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**VIA ELECTRONIC FILING – www.regulations.gov**

Ms. Gerie Voss  
Center for Tobacco Products  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993-0002

RE: Tobacco Product Standard for Nicotine Level of Combusted Cigarettes; Docket No.  
FDA-2017-N-6189

Dear Ms. Voss:

The National Association of Convenience Stores (“NACS”) and the Society of Independent Gasoline Marketers of America (“SIGMA”) (collectively “the Associations”) appreciate this opportunity to provide comments on the Food and Drug Administration’s (“FDA” or the “Agency”) advance notice of proposed rulemaking (“ANPRM”) on a tobacco product standard for the nicotine level in combustible cigarettes.<sup>1</sup> These comments are intended to ensure the Agency is fully aware of the impact implementing a tobacco product standard for nicotine levels, as well as regulating tobacco flavors,<sup>2</sup> will have on the illicit trade of tobacco products, which FDA is considering in its draft concept paper entitled “Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard” (“White Paper”).<sup>3</sup>

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<sup>1</sup> Dep’t Of Health And Human Services, Food and Drug Administration; Tobacco Product Standard for Nicotine Level of Combusted Cigarettes; 83 Fed. Reg. 11818 (Mar. 16, 2018) *available at* <https://www.gpo.gov/fdsys/pkg/FR-2018-03-16/pdf/2018-05345.pdf>.

<sup>2</sup> Dep’t Of Health And Human Services, Food and Drug Administration; Regulation of Flavors in Tobacco Products; 83 Fed. Reg. 12294 (Mar. 21, 2018) *available at* <https://www.gpo.gov/fdsys/pkg/FR-2018-03-21/pdf/2018-05655.pdf>.

<sup>3</sup> Dep’t Of Health And Human Services, Food and Drug Administration; Draft Concept Paper: *Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard*; 83 Fed. Reg. 52 (Mar. 16, 2018) *available at* <https://www.gpo.gov/fdsys/pkg/FR-2018-03-16/pdf/2018-05346.pdf> (hereinafter “White Paper”).

The Associations’ members are consumer-facing entities that constantly adapt to changing consumer demands, and are thus effective surrogates for consumers. It is important to remember that offering a product for sale does not guarantee that consumers will purchase it. The Associations believe promulgating tobacco regulations that effectively ban nicotine in combustible tobacco products could leave consumers with a product they do not want and risk giving rise to an entire industry of unregulated cigarettes. Similarly, banning all flavors (including menthol) could push a portion of current smokers to the illicit market.

## **I. Background on the Associations**

The convenience and petroleum retailing industry has become a fixture in American society and a critical component of the nation’s economy.<sup>4</sup> In 2017, the fuel wholesaling and convenience industry employed more than 2.48 million workers and generated \$601.1 billion in total sales, representing approximately 3 percent of U.S. Gross Domestic Product.<sup>5</sup> Because of the number of fuel and other transactions in which the industry engages, fuel retailers and marketers handle approximately one of every 30 dollars spent in the United States. Convenience stores serve about 160 million people per day—around half of the U.S. population—and the industry processes over 74 billion payment transactions per year. Nevertheless, the convenience store and fuel retail industry is truly an industry of small businesses. Approximately 63 percent of convenience store owners operate a single store.

Sales of cigarettes and other tobacco products are vital to the convenience store industry’s economic viability, which maintains nearly 90 percent of the cigarette market share. Tobacco products accounted for approximately 34 percent of convenience stores’ in-store sales in 2017. Tobacco products are the most regulated products the industry sells. The Associations have devoted a substantial amount of time and resources to ensuring that convenience store operators are equipped to comply with federal, state, and local tobacco regulations. As a result, the Associations have played a prominent role in the development of United States tobacco policy for the last two decades; its membership has a deeply vested interest in the outcome of the policy choices that FDA makes.

