

# Strategies to Reduce Illicit Trade of Regular Nicotine Tobacco Products After Introduction of a Low-Nicotine Tobacco Product Standard

The US Food and Drug Administration is considering mandating a substantial reduction in the nicotine level of cigarettes and possibly other combusted tobacco products to render them minimally addictive. This would likely result in several public health benefits, including increased cessation, decreased progression to dependence, and reduced consumption of combusted tobacco products.

However, findings from clinical trials of reduced-nicotine cigarettes suggest that many smokers consuming low nicotine-content cigarettes sought out regular nicotine-content cigarettes, even when they were asked to only smoke free low-nicotine cigarettes. If this policy were implemented without ensuring that cessation treatments and appealing alternative products (e.g., e-cigarettes) were readily available, some consumers would be likely to seek banned regular nicotine-content combusted tobacco products from illicit sources: retail, online, and individuals. Left unchecked, this illicit market could undermine the public health benefits of the policy.

We describe supply and demand factors in an illicit market. Informed by the literature on controlling Internet tobacco sales and reducing illicit trade in low-cost cigarettes when there are price differentials, we recommend tracking and tracing products and greater surveillance and enforcement efforts to minimize illicit trade in normal nicotine products under a low-nicotine tobacco product standard. (*Am J Public Health*. 2019;109:1007–1014. doi: 10.2105/AJPH.2019.305067)

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See also Lindblom, p. 960.

The 2009 Family Smoking Prevention and Tobacco Control Act enabled the US Food and Drug Administration (FDA) Center for Tobacco Products to establish nicotine product standards for tobacco products if they are likely to improve public health.<sup>1</sup> Although researchers initially proposed the idea of reducing the levels of nicotine in cigarettes more than 2 decades ago,<sup>2</sup> the FDA recently issued an Advance Notice of Proposed Rule-Making for a Reduced-Nicotine Standard.<sup>3</sup> The FDA could mandate reduced-nicotine content in cigarettes and other combusted tobacco products to minimize their addictive potential.<sup>3–5</sup> Clinical trials showed that current smokers randomly assigned to very low nicotine-content (VLNC) cigarettes reduced their nicotine exposure and dependence, smoked fewer cigarettes, and experienced more smoke-free days.<sup>6–10</sup> If reduced-nicotine products encouraged current smokers to quit and made new smokers less likely to develop dependence, the public health impact of the low-nicotine product standard would be enormous.<sup>11–13</sup> In fact, a recent estimate of the impact of the reduced-nicotine standard would be 2.8 million tobacco-related deaths averted and 33.1 million life-years gained by 2060.<sup>13</sup>

Product standards to reduce nicotine content in all combusted

tobacco products will render the most harmful products less addictive. Otherwise, consumers may switch to combusted cigarette substitutes, such as little cigars.<sup>14–16</sup> As the reduced-nicotine product standard is implemented, it is important to ensure the widespread availability of cessation treatments and appealing noncombusted substitutes, such as e-cigarettes.<sup>17</sup>

Cigarettes with VLNC are markedly different from “light” or low-yield cigarettes. Light cigarettes (e.g., Marlboro Gold) decrease the machine-measured nicotine yield through filter ventilation and other design features, but the nicotine content is similar to “normal” cigarettes.<sup>18,19</sup> Research shows that light cigarettes do not lower nicotine exposure; consumers can maintain their nicotine exposure by smoking more cigarettes, blocking filter ventilation holes, and inhaling deeper.<sup>19</sup> By contrast, nicotine product standards would target

the actual nicotine content of the filler tobacco, drastically reducing users’ nicotine exposure. As a result, smoking more cigarettes is unlikely to maintain normal nicotine levels for VLNC users. In fact, numerous studies did not observe compensatory smoking beyond the first few VLNC cigarettes smoked.<sup>6–8,20–22</sup>

We anticipate that after implementing a new reduced-nicotine standard some smokers will seek combusted tobacco products with normal nicotine-content, thus creating demand for the development of an illicit market. A recent analysis of controlled clinical trials showed that, without adherence incentives, 75% to 80% of participants supplemented the study-provided VLNC cigarettes with commercial normal nicotine cigarettes.<sup>23</sup> Compared with studies providing commercial or normal nicotine cigarettes, the rate of nonadherence in studies of VLNC cigarettes is substantially

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higher.<sup>6</sup> These nonadherence rates with VLNC cigarettes are not surprising, considering that normal nicotine cigarettes are legal and readily available. Nevertheless, in VLNC cigarette studies, total nicotine exposure is reduced for most participants.

