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Dockets Management
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

The undersigned public health officials and advocacy organizations submit this petition requesting that the U.S. Food and Drug Administration (the FDA) fulfill its responsibilities under Section 920(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) by implementing a track and trace system to monitor manufacturing and the flow of tobacco products from production through distribution to retail outlets. In 2009, Congress granted the FDA broad authority over the constituents, manufacture, distribution, marketing, and sale of tobacco products with the enactment of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or Act). As explained below, by providing an accountability mechanism, a track and trace system would facilitate achievement of the purposes of the Tobacco Control Act, enhance timely compliance with the Act and associated regulations, and promote their public health objectives. A track and trace system would also reduce the evasion of tobacco taxes. Recent technological advances have made it feasible to establish a system that can substantially reduce the sale of illicit tobacco products and greatly enhance the effectiveness of the important regulatory authorities granted to the FDA under the Act.

I. DETAILED DESCRIPTION OF ACTION REQUESTED

We request that, on or before July 1, 2013, the FDA propose regulations mandating that each tobacco product produced or sold in the United States bear a unique counterfeit-resistant identifying code that allows its origin to be identified, and links to a computer database of required records that permits the product to be tracked and traced. Tracking and tracing means the ability to track goods

from the point of manufacture through each stage in the supply chain to the ultimate point of retail sale, and the capacity to trace back those goods to identify points along the chain where the goods changed hands. A track and trace system can help to ensure the integrity of the supply chain, deter smuggling or trafficking, and strengthen enforcement efforts to prevent illegal diversion. A track and trace system also provides a mechanism enabling the FDA to implement and ensure timely compliance with regulations related to product standards, adulteration, misbranding, and other packaging requirements. Because, as discussed *infra*, a track and trace system is called for by the statute, the FDA's regulations should take effect on or before December 31, 2013. This timeline is appropriate, given that the creation of a track and trace system is specifically called for by Section 920(b) of the Tobacco Control Act and FDA has yet to begin regulatory proceedings on this subject.

To accomplish all of these goals, a national track and trace system should, at minimum, have the features outlined by the World Health Organization's Framework Convention on Tobacco Control's (FCTC) analysis of available technologies,¹ including:

- Non-predictable serialization of all tobacco products to the level of the smallest saleable unit (generally a pack), with each unique code linked to a secure database of information about that product (such as manufacturer, manufacture date, brand, sub-brand, payment records, shipping information, etc);
- Common numbering standards for serialization, which should, at minimum, contain information about the manufacturer, date of manufacture, brand, and sub-brand;
- Human-readable printing/labeling of serialization numbers on all traded units. Human readability can also facilitate compliance of less technologically advanced manufacturers and participants along the distribution chain;
- Establishment of parent-child relationships between different packaging units so that individual cartons and cases can be separated from master cases during shipping without need to open and scan each pack (aggregation). Aggregation allows easier tracking of shipping movements, while preserving tracing capacity for individual packs;
- Recordkeeping of any changes in the parent-child relationship along the supply chain (recording changes in aggregation ensures that track and trace is preserved);
- Recordkeeping of any shipping and receiving events to the level of each pack along the supply chain. This is the most critical element in establishing accountability for legal sales of a product;

¹ World Health Organization Framework Convention on Tobacco Control. Analysis of the available technology for unique markings in view of the global track and trace regime proposed in the negotiating text for a protocol to eliminate illicit trade in tobacco products. In: Conference of the Parties; 2010; Geneva, Switzerland; 2010. Available at: http://apps.who.int/gb/fctc/PDF/it4/FCTC_COP_INB_IT4_ID1-en.pdf.

- Maintenance of relevant data by supply-chain partners;
- Query interfaces between the databases of the supply-chain partners and enforcement authorities, which would allow authorized users to verify products' legal status, as well as get information needed to assist in tracing the origins of diverted products (e.g. with scanners, mobile devices, etc.);
- A standard as a protocol for transferring queries and data.

In addition, any track and trace system implemented by the FDA should be under the direct management and control of the federal government and be designed to allow states and local jurisdictions shared access to data systems storing shipping and receiving information to and from local jurisdictions (all of which is technologically feasible today) to ensure that required taxes have been paid and to assist with enforcement.

II. STATEMENT OF GROUNDS

A. The FDCA, as Amended by the Tobacco Control Act, Calls for a Track and Trace System as a Key Component of its Regulatory Scheme

The FDCA, as amended by the Tobacco Control Act, calls for a track and trace system to achieve the public health objectives served by regulation of tobacco products. Among the ten stated purposes of the statute articulated by Congress is the need “to strengthen legislation against illicit trade in tobacco products,” a recognition that the efficacy of any regulatory structure governing tobacco products may be potentially threatened by the existence or the threat of an illegal market in tobacco products that do not conform to the FDA’s regulations.

