



April 5, 2016

Mr. Mitchell Zeller
 Director, Center for Tobacco Products
 U.S. Food and Drug Administration
 10903 New Hampshire Ave.
 Silver Spring, MD 20993-0002

Dear Mr. Zeller:

We write in support of the Citizen Petition, submitted on March 6, 2013 by the New York City Department of Health & Mental Hygiene and several of the undersigned organizations, urging the Food and Drug Administration (FDA) to establish a national track and trace system to reduce the illicit trade in tobacco products. Nearly three years have passed with no action by FDA. During this period there have been important new developments and the major tobacco companies have continued to use the threat of illicit trade to oppose virtually every major tobacco control effort at every level of government.

FDA has not just the clear authority, but a mandate to act. Section 920(b) of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, requires the FDA to promulgate regulations concerning the establishment and maintenance of records by the tobacco industry in order to implement the “tracking and tracing” of tobacco products from manufacture to sale to combat the illicit trade of those products. The case for such a system has become even more compelling in light of two recent government reports on the nature of the illicit tobacco market and how it can be addressed: (1) the report of the National Research Council and the Institute of Medicine, *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context and Lessons from International Experiences* (2015) (NRC/IOM Report), which was prepared in response to FDA’s request; and (2) the report of the Centers for Disease Control and Prevention, *Preventing and Reducing Illicit Tobacco Trade* (2015) (CDC Report). In several ways, these

reports echo the central themes of the Citizen Petition supporting a federal track and trace system.

First, both reports make it clear that when the illicit market in tobacco products involves state tax avoidance, it effectively reduces the price of cigarettes. This undercuts efforts to reduce tobacco consumption, a result directly at odds with FDA's mission. Thus, tax avoidance through cigarette trafficking is not simply a revenue issue; it is a public health issue as well.

The NRC/IOM Report observes: "By undermining the effect of tax measures on tobacco product price and use, the illicit trade has resulted in greater accessibility and consumption of cigarettes, especially among poor people and young people and so increases smoking and, hence, tobacco-related diseases in those groups."¹ The CDC similarly found that "[i]llicit tobacco trade (illicit trade) can undermine the effectiveness of raising tobacco prices by increasing the accessibility and affordability of tobacco products." Thus, when it occurs, the availability of cheap, illicit cigarettes directly undermines efforts to reduce youth smoking through such initiatives as the FDA's excellent "Real Cost" media campaign. A national track and trace system to curb the illicit market would directly serve FDA's public health objectives.

Second, the NRC/IOM Report notes the value of a track and trace system if it were implemented nationally, and its superiority over individual state systems that could be created. (NRC/IOM Report at 5-12) The CDC Report likewise concludes that a track and trace system should be a component of a comprehensive approach at the national level to curb illicit trade (CDC Report at 6), finding that "[c]ontrolling the tobacco product distribution chain from manufacture/import through retail sale is an essential component of curbing illicit tobacco trade" (CDC Report at 28) and emphasizing the necessity of a national system that allows for "information sharing between states [that] could be important for maximizing the effectiveness of tracking and tracing." (CDC Report at 26).

Third, the NRC/IOM Report finds that track and trace technologies would be useful in identifying contraband products, even if illegally manufactured. (NRC/IOM Report at 5-11.) Thus, track and trace could be a valuable tool to enforce product standards for tobacco products.

¹ In light of this strong statement by NRC and IOM, it is difficult to understand the tangential treatment of the public health effects of the illicit market in the State Department's December, 2015 report, *The Global Illicit Trade in Tobacco: A Threat to National Security*. The State Department report, joined by the Department of Health and Human Services and several other Executive Departments, notes in passing that cigarette smuggling "[u]ndermines government health policy objectives by increasing the use of tobacco products and depriving funds for anti-smoking campaigns and healthcare costs," with no further analysis of the impact of smuggling on government efforts to maintain high cigarette prices through tax increases. Despite being issued after the NRC/IOM Report, the State Department report does not mention it.