These findings raise an important question: “If normal nicotine–content combusted products were removed from the legal market, what would smokers do?” Some may quit using tobacco products, some may attempt to add nicotine to VLNC products (e.g., by dripping e-liquids on them), and some may switch to noncombusted products (e.g., medicinal nicotine, e-cigarettes). Indeed, smokers in 1 study assigned to VLNC cigarettes demonstrated a greater uptake of alternative nicotine–containing delivery systems, such as e-cigarettes, than did those assigned to normal nicotine–content cigarettes.<sup>24</sup> However, some smokers would seek combusted tobacco products with normal nicotine–content from a potential black market.

The FDA has stated that it expects “there would be a subset of consumers uninterested in switching to VLNC cigarettes or quitting tobacco products altogether. This subset of consumers may seek to obtain illicit tobacco products.”<sup>3</sup> Others note that a potential illicit market would be a significant barrier to implementing a reduced-nicotine standard and are concerned that nicotine reduction will be viewed as a form of prohibition, giving rise to a black market similar to that during the US prohibition of alcohol.<sup>25,26</sup> However, this analogy fails to recognize at least 1 important distinction: a reduced-nicotine standard will not prohibit smoking or nicotine use, but instead reduces nicotine content

only in combusted products because they cause the most harm.<sup>27</sup>

A better analogy is lowering alcohol content in spirits associated with high-risk adverse health consequences, while allowing alcohol content to remain high in other spirits with lower risk. In essence, the reduced-nicotine standard would shape the market, motivating smokers to quit or switch to less harmful nicotine–containing products, without prohibiting the drug itself. Indeed, alternative nicotine–containing products (e.g., e-cigarettes) may help reduce the size of a potential illicit market under a reduced-nicotine standard.<sup>28</sup> Our goal is to provide an analysis of the factors that will likely influence the development of an illicit market should the FDA proceed with establishing a low-nicotine product standard. Precisely estimating how many smokers will turn to an illicit market is beyond the scope of this essay. Rather, we present a framework that outlines the determinants of illicit supply and demand and suggest strategies that regulators could employ to reduce the risk of illicit trade in normal nicotine–content cigarettes.

## ILICIT TRADE SUPPLY CHAIN AND CONSUMER DEMAND

Modeled after reports by the US General Accounting Office and the National Academy of Science on illicit trade<sup>29,30</sup> of untaxed or undertaxed cigarettes, Figure 1 shows the supply chain for the distribution of VLNC and normal nicotine–content tobacco products through the legal and illegal markets. If implemented, a reduced-nicotine standard would make it illegal for

US manufacturers to distribute normal nicotine–content products in the domestic market. However, a manufacturer could legally export normal nicotine–content products for overseas distribution. These products could be diverted at export warehouses or exported and reimported into so-called gray market distribution. Legal VLNC products could be manufactured domestically or imported from other countries and ultimately reach retailers and consumers. Demand for normal nicotine products could provide incentives for illegal manufacturing of normal nicotine–content products. These products would likely be sold illegally through interpersonal (e.g., street) or Internet supply channels without exportation. Additionally, normal nicotine–content cigarettes could be imported (or purchased online from overseas vendors) and join the supply chain.

