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Division of Dockets Management  
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Rockville, MD 20852  


The Center for Tobacco Studies (CTS) is pleased to submit this comment to assist the U.S. Food and Drug Administration (FDA) in their review of the Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard. Since 2000, CTS has worked to promote and elevate research in tobacco use, policy, and marketing for the benefit of peers, practitioners, and policy makers. Our mission is to enhance the evaluation and surveillance of tobacco control as well as industry initiatives and strategies, by conducting research studies, that include primary and secondary data collection and analysis and qualitative and quantitative methods, and to translate and disseminate findings to program planners and policy makers. Our team of researchers, based at the Rutgers School of Public Health in Piscataway, NJ, conducts applied research of high quality, integrity, and innovation. 

Below we provide evidence that domestic counterfeiting is not a problem in the US and there is limited potential for growth in the context of a new product standard. However, we recommend that the FDA consider the potential for cross border bootlegging (e.g., Canada) and international counterfeiting (e.g., China, Paraguay, etc.) of non-standardized products.  

**Minimal evidence of domestic counterfeiting in the United States**  

The United States currently confronts an illicit cigarette market that is shaped by tax disparities between states.\(^1\) Illegal cigarettes in the US are largely bootlegged from low tax states or Native American jurisdictions and resold in high tax states. Illegal cigarette sales occur on the street,  

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through social networks and most notably inside legal retailers.\(^2\)\(^3\) The illegal trade is particularly appealing to low income smokers who are price conscious, and criminal entrepreneurs who take advantage of the tax disparities across states.\(^4\) In terms of counterfeit cigarettes, apart from isolated case studies of interdictions in major US seaports (NJ\(^5\) and CA), there is no independent empirical evidence that counterfeit tobacco and packaging is a major component of the illicit trade in tobacco products.

Counterfeiting in the US appears to be largely tied to tax stamps that are a feature of the illicit market but have generally been affixed to cigarette packs to conceal bootlegging ventures.\(^6\) For example, a Virginia tax stamp may be removed and replaced by a counterfeit New York City/New York State tax stamp. Independent researchers find it difficult to estimate the size of cigarette counterfeiting because of the industry’s trademark secrets. Only recently have researchers attempted to develop tools to identify counterfeit cigarettes relying on the packaging information.\(^7\) A recent study applied these forensic methods to 1,021 Marlboro Gold packs purchased in a random sample of tobacco retailers in New York City and found there were no verified counterfeits.\(^8\) Other indicators of the size of the counterfeit market are law enforcement seizures of counterfeit product and civil lawsuits under the federal Lanham Act\(^9\) brought on by the tobacco industry against retailers and individuals selling counterfeit cigarettes.\(^10\) However, relying on the number of seizures or civil cases brought by the industry is not a reliable indicator of the extent of the counterfeit trade in the US but rather a measure of the level of law enforcement or preemptive civil litigation by the tobacco industry.\(^11\)

**Barriers to product counterfeiting entering the US**

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In the event of the implementation of a tobacco product standard such as a ban on menthol cigarettes or reduced nicotine content, it is unlikely that the counterfeit cigarettes will be produced domestically. It is more likely that counterfeit brand name products will come from distant countries (e.g., Paraguay, Ukraine, and China) via fright and airmail. Genuine product without such standards will be diverted into the illegal marketplace from bordering countries (e.g., Mexico and Canada). There already exists bootlegging ventures from Mexico to the US through duty free shops along the US-Mexico land border (spanning Texas, New Mexico, Arizona and California). Persons leaving the US can buy an unlimited amount of duty free cigarettes from land border shops. Some persons purchase duty free cigarettes but remain in the US, or bootleg cigarettes back into the US after initially bootlegging them into Mexico.