## **II. Comments for Consideration by the Agency**

Congress, when it passed the Family Smoking Prevention and Tobacco Control Act<sup>6</sup> (“Tobacco Control Act”) in 2009, granted FDA the authority to regulate tobacco products to reduce their use and prevent their uptake by underage children.<sup>7</sup> To that end, a recent report from the Centers for Disease Control and Prevention (“CDC”) found that smoking rates have

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<sup>4</sup> NACS is an international trade association representing the convenience store industry with more than 2,100 retailer and 1,750 supplier companies as members, the majority of whom are based in the United States. SIGMA represents a diverse membership of approximately 260 independent chain retailers and marketers of motor fuel.

<sup>5</sup> All data in Section I comes from the NACS, State of the Industry Annual Report of 2017 Data (June 2018).

<sup>6</sup> Pub. L. 111-31 (2009); 123 Stat. 1776.

<sup>7</sup> Congress, however, did not give FDA the authority to ban, or effectively ban, tobacco products.

declined approximately 5.5 percent since 2005.<sup>8</sup> During this time, however, illicit trade in tobacco products has flourished. If FDA expands its regulations by limiting the amount of nicotine in combustible tobacco products, the black market will undoubtedly grow in response to meet the consumer demand that exists among adult smokers.

A. Many adult consumers are addicted to tobacco products and will struggle to move to a lower nicotine product.

According to the CDC, 37.8 million people in the U.S., or 15.5 percent of adults, smoked cigarettes in 2016,<sup>9</sup> and the majority of these smokers are addicted to them.<sup>10</sup> Moreover, tobacco products are more likely utilized by individuals living below the poverty line than their more wealthy counterparts.<sup>11</sup> While the Associations understand FDA’s desire to move these adults from more harmful combustible nicotine products to other products considered less harmful,<sup>12</sup> the Associations believe that a nicotine product standard will not accomplish that goal. Instead, addicted smokers will either smoke more cigarettes to get the nicotine they need or they will turn to the illicit market.

As FDA acknowledges in its White Paper,<sup>13</sup> some consumers, due to their addiction to nicotine, will be uninterested or unable to switch to a product with lower nicotine levels. In fact, FDA recognizes that during studies on very low nicotine content (“VLNC”) cigarettes, many consumers were “unable to tolerate the reduction in nicotine.”<sup>14</sup> Likewise, when studying low-yield cigarettes, the National Cancer Institute found that in order to compensate for a lower nicotine yield, smokers will simply change their smoking patterns, including modifying the cigarettes or increasing the number of cigarettes they smoke each day.<sup>15</sup> And, since smokers that

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<sup>8</sup> Ahmed Jamal, Elyse Phillips, Andrea S. Gentzke, et al., *Current Cigarette Smoking Among Adults — United States, 2016*, Ctrs. for Disease Control and Prevention, Morbidity and Mortality Weekly Report 2018, 67:53–59 (Jan. 19, 2018) available at <https://www.cdc.gov/mmwr/volumes/67/wr/mm6702a1.htm>.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

The Centers for Disease Control and Prevention estimate that 68 percent of adults that smoke would like to quit and 55 percent of adults that smoke have made an attempt to quit, which implies that these adults are addicted to cigarettes and do not continue to smoke by choice.

<sup>11</sup> *Id.*

<sup>12</sup> News Release, Food and Drug Administration, *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death* (July 28, 2017) available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm>.

<sup>13</sup> White Paper at p. 13.

<sup>14</sup> White Paper at p. 15.

<sup>15</sup> Dep’t Of Health And Human Services, Public Health Service, Nat’l Institutes of Health, Nat’l Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph No. 13 (Nov. 2001).

are uninterested or unable to quit smoking are more likely to utilize price-minimizing strategies, they may also be more likely to meeting their nicotine needs with illicit products.<sup>16</sup>

Effectively eliminating nicotine in combustible tobacco products will not eliminate smokers' addiction to nicotine—smokers will merely adjust. If the FDA's goal is to move consumers from combustible products to non-combustible products, it should set regulations allowing alternatives that consumers enjoy, which also meets their nicotine needs (and which may need to include flavorings to effectively attract current smokers). If not, consumers will likely seek unregulated cigarettes on the black market.

