscript{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,\textsuperscript{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, \textit{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.\textsuperscript{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;

\textsuperscript{157} ALCS’ comments to Nicotine ANPRM at Section VI.

\textsuperscript{158} See Nicotine ANPRM.

\textsuperscript{159} See, \textit{e.g.}, Jack Kimball, \textit{Cuba’s Cigars: A Black Market Tale of Survival}, \textsc{Reuters} (Dec. 15, 2011) https://www.reuters.com/article/us-cuba-cigars/cubas-cigars-a-black-market-tale-of-survival-idUSTRE7BE1N20111215; 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

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162 Id.

163 Id.


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.\footnote{ALCS’ comments to Nicotine ANPRM.} In one study, up to 77% of the participants reported that they would “never” switch to VLNC cigarettes.\footnote{Id.} Actual industry experience mirrors the study results. In the late 1980s, PM USA extensively researched and tested a VLNC cigarette it ultimately marketed as “\textit{Next}.” Test groups, as large as 4,000 smokers, reported that they preferred their regular brands and would not continue to smoke \textit{Next} cigarettes.\footnote{Id.} The product performed poorly in the marketplace, even after improvements to the product formula and promotional efforts, and was ultimately discontinued.\footnote{Id.} 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.\footnote{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.} Indeed, opioids are the main cause of drug overdose deaths.\footnote{Lisa N. Sacco & Erin Bagelman, Cong. Research Serv., R44987, The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions 8 (2017).} Researchers found that the current opioid problem has been made worse by the introduction, in 2010, of an abuse-deterrent formulation of OxyContin that

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166 ALCS’ comments to Nicotine ANPRM.
167 Id.
168 Id.
169 Id.
made this prescription drug harder to crush and abuse. The FDA approved the reformulation in 2012.\footnote{Id. at 6.} Unfortunately, in response to these agency actions, experts in the field noted a subsequent rise in heroin supply and use.\footnote{Id. at 6-7.}

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.”\footnote{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).} 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.”\footnote{Dryden, supra note 174 (quoting Cicero).} 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.”\footnote{Id. (quoting Cicero).} “Heroin is a very dangerous drug, and dealers always “cut” the drug with something, with the result that some users will overdose.”\footnote{Id.}

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.\footnote{Id.} 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.\footnote{Id.} 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.\footnote{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).} 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.\footnote{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.
\(^{185}\) Id.
\(^{186}\) Id.
\(^{188}\) 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.

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\(^{191}\) 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.


\(^{194}\) 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”).

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.”\textsuperscript{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.”\textsuperscript{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.\textsuperscript{198}

The expansion of the black market during Prohibition was astounding and created “criminal operations of a size and sophistication Americans had never known.”\textsuperscript{199} And “the criminal activity that had blossomed at Prohibition’s dawn—largely local, infrequently violent—multiplied in scale and in carnage.”\textsuperscript{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.”\textsuperscript{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,”\textsuperscript{202} which is almost $51 billion in today’s dollars.\textsuperscript{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.\textsuperscript{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

\textsuperscript{196} DANIEL OKRENT, LAST CALL: THE RISE AND FALL OF PROHIBITION 118 (2010).

\textsuperscript{197} Id. at 124.


\textsuperscript{199} OKRENT, supra note 196, at 271-72.

\textsuperscript{200} Id. at 271.

\textsuperscript{201} Id. at 274.

\textsuperscript{202} Id.


\textsuperscript{204} OKRENT, supra note 196, at 268.
billion in today’s dollars\textsuperscript{205}, he said, was now going into ‘the pockets of foreign and domestic lawbreakers.’\textsuperscript{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.\textsuperscript{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.\textsuperscript{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,\textsuperscript{209} which translates to almost $4.5 million in today’s U.S. dollars.\textsuperscript{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. Alarmingly, and unlike the cigarette black market, prior to the enactment of Prohibition, the smuggling

\textsuperscript{205} U.S. Inflation Calculator, \textit{supra} note 203.

\textsuperscript{206} \textsc{Okrent, supra} note 196, at 268; \textit{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.”).

\textsuperscript{207} \textsc{Okrent, supra} note 196, at 373; \textit{see also} Mark Thornton, \textit{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).

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

\textsuperscript{209} \textsc{Okrent, supra} note 196, at 150-53.

\textsuperscript{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. 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.”

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.”

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.” 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. “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.” 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.” 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.” Further, “to the extent that the illicit trade creates low-price options for smokers, or lowers prices generally, youth[] (like adults) will smoke more.” 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 “[I]hen go be a monk.”).  
218 Chen, supra note 213, at 3.  
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.”

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.”

“As 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.”

Indeed, law enforcement nationally has observed that organized crime has moved into the business of cigarette trafficking. “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.” The Virginia State Crime Commission concluded that “[i]llegal cigarette trafficking is not a ‘cigarette issue.’ IT IS AN ORGANIZED CRIME ISSUE.”

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.” James T. Hayes Jr., Special Agent in Charge, Office of Homeland Security, observed that the proceeds from an

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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).
228 Id.
229 Id. at 14 (emphasis in original).
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.”

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.” 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. 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.” “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 . . . .” 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. 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.

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.

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232 Kulick et al., supra note 17, at 4.
234 Id. at 74.
235 Id. at 72.
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. 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.” Researchers in Canada found that “[t]he use of contraband cigarettes in this age group [14-18 years] is striking.” “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.”