Consistent with this purpose, Section 920(b) of the statute, entitled “Regulations Concerning Recordkeeping for Tracking and Tracing,” calls for the FDA to implement a comprehensive system of track and trace involving every link in the supply chain for tobacco products:

- (1) In general. – The Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.
- (2) Inspection. – In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.
- (3) Codes. – The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.
- (4) Size of business. – The Secretary shall take into account the size of a business in promulgating regulations under this section.

Given that Subsection (1) unequivocally mandates (“shall promulgate”) recordkeeping regulations and that the express purpose of those regulations, as reflected in the title of Section 920(b), is “for Tracking and Tracing,” Section 920(b), when read in its entirety, calls for the FDA to establish a track and trace system. The language in Subsection (2) confirms this reading by requiring that, in promulgating the mandated regulations, the Secretary must consider “the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.”²

Thus, Section 920 calls for the FDA to establish a track and trace system and envisions at least two central components of that system: (1) comprehensive recordkeeping at every level of distribution, and (2) unique identifying codes applied to each tobacco product. Under such a system, every participant in the legal market for tobacco products – from manufacturer to wholesaler to retailer – would be accountable for every product produced, received, maintained and transferred, and law enforcement would be better positioned to identify where in the distribution chain a product was diverted into the illegal market. In Section 920, Congress, in clear and strong terms, required the FDA to ensure such accountability.

B. The Track and Trace System Called for by the Tobacco Control Act Will Protect the Integrity of the Regulatory Scheme, and Its Public Health Benefits, Against the Threat of Illicit Markets

In its findings accompanying the Tobacco Control Act, Congress determined that “Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.”³ Congress found that those problems include the tragic reality that “[t]obacco use is the foremost preventable cause of premature death in America,” accounting for “over 400,000 deaths in the United States” and finding further that “approximately 8,600,000 Americans have chronic illnesses due to smoking.”⁴

Section 920 requires that the FDA ensure that the risk of illegal markets does not diminish the capacity of regulations to deliver the full range of public health protections envisioned by the statute. Congress did not conclude that the threat of illicit markets is a reason to refrain from regulation, but rather explicitly required the FDA to protect against such a threat – whether real or posited by the tobacco industry as a pretext for opposing effective regulation. Notably, the tobacco industry has frequently claimed that virtually any form of regulation of its products (including stronger warning labels or restrictions on its packaging of its products) would give rise to illegal trafficking and illicit markets. Indeed, it is already clear that the tobacco industry will resist establishment of product standards by claiming that virtually any effort by the FDA to regulate the content of its products will produce a “black

² Subsection (3) of Sec. 920(b) gives the FDA the authority to require identifying codes on the labels of tobacco products as a component of track and trace regulations. As explained *infra*, such codes should be regarded as essential to an effective track and trace system.

³ P.L. 111-31, §2(7) (June 22, 2009), 123 Stat. 1775, 1777.

⁴ P.L. 111-31, §2(13) (June 22, 2009), 123 Stat. 1775, 1777.

market.” For example, *The Industry Menthol Report*, submitted in March 2011 to the Tobacco Product Scientific Advisory Committee (TPSAC) by the Non-Voting Industry Representatives on TPSAC, argued against a ban on menthol cigarettes, in part because such a ban “would increase black market cigarette sales.”⁵ This view was echoed in the submission to TPSAC by Altria Client Services for Philip Morris USA, in which the company asserted that “[a] ban on menthol cigarettes would likely expand unregulated sources of cigarette supply, mostly through the development and growth of the illicit market.”⁶ Similarly, if the FDA rejects an application for the marketing of a new product, the industry may claim that the product in question was intended to fill an unmet demand in the marketplace and that the denial of an application will lead to an illegal market.

Whether or not such arguments have any validity, the establishment of a federal track and trace system, as called for by the statute, furnishes a compelling answer. A track and trace system would facilitate the identification of contraband products, which may be of particular importance for products that diverge from the FDA standards in ways not immediately obvious to sellers and consumers (e.g., products that contain a particular ingredient in levels that violate a specific standard).⁷ A track and trace system would also facilitate enforcement with regard to non-compliant products bearing the identifying codes by enabling law enforcement officials to track those goods from manufacturer to retailer. It would promote timely compliance with new and existing rules and regulations; capture information sufficient to detect production anomalies which might reflect efforts to frustrate impending rule changes (such as greatly increasing production of a product impacted by an impending product standard), as well as shipping and receiving anomalies which could alert authorities to potentially illicit activity; and assist in exposing when products intended for export are re-routed to the domestic market.