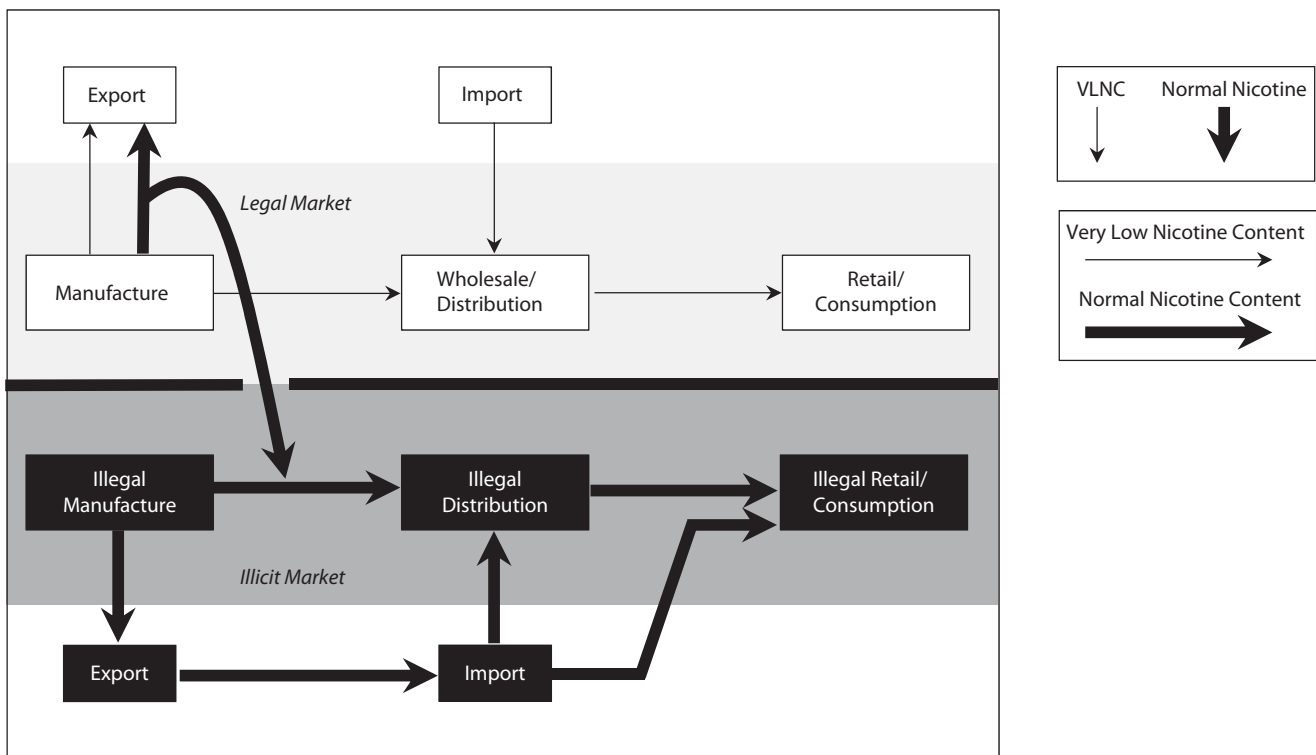
Figure 2 is a conceptual model adapted from a report by the National Academy of Sciences on illicit trade.<sup>29</sup> It illustrates the factors influencing smokers’ participation in the illicit market after implementation of a reduced-nicotine standard. Although product and brand characteristics (e.g., price, marketing, and taste), as well as user characteristics (e.g., demographics and degree of nicotine dependence), affect consumer demand for tobacco products, a reduced-nicotine standard would reduce the appeal and addictiveness of these combusted products. The model shows the supply and demand–based moderators that may influence a consumer’s propensity to engage in the illicit market or pursue other tobacco products.

Several supply-side factors will affect the number and type of illicit tobacco products, the

availability of legal alternative nicotine–containing products (e.g., e-cigarettes, medicinal nicotine), and the availability of VLNC products. These factors include enforcement efforts, policies, and the tobacco industry. These factors coupled with the demand-side factors (e.g., consumer acceptability of legal alternative nicotine–containing products, acceptability of illicit tobacco use, and appeal of VLNC products) will influence the behavioral changes resulting from a reduced-nicotine standard. Although illicit products would avoid taxation, other “costs” of procuring normal nicotine products will be higher because they are more inconvenient to purchase and are illegal. We propose 5 primary behavioral changes that current smokers could demonstrate:

1. quit use of all tobacco products;
2. completely switch to a legal alternative nicotine–containing product;
3. exclusively use a VLNC product;
4. use a combination of illicit normal nicotine–content products, legal VLNC products, or legal alternative nicotine–containing products; or
5. completely switch to an illicit normal nicotine–content product.