Fourth, both IOM and CDC contradict the assertion² that encrypted/digital tax stamps, of the kind that could support a track and trace system, have not been cost-effective. The NRC/IOM Report finds that the costs of encrypted tax stamps may be borne by producers and distributors, who may pass the costs on to purchasers through higher prices (a result that would tend to drive down consumption) and that “even when the costs are borne by governments, the costs of the stamps, related technologies, and enforcement efforts appear to be cost-effective, with the additional tax revenues that result from improved tax compliance and a reduction in the illicit tobacco trade more than offsetting the increased costs.” (NRC/IOM Report at 5-9). The CDC Report endorses the IOM finding that “[i]n the first decade following the implementation of upgrading of California’s encrypted tax stamp, the state has recovered an estimated \$450 million in additional tax revenue, well beyond the incremental implementation and enforcement costs.” (CDC Report, at 32.)

CDC also notes the findings of the Massachusetts Commission on Illegal Tobacco that, in the first three years following the full implementation of an encrypted stamp in Massachusetts, the state’s cigarette tax revenue declined far less than would have been expected from the downward trend in cigarette smoking during that period. (CDC Report at 32.) In Turkey, the first nation to implement a track and trace system, the country’s tobacco tax revenues rose by 31.5% within the first year, even though tax rates remained the same, with subsequent tax rate increases yielding increases in revenues despite reductions in tobacco use. (CDC Report at 27).

Finally, the IOM/NRC Report provides strong support for the importance of ensuring that any FDA track and trace system be free from tobacco industry influence or control. The Report finds that the “tobacco industry has also been at least partly complicit in the global illicit tobacco trade” and explains that the industry actually has an interest in perpetuating tobacco smuggling because “[t]he smuggling of legally manufactured cigarettes is a way of introducing the industry’s products into new markets and of expanding its share in existing markets.” (NRC/IOM Report at 1-9.) The absence of a finding of current tobacco industry complicity in the domestic illicit market does not diminish the importance insulating any FDA track and trace system from tobacco industry influence or control.

Indeed, the Report notes that the industry exploits the existence of an illicit market by using it as an argument against increased tax rates and more stringent regulatory changes, insisting that such measures will add to the illicit market, “although industry-sponsored estimates of the size of the illicit market tend to be inflated.” (NRC/IOM Report at 1-9-10.) The Report also finds that the industry’s own “track and trace” system, known as Codentify, “is regarded as having serious technical limitations.” (NRC/IOM Report at 5-10.) The NRC/IOM Report’s analysis of the industry’s incentives to maintain the illicit

² See e.g. Response of Altria Client Services Inc., on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company to Citizen Petition in Docket No. FDA-2013-P-0285, at 12-13 (September 6, 2013).

market, and its active role in contributing to that market across the globe, strongly support the conclusion in the pending Citizen Petition that “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.” (Citizen Petition, at 13.)

The Citizen Petition calling on FDA to implement its statutory track and trace mandate has been pending for almost three years without action by the agency. FDA now has the benefit of the report on illicit trade it requested from the NRC and the IOM, as well as CDC’s analysis, supporting the establishment of a track and trace system. The tobacco industry continues to use the threat of illicit trade to oppose tobacco control measures, including possible FDA action on menthol tobacco products,³ that are important to the protection of public health.

We therefore urge FDA to commence the rulemaking process leading to a national track and trace system to curb the illicit market that diminishes the nation’s efforts to reduce the disease and death caused by tobacco products.

Sincerely yours,

Action on Smoking and Health
American Academy of Pediatrics
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American Heart Association
American Lung Association
American Public Health Association
American School Health Association
Association of Schools and Programs of Public Health
Campaign for Tobacco-Free Kids
Eta Sigma Gamma - National Health Education Honorary
International Association for the Study of Lung Cancer
National Association of County & City Health Officials
National Latino Alliance for Health Equity
New York City Department of Health & Mental Hygiene
Oncology Nursing Society
Public Citizen
The Society of State Leaders of Health and Physical Education
Tobacco Control Legal Consortium
Truth Initiative

³ See e.g., *The Industry Menthol Report, Menthol Cigarettes: No Disproportionate Impact on Public Health*, submitted to FDA by the Non-Voting Industry Representatives on TPSAC and Other Tobacco Industry Stakeholders (March 13 2011), at 213 (arguing against ban on menthol cigarettes, in part because it “would increase black market cigarette sales.”)