#### B. Banning flavored tobacco products will increase illicit activity.

A ban on flavors may not reduce underage smoking. Because of the relative ease of obtaining flavorings (especially online), an opportunity exists for black market manufacturers to bypass FDA's regulations.<sup>17</sup> For example, illicit actors can easily modify tobacco products with an aftermarket flavor additive—especially if the flavoring itself is not illegal. The FDA simply does not have the ability to stop illicit actors from adding flavors to tobacco products.

It is unreasonable to expect that the menthol market, which accounts for roughly 30 percent of cigarette sales today, will vanish. A menthol ban will undoubtedly lead to a black market in menthol cigarettes because of the broad consumer base that exists among adult smokers. And, the purveyors of menthol cigarettes, operating outside of the law, will not discriminate among their customers based on age.

In addition, FDA Commissioner Scott Gottlieb has publically advocated that “adults who still need or want nicotine...get it from alternative and less harmful sources.”<sup>18</sup> In fact, the National Academies of Sciences, Engineering, and Medicine found conclusive evidence that e-cigarettes contain fewer harmful ingredients than combustible tobacco cigarettes.<sup>19</sup> As Commissioner Gottlieb acknowledged, “flavors may help adult cigarette smokers switch to potentially less harmful forms of nicotine delivery.”<sup>20</sup> FDA should consider that in the context of any rulemaking on flavors.

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<sup>16</sup> Jonathan Kulick, James E. Priege, Mark A.R. Kleiman, *Unintended Consequences of Cigarette Prohibition, Regulation, and Taxation*, Int'l Journal of Law, Crime and Justice 46 (2016).

<sup>17</sup> White Paper at p. 8-9.

<sup>18</sup> Scott Gottlieb, M.D., Commissioner, Food and Drug Administration, Public Discussion on The Regulation of Nicotine, Johns Hopkins Bloomberg School of Public Health (Oct. 19, 2017) available at <https://www.fda.gov/newsevents/speeches/ucm581314.htm>.

<sup>19</sup> Nat'l Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* (Jan. 23, 2018).

<sup>20</sup> *Id.*

C. The illicit trade of tobacco products already exists.

A substantial black market for tobacco products has developed as a way to circumvent regulations and state excise taxes. Although it is difficult to quantify the extent of any illicit activity, between 8.5 percent and 21 percent of tobacco products in the U.S. are estimated to be purchased on the black market.<sup>21</sup> Since the tobacco market is a “dual market” (*i.e.*, there are both legal and illegal tobacco transactions), it is difficult to distinguish between legal and illegal tobacco products, which makes it harder to detect illicit products and measure their trade. Currently, the illicit trade market in the U.S. is conducted through bootlegging, smuggling, and illegally producing cigarettes.<sup>22</sup>

According to the Alcohol and Tobacco Tax and Trade Bureau (“TTB”), the black market for tobacco products is successful because “the potential for illicit gains is high and the risk to illegal operators is low.”<sup>23</sup> For example, in New York, the penalty to bring cigarettes from Virginia to New York is equal to the expected profit, meaning a smuggler can still break even in the unlikely event he is caught.<sup>24</sup> As more people participate in the illicit trade of tobacco, the risk associated for each person participating decreases.<sup>25</sup> And, as the individual risk decreases, even more people will be willing to participate.

Furthermore, the illicit trade market has proven adaptable. A study published in the *American Journal of Public Health* found that a New York tax law prohibiting Native American tribes from selling cigarettes to non-tribal members did not end the illicit trade of tobacco products in New York.<sup>26</sup> Instead, tobacco products sold on the black market in New York were supplied by a different, but still cheaper jurisdiction (*e.g.*, states like Virginia and North Carolina). As described in a report produced by the Government Accountability Office (“GAO”), the tobacco black market is “like a whack-a-mole problem” and “although illicit trade

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<sup>21</sup> Nat’l Research Council, Comm. on the Illicit Tobacco Market, *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences* (Peter Reuter and Malay Majmundar, Editors, (Feb. 19, 2015)).

