



Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard

Call for Nominees to Conduct a Formal
Peer Review

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INTRODUCTION The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) grants the U.S. Food and Drug Administration (FDA) the authority to implement a variety of tobacco product standards designed to protect public health. The effectiveness of these standards, however, could be compromised by illicit trade in contraband or nonconforming products. To stimulate dialogue on this topic, FDA has developed and made available to the public a draft concept paper (see Attachment 1) regarding the potential for illicit markets in tobacco products to develop in response to a tobacco product standard.

The Tobacco Control Act specifically requires FDA to consider the potential countervailing effects of demand for contraband products in its assessment of the public health impacts of a tobacco product standard. Assessing the potential for an illicit market to develop in response to a particular standard is a complex task. FDA's draft concept paper attempts to assist this effort by (1) describing the key elements of trade in illicit tobacco markets and (2) examining the factors that could support or hinder the establishment and persistence of an illicit market in response to an FDA tobacco product standard.

FDA has contracted with Industrial Economics, Incorporated (IEc) to coordinate a formal peer review of the draft concept paper. IEc's responsibilities include:

- Determining the method and protocol for conducting the review;
- Selecting and enlisting peer reviewers;
- Managing the peer review process;
- Providing FDA with the peer reviewers' comments; and
- Summarizing the peer review process and its findings in a memorandum to FDA.

CALL FOR NOMINATIONS This call for nominees to conduct the peer review addresses the second item noted above. In soliciting nominations, IEc is seeking individuals whose technical expertise will allow them to provide an informed, independent perspective on whether FDA's paper presents an objective, accurate, and complete description of the factors that may affect the development of illicit tobacco markets following the implementation of a product standard. Potentially applicable fields of expertise include but are not necessarily limited to economics, public policy, tobacco control, law, and criminology. Evidence of familiarity with the U.S. tobacco market, the regulation of tobacco products, and factors that may contribute to the development and persistence of illicit tobacco markets is preferred, but not required.

Attachment 2 provides a preliminary draft of the specific questions reviewers will be asked to consider. Additional details on the peer review process and instructions for submitting nominations are provided below.

**THE PEER REVIEW
PROCESS**

The peer review will be conducted in accordance with the following guidelines:

- U.S. Office of Management and Budget, “Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies,” September 24, 2001;
- U.S. Department of Health and Human Services, “Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public,” October 1, 2002;
- U.S. Office of Management and Budget, “Final Information Quality Bulletin for Peer Review,” December 16, 2004.

In keeping with these guidelines, IEC anticipates retaining three independent reviewers, each of whom will be asked to prepare a letter summarizing his or her comments on FDA’s paper. We will prepare a brief memorandum to FDA summarizing the reviewers’ comments. The detailed comments provided by each peer reviewer will be forwarded to FDA as appendices to our memorandum. The identities and professional affiliations of all peer reviewers will be noted in our summary of the peer review’s findings and will be made publicly available; however, neither the summary memorandum nor the appendices will attribute comments to a specific reviewer.

**CONDITIONS OF
PARTICIPATION**

IEC will compensate all peer reviewers in accordance with the terms and conditions of its contractual agreement with FDA. Compensation will be in the form of a fixed honorarium, to be paid upon submission and acceptance of the completed written review.

Before the review begins, all reviewers will be required to certify that they are free of any actual, apparent, or potential conflict of interest. Specific criteria to be considered in evaluating potential conflicts are listed in Attachment 3.

SCHEDULE

Work on the peer review is expected to begin in May. Reviews must be completed and submitted to IEC no later than July 16, 2018.

**INSTRUCTIONS AND
DEADLINE FOR
NOMINATIONS**

Nominations are open to the public. Self-nominations are welcomed. Nominations should consist of a brief letter (*no more than two pages*) summarizing the qualifications and experience of the nominee, along with the nominee’s resume or *curriculum vitae*.

Please submit your nomination no later than **5:00 p.m. Friday, April 20**; nominations received after this deadline may be too late to be considered. Nominations should be submitted electronically and addressed to:

Brian G. Morrison
Principal
Industrial Economics, Incorporated
Email: bgm@indecon.com

SELECTION OF REVIEWERS

IEc will consider the following factors in evaluating nominations:

- The qualifications and experience of the nominee;
- Evidence of familiarity with the U.S. tobacco market and regulation of tobacco products;
- Evidence of familiarity with factors that contribute to the development of markets for illicit tobacco products;
- Independence from FDA, and
- The absence of any actual, potential, or apparent conflicts of interest.

We will extend invitations to the nominees we determine offer the best combination of technical expertise and the desired range of independent perspectives. Invitations will be issued approximately two weeks after the deadline for nominations.

QUESTIONS

Questions concerning this request for nominations should be emailed to:

Brian G. Morrison
Principal
Industrial Economics, Incorporated
Email: bgm@indecon.com



Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard

March 15, 2018

Contact:

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I. Introduction

The U.S. Food and Drug Administration (FDA) has the authority to implement a wide variety of product standards that impact different characteristics of tobacco products. This draft paper represents an initial step in assessing the possible health effects of a tobacco product standard in the form of demand for contraband or nonconforming tobacco products. In order to examine such effects, the potential for a market for such products should be assessed, including how such market could develop and factors that might influence behavior of users and nonusers of tobacco products after an FDA product standard. Accordingly, this draft paper describes aspects of the tobacco product market and consumer behavior that may be relevant to the potential development of markets for contraband and nonconforming tobacco products, specifically through illicit trade, after FDA implements a tobacco product standard.

Each illicit trade market for intentionally nonconforming products carries its own set of incentives and disincentives, thus it is difficult to compare one set of circumstances to another, or to effectively predict the illicit activities that arise following any particular regulation (particularly when there are no comparable existing illicit markets and much depends on inherently unpredictable human behavior). It is similarly difficult to capture an accurate picture of any existing illicit market due to data gathering challenges regarding illegal activities.¹ Thus, FDA faces a complex task when assessing the potential for an illicit trade market to develop in response to a tobacco product standard. This draft paper assists that effort by breaking down the mechanics of an illicit trade market into their various components, and examining the factors that might support or hinder the establishment of a persistent illicit trade market in the face of an FDA tobacco product standard.

This draft paper first discusses the approach to establishing tobacco product standards, then discusses the different components of illicit trade markets, followed by relevant research in consumer behavior and potentially applicable economic research.

II. FDA approach to tobacco product standards

A. Characteristics of an FDA tobacco product standard

Under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act),² FDA has the authority to regulate tobacco products in the United States to protect the public health. Among the authorities included in the Tobacco Control Act is the ability to establish tobacco product standards. To establish a tobacco product standard, FDA is required to find that the

¹ In addition to data gathering challenges, it is often unclear what assumptions are being made and the specifics of the analysis that goes into estimating illicit trade rates. Blecher E., Liber A., Ross H., et al. (2013). Research letter: Euromonitor data on the illicit trade in cigarettes. *Tobacco Control*, 24, 100-101 (identifying challenges in evaluating Euromonitor estimates of illicit trade rates).

Carpenter, C. M., Connolly, G. N., Ayo-Yusuf, O. A., & Wayne, G. F. (2009). Developing smokeless tobacco products for smokers: an examination of tobacco industry documents. *Tobacco Control*, 18, 54-59.

² Pub. L. 111-31 (2009); 123 Stat. 1776. Unless otherwise noted, all statutory citations are to the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, appearing in title 21 of the U.S. Code.

standard is appropriate for the protection of the public health, taking into consideration scientific evidence concerning:

- The risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.³

FDA may establish tobacco product standards that are appropriate for the protection of the public health, including provisions, where appropriate, for the:

- Reduction or elimination of constituents or harmful components of tobacco products;
- Construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;
- Testing of the tobacco product; and
- Measurement of the tobacco product characteristics of the tobacco product.⁴

Additionally, FDA is required to consider other information submitted in connection with a proposed product standard, including information:

- Regarding the technical achievability of compliance with such standard; and
- 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 that do not meet the requirements of the product standard and the significance of such demand.⁵

In order to assist FDA in assessing the potential health effects of a product standard, this paper examines the potential for the development of a market for products that do not conform to a product standard. Moreover, to gauge the potential health effects arising from demand for such products, the availability of such products and avenues by which users and nonusers could obtain them should also be considered. Because it is likely that illicit trade⁶ could be a primary source of nonconforming tobacco products following issuance of a product standard, it will be considered in this paper.

For efficiency and concision, this paper will use the term “illicit tobacco product” to refer to products that are intentionally manufactured, distributed, and/or sold in violation of an FDA tobacco product standard. This term is not meant to encompass products that are unintentionally nonconforming through a manufacturing defect. For the purposes of this paper, the term also

³ § 907(a)(3).

⁴ § 907(a)(4).

⁵ § 907(b)(2).

⁶ The term ‘illicit trade’ means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity. § 900(8).

does not include those products that are legally manufactured (in conformance with all applicable standards) but sold illegally for the purpose of evading taxes and fees only. An ongoing illegal scheme involves moving tobacco products from a state with lower taxes to one with higher taxes, to sell at the higher price and collect the difference as profit. That scenario is not included in this analysis.⁷

B. Examples of FDA tobacco product standards

FDA could establish tobacco product standards that would reduce or eliminate certain harmful constituents in tobacco products, as well as standards that would limit appealing and/or addictive constituents. Both design and manufacturing changes may be required in order to meet the standards, and the resulting changes to the tobacco products may affect the user's experience. This, in turn, could create some consumer demand for products that do not conform to the standard. It is assumed that product standards that do not noticeably impact the user experience of a tobacco product will not drive the demand required to establish and maintain an illicit trade market for nonconforming products. Thus, those standards are not helpful examples here.