A track and trace system would enhance virtually every component of the FDA’s regulatory authority over tobacco products. Examples include:

- Establishment of a track and trace system would reduce the threat of evasion of product standards established pursuant to Section 907 banning the use of characterizing flavors in cigarettes, as well as future product standards under Section 907(a)(3)(A) “appropriate for the protection of public health.” Traceability would ensure that manufacturers met new product standards in a timely fashion, or would provide a mechanism for accountability if they did not. Non-compliant products without identifying codes would be made easily identifiable to distributors, retailers, and consumers. It would help retailers to spot illicit products and to minimize their risk, and financial and administrative burden.

⁵ *The Industry Menthol Report, Menthol Cigarettes: No Disproportionate Impact on Public Health*, (“*Industry Menthol Report*”) submitted to FDA by the Non-Voting Industry Representatives on TPSAC and Other Tobacco Industry Stakeholders (March 23, 2011), at 213.

⁶ *Countervailing effects of a ban on menthol cigarettes*, Prepared and submitted by Altria Client Services on behalf of Philip Morris USA for the January 10-11, 2011 meeting of TPSAC, at 4.

⁷ A product without the required identifier could be regarded as misbranded under Sec. 903 of the Act and sellers of such products could be subject to sanctions for the sale of misbranded products.

- Establishment of a track and trace system would provide the same advantages for the introduction of new tobacco products under Section 910 as those provided with regard to tobacco product standards established under Section 907. It would allow the FDA to easily identify any product not legally manufactured by a licensed manufacturer.
- Enforcement of the protections against adulterated tobacco products under Section 902 would be enhanced by a track and trace system that could identify the point in the distribution chain at which the product became adulterated.
- A track and trace system would protect the labeling requirements under Section 903 from the threat of an illegal market in mislabeled products, both by detecting production increases occurring immediately prior to new labeling regulations and ensuring timely compliance with labeling regulations.
- Track and trace would provide an additional mechanism for the FDA to ensure compliance with Section 904 requiring tobacco manufacturers to provide a listing of ingredients, substances, compounds, and additives that are added to their products, as retail products could be purchased by the FDA and tested for agreement with manufacturer-provided ingredients lists by production date.
- A track and trace system would make more effective and efficient the exercise of the FDA's authority to recall certain tobacco products under Section 908(c).

Thus, an effective track and trace system would strengthen the full range of the FDA regulatory actions by protecting against the threat of illicit tobacco markets. Such a system would enhance the FDA's ability to monitor the effectiveness of any of its regulatory actions, and permit the agency to adjust such actions to meet unanticipated problems.

C. A Track and Trace System Would Materially Reduce Evasion and the Threat of Evasion of Federal Excise Taxes, Generate Revenue, and Promote Public Health

In addition to maximizing the public health benefits of the FDA's regulation of the tobacco industry, a track and trace system would serve the public health by reducing evasion of federal excise taxes. In a report to Congress, the Treasury Department explained the link between the illicit tobacco trade, excise tax avoidance, and harm to public health:

In terms of public health concerns, the introduction of illegally manufactured or distributed products into the marketplace aggravates health issues and contributes to rising healthcare costs, as it lowers the price to the consumer of cigarettes, so that cheap cigarettes are available to young people and to price-sensitive smokers who might otherwise quit smoking.⁸

⁸ *Department of the Treasury Report to Congress on Federal Tobacco Receipts Lost Due to Illicit Trade and Recommendations for Increased Enforcement* (February 4, 2010), at 4.

The Treasury Department report specifically noted the value of a track and trace system in reducing federal excise tax avoidance because such a system “has the potential to allow tracking of any tobacco product from its removal from a manufacturer’s premises or its release from customs custody to its sale at retail to the consumer.”⁹ While tax evasion schemes vary, federal excise tax evasion typically involves either: (a) foreign tobacco products that are diverted or smuggled into the domestic market or (b) domestic tobacco products that are unrecorded, whether made by a licensed or unlicensed manufacturer.¹⁰ According to the Treasury Department, “[a] federal ‘track and trace’ system, which would support the tax administration mission of the Treasury Department as well as the public health mission of the FDA, would benefit both agencies and promote consistency and efficiency in government.”¹¹ A track and trace system would increase federal tax revenues by helping to reduce underreporting of production by domestic manufacturers and re-routing of packs intended for export, as well as helping make illegally imported or counterfeit cigarettes more easily identifiable as such. The Treasury Department therefore made a formal recommendation to “[e]nhance the traceability of tobacco products by working with the [FDA] on the ‘track and trace’ system that the FDA is authorized to develop under the [Tobacco Control Act] so that the system can be used to extent possible for enforcement purposes.”¹²

Thus, the FDA should move forward with establishing a track and trace system and should involve the Treasury Department’s Alcohol and Tobacco Tax and Trade Bureau in designing the system to ensure that the important interests and objectives of both agencies are served. Such a system will serve the public health, both by enhancing the effectiveness of the FDA’s regulation of the tobacco industry and by more fully realizing the benefits of diminished demand for tobacco products due to enforcement of all applicable excise taxes.