<sup>22</sup> *Id.* Bootlegging is the legal purchase of cigarettes in one jurisdiction and their consumption or resale in another jurisdiction without the payment of applicable taxes or duties. Smuggling is defined as the sale of cigarettes without any payment of taxes or duties. Illegal production, on the other hand, can either be the unlicensed production of legitimate tobacco products or the production of counterfeit cigarettes.

<sup>23</sup> Dep’t of the Treasury Alcohol and Tobacco Tax and Trade Bureau, *Department of the Treasury Report to Congress on Federal Tobacco Receipts Lost Due To Illicit Trade and Recommendations for Increased Enforcement*, (Feb. 4, 2010) available at <https://ttb.gov/pdf/tobacco-receipts.pdf>.

<sup>24</sup> Kulick, *supra* note 15.

<sup>25</sup> Kulick, *supra* note 15.

<sup>26</sup> Martin Kurti, Klaus von Lampe, and Jacqueline Johnson, *The Intended and Unintended Consequences of a Legal Measure to Cut the Flow of Illegal Cigarettes Into New York City: The Case of the South Bronx*, *American Journal of Public Health*, Vol. 105, Issue 4 (Apr. 2015).

may decrease immediately following successful law enforcement efforts, these activities usually resume after a period.”<sup>27</sup>

D. The federal government has been unsuccessful at enforcing the current tobacco regulations – and fighting the illicit trade market.

As FDA contemplates a nicotine product standard, the Agency must consider how it would administer new regulations in light of the fact that the federal government has been unsuccessful in enforcing current laws and regulations, which has allowed the illicit trade of tobacco to flourish. Ignoring the government’s inability to enforce tobacco regulations underestimates the burden associated with FDA promulgating new regulations.<sup>28</sup>

The enforcement of current tobacco regulations is shared by many federal agencies – including the Bureau of Alcohol, Tobacco, Firearms and Explosives (“ATF”) in the U.S. Department of Justice (“DOJ”); the Immigration and Customs Enforcement (“ICE”) and Customs and Border Protection (“CBP”) in the U.S.; the TTB in the U.S. Department of the Treasury (“Treasury”); and the Center for Tobacco Products (“CTP”) in the U.S. Department of Health and Human Services (“HHS”) Food and Drug Administration (“FDA”). Moreover, states and localities have additional laws to regulate tobacco. The enforcement of regulations, however, is not consistent or coordinated between these entities, especially considering the scope of the black market.

ATF is primarily responsible for enforcing the Contraband Cigarette Trafficking Act<sup>29</sup> and the Prevent All Cigarette Trafficking Act,<sup>30</sup> laws implemented to combat the illicit trade of tobacco products. ATF, however, spends less than 2 percent of its annual budget and less than 1 percent of its time on investigating the tobacco black market.<sup>31</sup> In 2010, ATF announced it would focus on violent criminal investigations rather than nonviolent alcohol and tobacco investigations.<sup>32</sup> As a result, ATF’s investigations into alcohol and tobacco crimes plummeted 85 percent – to a mere 25 investigations in 2013.<sup>33</sup> Soon after, an audit conducted by the DOJ found “a serious lack of oversight by ATF” in its investigation of the illicit trade of tobacco,

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<sup>27</sup> Gov’t Accountability Off., GAO-11-313, *Illicit Tobacco: Various Schemes Are Used to Evade Taxes and Fees* (Mar. 7 2011).

<sup>28</sup> Mark A.R. Kleiman, James E. Prieger, Jonathan Kulick, *Illicit Trade as a Countervailing Effect: What the FDA Would Have to Know to Evaluate Tobacco Regulations*, *Journal of Drug Policy Analysis* (Apr. 12, 2016).

<sup>29</sup> 18 U.S.C. § 2341-2346.

<sup>30</sup> 15 U.S.C. § 375-378, as amended.

<sup>31</sup> Dep’t of Justice, Office of the Inspector General, *The Bureau Of Alcohol, Tobacco, Firearms And Explosives’ Efforts To Prevent The Diversion Of Tobacco* (Sept. 2009), available at [oig.justice.gov/reports/ATF/e0905.pdf](http://oig.justice.gov/reports/ATF/e0905.pdf).