From a public health standpoint, the first option—quitting—is, of course, the best. Although it will be difficult for some users, most smokers want to quit, and the lowered nicotine will facilitate quitting. Option 2 (e.g., using an e-cigarette or medicinal nicotine exclusively) is the next best option. Implementation of a reduced-nicotine standard would be a catalyst creating large economic incentives for manufacturers of e-cigarettes, other noncombusted products, and nicotine



Note. VLNC = very low nicotine content.

Source. Adapted from General Accountability Office and National Academy of Science.<sup>29,30</sup>

**FIGURE 1—Opportunities to Divert Normal Nicotine–Content Combusted Products Into the Illicit Market**

replacement therapies to promote their products to eager smokers looking for alternative products. Ensuring minimal youth uptake during this transition will be essential. Option 3 involves continued use of a combusted product, which is undesirable and is not likely to lead to a substantial public health benefit. Switching to illicit tobacco products along with other products (option 4) or exclusively using illicit products (option 5) will be deleterious to public health, especially if either is a common choice.

Factors that can discourage options 4 and 5 include the appeal, marketing, and pricing of VLNC options; the appeal, marketing, and pricing of alternative nicotine-containing legal products; and regulation and enforcement to control illicit tobacco products. Policymakers

should ensure that alternative nicotine-containing products are available and are properly marketed and priced to promote substitution while minimizing uptake among youths.

Thoughtful marketing and pricing strategies can help smokers successfully transition to lower risk products. First, because many smokers think nicotine causes cancer, the misconception that smoking VLNC cigarettes will reduce the risk of cancer compared with smoking normal cigarettes must be rectified.<sup>31</sup> Second, nearly 40% of US current or former smokers mistakenly believe that e-cigarettes are as or more harmful than cigarettes.<sup>32</sup> In reality, completely switching to e-cigarettes from combusted cigarettes reduces exposure to toxicants and carcinogens found in tobacco