An example of a tobacco product standard that would impact the user's experience is one that sets a maximum nicotine level for certain tobacco products. Noting that tobacco-related harms primarily result from addiction to products that repeatedly expose users to toxins, FDA has announced its intention to consider establishing a maximum nicotine level to reduce the addictiveness of certain tobacco products.⁸ A nicotine product standard could increase successful cessation attempts by current users as well as prevent experimental users of the covered tobacco products from becoming regular users.

FDA is also considering establishing a product standard prohibiting the manufacture, sale, and distribution of tobacco products with certain characterizing flavors.⁹ This standard could significantly reduce the appeal and initial palatability of certain tobacco products, thereby limiting the number of experimental users who progress to lifetime daily use.

Tobacco product standards can also be focused in their application to certain types of products. For example, FDA has proposed a standard limiting a harmful constituent typically found in

⁷ Although tax-evading illicit trade is a different from the illicit trade analyzed in this paper, it can still provide useful information. For example, when New York State imposed a cigarette tax increase and restricted the ability of Native American tribes to sell to non-native consumers, the volume of untaxed cigarettes purchased by tribes for resale dropped from 23.3 million in 2010 to 16,000 in 2012. However, during a similar time period (2011-2013), the proportion of cigarette packs discarded in New York City bearing the tax stamps of southern states (i.e., likely illegal tax-evading cigarettes) increased from 9.7% to 58.6%, suggesting that the illicit tobacco market has the ability to quickly adapt to regulatory changes. Marin Kurti, "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," *Am. J. Public Health*. 2015; 105: 750-56.

⁸ "FDA's Plan for Tobacco and Nicotine Regulation," available at <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm> (last accessed 11/27/17).

⁹ *Id.*

smokeless products.¹⁰ Rather than targeting the appeal of the product, this proposed standard aims to reduce the health harms to individual users who consume the product on a regular basis.

Beyond the product standard itself, there are various other provisions that could be included to help support implementation and enforcement. For example, to ensure that the covered tobacco products comply with a proposed standard, FDA could include provisions to require that manufacturers test their products using a specified testing procedure (or accepted alternative that meets or exceeds certain requirements) for compliance with the limit.¹¹

In addition, FDA could propose requirements to ensure that reports of nonconforming products are examined and investigated by manufacturers, that measures are taken to ensure that nonconforming products are not distributed to consumers, and that steps are taken to prevent reoccurrence. Manufacturers might be required to maintain records related to the manufacture, processing, testing, packaging, and labeling of the product to ensure conformance with the standard.

Further, FDA could help ensure identification of the product as being in conformance with the proposed standard by requiring that the labeling of covered products contain a manufacturing code. In addition, FDA could consider prohibiting the sale and distribution of any tobacco product, including a component or part of a tobacco product, sold for the purpose of enabling consumers to evade the tobacco product standard.

The discussion in this document could be relevant to any number of potential FDA product standards, to varying degrees, based upon the particular standard implemented. As noted above, this paper represents an initial step in assessing the potential for illicit trade after an FDA product standard. Because it is possible for manufacturers to comply with product standards in a variety of ways, and each change to a product may impact the consumer experience differently, it is difficult to categorize the standards based upon their likelihood to create consumer demand for illicit products.

III. The elements of trade in illicit tobacco products

A. Sources of tobacco

The capacity to produce illicit tobacco products will depend upon a variety of factors, including the ease of acquiring the raw materials (particularly tobacco), the sophistication required to construct the desired product, and the purpose (whether it is for an individual's personal use, or for wider distribution and sale). One of the first tasks in producing a tobacco product is to acquire the tobacco.

¹⁰ Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products, 82 Fed. Reg. 8004 (Jan. 23, 2017).

¹¹ § 907(a)(4)(B)(ii)-(iv).

Tobacco product manufacturers obtain their tobacco either in full leaf form, or partially processed, from a number of sources, such as tobacco farms or a distributor.¹² Some manufacturers, particularly larger firms, have significant control over the growing practices and overall supply of tobacco. A tobacco product standard may impact the demand of such manufacturers, and thus, their arrangements with growers. For example, a nicotine standard as previously described might result in changes in growing patterns or the manufacturing process, while a limit on a particular constituent in tobacco smoke might be addressed exclusively during the manufacturing process. Unless the product standard mandates the method for complying with the standard, FDA generally may assume that both agricultural and manufacturing changes are possible.

The particular product standard implemented will impact whether tobacco farms or distributors are a potential source of illicit tobacco. If a product standard were to set a limit on the nicotine level in a class of tobacco products, a tobacco farm might employ growing techniques and seed choices to be able to competitively provide manufacturers with tobacco compliant with the standard. There might be legitimate and lawful purposes for growers to produce full-nicotine tobacco as well, such as manufacturing noncombustible tobacco products not subject to a nicotine product standard, for subsequent processing into low-nicotine products (through chemical reduction of the nicotine), or for extraction of nicotine for use in cessation products, e-liquids, or other products. These lawful purposes could thus keep demand for full-nicotine tobacco relatively high. Legitimate demand, combined with FDA not regulating tobacco growers directly,¹³ may make it difficult and/or inefficient for the agency to engage in enforcement action against tobacco growers involved in illicit trade. This would not, however, impact the ability of other agencies or authorities to enforce against such actors, nor would it prevent FDA from using its enforcement authorities at other stages of an illicit market.

If a product standard placed a limit on a harmful constituent in tobacco or tobacco smoke, and growing practices were irrelevant to a tobacco product complying with a standard, it is likely that no changes would take place on individual farms, and as such there would be no real incentive to sell the tobacco to illicit product manufacturers (unless they are willing to pay higher prices for the tobacco and/or there is sufficient consumer demand to incentivize it). Similarly, if manufacturers chose to comply with a nicotine product standard by reducing nicotine levels through a chemical process, the growing processes of farmers could remain unchanged, and the potential illicit trade markets would have to focus on diverting the full-nicotine tobacco prior to processing.

B. Manufacturing illicit tobacco products

Once the tobacco is acquired, the product must be manufactured. Generally, tobacco product manufacturing consists of the manufacture, preparation, compounding, and/or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling

¹² “Making Our Cigarettes,” Philip Morris USA, available at <http://www.altria.com/our-companies/philipmorrisusa/making-our-cigarettes/Pages/default.aspx?src=leftnav> (last accessed 11/27/17); “Farm Labor Issues,” RJ Reynolds Tobacco, available at <http://www.rjrt.com/laborissues.aspx> (last accessed 11/27/17).

¹³ § 901(c)(2) (except as provided for in § 901(c)(2)(B)).

of any tobacco product package.¹⁴ Tobacco products can also be constructed by individuals making roll-your-own (RYO) tobacco products for their use or consumption.

RYO cigarettes, while not in widespread use relative to factory-made cigarettes,¹⁵ are easy to make, and instructions for beginners are available on the internet.¹⁶ Similarly, there are small, relatively inexpensive devices available to assist consumers.¹⁷ This supports the idea that consumers could manufacture illicit cigarettes for their own personal use and in small quantities for friends, family members, and coworkers. Although it is likely that RYO tobacco would be subject to the same product standard requirements as factory-made cigarettes, if an individual obtained non-compliant tobacco and the other required components and parts, it would be possible to create illicit cigarettes. It is also the case that the potential for creation and use of illicit cigarettes in this way could be subject to mitigation through employment of various FDA enforcement authorities.

Because a product standard cannot ban all cigarettes, smokeless tobacco products, cigars, pipe tobacco, or RYO tobacco products, the other basic materials required to assemble such products likely will be available for legal sale. For example, cigarette papers would still be available for purchase after a nicotine standard, as would the various other components required (cellulose filters, glue, etc.). However, the time and effort required for an individual to make cigarettes in this manner, as well as the risk of enforcement action for any distribution beyond their own personal use, may not support widespread distribution or high-volume production of illicit cigarettes. To the extent that such production develops, there is no indication that FDA enforcement authorities are insufficient to address it. Further, the quality and consistency of the product will vary significantly with each cigarette constructed, and it is unclear whether it is possible to create a roll-your-own cigarette that mimics the taste or “experience” of commercially manufactured ones. Additionally, it may be difficult for average consumers to construct certain classes of products on their own, such as smokeless products that require strict controls on fermentation and aging to maintain a consistent product, and liquids commonly used in electronic nicotine delivery systems (ENDS) that require complex chemical interactions.

There are, however, more sophisticated means of manufacturing cigarettes on a larger scale (again, assuming the availability of sufficient quantities of the tobacco and the components and

¹⁴ § 905(a)(1).

¹⁵ In fiscal year 2011, there were approximately 2.56 billion RYO cigarette stick equivalents sold in the U.S., compared to 288.50 billion factory-made cigarettes. Even assuming that some proportion of RYO tobacco is misreported as pipe tobacco for tax evasion purposes, there remains a wide gap in volume. Pipe tobacco sales in that same year were only 15.02 billion cigarette stick equivalents. U.S. Government Accountability Office (GAO), “Tobacco Taxes: Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes,” Table 5, April 2012.