Further, given the established illicit drug networks that allow large quantities of illicit drugs to enter the US through the Southwest border, bootlegging of non-standard products across the land border pose a greater threat than counterfeit product transported via airmail or freight. Federal law enforcement agencies in the US are quite experienced in interdicting such contraband, though funding, resources and shifting political priorities may influence the effectiveness of their operations. The leading law enforcement agencies who intercept contraband entering the US border are US Immigration and Customs Enforcement (ICE) and Customs and Border Protection (CBP). These agencies can minimize the impact of counterfeit product entering the country as well as domestic production of non-standardized products reentering. For example, in the event that domestic producers develop non-standard product destined for the international market, the ICE Tobacco Program, which mainly handles in-bond diversions would be able to neutralize this threat. Similarly, counterfeit cigarettes entering the US can be targeted using its Automated Targeting System (ATS) that examines products based on gathered intelligence.

In a recent presentation to the Institute of Medicine, CBP staff recognized that increases in the recent seizures of illicit cigarettes, mainly in the early 2000s, is related to the quality of intelligence and inspections. Given the practical reality that inspecting every shipment entering the US is not feasible, some product will likely make its way in the US.

The US has enacted several federal laws that make it difficult for smokers to purchase product on the Internet and across borders including the Prevent All Cigarette Trafficking Act and the Contraband Cigarette Trafficking Act. More recently, some high tax jurisdictions like New

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13 Ibid
16 Ibid, page 144.
York City have taken affirmative action in the form of civil litigation against large shipping companies (i.e., FedEx\(^\text{19}\) and United Parcel Service\(^\text{20}\)) who have been non-compliant with prior state agreements. These lawsuits have made substantial steps—including a verdict after a federal trial, currently on appeal—towards recouping hundreds of millions of dollars, and are expected to act as a deterrent to shipment companies who may not have previously prioritized compliance with these laws.\(^\text{21}\)

One of the main countries currently involved in the counterfeit marketplace is China, whose entry into the illegal cigarette marketplace was facilitated by the restructuring of the Chinese tobacco sector and the forced expansion of the Chinese cigarette market.\(^\text{22}\) Counterfeit cigarettes were first produced for Chinese brands (e.g., Hongtashan), but with the forced introduction of foreign brands, counterfeiters moved into Western brands (e.g., first media mention of counterfeit Marlboro in 1992).\(^\text{23}\) Counterfeiters were successful in purchasing excess tobacco from local tobacco farmers and use expert tobacco machinery, purchased from the State Monopoly. However, law enforcement operations detail illicit factories in other parts of the world that are capable of mass producing counterfeit cigarettes. For example, during Operation Black Poseidon, the international law enforcement agency, Interpol, uncovered a counterfeit cigarette factory in Ukraine that had a production line of 100,000 to 125,000 packs of cigarettes per day.\(^\text{24}\) However, it is currently unknown how many counterfeit cigarette factories exist internationally and if they have similar production speed.

**Consumer awareness of counterfeit product in the US and abroad**

It seems unlikely that counterfeit cigarettes will be popular because smokers in the US have been able to identify taste differences. A recent analysis of seized counterfeit product from a variety of local, state, and federal agencies in the US find that counterfeit contain higher levels of trace elements (e.g., lead, cadmium and thallium) than their genuine counterparts.\(^\text{25}\) Differences in chemistry may contribute to differences in sensory perceptions. For example, focus groups with illicit buyers of cigarettes in the South Bronx finds that smokers prefer to purchase cigarettes from licensed cigarette retailers operating illegally than street hawkers because of worries over

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\(^\text{21}\) Ibid


\(^\text{23}\) Ibid


the quality of the product. Smokers find that counterfeit cigarettes are inferior and taste “stale,” “nasty,” or “disgusting.” Similar taste differences have been affirmed by smokers who have purchased counterfeit product in South Africa and Europe.