D. A Track and Trace System Would Materially Reduce Evasion, and the Threat of Evasion of State and Local Excise Taxes, Generate Revenue, and Promote Public Health

Implementing a track and trace system is also important to the integrity of state and local excise tax collection. All fifty states and many local jurisdictions, including Chicago, Cook County, Anchorage, and New York City (NYC), tax the sale of cigarettes. These excise taxes generate substantial revenue for states and localities, some of which are allocated to tobacco control programs or to defray health care costs. State and local taxes also make cigarettes more expensive, thereby reducing the prevalence of smoking and smoking-related illnesses.¹³ Every 10% increase in the real price of cigarettes reduces total cigarette consumption by 3-5%, and reduces the number of youth smokers by about 7%.¹⁴ Conversely,

⁹ *Id.* at 9.

¹⁰ *Id.* at 5-6.

¹¹ *Id.* at 10.

¹² *Id.* at 9.

¹³ Chaloupka, F., Tobacco control lessons learned: The impact of state and local policies (ImpacTEEN, Research Paper Series No. 28, 2010).

¹⁴ Levy DT., Chaloupka F. & Gitchell J., *The effects of tobacco control policies on smoking rates: a tobacco control scorecard*, 10 J. PUB. HEALTH MGMT. & PRAC. 338 (2004).

tobacco consumption increases when less expensive tobacco products are available.¹⁵ New York City has the highest cigarette taxes in the nation—a key component of its campaign to reduce smoking. Since 2002, combined New York State and City excise taxes on a pack of cigarettes have increased by \$4.66, and prevalence of smoking in NYC has dropped by 31% among adults¹⁶ and 52% among youth¹⁷—translating to almost 400,000 fewer smokers in the City. Since 2001, life expectancy in NYC has increased by 3 years to 80.9 years, exceeding the nationwide increase of 1.8 years over the same period.¹⁸ The efforts taken between 2002 and 2010 alone will prevent nearly 50,000 smoking-related deaths by the year 2052.¹⁹ Over the same time period, NYC revenue from cigarette excise taxes was more than \$1 billion and annual excise revenues remain higher than before the 2002 tax increase.²⁰ A federal track and trace system could have enhanced the already significant health and economic benefits of the recent tax increases by enabling enforcement officials to determine where cigarettes were diverted from the legal, tax-paying stream. A 2010 New York State Senate report estimated that if cigarette taxes were collected from Native American Reservations, 100,000 New Yorkers would quit smoking.²¹ Since June 2011, New York has imposed taxes on cigarettes prior to their sale to Reservations. However, the State Senate Report’s projected quit rate has not been fully realized because the illicit market for untaxed cigarettes has evolved.

Specifically, since June 2011, cigarette sales have spiked in low-tax states in relatively close proximity to New York, indicating that the tax evasion patterns along the Eastern seaboard have shifted from Native American Indian Reservations to interstate trafficking.^{22,23} One study, which examined

¹⁵ Chaloupka, F., Tobacco control lessons learned: The impact of state and local policies (ImpacTEEN, Research Paper Series No. 28, 2010).

¹⁶ New York City Department of Health and Mental Hygiene. Community Health Surveys 2002 and 2011.

¹⁷ New York City Department of Health and Mental Hygiene. Youth Risk Behavior Surveys 2001 and 2011.

¹⁸ City’s Health Initiatives Lead to All-Time Highest Life Expectancy of 80.9 Years; Infant Mortality Rate Falls to All-Time Low of 4.7 deaths per 1,000 Live Births. December 11, 2012. Available at:

http://www.nyc.gov/portal/site/nycgov/menuitem.c0935b9a57bb4ef3daf2f1c701c789a0/index.jsp?pageID=mayor_press_release&catID=1194&doc_name=http%3A%2F%2Fwww.nyc.gov%2Fhtml%2Fom%2Fhtml%2F2012b%2Fpr465-12.html&cc=unused1978&rc=1194&ndi=1

¹⁹ New York City Department of Health and Mental Hygiene, *Preventing Non-Communicable Diseases and Injuries: Innovative Solutions from New York City* (2011) at 8, available at

<http://www.nyc.gov/html/doh/downloads/pdf/ip/un-rpt.pdf>.