¹⁶ A Google search for “make your own cigarettes” returns approximately 3.3 million results, such as www.stuffyourown.com, www.thesmokingstore.com, and other websites dedicated to RYO production. Some of the websites include the ability to purchase machines and supplies, how-to videos, and other resources (search conducted 11/27/17).

¹⁷ A search for “cigarette machine” on Amazon.com yields a number of unique results, with a wide range in sophistication and price. They range from a handheld device costing \$0.99, to more automated, electric machines costing \$59.99. The same search on Ebay.com yields similar results, with machines ranging from \$0.90 to \$4,500.00 (searches conducted 11/27/17).

parts). After the CHIPRA¹⁸ tax increases of 2009, a number of tobacco product retailers invested in commercial cigarette-producing machines to help drive down the cost of cigarettes and increase profits by allowing consumers to produce their own cigarettes in retail locations. It is possible that machines like these could see a resurgence in popularity after an FDA tobacco product standard, and be used to produce larger quantities of illicit tobacco products. However, current federal tax law designates a proprietor of these machines in a retail setting to be a “manufacturer of tobacco products,” and imposes certain taxation and permit requirements based on this activity (TTB is responsible for the enforcement of these requirements).¹⁹ Therefore, it is unclear the extent to which such an investment would be worthwhile, given the dual risks of enforcement by FDA and by TTB for being an unregistered and untaxed manufacturer.²⁰

Large, commercial, tobacco product manufacturers have the resources, sophistication, and ability to manufacture illicit tobacco products. It is unclear, however, to what extent such manufacturers would be willing to risk their businesses (and resulting profits) by manufacturing illicit tobacco products. Due to regular FDA inspections of facilities and records,²¹ it is unlikely that such activity would continue undetected for a significant period of time.²²

Tribal manufacturers are an additional source of tobacco products, having relatively high sophistication and machinery in some instances, but usually lacking widespread distribution and sales capabilities. Although a tobacco product standard would apply to tribal-affiliated entities and on tribal lands, some individuals may attempt to exploit the unique nature of tribal lands for the purposes of illicit trade. While it seems plausible that tribes could initially engage in illicit manufacturing and sales relatively easily, existing FDA enforcement tools seem sufficient to end the practice, much like with large manufacturers. Tribes would also be subject to the same disincentives of large manufacturers, such as not wanting to risk their existing business, and the likely negative attention that would occur.

C. Other products used to evade FDA tobacco product standards

The extent to which retailers and consumers can modify legal products into illicit products will depend upon the particular product standard in question. For example, with a standard limiting nicotine levels in a tobacco product, there may be components, parts, or accessories, as well as

¹⁸ Children’s Health Insurance Program Reauthorization Act of 2009, Pub. L. 111-3, 123 Stat 8. Among other things, the law made the tax rates equivalent for cigarettes, roll-your-own tobacco, and small cigars. While it also increased the tax rate for pipe tobacco, the rate remains significantly lower than the other products, leading some manufacturers and retailers of roll-your-own tobacco to market such product as pipe tobacco to reduce overall costs.

¹⁹ Moving Ahead for Progress in the 21st Century Act, Pub. L. 112-141, section 100122, codified in relevant part at 26 U.S.C. § 5702.

²⁰ “Ongoing Enforcement in Connection with Cigarette-Making Machines,” Alcohol and Tobacco Tax and Trade Bureau (TTB), available at <http://www.ttb.gov/announcements/ttb-announcement-ongoing-enforcement-in-connection-with-cigarette-making-machines.pdf> (last accessed 11/27/17). The machines generally cost around \$35,000. “RYO Cigarette Machines Get a New Life?” CSPnet.com, available at <http://www.cspnet.com/category-news/tobacco/articles/ryo-cigarette-machines-get-new-life> (last accessed 11/27/17).

²¹ § 905(g). FDA is required to conduct inspections of registered establishments at least biennially.

²² Lauren Ohnesorge, “N.C. Claims \$2.2M in Illegal Cigarette Settlement After Fight with Feds,” Triangle Business Journal, December 30, 2014, available at <http://www.bizjournals.com/triangle/news/2014/12/30/nc-claims-2-2m-in-belcorp-tobacco-settlement.html> (last accessed 11/27/17).

non-tobacco products, which could be used to supplement the nicotine levels. For example, if e-cigarettes and concentrated e-liquids are not subject to that same product standard, and remain easy to purchase with higher nicotine concentrations, it may not require significant effort to add the liquid to a cigarette or other combusted product. While a nicotine product standard might contain provisions restricting the sale of such products, it is possible that a workaround would exist. Regardless of whether this results in a palatable product, it is illustrative of the experiments consumers may conduct in seeking to obtain more nicotine.

However, if a different product standard were to require a reduction of a harmful constituent in cigarette smoke, it is possible that manufacturers could comply with such standard through the use of a particular type of filter built into the cigarette. In that instance, it is unlikely that a consumer would be able to add an otherwise legal component, part, or accessory to the product to subvert the standard. Instead, it would require a different modification, such as destroying or removing the filter, or removing the tobacco and smoking it using a different mechanism. An important reminder is that if the product standard has little impact on the “experience” of the individual product or if an acceptable legal alternative exists, there will be little or no incentive for consumers to attempt to subvert it.

D. Distribution of illicit tobacco products

Tobacco product manufacturers (defined by the FD&C Act to include importers) may be subject to enforcement action if they import tobacco products that are not in compliance with FDA product standards.²³ Depending upon the source of the illicit products, there may be two separate issues for someone attempting to move illicit tobacco products: importation of the products (for those not manufactured domestically) and distribution within the United States. There would be different considerations for each.

There are various regulations and restrictions on the importation of consumer products into the United States.²⁴ FDA’s Office of Regulatory Affairs, Division of Imports, oversees importation of FDA-regulated products but does not have resources to inspect every entry. Although field officers work with multiple enforcement tools and systems to assist them in their task, a one hundred percent physical inspection rate for all products is not feasible. There is also a small customs allowance for travelers returning to the U.S. to bring small amounts of tobacco products back for personal use, though it is unclear whether it is possible to manipulate this allowance on a large scale, or whether importation of illicit tobacco products through this channel is possible on any scale.²⁵

²³ § 801(a)(3), and generally § 902 and § 903.

²⁴ U.S. Customs and Border Protection (CBP), Department of Homeland Security, “Importing into the United States: A Guide for Commercial Importers,” available at

<http://www.cbp.gov/sites/default/files/documents/Importing%20into%20the%20U.S.pdf> (last accessed 11/27/17).

This document highlights many requirements of importers, including some requirements and restrictions on the importation of tobacco products. For example, it notes that import permits must be obtained from TTB for the legal importation of tobacco products except in certain circumstances, and that other restrictions are placed on cigarette importers by laws such as Title IV of the Tariff Suspension and Trade Act, Pub. L. 106-476 (2000).

²⁵ U.S. Customs and Border Protection (CBP), Department of Homeland Security, “Traveler Bringing Tobacco Products (Cigarettes, Cigars, Bidis) to the U.S. for Personal Use,” available at

https://help.cbp.gov/app/answers/detail/a_id/53/~traveller-bringing-tobacco-products-%28cigarettes%2c-cigars%2c-

Distribution of cigarettes and smokeless tobacco products using common carriers or the U.S. Postal Service is prohibited after the implementation of the Prevent All Cigarette Trafficking (PACT) Act,²⁶ which was designed to help reduce the movement of illicit (tax evading) trade in tobacco products. Among other things, it made certain tobacco products nonmailable matter by USPS and codified voluntary agreements made by the major common carriers. However, there are anecdotal reports and occasional state enforcement actions suggesting tobacco products are still shipped to consumers regularly.²⁷ This may be related to limited enforcement resources rather than a lack of authority.

Evading reporting requirements and other regulations typically only requires disguising a shipment: either by misreporting the contents of packages and containers,²⁸ hiding illicit products within otherwise legitimate shipments, or exploiting apparent loopholes in systems such as the in-bond customs mechanism.²⁹

Further, “gray market” trade could emerge as a source of illicit products. For the purposes of this paper, “gray market” trade is where a domestic manufacturer produces a product for export, but during the movement of the product (whether it is still within U.S. borders or has been exported) it is returned and sold domestically. The impetus for doing so is that it is often cheaper: the products lack the standard manufacturer markups of domestic products.³⁰ While “gray market” trade largely disappeared from the U.S. when domestic tobacco manufacturers legally separated from their international counterparts, the ability to continue manufacturing tobacco products for export is legal. Domestic manufacturers are legally permitted to manufacture a nonconforming tobacco product for export, so long as such product meets the destination purchaser specifications, is not in conflict with the requirements of the destination country’s laws, is labeled for export, and is not sold or offered for sale domestically.³¹ This type of manufacturing and shipping provides opportunities to divert those products into domestic commerce.

E. Development of consumer awareness of illicit trade

[bidis%29-to-the-u.s.-for](#) (last accessed 11/27/17). Travelers generally may bring 100 cigars and 200 cigarettes into the U.S. without paying duty or taxes, depending upon the originating location.