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 [...] billion in lost revenue globally, and increases the availability of cheap cigarettes thus increasing consumption and tobacco related deaths in the future.” 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. 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.” 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.
243 Luk Joossens & Martin Raw, From Cigarette Smuggling to Illicit Tobacco Trade, 21 TOBACCO CONTROL 230 (2012).
245 NRC Illicit Trade Paper, supra note 15, at 104.
recent cigarette tax increases may never see them." 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. 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

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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, Delaware, Kansas, Louisiana, Minnesota, North Carolina, Pennsylvania, and West Virginia. Moreover, Washington, D.C. and Puerto Rico 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.” 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. The proposal ultimately failed.

Similarly, California currently taxes e-vapor products at 65.08% of the wholesale price, Pennsylvania at 40%, and Washington, D.C. at 60%. 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. In 2015, Kansas and Louisiana followed North Carolina’s approach taxing by volume at the same rate. Delaware, West Virginia and Puerto Rico later followed suit. 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).
251 LA. STAT. ANN. § 47:841(F) (2016).
253 N.C. GEN. STAT. § 105-113.35(a1) (2017).
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).
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).
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

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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).
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, 1017).
277 LOS GATOS, CAL., CODE § 18.60.020(c)(8) (2017).
281 SANTA CLARA COUNTY, CAL., ORDINANCES no. NS-300.903, § A18-369(i)(1) (Oct. 18, 2016)
retail stores. Such cities include Boston, Cambridge, Northampton, Chelsea, Gardner, West Boylston and Salem.

Other cities, including Central Falls, Rhode Island, Providence, Rhode Island, St. Paul, Minnesota, Shoreview, Minnesota and Minneapolis, Minnesota, 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.

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/528681f8e4b021c6d3ec997/v/5903c607d0f8a2400c03ab/1493419633486/mini+list+Flavored+OTP+Restriction+.pdf.
286 CENTRAL FALLS, R.I., CODE § 12-421(e)(2017).
287 PROVIDENCE, R.I., CODE § 14-309 (2016).
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.” 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.

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. Further, there is limited coordination among applicable federal and state enforcement agencies. 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. A growing black market becomes harder and harder to enforce against, further reducing the risks to traffickers and inviting still more growth. 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...
primarily a state and local enforcement issue.\textsuperscript{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.\textsuperscript{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.\textsuperscript{298}

“State and local enforcement is limited by the perception of ITTP [(Illicit Trade in Tobacco Products)] as a low-priority crime.”\textsuperscript{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.”\textsuperscript{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.”\textsuperscript{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.\textsuperscript{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.”\textsuperscript{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.”\textsuperscript{304} Given the states’

\textsuperscript{296} Kleiman et al., supra note 244, at §§ 2.2.2.1, 2.2.3.1.
\textsuperscript{297} Id.
\textsuperscript{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).
\textsuperscript{299} Kulick et al., supra note 17, at 7.
\textsuperscript{300} Id.
\textsuperscript{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).
\textsuperscript{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).
\textsuperscript{303} NRC Illicit Trade Paper, supra note 15, at 148.
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.”

Investigations and prosecutions of traffickers in black market tobacco products are arduous, require long-term commitments, and require a significant investment of resources. 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.’” 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.” 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.”

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.” Under the administration’s plan, the Treasury Department would inherit

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305 Kulick et al. supra note 17, at 7.
308 Id.
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.” (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.” 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.

There is no standing organization to coordinate the activities of these various agencies representing different jurisdictions and levels of government. 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
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.\textsuperscript{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.\textsuperscript{317}

Euromonitor International statistics estimate about $2,700 in cigarette revenue per smoker in the United States for 2018.\textsuperscript{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).\textsuperscript{319} Government is estimated to spend over $50 billion per year on its drug enforcement efforts.\textsuperscript{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.\textsuperscript{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

\textsuperscript{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.

\textsuperscript{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.

\textsuperscript{318} Euromonitor International, Passport Database.


\textsuperscript{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

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322 TRACY KYCKELHAHN, BUREAU OF JUST. STATS., U.S. DEP’T OF JUST., JUSTICE EXPENDITURE AND EMPLOYMENT
323 FED. BUREAU OF INVESTIGATION, DEP’T OF JUST., CRIME IN THE UNITED STATES, Table 18 (2016),
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
325 Altarum, Economic Toll of Opioid Crisis in U.S. Exceeded $1 Trillion Since 2001 (Feb. 13, 2018),
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.
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. 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. 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. 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

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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/nsleed.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 U.S 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.

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


\[^{332}\] FDA Illicit Trade Paper at 22.

manufactured products and depends on the willingness of the manufacturers and distributors to participate in the system. Illicit manufactures 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,
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. Notably, the company that sold Brazil on its track and trace system, SICPA, is under investigation for corruption related to its traceability technology.

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. Rather, it is merely a complex and expensive stamp program. The FCTC’s analysis not only highlights over $90 million in implementation costs, 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. 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 staving 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

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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.
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.\textsuperscript{346}

\textbf{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.\textsuperscript{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.”\textsuperscript{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:

\begin{itemize}
\item 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.
\item 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 Sherriff’s Office, should be evaluated by independent researchers.
\item 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.\textsuperscript{349}
\end{itemize}

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

\textsuperscript{346} For additional information and analysis of track and trace systems, see ALCS’ \textit{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).
\textsuperscript{347} See generally NRC Illicit Trade Paper, \textit{supra} note 15.
\textsuperscript{348} \textit{Id.} at 9.
\textsuperscript{349} \textit{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.”

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.”

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.

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.