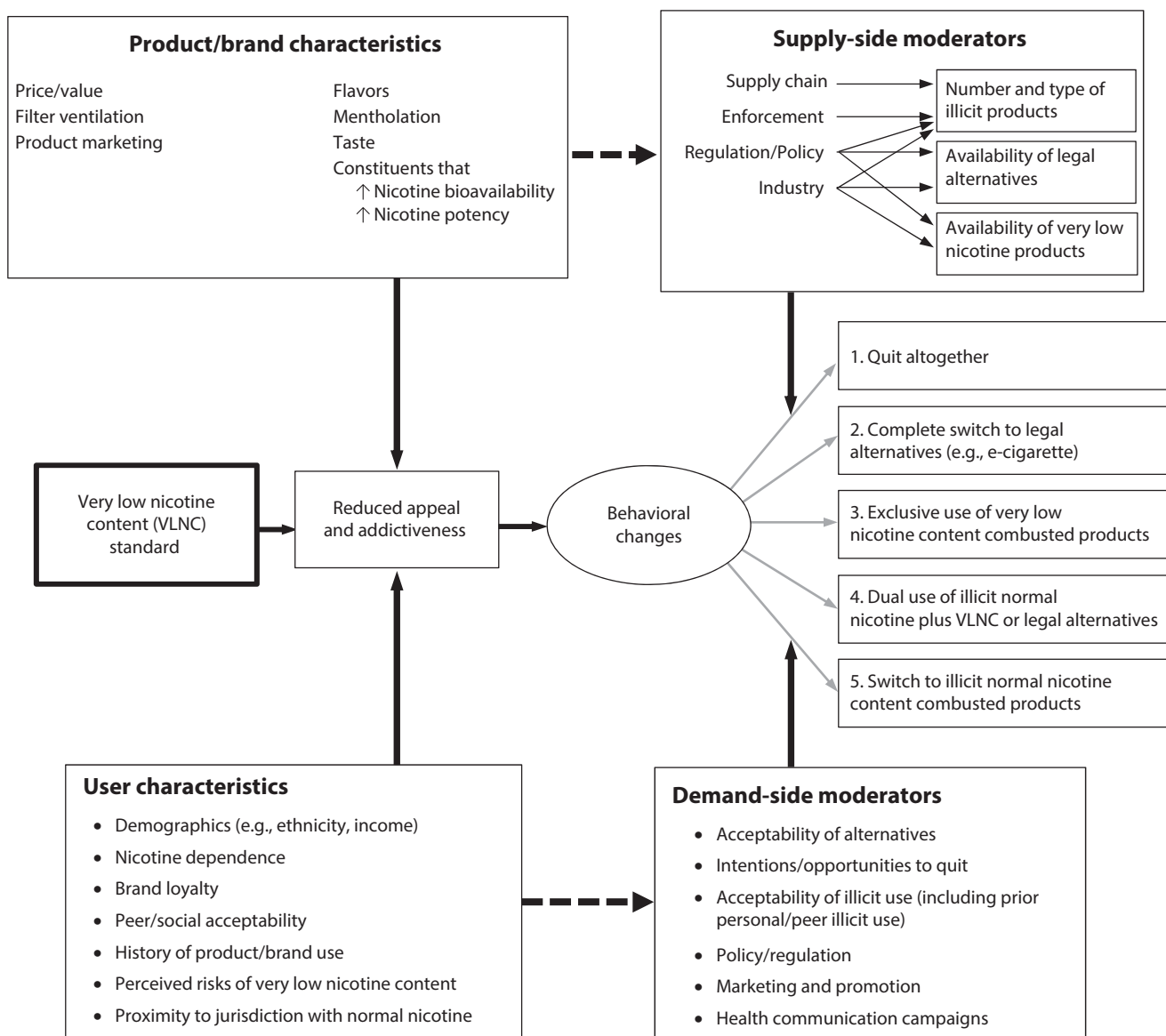
smoke, resulting in fewer short-term adverse health outcomes although unknown long-term outcomes.<sup>33</sup> These misconceptions may contribute to interest in illicit tobacco products. Therefore, the FDA may want to implement a paid media campaign addressing misperceptions to complement their reduced-nicotine standard and promote cessation resources or complete switching to alternate products.

### ILLICIT TRADE VIA THE INTERNET

One mechanism by which illicit normal nicotine products could be sold is the Internet. Cigarette sales have a long history of illicit trade via mail order. The

1949 Jenkins Act<sup>34</sup> was originally established to require tax reporting for cross-border cigarette sales, allowing states to collect taxes from consumers buying cigarettes from states with lower excise tax rates. In 2002, the General Accounting Office found that 195 Internet cigarette vendors (ICVs) failed to comply with the Jenkins Act<sup>35</sup> when selling to US customers. Two years later, the number of ICVs peaked at 775, before federal agreements with credit card companies and shippers were implemented. During this peak, 78% of ICVs advertised their noncompliance with tax laws.<sup>36</sup> Additionally, 95% of Internet sales failed to properly verify the age of purchasers to prevent sales to minors.<sup>37</sup>

With a wide variety of cheap tobacco products available



Source. Adapted from the National Academy of Sciences.<sup>29</sup>

**FIGURE 2—Model of Factors Influencing Smoker’s Participation in the Illicit Market to Procure Normal Nicotine-Content Tobacco Products**

online, ICVs were an easy alternative source of tobacco products for those seeking to skirt cigarette minimum age policies and high excise taxes. For instance, a pack-a-day smoker could save more than \$1500 annually by buying cigarettes online compared with buying them in a high-tax jurisdiction, such as New York City.<sup>38</sup> If the reduced-nicotine product standard is implemented, both the lure of cheap cigarettes

online and the availability of illicit regular nicotine-content products could stimulate demand, leading to a resurgence of the ICV market, which was substantially hampered through recent US regulations described in the next paragraph.<sup>39</sup>

Internet sales are notoriously difficult to regulate because of the evasiveness of Internet vendors and the thorny jurisdictional issues, whereby the customer,