²⁶ Pub. L. 111-154 (2010), 124 Stat 1087.

²⁷ Dareh Gregorian, “FedEx Hit with \$235 Million Lawsuit from Attorney General Eric Schneiderman for Shipping Untaxed Cigarettes,” New York Daily News, March 30, 2014, available at <http://www.nydailynews.com/new-york/fedex-hit-235m-lawsuit-shipping-untaxed-cigarettes-article-1.1739975> (last accessed 11/27/17).

²⁸ “Revenue Seizes 7.7m Cigarettes in Container Concealed as ‘Breakfast Cereals,’” Irish Independent, January 23, 2015, available at <http://www.independent.ie/irish-news/news/revenue-seizes-77m-cigarettes-in-container-concealed-as-breakfast-cereals-30925770.html> (last accessed 11/27/17).

²⁹ The in-bond system allows goods to enter the U.S. and be transported to another port of entry to be formally processed or sent to another country (rather than being processed at the first port of entry and pay relevant duties there). However, there are indications that the system is relatively easy to exploit for the purposes of illicit trade. U.S. Government Accountability Office (GAO), “International Trade: Persistent Weaknesses in the In-Bond Cargo System Impede Customs and Border Protection’s Ability to Address Revenue, Trade, and Security Concerns,” April 2007.

³⁰ “Philip Morris Fails to Halt ‘Gray Market’ Cigarette Sales,” Los Angeles Times, April 12, 2000, available at <http://articles.latimes.com/2000/apr/12/business/fi-18739> (last accessed 11/27/17).

³¹ § 801(e)(1).

No matter the mechanism for producing, distributing, and selling illicit tobacco products after an FDA product standard is effective, any illicit trade market will require not only consumer demand, but knowledge of product availability, in order to be successful. Whereas current illicit trade markets are based entirely on financial (tax avoidance) motivations and thus, consumers can unknowingly purchase tobacco products that are illicit because taxes have not been paid, this likely will not be the case with tobacco products intentionally not conforming to a product standard. Rather, these likely will be products that consumers are actively seeking because of a certain characteristic. Illicit trade sellers may not attempt to sell to unsuspecting consumers because they run a higher risk of being reported to authorities when consumers realize the products are illicit (though, as discussed later, consumer behavior is difficult to predict). Sellers may also elect to price the products higher than comparable legal products to reflect the risks they undertake (issues of price are discussed later), which consumers would notice. Consumer reporting of illicit products is more likely in cases where the products have other defects or are poorly manufactured, as well as being illicit.³² There may also be illicit products masquerading as legal ones that consumers report to the legitimate manufacturers. For instance, a seller may create a label for the illicit product that mimics a well-known brand, resulting in consumers contacting the legitimate manufacturer when there are problems. Major domestic tobacco product manufacturers have their own investigative resources, usually employed when they perceive a need to protect the value of their brand and other intellectual property.³³

There are a variety of ways in which consumers might find out about the availability of illicit tobacco products. One of the most obvious methods is via the internet – a simple search is likely to reveal websites offering illicit products, as well as online forums, discussion groups, and bulletin boards where people might post information. This includes well-established non-tobacco websites that allow individual postings, such as craigslist or Facebook,³⁴ as well as websites that are created solely for illicit tobacco products. Additionally, if the existence of illicit tobacco products rises to the attention of news agencies, it is possible that news outlets, whether online, radio, print, or TV, might report on the ways in which consumers are acquiring the products.

Word-of-mouth is another likely option for consumers to find illicit products. Whether they are sold on the street, online, or via other means, consumers will likely discuss the opportunities with friends and family looking for similar products.

F. Sales of illicit tobacco products

The actual sale of illicit products would likely happen in one of two ways: online or person-to-person (e.g., street, tribal, international/duty free, gifts from family/friends). There is also the possibility of other types of sales, such as via mail order or phone, but given the widespread

³² Lee Moran, “Fake Cigarettes Containing Human Feces, Rat Droppings Flood British Market: Report,” New York Daily News, November 11, 2014, available at <http://www.nydailynews.com/news/world/fake-cigarettes-human-feces-hit-uk-market-report-article-1.2006457> (last accessed 11/27/17).

³³ “Combating Illicit Trade,” Altria, available at <http://www.altria.com/Responsibility/Combating-Illicit-Trade/Pages/default.aspx?src=topnav> (last accessed 11/27/17).

³⁴ Keith McLeod, “Sick Crooks Push Cheap Cigarettes on Facebook Laced with Potentially Life-Threatening Chemicals,” Daily Record, November 19, 2014, available at <http://www.dailyrecord.co.uk/news/crime/sick-crooks-push-cheap-cigarettes-4658440> (last accessed 11/27/17).

availability of and easy access to the internet in most of the United States, as well as existing prohibitions on use of the Postal Service and Common Carriers for shipment of tobacco products, these sales seem unlikely. It is also likely that the probability that consumers will seek to purchase illicit tobacco products online versus person-to-person will depend on geography.

For example, in a large, dense urban setting like New York City, a relatively significant portion of cigarette sales are tax evading (and thus illicit), and many of those sales occur on street corners or in retail settings.³⁵ Conversely, in a rural part of the country such sales might be less common because of the relatively low volume of sales and easy detectability by law enforcement. It is likely that illicit trade following a tobacco product standard would follow a similar pattern, and those living in areas that cannot support street sales in large numbers would be more likely to purchase any illicit tobacco products from online retailers.

While manufacturers and retailers on tribal lands would be subject to FDA enforcement of a tobacco product standard, some tribally-affiliated firms assert a different understanding as to the relationship between federal government authority and their self-governance.³⁶ Thus, initially, there may be a few tribally-affiliated manufacturers that offer illicit tobacco products for sale openly (or through word-of-mouth, the internet, etc.).

There are other market areas with interesting questions of applicability that may require further analysis or action to prevent unintentional loopholes. For example, it may be possible that duty-free locations will continue to sell tobacco products that do not meet the product standard, which would provide an avenue for relatively easy movement of illicit products into the U.S. for further sale (or distribution as gifts).³⁷

IV. Potential consumer behaviors in response to an FDA tobacco product standard

A. Overall consumer behavior

It is expected that if a product standard is implemented that changes the user “experience” of a tobacco product category, many users will either quit using tobacco or switch to a new tobacco product (if one exists that can satisfy the demand). The increase in consumer demand for other products will likely be met by the tobacco industry, which has a history of being nimble and responsive to market shifts. Many tobacco product companies have been expanding their portfolios over time to include new products. For example, the portfolio expansions for

³⁵ Christopher Mathias, “Inside New York City’s Dangerous, Multimillion-Dollar Cigarette Black Market,” Huffingtonpost.com, April 3, 2014, available at http://www.huffingtonpost.com/2014/04/03/cigarette-smuggling-new-york- n_5041823.html (last accessed 11/27/17). Illicit sales by otherwise legitimate retailers have been reported in other major cities, as well. Linda Stewart, “Bootleg Cigarettes Containing Asbestos on Sale in Belfast,” Belfast Telegraph, November 26, 2014, available at <http://www.belfasttelegraph.co.uk/news/local-national/northern-ireland/bootleg-cigarettes-containing-asbestos-on-sale-in-belfast-30775111.html> (last accessed 11/27/17).

³⁶ Associated Press, “Despite Law, Tribe Sells 1.7 Tons of Cigarettes Online,” New York Post, December 12, 2013, available at <http://nypost.com/2013/12/02/despite-law-tribe-sells-1-7-tons-of-cigarettes-online/> (last accessed 11/27/17).

³⁷ U.S. Government Accountability Office (GAO), “Duty-Free Cigarettes Sold in Unlimited Quantities on the U.S.-Mexico Border Pose Customs Challenges,” October 2017.

companies who were traditionally cigarette manufacturers began when restrictions on where smokers could smoke were put in place in the 1980s, 1990s, and early 2000s. During this time many companies began to enter the smokeless tobacco market.³⁸ More recently, with the advent of electronic cigarettes and other ENDS, the tobacco industry has once again responded to the changing market by acquiring many of the leading electronic cigarette companies.³⁹

However, it is expected that there will still be a subset of consumers uninterested in switching products or in quitting tobacco products altogether, as well as those who believe they are unable to switch or quit. Discerning the reason for their product or brand loyalty is unnecessary for the purposes of this discussion; the result is that these individuals may seek tobacco products from an illicit market after a standard is in place. There is no way to determine with certainty the prevalence and extent to which an illicit market will occur after any particular tobacco product standard is in place, nor how long such a market might be sustainable. However, there are factors that may influence whether and to what degree an illicit market may develop (using a nicotine product standard as an example), such as:

- The presence and use of legal alternative products, such as very low nicotine content (VLNC) cigarettes whose nicotine content is approaching or equivalent the limit proposed in a standard;
- The demand for cigarettes at various income levels and cigarette prices; and
- Consumer illicit market motives, facilitators, and buying behavior.⁴⁰

B. Illicit market buying behavior

Cigarettes have been the primary product studied in relationship to illicit tobacco product buying behavior, so they are the product discussed here, though this analysis may well apply to other tobacco products as well. Illicit cigarettes can be smuggled/bootlegged or fake/counterfeit. Smuggled/bootlegged cigarettes are legally manufactured but illicit because of where and how they are sold (usually without taxes paid, or without the proper markings and health warnings for that jurisdiction). Fake/counterfeit cigarettes are illegal for failing to comply with laws and regulations in the jurisdiction where they are sold in regards to manufacture, or because they illegally imitate a legal product (or both).