²⁰ New York City and New York State share revenue generated by New York City’s excise tax of \$1.50 per pack of cigarettes; 46% of the revenue is transferred to New York State, and the remaining 54% goes to the NYC General Fund. In 2011, 9 years after the 2002 New York City excise tax increase, the portion of the tax that the City keeps was still \$42 million more than tax revenue in 2002 before the tax increase. The City of New York, *New York Comprehensive Annual Financial Report of the Comptroller for the Fiscal Year Ended June 30, 3011*. Page 288. Available at: <http://www.comptroller.nyc.gov/bureaus/acc/cafr-pdf/cafr2011.pdf>, last accessed 12/14/2012.

²¹ Executive Refusal, supra note 8, at 12 (citing testimony of Russ Sciandra). Accessed 8/15/2011. Available at: <http://www.nysenate.gov/files/pdfs/Executive%20Refusal%20FINAL%20June%202010.pdf>.

²² Measuring tax evasion is difficult due to the clandestine nature of illegal sales. Because most jurisdictions in the U.S. with a cigarette excise tax require tax stamps on the cellophane wrappers of each pack, one method of analyzing trafficking patterns, known as a “littered pack study,” involves studying discarded cigarette packs that are found outdoors with intact cellophane wrappers. See: Kurti MK, von Lampe K, Thompkins DE. *The illegal cigarette market in a socioeconomically deprived inner-city area: the case of the South Bronx*, Tobacco Control. E-pub ahead of print. Examining discarded packs can reveal the state where a cigarette pack originated. When a large number of packs have stamps from distant, lower-tax states, this can indicate illegal trafficking, whereas the

littered packs in the South Bronx before and after the regulations went into effect, found that the percent of packs found without the required NYC tax stamp shifted proportionally from unstamped packs (presumably coming from Reservations), to low-tax states like Virginia. Prior to the regulations, 42% of packs found were unstamped and 9% bore a Virginia stamp, whereas after the regulations were in effect, 9% were unstamped and 49% bore a Virginia stamp.²⁴ The same trend was confirmed in another study of littered cigarette packs conducted in New York City, Boston, Providence, Washington, D.C., and Philadelphia, which found that a large number of discarded packs in NYC bore tax stamps from other low-tax jurisdictions, often those with low taxes, or had no tax stamps at all.²⁵ Although some of these packs may have been legally transported by commuters, tourists, or other travelers, the vast quantity of cigarettes that traveled long distances from low-tax states to high-tax states and cities is indicative of tax evasion and organized criminal activity, which is consistent with reports from law enforcement officials.^{26,27,28}

Ideally, tobacco prices would be close to the same high level nationwide, but that is not the case. Cigarette excise taxes range from as little as \$0.17 in Missouri to as high as \$5.85 in NYC (based on combined \$4.35 State and \$1.50 City excise taxes). In the immediate future, however, it is unrealistic to expect all of the states and local jurisdictions that tax cigarettes to increase their taxes in parallel. Disparities in state and local cigarette prices create opportunities for criminal actors to profit from tax evasion. A trafficker smuggling 10,000 packs of cigarettes, purchased in Virginia, could profit approximately \$55,500 by reselling them in NYC, earning more than double the initial outlay.²⁹ In total, the Department of Justice estimates that cigarette trafficking costs the federal and state governments \$5 billion annually.³⁰ The following chart presents data from the recent littered pack study of New York

existence of packs from nearby states with lower taxes may merely indicate legal cross-border purchases by individual smokers. Similarly, large numbers unstamped littered packs may mean the packs are counterfeit, they are from one of the few states that do not stamp cigarettes, or they were purchased from a Native American Reservation.

²³ Davis, et al. Unpublished data.

²⁴ Johnson, Jacqueline, Klaus von Lampe and Marin Kurti. "The Illegal Cigarette Market in the South Bronx: After a Tax Amendment." American Society of Criminology Annual Meeting, Chicago, IL, November 2012.

²⁵ Davis, et al. Unpublished data.

²⁶ Rashbaum WK. 8 Officer Charged with Gun Trafficking in US Corruption Case. New York Times 2011 October 25;Sect. A1.