Web site, business, and delivery site may each reside in different states or countries. The Quarantine of Unhealthy Internet Trade framework<sup>40</sup> was proposed to regulate Internet sales by severing the relationship between noncompliant Internet vendors and the companies that help them sell and ship their products to their customers (e.g., Web hosts, payment processors, shippers). In 2005, the federal

government and state attorneys general implemented aspects of the Quarantine of Unhealthy Internet Trade framework by convincing credit card companies (e.g., Visa, PayPal), UPS, FedEx, and DHL to voluntarily agree to stop being a party to illicit Internet cigarette sales transactions.<sup>41-44</sup> Before the payment and shipping bans, the 50 most popular ICVs had, on average, approximately 36 000 visits per month. In the

year following the bans, monthly traffic dropped to fewer than 8000 visits per month, and 61.8% of ICVs went out of business.<sup>45</sup> This demonstrates that it is possible to regulate Internet sales and reduce the flow of illicit tobacco products.

Unfortunately, the highly adaptable ICVs switched to unbanned shipping and payment methods.<sup>45,46</sup> A loophole in the agreements allowed the US Postal Service to continue shipping products, and payment methods like e-checks, wire transfers, and PayPal-like services were not banned. In response, the US Congress passed the Prevent All Cigarette Trafficking (PACT) Act in 2009,<sup>47</sup> adding the US Postal Service to the list of banned shippers, requiring rigorous age verification for Internet cigarette sales, and providing a framework for enforcing the Jenkins Act and collecting taxes from ICV customers. Before PACT, lack of enforcement had resulted in little initial change in ICV sales practices<sup>38</sup>; eventually nearly all ICVs moved overseas (while still targeting US customers) or went out of business.<sup>39</sup>

Other types of illicit tobacco products sold online are formerly legal products that are now restricted by the FDA. In 2009, the Family Smoking Prevention and Tobacco Control Act<sup>1</sup> prohibited the sale of flavored cigarettes (other than menthol) and of cigarettes labeled with misleading descriptors (e.g., “light”). Despite the new law, a significant proportion of ICVs continued to sell these prohibited light and flavored products. Many of these ICVs were based internationally, but that did not matter because they are still accessible to US consumers.<sup>48</sup> Google searches for the banned Djarum clove-flavored cigarettes remained twice as high as the nonbanned

Djarum flavored cigars 3 years after the ban. This demonstrates some consumers’ enduring interest in searching for and purchasing banned products online.<sup>49</sup> To our knowledge, the prevalence of purchasing these banned products from online sources is unknown.

Considering that many Internet tobacco vendors have sold banned or restricted products, it seems likely that they will attempt to sell normal nicotine-content cigarettes to US customers if the FDA mandates VLNC combusted tobacco products. Therefore, policy-makers must effectively restrict online sales of normal nicotine products from US and international sources as well as expand PACT to include all regular nicotine combusted products. Better enforcement of PACT to ban delivery of cigarettes to consumers is 1 way to thwart ICVs. For example, effective package screening to detect cigarettes, particularly in packages delivered from overseas, could substantially affect the illicit supply chain of normal nicotine-content cigarettes. Lessons learned from previous studies of the ICV industry include regularly surveilling the sales and marketing practices of Internet vendors, restricting shipping and payment options for vendors, and conducting regular enforcement through monitoring Web site content and conducting test purchases.

## ILLICIT TRADE AND TAX AVOIDANCE

Because most illicit trade for tobacco products is related to taxation, we reviewed the similarities and differences between what is known about tax-related

illicit trade and potential reduced nicotine content-related trade. Although raising tobacco taxes is 1 of the most effective ways to reduce tobacco use,<sup>50–52</sup> it may also lead to compensatory behaviors aimed at circumventing tax increases through both licit (i.e., tax avoidance) and illicit (i.e., tax evasion) channels.<sup>50,51</sup> Tax avoidance activities include purchasing tobacco products in other jurisdictions (e.g., cross-border shopping) in amounts allowable under tax laws and stockpiling. Tax evasion and illicit trade involve transporting or purchasing smuggled and illegally manufactured tobacco products (both genuine tobacco products diverted through illegal channels and counterfeit products).