Currently, smuggled/bootlegged cigarettes are often purchased from friends and family, though the research does not conclusively indicate where those sources initially obtained the illicit

³⁸ Carpenter, C. M., Connolly, G. N., Ayo-Yusuf, O. A., & Wayne, G. F. (2009). Developing smokeless tobacco products for smokers: an examination of tobacco industry documents. *Tobacco Control*, 18, 54-59.

³⁹ Bullen, C. (2014). Electronic Cigarettes for Smoking Cessation. *Curr Cardiol Rep*, 16, 1-8.

⁴⁰ There are other ways to describe and illustrate the factors supporting or opposing the development of illicit trade in tobacco products. See, e.g., National Research Council and Institute of Medicine (2015). *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences*. Committee on the Illicit Tobacco Market: Collection and Analysis of the International Experience, P. Reuter and M. Majmundar, Eds. Committee on Law and Justice, Division of Behavioral and Social Sciences and Education and Board on Population Health and Public Health Practice, Institute of Medicine. Washington, DC: The National Academies Press. Figure 1-1.

cigarettes.⁴¹ Should an individual with family members, friends, or coworkers who use tobacco products discover a relatively easy and low-risk avenue by which to obtain illicit tobacco products, it is likely to assume that they will continue to make use of it and provide the product (or information about the illegal channel) to others for their use. Conversely, fake/counterfeit cigarettes are more often associated with organized crime and street sellers – generally not an easy and low-risk avenue for access – though in certain instances, street sellers also sell commercially manufactured cigarettes that have been diverted from legal channels.⁴²

Discomfort with illicit tobacco influences consumer buying behavior.⁴³ The sale of illicit tobacco is mostly from acquaintances and strangers (as opposed to family and friends).⁴⁴ There are two types of buyers: opportunistic and seeker smokers. Each has a unique profile and buying characteristics. Opportunistic buyers are regular tobacco users who are more uncomfortable with illicit tobacco. They tend to have a distant relationship with the seller, viewing them more as a stranger than as an acquaintance. Seekers are heavier tobacco users who are comfortable with illicit tobacco. Seekers perceive the availability of a product as an enabler to allow them to smoke.⁴⁵

According to a 2013 survey of adults in the United Kingdom, twenty percent of illicit buyers will always purchase illicit tobacco when offered by a seller. On the other hand, eighty percent are open to other factors influencing their decision. Leading factors include:

- Illicit tobacco not tasting right;
- Illicit tobacco not always being available; and
- Uncertainty about what illicit tobacco products contain.

Only one percent of current U.K. smokers offered illicit tobacco reported considering the illegality of the purchase in their decision making.⁴⁶

Convenience and availability are drivers in illicit tobacco prevalence and market composition. In the United Kingdom, the three main venues of illicit tobacco sales are pubs/clubs, private residential addresses, and shops.⁴⁷

C. Research on VLNC cigarettes

Returning to the example of a product standard that limits the presence of nicotine in cigarettes, there have been some efforts to study the behaviors of consumers exposed to VLNC cigarettes. Some of the current literature on VLNC cigarettes is comprised of studies with participants who are interested in quitting smoking. For the purpose of estimating the illicit market after a product

⁴¹ LACORS (2010). *Illicit Tobacco: An introductory guide for enforcement agencies*. London, United Kingdom.

⁴² *Id.*

⁴³ LACORS (2010). *Illicit Tobacco: An introductory guide for enforcement agencies*. London, United Kingdom.

⁴⁴ NEMS Market Research (2013). *North East Illicit Tobacco Survey 2013, Executive Summary*. Billingham, United Kingdom.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

standard, these studies may not provide a complete picture, as they do not include the segment of the population uninterested in quitting smoking. These individuals might be resistant to change and likely candidates to seek out illicit cigarettes, though it is expected to be a minority of the smoking population.⁴⁸

It is noteworthy that participants in the studies described below often were non-compliant with the study protocols, smoking their usual commercially-branded cigarettes during the study. These studies also often had high attrition rates. Both non-compliance and attrition from the studies, especially in participants uninterested in quitting, may indicate that they were unable to tolerate the reduction in nicotine (though the easy access to legal, high-nicotine cigarettes also likely played a role). The research studies discussed below include results dealing with non-compliance and attrition rates.

Rezaishiraz et al., (2007) explored cessation rates associated with denicotinized cigarettes and nicotine replacement therapy (NRT).⁴⁹ Whether or not participants were interested in quitting was not described. For two weeks prior to the quit date, participants were randomized to receive denicotinized cigarettes (Quest, 0.05 mg nicotine yield; 0.4 mg/cigarette nicotine content) plus the 21 mg nicotine patch or “light” cigarettes (Quest, 0.6 mg nicotine yield; 8.9 mg/cigarette nicotine content). After the quit date, all participants received progressively lower NRT patches and behavioral treatment for up to eight weeks. At three and six month follow-ups, self-reported quit rates did not differ between the two groups, although these data were not biochemically confirmed. The study ended up with a small sample size (ninety-eight participants) from the original 150 people screened, due to a loss of nearly one-third who were unable to remain smoke-free for a minimum of twenty-four hours after the study designated quit date. Additionally, of the twenty-one participants who reported not smoking any cigarettes in the seven days prior to the six-month follow up, eight did not send in the requested biological sample to confirm this self-report. Of the thirteen who did send in samples, ten had salivary cotinine (a metabolite of nicotine) levels which indicated tobacco use and non-compliance.

A 2013 Hatsukami et al. publication detailed a two-week study where participants were allowed to smoke their own cigarettes for one week (control) and then randomized into three groups which received Spectrum research cigarettes that were either low nicotine (LN; <0.04 mg yield; 0.4 mg/g nicotine content), intermediate nicotine (IN; 0.3 mg yield; 5.7-5.8 mg/g nicotine content), or high nicotine (HN; 0.6 mg yield; 11.4-12.8 mg/g nicotine content) for an additional test week.⁵⁰ The participants (fifty-two total) had no plans to quit or reduce their tobacco use. The aim of this study was to determine whether these research cigarettes with varying nicotine yields would produce a dose-response effect on smoking behavior. Cigarettes per day were recorded by the participants in a daily smoking diary and results indicated that the LN group smoked fewer experimental cigarettes than those in the HN group during the test week.

⁴⁸ In 2015, 68% of adult cigarette smokers reported wanting to quit and 55.4% had made a quit attempt in the past year. Centers for Disease Control and Prevention, “Smoking & Tobacco Use,” available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm (last accessed 11/27/17).

⁴⁹ Rezaishiraz, H., Hyland, A., Mahoney, M. C., O'Connor, R. J., & Cummings, K. M. (2007). Treating smokers before the quit date: can nicotine patches and denicotinized cigarettes reduce cravings? *Nicotine Tob Res*, 9, 1139-1146.

⁵⁰ Hatsukami, D. K., Heishman, S. J., Vogel, R. I., Denlinger, R. L., Roper-Batker, A. N., Mackowick, K. M. et al. (2013). Dose-response effects of spectrum research cigarettes. *Nicotine Tob Res*, 15, 1113-1121.

Compared with the first control week, the HN group smoked more during the test week. When looking at biomarkers indicative of compensation, the researchers found higher carbon monoxide (CO) levels and urinary cotinine in the HN and IN group than in the LN, likely reflecting the group's reduction in cigarettes per day. This study explicitly asked participants to report the number of own-brand cigarettes smoked during the course of the study to record non-compliance. In the LN group they had five participants who reported non-compliance, including one who only reported smoking own-brand cigarettes, and none of the experimental cigarettes throughout the study. In the IN group, four participants reported non-compliance and in the HN group, two participants reported non-compliance during the treatment week. The increase in non-compliant participants (in each progressively lower nicotine content group) suggests that non-compliance was possibly connected to the nicotine levels; however, the authors did not mention whether these results were significantly different. Overall, eleven of the fifty-two participants reported non-compliance.

Finally, Donny et al. assessed the effects of smoking cigarettes containing different levels of nicotine in participants who were not interested in quitting.⁵¹ After a baseline period, participants were randomly assigned one of seven types of cigarettes to smoke for the following six weeks: two types of control cigarettes and five with varying nicotine levels (from 2% to 33% of the nicotine in the control cigarettes, or 0.4-5.2 mg/g). Data were then collected from the 839 participants, of which 780 completed the full six week study. Of significance here, the participants who were assigned the cigarettes with the lowest nicotine levels (0.4-2.4 mg/g) smoked significantly fewer cigarettes per day (14.9-16.5) than those who smoked cigarettes with higher nicotine levels (20.8-22.2), and had significantly lower urinary total nicotine equivalents. This reduction is despite participants in the low-nicotine groups reporting use of non-study, full-nicotine cigarettes on 15-35% of the study days. Although participants were provided study cigarettes at no cost and were asked to refrain from smoking non-study cigarettes, there was no disincentive for doing so. Additionally, 30 days after the study, participants assigned to the study cigarettes with the lowest nicotine level (0.4 mg/g) reported significantly higher rates of quit attempts (34.7%) than those assigned to higher nicotine levels (17% of those smoking the cigarettes with 15.8 mg/g, for example). This study suggests that certain low levels of nicotine in cigarettes might decrease smoking rates and increase quit attempts, even when, as here, full-nicotine cigarettes are easily accessible.