²⁷ DePompa R. Cigarette smuggling's link to terror. NBS News12 Investigates. Posted November 13, 2012. Last accessed November 20, 2012. Available at: <http://www.nbc12.com/story/20086873/12-investigates-cigarette-smugglings-link-to-terror>

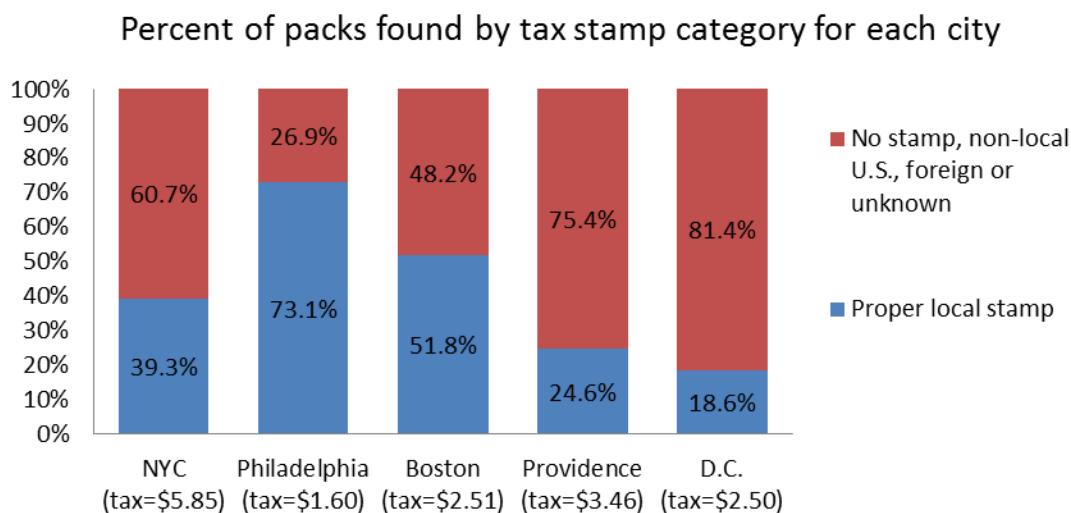
²⁸ Virginia State Crime Commission. SJR 21: Illegal Cigarette Trafficking. November 12, 2012. Last accessed November 12, 2012. Available at:

http://vscc.virginia.gov/FINAL_Cigarette%20trafficking%20November%20presentation.pdf

²⁹ U.S. Government Accountability Office, Report to Congressional Committees, *Illicit Tobacco: Various Schemes Are Used to Evade Taxes and Fees*, GAO-11-313 at 14. (Mar. 2011)

³⁰ U.S. Department of Justice Office of the Inspector General Evaluation and Inspections Division. Bureau of Alcohol, Tobacco, Firearms and Explosives' Efforts to Prevent the Diversion of Tobacco. September 2009. Last accessed November 21, 2012. Available at: www.justice.gov/oig/reports/ATF/e0905.pdf

City, Boston, Providence, Philadelphia, and Washington, D.C. and shows substantial evidence of cigarette trafficking:³¹



Analyses of these littered pack data suggest that each city has millions in annual revenue losses in unpaid taxes from cigarette trafficking, and that revenue loss in some, such as NYC, is hundreds of millions of dollars.³² As cigarette trafficking is not limited to the five northeastern cities listed above, this means that states and cities across the United States are losing billions of dollars in unpaid taxes each year to cigarette trafficking. The FDA should move expeditiously to put a track and trace system in place to control this interstate trafficking and maximize the health benefits of tobacco taxes.

E. Advanced Track and Trace Technology is Available and Should Be Implemented on a National Level

The potential effectiveness of unique identifying codes linked to a national database for tracking and tracing product movement has been enhanced by rapidly evolving technology. Other industries already use unique identifiers for analogous tracking and tracing functions, including pharmaceuticals, consumer products, delivery and postal services, and airlines.³³ Moreover, technologically-advanced product coding systems are being applied for tobacco products, both domestically and in other countries. For example, the States of California and Massachusetts are using counterfeit-resistant cigarette tax stamps embedded with invisible and secure 2D DataMatrix codes unique to each pack of cigarettes sold in the State (this is in addition to a human-readable 6-digit serial

³¹ Davis, et al. Unpublished data.

³² Davis, et al. Unpublished data.

³³ World Health Organization Framework Convention on Tobacco Control. Analysis of the available technology for unique markings in view of the global track and trace regime proposed in the negotiating text for a protocol to eliminate illicit trade in tobacco products. In: Conference of the Parties; 2010; Geneva, Switzerland; 2010. Available at: http://apps.who.int/gb/fctc/PDF/it4/FCTC_COP_INB_IT4_ID1-en.pdf

number).^{34,35} Brazil and Turkey employ the same technology at the national level for comprehensive supply chain traceability.³⁶ In 2010, Canada implemented a high-tech tax stamp compatible with track and trace database technologies;³⁷ although this feature is not currently utilized, it is a first step in a phased approach to a full traceability.³⁸ Mauritius also recently announced that it would be upgrading its tobacco stamp to include technologies compatible with track and trace.³⁹ These developments mean that a state-of-the-art track and trace system can be far more effective now than previously available technology allowed.