The extent to which compensatory behaviors may undermine the public health benefits of raising tobacco taxes is largely determined by the prevalence of tax avoidance and evasion behaviors. The reduced-nicotine standard, if implemented, is unlikely to create cross-border purchase within the United States because it will be at the federal level. However, cross-border purchase could occur in areas that share a border with Canada and Mexico. The extent that large-scale smuggled and illegally manufactured normal nicotine-content cigarettes could occur will be largely determined by law enforcement and penalties associated with these behaviors.

Several measures have been used to estimate the extent of tobacco tax avoidance and evasion, including collecting littered cigarette packs from sidewalks and trash cans, examining cigarette packs in face-to-face interviews with smokers, and asking smokers to submit their empty cigarette packs to

researchers. In the United States, researchers collected littered cigarette packs in high-tax jurisdictions, such as Chicago, Illinois, and New York City, to assess the extent of tax avoidance and evasion. They found that about 75% of cigarette packs collected in Chicago lacked the proper tax stamp.<sup>53</sup>

However, this overestimates the extent of tax avoidance and evasion among Chicago residents, because it includes the large numbers of daily visitors in Chicago who may have purchased their cigarettes elsewhere. After the state cigarette excise tax rate increased from \$1.50 to \$2.75, researchers found that tax avoidance in New York City increased from 15% to 24%, as measured by the percentage of littered packs without a New York tax stamp.<sup>54</sup> Examining littered cigarette packs as a way to determine tax evasion has also been used in France<sup>55</sup> and Poland.<sup>56</sup> Other measure of illicit trade related to higher tobacco taxes are examining discrepancies between imports and exports<sup>57</sup> and between sales and consumption,<sup>58</sup> as well as survey-<sup>59</sup> and model-based<sup>57,60</sup> methods. These same methods can be applied to estimate the potential size of the illicit market attributable to the reduced-nicotine standard.

In 2007, illicit cigarettes accounted for an estimated 11.6% of cigarette consumption in 84 countries.<sup>61</sup> Also in 2007, the National Academy of Medicine estimated that between 8.5% and 21.0% of the total cigarette market in the United States was accounted for by illicit sales.<sup>29</sup> Estimates of the potential size of the illicit market for regular content cigarettes under a reduced-nicotine standard are not available. Although tobacco tax and price differences across jurisdictions incentivize tobacco

tax avoidance and evasion behaviors,<sup>57,62–64</sup> research has demonstrated that tobacco tax evasion was largely attributable to weak governance, corruption, lack of control of authorities, ineffective tax and customs administration, complex tax structures, loopholes in tobacco tax systems, weak control of illicit trade, and lack of enforcement and strong penalties.<sup>57,65–68</sup>

Countries that strengthened their governance, tax administration, control of illicit trade, and law enforcement have seen large declines in tobacco tax avoidance and evasion.<sup>29,51,69</sup> Although the implementation and strengthening of these measures have financial costs, the resulting economic and public health benefits outweigh those costs. For example, in the 10 years following the implementation and upgrading of California's encrypted cigarette tax stamp, California recovered an estimated \$450 million in additional tax revenue, which well exceeded implementation and enforcement costs.<sup>29</sup> A similar pattern was observed in Massachusetts after implementing an encrypted cigarette stamp in 2010.<sup>70</sup> Similarly, strong governance, effective administration, strong control of illicit trade, and strong enforcement and penalties will reduce the likelihood that an illicit market could occur after a reduced-nicotine standard is implemented; these measures will also reduce the size of the potential illicit market.

## CONCLUSIONS

Although a new FDA product standard to reduce nicotine levels in cigarettes and other combusted tobacco products would reduce tobacco use and related harms, the extent to which smokers

would be motivated and able to obtain illicit regular nicotine content products would reduce those gains. A large body of research has demonstrated that raising tobacco taxes reduces tobacco use and that tax avoidance and evasion diminishes but does not eliminate the beneficial impact of these taxes.<sup>51,71</sup> Research on factors that affect both the supply and demand of illicit combusted tobacco products offers valuable lessons for the FDA and other regulators outside the United States considering lowering the nicotine content of combusted tobacco products. From the supply side, the federal government and law enforcement agencies can reduce the supply of illicit combusted tobacco products through coordinated and stronger law enforcement efforts (e.g., better screening of packages and purchase operations), improved tax stamp technology (e.g., encrypted tax stamps<sup>29</sup>), and higher penalties for engaging in illicit trade.