D. Comparators: prisons and the prohibition era

When considering the development of illicit markets after a tobacco product standard, two situations are often mentioned for comparison: prisons and prohibition of alcohol in the United States. They will be addressed briefly in turn.

While it is possible that there will be similarities between the black market that may develop around illicit cigarettes after a product standard and the current illicit trade in cigarettes in prisons where cigarette use is limited or banned, there are significant differences between the situations. A study of sixteen jails and prisons across the U.S. detailed the motivation of the

⁵¹ Donny, E.C., Denlinger, R.L., Tidey, J.W. et al. (2015). Randomized trial of reduced-nicotine standards for cigarettes. *N Engl J Med*, 373, 1340-1349.

members involved in the illicit trade in cigarettes in these facilities.⁵² To those involved in the illicit market, cigarettes represented a unique commodity. Although illicit within the prison, cigarettes were obtained legally outside the prison at no risk to their associates. Cigarettes were obtained at much lower costs than illegal drugs, such as heroin, which are illegal both inside and outside the prison. Facility officers and staff did not find cigarettes to be immoral or dangerous, and many of them were smokers themselves. As a result, they did not always monitor it with the same vigilance as other trade, and the researchers often found that many of the officers admitted to participating in the cigarette black market. Thus, despite the reduction in availability of cigarettes and the higher cost to obtain them (compared to the general population), generally there remained a sufficient supply to maintain steady consumption levels. For example, although one prison, after implementing a more restrictive tobacco policy, saw a reduction in numbers of cigarettes consumed by inmates decline from approximately 30 cigarettes per day to 5-10 per day, the steady demand suggested this lower amount was still sufficient to support addiction by some inmates.⁵³ While a lower volume of illicit cigarettes appeared sufficient to maintain addiction in this instance, it is unclear whether even this reduced supply would be possible to maintain if cigarettes were also restricted outside the prison.

The modification of cigarettes in prisons and jails has also been discussed, and although it could indicate the potential for adulterations of cigarettes in the illicit market once a tobacco product standard were in place, the motivations were quite different. In order to make the cigarettes go further and increase profit margins, cigarettes were often broken down from one stick into two, for example. Also, consumers of whole cigarettes in prisons often tried to increase their exposure to the limited product (i.e., the nicotine that supported their addiction) by removing the cigarette's filter. This leads to increased exposure to the toxic constituents of the cigarette, as well.⁵⁴ It may be that in the face of a tobacco product standard, some of these tactics might be employed.

Whether such behavior by consumers would be part of an illicit market after implementation of a tobacco product standard is unknown, but there are some critical differences between the situations that counsel against assuming too close a comparison. While cigarettes can be used as currency in prisons, it is hard to imagine such value would be placed on them in non-prison settings, suggesting they would carry a much lower value, and thus, demand. Additionally, the very individuals responsible for enforcing cigarette bans in prisons are often complicit in smuggling them into the facilities (purchased from readily available, legal retailers), which is unlikely to occur under the model of enforcement that would take place after an FDA tobacco product standard.

Similarly, despite the widespread illegal alcohol production during the prohibition era, caution is warranted when making a comparison to illicit tobacco products. While illegal alcohol was produced in tremendous quantities, and thus it may be appealing to assume that illicit trade in tobacco products would mirror that of "moonshine," there are some notable differences. First, in addition to alcohol likely being more socially acceptable and less stigmatized, it is relatively easy

⁵² Lankenau, S.E. (2001). Smoke 'Em If You Got 'Em: Cigarette Black Markets in U.S. Prisons and Jails. *Prison J.*, 81, 142-161.

⁵³ *Id.*

⁵⁴ *Id.*

to make with cheap, widely available ingredients, and equipment that can be constructed with basic parts from a hardware store.⁵⁵ Second, the ease of production makes it possible to rapidly scale up (or down) production on a relatively minor physical footprint, which helps evade detection. Third, illegal alcohol production does not have the same climate and agricultural requirements as tobacco, as it can be made with a variety of grains grown in many different regions, while tobacco plants are limited to certain areas. Finally, during prohibition, all alcohol production for human consumption was banned, and the only source of it was through illegal production. An FDA tobacco product standard would not ban all tobacco products or even all cigarettes, and alternative sources of tobacco would remain legal. Moreover, cessation support and other sources of nicotine, such as nicotine replacement therapy (NRT) products and ENDS would remain available.

V. Price of illicit cigarettes

The majority of research in the area of illicit trade in cigarettes focuses on the trade of cigarettes purchased in areas with lower cigarette prices and sold in higher priced markets. The main stimulus for this illicit trade is the lower cost of cigarettes, and it makes it difficult to use data on such scenarios to predict future illicit markets where the price of illicit products is unknown. However, price will be relevant to some degree in any future illicit market, either encouraging or discouraging consumers to purchase the products.

A. Factors affecting the price of illicit cigarettes

The price of illicit cigarettes (still using the scenario of a nicotine standard as an example) is likely based upon the following components:

- The costs to manufacture and distribute;
- The absence of taxes; and
- Consumer response (e.g., quitting among smokers, demand for illicit full-nicotine cigarettes, demand for legal low-nicotine cigarettes, and demand for other legal nicotine-containing products).

The costs of manufacturing and distributing illicit cigarettes after a standard is implemented would likely be higher than the costs to manufacture and distribute current legal cigarettes. Illicit cigarettes would likely be produced on a smaller scale to avoid detection by law enforcement, and there are very large economies of scale in tobacco manufacturing.⁵⁶ In addition, there would be transaction or search costs for consumers and sellers associated with taking part in illegal activity. However, illicit cigarettes would incur no taxes; that is, these cigarettes necessarily

⁵⁵ Oklahoma Historical Society, “Moonshine,” available at <http://www.okhistory.org/publications/enc/entry.php?entry=MO013> (last accessed 11/27/17).

⁵⁶ For example, at least one domestic facility is capable of producing 20,000 cigarettes *per minute*. John Reid Blackwell, “Cigarette Making Still Going Strong in South Richmond,” Richmond Times-Dispatch, August 30, 2013, available at http://www.richmond.com/business/manufacturing/cigarette-making-still-going-strong-in-south-richmond/article_27bad786-788e-570a-b837-b008519c1c39.html (last accessed 11/27/17).

would be produced and sold outside of all legal channels.⁵⁷ One significant uncertainty remains: the consumer response. For example, the price of illicit cigarettes would be impacted by how many consumers would participate in an illicit full-nicotine cigarette market, how many would quit tobacco use entirely, how many would use VLNC cigarettes, and how many begin using other legal tobacco or nicotine-containing products.

The future price of illicit full-nicotine cigarettes relative to the future price of legal VLNC cigarettes cannot be predicted with certainty. It requires consideration of: (1) the future price of illicit full-nicotine cigarettes compared to the current price of legal full-nicotine cigarettes, and (2) the future price of legal VLNC cigarettes compared to the current price of legal full-nicotine cigarettes. Neither comparison can be made with confidence at this time due to the following factors:

(1) The price of illicit cigarettes will depend on the relative size and importance of each factor in determining the supply and demand for full-nicotine cigarettes. For example, if manufacturing costs are much higher and many consumers choose to participate in the illicit market, then the price of illicit full-nicotine cigarettes may be higher than the price of currently legal full-nicotine cigarettes (and may compensate for the lack of taxation of illicit products). However, if costs to manufacture and distribute are low, no taxation takes place, and consumers seek legal nicotine substitutes, then the price of illicit full-nicotine cigarettes would likely be lower than currently legal full-nicotine cigarettes.

(2) Similarly, the future price of legal VLNC cigarettes will depend on the costs to manufacture and distribute, as well as the consumer response to the products. Legal VLNC cigarettes will be subject to cigarette excise taxes and all other costs associated with regulatory requirements.

B. Data comparing legal and illicit products

As discussed previously, there is great uncertainty about the price of legal VLNC cigarettes compared to legal full-nicotine cigarettes (and to illicit full-nicotine cigarettes, obviously, since the product standard being used as an example does not exist to render them illicit). This section discusses data that compares the *same product* sold both legally and in the illicit market, since there are some data available, and since other factors that may affect price can be held constant in some instances. There are some potential sources of data that meet these criteria, each with flaws preventing an ideal comparison.

There are studies of the price of illicit drugs. However, most of these products have no legal counterpart, so it is not possible to determine how the illicit price would compare to the price paid if these products were legal. When it comes to potentially addictive prescription drugs (such

⁵⁷ For a full explanation of the various taxes and fees that may be evaded at different points in the supply chain, see, e.g., National Research Council and Institute of Medicine (2015). *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences*. Committee on the Illicit Tobacco Market: Collection and Analysis of the International Experience, P. Reuter and M. Majmundar, Eds. Committee on Law and Justice, Division of Behavioral and Social Sciences and Education and Board on Population Health and Public Health Practice, Institute of Medicine. Washington, DC: The National Academies Press. Table 1-1.

as painkillers), where there is both a legal and an illegal market, there are some data, mostly anecdotal, regarding the price of the illegal version and some indicators of demand.⁵⁸ However, prices for legal versions are difficult to obtain and are heavily influenced by health insurance and drug companies, muddying comparisons.