It is vitally important that a tobacco track and trace system be implemented at the national level. The existing patchwork quilt of state and local tax stamps and its varying tax rates was not designed to block interstate cigarette trafficking. Tax stamps currently are applied by wholesalers in the state of distribution. Consequently, when a law enforcement officer finds an unstamped pack of cigarettes, she cannot determine when or where it was diverted to the illicit market. Similarly, when an enforcement officer discovers a pack bearing a stamp from a distant low-tax state, she cannot easily determine who previously handled the product. Complicating matters, high quality counterfeit tax stamps have been found in increasing numbers. Sometimes, these counterfeit stamps are placed on unstamped packs; other times, they are used to obscure legitimate stamps from low-tax states. In addition, some low-tax states, such as North Carolina and South Carolina, have no tax stamps to evidence payment of their taxes. Cigarette trafficking not only deprives states of revenue and public health benefits, it also creates interstate corridors traveled by organized criminal actors.⁴⁰ High tax states like New York⁴¹ and low tax states like Virginia⁴² have both come to the same conclusion— improved recordkeeping which provides the ability to quickly and easily track tobacco products through the supply chain is critical to reducing cigarette tax evasion and trafficking. Even states with high-tech

³⁴ *New California Counterfeit-Resistant Cigarette Tax Stamp*, State Board of Equalization, Publication 403 (December 2010). Even before recent improvements to the California system, the use of high tech tax stamps in California, along with increased enforcement, reduced cigarette tax evasion and increased tax revenue. See A. McIntosh, "Tobacco Tax Cheating Falls," *Sacramento Bee*, June 27, 2007.

³⁵ Massachusetts Department of Revenue. *Cigarette Stamp Validator Information*. Available at: <http://www.mass.gov/dor/businesses/help-and-resources/cigarette-and-tobacco-tax/cigarette-stamp-validator-information.html>

³⁶ FTC technology analysis, at 5.

³⁷ *Combining the Interests of Brand Owners and Revenue Agencies*. Tax Stamp News 2919;2(6):2. Last accessed November 21, 2012. Available at: http://www.taxstampnews.com/images/stories/PDFs/TSN_Nov.Dec_10_web.pdf

³⁸ McLester P. Canada's New Tobacco Stamping Regime. FTA Tobacco Tax Section Annual Meeting; 2012 August 27; 2012

³⁹ *Mauritius to Upgrade Tobacco Stamps*. Tax Stamp News 2012;4(9): 1. Last accessed November 21, 2012. Available at: http://www.taxstampnews.com/images/stories/PDFs/TSN_Sep_12.pdf

⁴⁰ Virginia State Crime Commission. SJR 21: Illegal Cigarette Trafficking. November 12, 2012. Last accessed November 12, 2012. Available at:

http://vscc.virginia.gov/FINAL_Cigarette%20trafficking%20November%20presentation.pdf

⁴¹ New York State Bill A10749. Introduced June 18, 2012. Available at:

http://assembly.state.ny.us/leg/?default_fld=&bn=A10749&term=2011&Summary=Y&Actions=Y&Text=Y

⁴² Virginia State Crime Commission. SJR 21: Illegal Cigarette Trafficking. November 12, 2012. Last accessed November 12, 2012. Available at:

http://vscc.virginia.gov/FINAL_Cigarette%20trafficking%20November%20presentation.pdf

tax stamps and robust law enforcement efforts struggle to combat trafficking because tax stamps provide only an intrastate solution to an interstate problem. With an interstate track and trace system, on the other hand, law enforcement would be able to access the history of each product's chain of custody. Enforcement officials could easily authenticate a product and verify whether it is at or near its intended destination. Absent an interstate system which tracks product sales through the supply chain and can trace products to their last legal possession, stamps simply fail to provide the necessary information for enforcement against illegal product sales.

A national track and trace system applied at the level of manufacture⁴³ and overseen by the FDA and relevant federal tax agencies is the best solution for improving tax enforcement and public health policies related to tobacco nationwide.

F. The Track and Trace System Established Under Section 920 Must Be Free From Industry Influence or Control

The track and trace system established pursuant to the statute can only be effective if it is fully independent of industry influence or control. Moreover, the data generated by such a system must remain within the control of the federal government and accessible by state and local authorities. Major tobacco companies have developed their own surveillance systems and frequently suggest that governmental systems incorporate elements of such systems or rely on industry data and expertise to run them. Such suggestions must be rejected.