**Bootlegging as the main source of concern in the implementation of a product standard**

In the event of a product implementation standard, the US FDA’s main concerns should be bootlegging and large scale smuggling. This is especially the case when neighboring countries including Canada and Mexico may not have implemented similar product standards. For example, in the US, criminal entrepreneurs have incentives to travel to nearby locations to purchase product (often at lower costs) and resell them in high tax jurisdictions. Even when these jurisdictions are cut off due to legislative changes, entrepreneurs find alternate routes to find product. While there is evidence that cigarettes have been bootlegged from New York to Canada in the late 1990s, reverse bootlegging can also occur. The tobacco industry was complicit in this scheme (accounting for 30% of the total market share in Canada), by exporting cigarettes to the US, with the intention that it would be smuggled back into Canada.

**Draft Re-Considerations**

Below we offer insight on improving elements of the draft proposal and advice on referring to international experiences.

1) **Tobacco bans in prisons and the Prohibition Era are poor comparisons**

The FDA’s comparison of the implementation of standard with the tobacco bans in prisons and US prohibition are not useful comparisons. These cases are extreme because of the totality of the bans. In both cases, neither populations (institutionalized and non-institutionalized) were allowed to consume any form of the product (e.g., low alcohol content or alternative nicotine delivery system such as e-cigarette). Also, in both cases, the prices for illicit products were higher because of low supply. However, the primary factor driving today’s illicit market in the US is the

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33 Ibid p. 233
price differentials between cigarettes from one locality to another, which create arbitrage opportunities for smugglers. If the FDA creates a product standard, different market forces would drive demand for an illicit market, and it is difficult to predict the prices of illicit products. Nevertheless, despite the accessibility of alternative nicotine delivery products, there would likely be demand for full nicotine cigarettes.

2) Price for bootlegged and counterfeit cigarettes in the US are cheaper than their legal equivalent

Illicit cigarettes in the US, including bootlegged and counterfeit product, are typically sold at lower prices. That is because one of the main incentives of the illicit trade is its low prices. For example, a focus group study conducted in 2013 found that the price between licit and illicit was significant. Smokers reported purchasing illegal packs of cigarettes for $7-8 when the legal price of cigarettes was $11.50. Similarly, smokers reported purchasing single cigarettes (“loosies”) for $0.50 each. As long as nearby countries impose lower cigarette taxes (e.g., Mexico), US consumers will continue to benefit from bootlegged product.

3) Draw from the international experience and independent expert panels

We urge the FDA to look to other developed countries as evidence on the impact that a product implementation standard would have on the US. Australia is a useful starting point since it has an established illicit market, and has evaluated impacts of plain packaging. A recent study in Australia using attempting to covertly purchases non-standardized cigarettes from a stratified random sample of stores before, during and after the implementation of plain packaging standard, found that the number of non-compliant packs remained quite low (2.2%, 1.3%, and 0.6% respectively). A recent examination of 49 female Australian smokers found that plain packaging did not affect their willingness to purchase counterfeit cigarettes. Non counterfeit and counterfeit buyers stated that they would continue to buy their respective brands despite changes in standardized packaging.

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37 Ibid

38 Ibid


The FDA should also consult with expert panels convened by the Institute of Medicine, not affiliated with the industry who have provided a set of guidelines and recommendations on studying the illicit marketplace as well an analysis on the impact that changes in tobacco products can have on the illicit marketplace. Similar ventures can be undertaken by assembling a panel of international experts who have had experiences with implementing tobacco control policies that include changes to the branding or physical features of the product (e.g. plain packaging, lowering nicotine, etc.). Lastly, the FDA should also look to the World Health Organization Framework Convention on Tobacco Control (FCTC) Protocol to Eliminate Illicit Trade in Tobacco Products to guide their implementation of enforcement activities to curb the illicit trade.

Sincerely,

Marin Kurti

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(signing on behalf of Cristine Delnevo, PhD, MPH, Kevin Schroth, JD, Mary Hrywna, MPH, Center for Tobacco Studies, Rutgers School of Public Health)

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