The sale of legal recreational marijuana in Colorado and Washington began relatively recently, so these policies are too new for there to be published peer-reviewed journal articles. But there are articles by investigative reporters comparing the legal and illegal prices for this product.⁵⁹ Data from the International Business Times suggests that the black market price is approximately fifty percent of the legal price charged at dispensaries for recreational marijuana.⁶⁰ This may be a result of the illegal version of the product not being subject to taxes, reduced manufacturing and regulatory costs, no quality control costs, and/or lower demand for the illicit product. While there may be some cross-jurisdictional data available (such as the price of illicit marijuana in a state where recreational marijuana is legal, such as Washington or Colorado, compared to the price of marijuana in a state where it is not legal), it would be difficult to account for possible differences in social or law enforcement attitudes, among other factors.

A report by Statistics Canada on the underground economy estimates that a carton of black market cigarettes can be sold for as little as thirty percent of the legal retail price. The same report estimates that illicit alcoholic beverages sell for sixty percent of the legal pre-tax price.⁶¹ This price differential may be attributable to the tax difference between the two products, and also to lower demand for illegal products (which may not be the case in all illegal markets).

It is not possible to create a direct estimate of the price of illicit full-nicotine cigarettes compared to the price of legal low-nicotine cigarettes after a product standard, as there are far too many factors that cannot currently be measured. However, based on the above, there is some indication that legal low-nicotine products could sell for more than illicit – and therefore untaxed – cigarettes. It is also possible that other factors, such as economies of scale in production, enforcement risks, and lower volumes of raw materials could result in the reverse outcome.

C. Potential impacts of differences in price between products

Regardless of the price of illicit tobacco products, there is evidence that the likelihood of a consumer obtaining cigarettes from the illicit market would be unevenly distributed according to socioeconomic status. Unlike the current illicit trade in cigarettes, which is driven by the ability to buy cigarettes at a reduced price on the black market, the black market that might develop

⁵⁸ Narcotic painkillers, such as OxyContin, can sell illegally for upwards of \$1 per mg, or \$80 for a single 80mg pill, according to anecdotal reports. Donna Leinwand Leger, “OxyContin a Gateway to Heroin for Upper-Income Addicts,” USA Today, June 28 2013. <http://www.usatoday.com/story/news/nation/2013/04/15/heroin-crackdown-oxycodone-hydrocodone/1963123> (last accessed 11/27/17).

⁵⁹ Walt Hickey for FiveThirtyEight Life. “Medical Marijuana is Still the Best Deal on Pot in Colorado.” <http://fivethirtyeight.com/features/medical-marijuana-is-still-the-best-deal-in-colorado/> (last accessed 11/27/17).

⁶⁰ International Business Times. “Marijuana Costs in the US: How Black Market, Retail and Medical Pot Prices Compare.” July 8, 2014. <http://www.ibtimes.com/marijuana-costs-us-how-black-market-retail-medical-pot-prices-compare-1622362> (last accessed 11/27/17).

⁶¹ Statistics Canada. “The Underground Economy in Canada, 1992 to 2011.” Income and Expenditure Accounts Technical Series, pg. 36 fn 49.

after a nicotine standard were put in place might involve significant consumer demand, higher manufacturing costs, or other yet-unknown factors, and any number of factors could be operating at the same time. Koffarnus et al. investigated the effect that change in price has on cigarette consumption at different simulated socioeconomic levels.⁶² The principle being investigated was the behavioral economic demand for cigarettes at various simulated income levels and cigarette prices. In this study, participants were asked to estimate how many study cigarettes at various prices they would be willing to buy with different weekly budgets for cigarettes. They were then randomly assigned one of these estimated numbers of study cigarettes to smoke for the week. The participants were allowed to keep any money that was not spent on study cigarettes for that week, but were asked to smoke only the study cigarettes. The study found that the weekly budget available to purchase the cigarettes had a large effect on cigarette consumption when the cigarettes were more expensive. Those who had a larger budget were willing to continue to buy the cigarettes as they increased in price, although overall, as the cigarettes increased in price, demand dropped off.

This research suggests that higher income consumers are likely to be willing to continue to buy illicit tobacco products in the case of a tobacco product standard even if they are priced higher. As discussed earlier, it is unclear whether the prices would be higher or lower than current legal products in such a scenario. Individuals with lower incomes who engage in illicit trade might consume less or choose to quit. This does not take into consideration the additional barriers of legal consequences or lack of availability if the trade in these illicit products were to fail to fully penetrate all areas of the country. It also assumes that consumers who can afford higher-priced illicit tobacco products would not be deterred by the illegal nature of the transaction, and would not pursue alternative legal nicotine-delivery products.

VI. Potential enforcement actions and other controls on illicit trade

The potential enforcement actions against illicit products described below are related to acts that represent intentional diversion, counterfeiting, and black market sales of tobacco products. In general, FDA enforcement actions will depend on: (1) the requirements of the specific product standard; (2) the specific facts of the case; and (3) legal and policy considerations. For violations of a product standard, a Warning Letter could be issued as a first step to solicit voluntary compliance. Additional controls on illicit trade are provided for in the Tobacco Control Act and by other entities that can pursue enforcement actions to prevent or curtail illicit trade in tobacco products.

Importation is a possible source for illicit products in the United States. Tobacco products imported or offered for import into the United States must comply with all applicable requirements under the FD&C Act. If imported tobacco products are, or appear to be, adulterated or misbranded, such imported tobacco products would be subject to refusal of admission under section 801 of the FD&C Act. Illicit tobacco products may be subject to an import alert, which alerts FDA field staff that the agency has enough evidence or other information to refuse admission of shipments of such imported tobacco products.

⁶² Koffarnus, M. N., Wilson, A. G., & Bickel, W. K. (2014). Effects of Experimental Income on Demand for Potentially Real Cigarettes. *Nicotine & Tobacco Research*.

FDA could utilize its advisory, administrative, and judicial enforcement tools against illicit trade in tobacco products. For example, adulterated or misbranded products might be seized at any time. Entities involved in initiating and taking a seizure action include FDA's Center for Tobacco Products (CTP), ORA, FDA's Office of Chief Counsel, the U.S. Attorney's Office, and the U.S. Marshal's Service. FDA also might seek to enjoin any person from engaging in a prohibited act.⁶³ If a firm had a history of violations and had promised correction in the past, but had not made the corrections, an injunction might be pursued. In considering an injunction, FDA evaluates the seriousness of the offense, the actual or potential impact of the offense on the public, whether other possible actions could be as effective or more effective, the need for prompt judicial action, and whether FDA will be able to demonstrate the likelihood of the continuance of the violation in the absence of a court order.⁶⁴ Finally, FDA might initiate a criminal action through FDA's Office of Criminal Investigations (OCI). Persons engaging in illicit trade in tobacco products could be prosecuted under section 303 of the FD&C Act or U.S.C. Title 18.

Further, the Tobacco Control Act provides FDA with a number of authorities beyond the ability to inspect manufacturers of tobacco products, including the authority to issue recordkeeping regulations for the purpose of tracking and tracing tobacco products through the supply chain. Specifically, it directs FDA to issue regulations "regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products," taking into consideration which records are needed to monitor tobacco products from the point of manufacture through distribution to retail outlets.⁶⁵

The Tobacco Control Act also contains provisions requiring that manufacturers and distributors with knowledge of illegal transactions promptly notify the Attorney General and the Secretary of the Treasury of such information. Illegal transactions include importing, exporting, distributing, or offering for sale in interstate commerce without paying taxes or duties, or importing, exporting, distributing, or diverting for possible illicit marketing. Failure to notify the Attorney General and the Secretary of the Treasury of the knowledge of illegal transactions is a prohibited act under section 301(ss) of the FD&C Act and subject to enforcement action.⁶⁶ While legitimate companies already had a business incentive to report illicit trade (the risk of losing customers), these provisions increase the likelihood they will report bad actors.

Other key players in the prevention of illicit trade include the Alcohol and Tobacco Tax and Trade Bureau (TTB), U.S. Customs and Border Protection (CBP), and the National Association of Attorneys General (NAAG). TTB enforces the provisions of Chapter 52 of the Internal Revenue Code (Title 26 of the U.S. Code). In general, TTB deals mainly with the federal excise taxes on tobacco products and cigarette papers and tubes, and other requirements, such as permits required for engaging in business related to the manufacturing, importation, and other operations involving these products. CBP enforces trade laws against counterfeit, unsafe, and fraudulently entered goods, to enable legitimate trade, contribute to American economic

⁶³ § 301.

⁶⁴ FDA Regulatory Procedures Manual, 6-2-4 (2015).

⁶⁵ § 920(b)(1) and (2).

⁶⁶ § 920(d).

prosperity, and protect against risks to public health and safety. NAAG administers the Master Settlement Agreement (MSA) which, among other things, restricts marketing activities by tobacco product manufacturers and requires yearly payments to most states.