<sup>32</sup> Gov’t Accountability Off., GAO-14-553, *Bureau Of Alcohol, Tobacco, Firearms And Explosives: Enhancing Data Collection Could Improve Management Of Investigations*, (June 30, 2014) available at <https://www.gao.gov/assets/670/664514.pdf>.

<sup>33</sup> *Id.*

including the failure to meet its own standards when conducting investigations.<sup>34</sup> Separately, the TTB is responsible for federal excise tax compliance of tobacco products. In 2016, TTB completed approximately 400 investigations of alcohol and tobacco diversions, but only collected tax revenues of \$57 million from these investigations, or approximately one percent of the estimated taxes lost from illicit trade.<sup>35</sup>

There is also a “grey” market for cigarettes that are manufactured legally abroad, but imported into the U.S. under dubious legal circumstances. According to officials from CBP and ICE, smugglers frequently import cigarettes into the United States by not declaring them, disguising them, and hiding them behind other items.<sup>36</sup> FDA itself admits that it “is not feasible” to inspect all imported tobacco products,<sup>37</sup> creating a pipeline into the U.S. for illicit cigarettes. Furthermore, FDA acknowledges that duty-free locations will continue to sell high-nicotine cigarettes even if a product standard is created, allowing for “relatively easy movement” of illegal tobacco products into the country.<sup>38</sup>

The ubiquity of the Internet has provided consumers with greater access to illicit tobacco products, whether they are bootlegged, smuggled, and counterfeit. As FDA describes in its White Paper, websites not only offer illegal tobacco products for purchase, but also provide information on how consumers can procure them.<sup>39</sup> Websites including social media and individual sale sites facilitate illicit trade by allowing consumers to easily connect with distributors.<sup>40</sup>

It is unsurprising the black market continues to expand with the lack of enforcement by the federal government. The Associations can only imagine how many tobacco products will be sold illicitly if a tobacco product standard on nicotine or flavorings is issued. Without a domestic and legal source for the tobacco products they prefer, smokers will simply purchase the products they want over the Internet or rely on illicit importers and distributors.

#### E. Tribal sovereignty should be considered when creating a tobacco standard.

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<sup>34</sup> Dep’t of Justice, Office of the Inspector General Audit Division, *Audit Of The Bureau Of Alcohol, Tobacco, Firearms And Explosives’ Use Of Income Generating, Undercover Operations*, Audit Report 13-36 (Sept. 2013) available at <https://oig.justice.gov/reports/2013/a1336.pdf>.

<sup>35</sup> Dep’t of the Treasury Alcohol and Tobacco Tax and Trade Bureau, Cong. Justification for Appropriations and Annual Performance Report and Plan (FY 2018)

<sup>36</sup> Gov’t Accountability Off., *supra* note 22.

<sup>37</sup> White Paper at p. 9.

<sup>38</sup> White Paper at p. 12.

<sup>39</sup> White Paper at p. 1.

<sup>40</sup> Keith McLeod, *Sick Crooks Push Cheap Cigarettes on Facebook Laced with Potentially Life-Threatening Chemicals*, Daily Record (Nov. 19, 2014) available at <http://www.dailyrecord.co.uk/news/crime/sick-crookspush-cheap-cigarettes-4658440> and Jonathan Gibson, *Websites Allowing Illegal Activity 'Complicit in Crime*, BBC Inside Out (Oct. 23, 2017) available at <https://www.bbc.com/news/uk-england-41601075>.

Native Americans reservations, which are not subject to state cigarette taxes, often enter the lucrative business of selling untaxed cigarettes to non-tribe members, a form of illicit trade. By way of example, the Poospatuck Reservation, located in Long Island, New York, purchased 8.4 million cartons of cigarettes in 2008, while the population of the reservation is only 376.<sup>41</sup> Reservations like this are able to provide cigarettes to smokers that are not members of their tribe at an attractive price—often the tribes themselves are involved in the sale of tobacco. Although some states, like New York, have challenged tribes’ ability to sell to tobacco without appropriately taxing them, tribes continue to assert their sovereignty and ability to sell cigarettes without interference.<sup>42</sup> And, the federal government has repeatedly failed to enforce laws regulating illicit trade.