The surveillance systems established by the industry function not to enhance the effectiveness of public health regulation, but rather to serve the narrow economic interest of tobacco product manufacturers. Such systems function in the public interest only to the extent that those interests are convergent. It is essential to recognize that tobacco product manufacturers have historically been major participants in illicit trafficking when it has served their economic interests and cannot be trusted to design or operate surveillance systems in the public interest. The *Industry Menthol Report* uses Canada as an example of illegal markets for cigarettes.⁴⁴ The report, however, fails to mention the industry's complicity in creating an illicit market in Canada more than a decade ago. For example, affiliates of R.J. Reynolds, Philip Morris and BAT were implicated in operations in which they knew that their Canadian-made cigarettes would be exported to the U.S., only to be smuggled back into Canada.⁴⁵ An RJR company, Northern Brands International, and its former president, Les Thompson, each pled guilty to charges of being directly involved in the Canadian smuggling.⁴⁶ In 1997, two former Brown & Williamson ("B&W") sales managers pled guilty to the charge of providing smugglers who were illegally bringing

⁴³ Since tobacco manufacturers are responsible for putting their products in the stream of commerce, and since an effective track and trace system must operate from the point of manufacture through ultimate retail sale, it is appropriate that the obligation for compliance with the system be placed primarily on the manufacturers, rather than small businesses (whose recordkeeping burden should in fact be eased by such a system).

⁴⁴ *Industry Menthol Report*, at 215.

⁴⁵ Campaign for Tobacco-Free Kids, *Illegal Pathways to Illegal Profits: The Big Cigarette Companies and International Smuggling* (2003) (*Illegal Pathways*), at 27.

⁴⁶ *Id.* at 28.

cigarettes into Canada with untaxed cigarettes from a bonded B&W warehouse in Alabama.⁴⁷ The Canadian experience is only one of many examples of tobacco industry complicity in smuggling and trafficking operations.⁴⁸ An effective track and trace system would have made it far more difficult for the industry to have evaded these legal requirements and might have prevented these unfortunate occurrences.

Moreover, domestic tobacco manufacturers profit from increased sales when their products stamped for sale in low-tax jurisdictions are smuggled into high-tax jurisdictions. It is unrealistic to expect surveillance systems devised by the industry to police such illicit diversions successfully. The FCTC has also recognized the need to keep the industry out of the business of regulating its own product. Under Article 8 of the FCTC's protocol to eliminate illicit tobacco, "obligations assigned to a Party shall not be performed by or delegated to the tobacco industry."⁴⁹ Therefore, the track and trace system developed by the FDA – including the data it generates – must remain within the control of government authorities, not the industry.

The Tobacco Control Act calls for the FDA to create a comprehensive track and trace system to counter the threat of illicit markets and maximize the public health benefits of strong regulation. The inclusion of Section 920 in the TCA must be understood in the context of the history of tobacco industry complicity in supplying illicit markets, the industry's repeated use of the "black market" argument against the enactment of regulation and taxation proposals to protect the public health, and the economic benefit derived by major manufacturers from the illicit diversion of their own products. The call for the FDA to design and implement a track and trace system reflects the judgment of Congress that, in light of this regrettable history, the federal government cannot rely upon the industry to police itself and develop a track and trace system that truly ensures that the public's health will be protected; nor can the federal government justifiably delegate this task to the industry. In short, it is critical that the FDA implement and maintain a track and trace system, as clearly called for by Congress.

III. ENVIRONMENTAL IMPACT

⁴⁷ *Id.*

⁴⁸ *See generally, Illegal Pathways.* The international dimensions of smuggling and trafficking in tobacco products, and their public health implications, are recognized in Article 15.2(b) of the World Health Organization's Framework Convention on Tobacco Control, which calls on the parties to "consider, as appropriate, developing a practical tracking and tracing regime that would further secure the distribution system and assist in the investigation of illicit trade." The parties to the Framework Convention recently approved a protocol to eliminate illicit trade in tobacco products, which includes both global and national tracking and tracing systems featuring unique identification markings, such as codes or stamps (Article 8), and required "complete and accurate records of all relevant transactions." (Article 9) . *Draft protocol to eliminate illicit trade in tobacco products*, Conference of the Parties to the WHO Framework Convention on Tobacco Control, May 11, 2012, at 13-14 (approved without amendment at FCTC Conference of the Parties, November 12, 2012). Although the U.S. is not yet a party to the Framework Convention, the 176 parties who have joined reflect a broad international consensus supporting the implementation of track and trace systems to address the threat of illegal tobacco markets.

⁴⁹ *Protocol to eliminate illicit trade in tobacco products*, Conference of the Parties to the WHO Framework Convention on Tobacco Control, November 12, 2012, at 13-14.

There is no environmental impact associated with this petition.

IV. CERTIFICATION

The undersigned certify that, to the best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition (21 CFR Section 10.30b).

Respectfully submitted,



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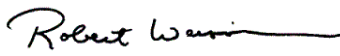
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