VII. Conclusion

While it remains difficult to measure existing illicit trade markets and use existing data to reliably predict future demand for illicit tobacco products, it is possible to isolate some of the key factors that may encourage or discourage illicit trade in tobacco products. For example:

- Depending upon the standard, there might remain strong, legal demand for components that, while intended for legal products outside the scope of the standard, could be used to make an illicit product. If diverted into an illicit channel, such components would represent a means by which illicit trade in full-nicotine cigarettes might develop.
- Manufacturing costs for illicit tobacco products might be higher because of economies of scale, and large-scale production difficult to achieve (and easy to detect by enforcement authorities). This might limit how significant illicit trade could ever become.
- Assuming that the primary motivator in selling tobacco products that do not comply with a product standard is profit (which is the case with tax-evading illicit trade), a limited market combined with the risk of enforcement action and possible criminal prosecution could end up discouraging people from becoming involved. This is particularly likely to be true if there are other illegal markets providing higher profit potential.
- Consumer behavior and the number of available alternatives to products compliant with the standard would also impact the development of illicit markets.
 - To the extent that current smokers could evade product standards by manipulating legal products, there might develop an illicit market providing the mechanism to do so, which would face the same obstacles described above (cost of production, evading enforcement, etc.). Including restrictions on the sale of such products might result in the prevention of illicit trade hinging on enforcement.
 - If the product standard affected consumer “experience” and consumers could use other tobacco products to achieve the “experience” missing due to the product standard, there might be little interest in engaging in illegal behavior, particularly as time went on (stockpiling small supplies of products in advance of a standard seems likely in most cases, potentially impacting the timing and extent of consumer demand for alternatives, whether legal or illegal). Additionally, to the extent that consumers used a product standard such as a nicotine standard for cigarettes as an opportunity to quit the most harmful products, or tobacco products altogether, demand for illicit products would drop, especially over time.

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.

Attachment 2

Draft Concept Paper: Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard

Charge to Peer Reviewers

Introduction

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) grants the U.S. Food and Drug Administration (FDA) the authority to implement a variety of tobacco product standards designed to protect public health. The effectiveness of these standards, however, could be compromised by illicit trade in contraband or nonconforming products. To stimulate dialogue on this topic, FDA has developed and made available to the public a draft concept paper regarding the potential for illicit markets in tobacco products to develop in response to a tobacco product standard.

The Tobacco Control Act specifically requires FDA to consider the potential countervailing effects of demand for contraband products in its assessment of the public health impacts of a tobacco product standard. Assessing the potential for an illicit market to develop in response to a particular standard is a complex task. FDA's draft concept paper attempts to assist this effort by (1) describing the key elements of trade in illicit tobacco markets and (2) examining the factors that could support or hinder the establishment and persistence of an illicit market in response to an FDA tobacco product standard.

FDA has contracted with Industrial Economics, Incorporated (IEc) to coordinate a formal peer review of the draft concept paper. This review is being conducted in accordance with the following guidelines:

- U.S. Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," September 24, 2001;
- U.S. Department of Health and Human Services, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public," October 1, 2002;
- U.S. Office of Management and Budget, "Final Information Quality Bulletin for Peer Review," December 16, 2004.

Charge to Peer Reviewers

Your review of FDA's draft concept paper, "Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard," should address the following questions:

1. Does the paper present an objective, accurate, and complete description of the factors that may affect the development of illicit tobacco markets following implementation of a product standard?
2. What are the strengths and weaknesses of the paper?
3. How could the paper be improved?

In preparing your review, please consider the following specific questions. You need not answer each of these questions individually, but should use them as a general guide. You should also feel free to address other issues that you believe are relevant to evaluating the paper.

1. ***FDA Approach to Tobacco Product Standards***
 - a. Does the description of FDA's authority to establish tobacco product standards, coupled with several examples of potential standards, provide sufficient context for the discussion that follows? If not, how could the description of FDA's authority be improved?
 - b. Is there a useful way to categorize tobacco product standards based upon their potential to create consumer demand for illicit products? If so, how would this classification scheme be defined?
2. ***The Elements of Trade in Illicit Tobacco Products:***
 - a. Does the discussion of the elements of trade in illicit tobacco products adequately capture the factors that contribute to the capacity to produce illicit products? If not, how could FDA improve the discussion? What additional factors, if any, should the paper consider?
 - b. Does the discussion accurately and sufficiently address the likelihood that tobacco growers or distributors will serve as a potential source of illicit tobacco?
 - c. Does the discussion adequately characterize the capability and incentives of individuals, tobacco product retailers, commercial tobacco product manufacturers, and tribal manufacturers to produce noncompliant products or otherwise attempt to evade a tobacco product standard?
 - d. Does the discussion adequately address factors that would affect the importation or distribution of illicit tobacco products, consumer awareness of illicit trade, and the actual sale of illicit products?
3. ***Potential Consumer Behaviors in Response to an FDA Tobacco Product Standard***
 - a. Does the discussion of potential consumer behavior in response to a tobacco product standard adequately address the aspects of consumer behavior that influence whether and to what degree an illicit market may develop? If not, how could FDA improve the discussion?
 - b. Does the discussion of illicit market buying behavior sufficiently capture the factors that influence decisions to purchase illicit tobacco products?
 - c. Does the discussion of the research on VLNC cigarettes accurately and sufficiently characterize the insights this research offers on consumers' potential response to a nicotine standard? Are there other studies of VLNC cigarettes that would provide additional or contrary insights?
 - d. Do the discussion of illicit markets for tobacco in prisons and the discussion of prohibition of alcohol accurately and sufficiently capture the insights these examples offer? Are there other examples that would offer important insights?
4. ***Price of Illicit Cigarettes***
 - a. Does the discussion of the factors affecting the price of illicit cigarettes adequately address this topic? If not, how could FDA improve the discussion? What other factors, if any, should the paper consider?
 - b. Beyond the examples the paper cites, are there other examples that would inform assessment of the potential price of contraband or nonconforming tobacco products, relative to the price of legal products?

- c. Does the paper adequately address the impact of differences in the price of legal and illicit tobacco products on the potential development of a market for illicit products?
5. **Potential Enforcement Actions and Other Controls on Illicit Trade**
 - a. Does the discussion of potential enforcement actions and other controls on illicit trade adequately address the impact of these factors on the potential development of illicit markets for tobacco products? If not, how could FDA improve the discussion?
 - b. Are there additional factors that should be considered in characterizing the likely impact of enforcement actions and other controls on illicit trade? If so, what are these factors?
6. **Conclusions**
 - a. Are the paper's conclusions clear and adequately supported? If not, how should FDA modify its conclusions?
 - b. Should the conclusions be expanded in any way? If so, how?
7. **General**
 - a. Is the report paper clearly written and sufficiently complete?
 - b. What are the paper's most important strengths and weaknesses?
 - c. What changes would you recommend to improve the overall quality of the paper?

Please summarize your comments in a letter to IEC, which is to be submitted to IEC's project manager no later than July 16, 2018. IEC will prepare a brief memorandum to FDA summarizing your comments and those of two other independent peer reviewers. The detailed comments provided by each peer reviewer will be forwarded to FDA as appendices to our summary memorandum. Please note that the identities and professional affiliations of all peer reviewers will be provided in our summary of the peer review's findings and will be made publicly available; however, neither the summary memorandum nor the appendices will attribute comments to a specific reviewer.

Attachment 3

Criteria for Evaluating Actual, Apparent, or Potential Conflicts of Interest

A conflict of interest arises in the performance of government-sponsored research when an individual or organization has interests, financial or otherwise, which place the individual or organization in a position that may be unsatisfactory or unfavorable from the government's standpoint in being able to secure impartial, technically sound, objective assistance. Conflicts may be actual, apparent, or potential in nature. For purposes of identifying any actual, apparent, or potential conflicts of interest related to this peer review, IEC and FDA have established the following criteria:

1. No member of the peer review panel shall, during the period of participation in the peer review or during the preceding thirty-six (36) months:
 - Hold a proprietary interest in a product or technology,
 - Receive salary or consulting fees,
 - Receive a grant and/or salary support from a grant,
 - Be party to a contract, including as a subcontractor, for research or other activities on behalf of,
 - Receive payment for expert testimony, or
 - Hold stock or stock options in, or receive payment of stock or stock options fromany business that manufactures, distributes, markets, or sells any tobacco products, including electronic cigarettes, other electronic nicotine delivery devices, or any nicotine- or tobacco-related pharmaceutical products.
2. No member of the peer review panel shall have received honoraria totaling more than \$10,000 from all private sector sources that manufacture, distribute, market, or sell any tobacco products, including electronic cigarettes, other electronic nicotine delivery devices, or any nicotine- or tobacco-related pharmaceutical products in any one of the following calendar years: 2015; 2016; 2017; or 2018.
3. Research grants and honoraria from governmental (e.g., NIH) or non-profit organizations not funded by the tobacco industry (e.g., Robert Wood Johnson Foundation) are permissible.
4. No member of the peer review panel shall, during the period of participation in the peer review, be an employee of the Food and Drug Administration or the lead on a current direct contract with the Food and Drug Administration. Contracts from other government agencies (e.g., NIH) are permissible.
5. No member of the peer review panel shall have received honoraria or consulting fees from the Food and Drug Administration totaling more than \$10,000 during any one of the following calendar years: 2015; 2016; 2017; or 2018.
6. No member of the peer review panel shall, during the period of participation in the peer review, be a Food and Drug Administration “special Government employee” (SGE).