If a large illicit supply chain were to develop, it should be apparent to enforcement authorities, who could swiftly address it. Additionally, the government could implement measures, such as developing a tracking and tracing system for all tobacco products from seeds to sale (as is done with marijuana in many states); licensing those involved in tobacco product manufacturing or distribution, as well as those involved in the manufacturing or distribution of the machinery used to produce tobacco products; and strengthening control measures in international free trade zones and for tobacco products in international transit. From the demand side, the government can use tobacco tax and other policy options to increase smokers'

access to and use of alternative nicotine-containing products, thereby reducing the demand for illicit combusted tobacco products. At the same time, to reduce the potential uptake of these alternative products among youths, several policies could be considered, including, but not limited to, policies that reduce their appeal (e.g., restricting e-cigarette flavors or marketing), public education campaigns, and excise taxes.

On the basis of research reviewed in previous sections for minimizing tax evasion and illicit trade online and through retail channels, several methods for controlling an illicit market for normal nicotine-content combusted tobacco products could inform the FDA if they require US cigarette manufacturers to market only VLNC cigarettes in the United States. The 5 key lessons for the United States and other countries considering implementing a reduced-nicotine standard are as follows:

1. Implement a robust track and trace system for all combusted tobacco products that includes encrypted tax stamps and other product markings on tobacco packages.
2. Strengthen and enforce regulations prohibiting online payment processing and shipping options for Internet tobacco vendors.
3. Require licenses for those involved in the tobacco manufacturing and distribution chain, conduct regular compliance testing and enforcement operations to curtail illicit manufacturing, and strengthen penalties for engaging in illicit trade.
4. Apply the reduced-nicotine standard to cigarettes and all other combusted products, because of their high toxicity,

to deter smokers from substituting little cigars and other products for VLNC cigarettes.

5. Ensure that both smoking cessation treatments and alternative nicotine-containing products (e.g., e-cigarettes) are readily available, priced at a lower rate than combusted products but high enough that it prevents uptake among youths, and are appealing to smokers but not youths.

The FDA and other stakeholders should consider these recommendations to minimize the potential size of an illicit trade of tobacco products under a reduced-nicotine standard. Not implementing these or other strategies could allow the illicit market to develop and flourish, and the great public health benefit of VLNC products will not be fully realized. Fortunately, decades of experience in regulating the sales, taxation, and marketing of tobacco products can inform strategies to minimize an illicit market and increase the likelihood of a successful implementation of a reduced-nicotine product standard. **AJPH**

## CONTRIBUTORS

K. M. Ribisl conceptualized the essay, drafted the summary and recommendations section, and compiled the first draft of the essay. D. K. Hatsukami and E. C. Donny drafted the introduction section. J. Huang drafted the section on tax evasion. R. S. Williams drafted the section on Internet sales. All authors edited the essay and approved the final version.

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**Note.** The content is solely the responsibility of the authors and does not

necessarily represent the official views of the National Institutes of Health or the FDA.

## CONFLICTS OF INTEREST

K. M. Ribisl has served as an expert consultant in litigation against cigarette manufacturers and Internet tobacco vendors. R. S. Williams has served as an expert consultant in litigation against delivery services shipping products to Internet tobacco vendors.

## HUMAN PARTICIPANT PROTECTION

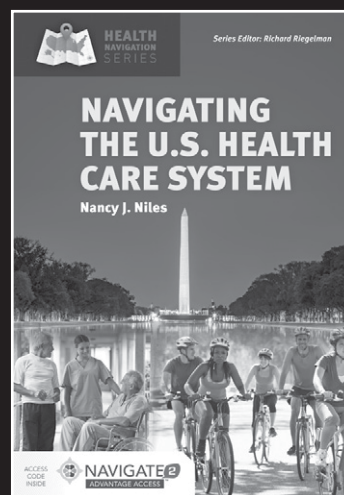
No protocol approval was necessary because there were no human participants in this study.

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