When considering a product standard, the FDA should include concrete provisions for enforcement on Indian reservations as part of its overall enforcement plan. With that in mind, FDA should implement a plan such that the agency directly enforces the law on reservations. Contracting that important function to tribes that act as retailers of tobacco products is unrealistic and unlikely to lead to compliance.

F. The black market creates health concerns.

FDA is considering promulgating regulations in order to protect public health.<sup>43</sup> In satisfying customer demand, tobacco manufacturers create products that are fully scrutinized and regulated by the FDA, but illegal manufacturers obviously do not operate within those regulations. FDA, therefore, cannot oversee the contents and purity of counterfeit cigarettes, which are subject to illicit manufacturers’ whims. In fact, Chinese counterfeit cigarettes have been found to emit higher levels of nicotine and carbon monoxide than brand-name cigarettes—and include insect eggs and human feces in their composition.<sup>44</sup> It is unlikely that manufacturers will enforce the FDA requirements for the product if they are creating an illicit product.

When Congress gave the FDA authority to regulate tobacco products under the Tobacco Control Act, it did so with the intent that FDA should play a role in monitoring the production of cigarettes. If FDA creates a product standard that incentivizes more illicit trade, that will increase the health issues with cigarettes and do more damage than good.

G. Growth in the black market will reduce tax revenues for the federal, state, and local governments.

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<sup>41</sup> Hearing Before New York Senate Standing Comm. on Investigations and Government Operations, (Oct. 27, 2009) (Testimony of William J. Comiskey, State of New York, Department of Taxation and Finance), *available at* [www.tax.ny.gov/enforcement/criminal\\_enforcement/senate\\_written\\_testimony\\_102609.pdf](http://www.tax.ny.gov/enforcement/criminal_enforcement/senate_written_testimony_102609.pdf).

<sup>42</sup> Associated Press, *Despite Law, Tribe Sells 1.7 Tons of Cigarettes Online*, New York Post (Dec. 12, 2013) *available at* <http://nypost.com/2013/12/02/despite-law-tribe-sells-1-7-tons-of-cigarettes-online/>.

<sup>43</sup> *Supra* note 11.

<sup>44</sup> Te-Ping Chen, *China’s Marlboro Country*, Ctr. or Public Integrity (June 29, 2009), *available at* <https://www.publicintegrity.org/2009/06/29/6341/china-s-marlboro-country>.

As described previously, tobacco products are taxed in order to raise revenue for public health programs and to deter tobacco use. As such, cigarettes are often the highest taxed commodity.<sup>45</sup> When consumers purchase tobacco products illegally, tax revenue for federal, state, and local governments will be reduced. Currently, the annual state and local tax loss caused by the illicit trade of tobacco products is estimated between \$2.95 to \$6.92 billion.<sup>46</sup> By pushing a large portion of the legal cigarette market to the illicit market, the FDA would further reduce revenues derived from those sales. The FDA must conduct a thorough review of the wisdom – indeed, its ability – to eliminate these revenues by administrative action.

### **III. Conclusion**

The Associations appreciate this opportunity to present their views on the impact future rulemakings by FDA will have on illicit trade and the retail community. A tobacco product standard on nicotine levels and flavorings risks expanding the illicit trade of tobacco in the U.S. The Associations believe the federal government should enforce the tobacco regulations that currently exist and reduce the large problem of the illicit trade in cigarettes – especially from Native American reservations – before promulgating new rules. If you have any questions concerning these comments, please contact me.

Sincerely,



Douglas S. Kantor  
Counsel to NACS and SIGMA

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<sup>45</sup> Scott Drenkard, *How High Are Cigarette Taxes in Your State*, Tax Foundation (June 3, 2015) available at <https://taxfoundation.org/how-high-are-cigarette-taxes-your-state>.

<sup>46</sup> Nat'l Research Council, *supra* note 17.