



PHILIP MORRIS INTERNATIONAL

**COMMENTS ON FDA ADVANCE NOTICE OF PROPOSED RULEMAKING:  
REGULATION OF FLAVORS IN TOBACCO PRODUCTS**

July 19, 2018

VIA ELECTRONIC SUBMISSION

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. FDA–2017–N–6565 (83 Fed. Reg. 12294, March 21, 2018) Advance Notice of Proposed Rulemaking: Regulation of Flavors in Tobacco Products

**INTRODUCTION**

Philip Morris International (PMI)<sup>1</sup> welcomes this opportunity to respond to FDA’s Advance Notice of Proposed Rulemaking (ANPRM) on the regulation of flavors in tobacco products.<sup>2</sup> PMI is one of the world’s leading tobacco companies. We do not currently operate in the U.S., but we follow with interest FDA’s comprehensive plan to reduce smoking prevalence.<sup>3</sup>

FDA’s plan recognizes that tobacco products exist on a continuum of risk and that FDA should regulate them consistent with their different risk profiles. In pursuing its comprehensive strategy, FDA “envision[s] a world where cigarettes lose their addictive potential through reduced nicotine levels. . . [a]nd a world where less harmful alternative forms, efficiently delivering satisfying levels of nicotine, are available for those adults who need or want them.”<sup>4</sup> At PMI, we operate

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<sup>1</sup> Comments submitted by Philip Morris International Management S.A. Philip Morris International Management S.A. and Philip Morris Products S.A. are affiliates of Philip Morris International Inc.

<sup>2</sup> Regulation of Flavors in Tobacco Products (ANPRM), 83 Fed. Reg. 12294 (Mar. 21, 2018) (“ANPRM”), available at <https://www.gpo.gov/fdsys/pkg/FR-2018-03-21/pdf/2018-05655.pdf>.

<sup>3</sup> Gottlieb, S., Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (July 28, 2017), available at <https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm>.

<sup>4</sup> *Id.*

according to a manifesto that, in calling for a smoke-free future, aligns remarkably well with the future state that FDA seeks. Indeed, our business strategy envisions a world in which cigarettes eventually disappear altogether. To that end, our organization is dedicating itself to developing, scientifically assessing, and commercializing a range of non-combustible alternatives to which adult smokers will switch completely.<sup>5</sup>

In the ANPRM, FDA seeks information on the role of flavors in tobacco products. As an initial matter, we note that many of the questions in the ANPRM reflect FDA's concern about the impact of flavors on the initiation of tobacco and nicotine use, particularly among youth.<sup>6</sup> We agree that youth should not have access to or use tobacco or nicotine in any form and that marketing activities should not target youth or encourage youth use of tobacco or nicotine-containing products. PMI's products are only for, and our marketing and sales activities are tailored to, adult smokers.

Our comments in response to the ANPRM focus on flavors in authorized non-combustible products.<sup>7</sup> First, we share our views on the importance of flavors for supporting adult smokers in switching completely to less harmful alternatives.<sup>8</sup> Second, we discuss how FDA can manage concerns regarding youth initiation with flavored non-combustible products. Third, we discuss steps FDA can take to manage concerns about the toxicity of flavor ingredients.

#### **FLAVORS CAN HELP ADULT SMOKERS SWITCH TO LESS HARMFUL ALTERNATIVES**

The U.S. is at a crossroads with respect to smoking. Currently, about 40 million American men and women smoke, and projections show that tens of millions will continue to smoke for years to come.<sup>9</sup> Every day they smoke increases their risk of developing a deadly disease. For those

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<sup>5</sup> Information about our vision for a smoke-free future is available on our corporate website, [www.pmi.com](http://www.pmi.com). For detailed information on our research and development work, please visit [www.pmiscienceusa.com](http://www.pmiscienceusa.com).

<sup>6</sup> "Youth" refers to individuals under 18, consistent with FDA's definition in the ANPRM. ANPRM, *supra* note 2, at 12295.

<sup>7</sup> "Authorized non-combustible products" refers to products that have been or may be authorized for marketing in the U.S. pursuant to 21 U.S.C. §§ 387j, k.

<sup>8</sup> In discussing "less harmful alternatives" to cigarettes, we are referring to products that: 1) contain and deliver nicotine at levels smokers find satisfactory; and 2) support the Agency's stated objective of "ending the use of traditional cigarettes and switching to a non-combustible product made or derived from tobacco." Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses," (FDA Clarification) 82 Fed. Reg. 2193, 2214 (Jan. 9, 2017), available at <https://www.gpo.gov/fdsys/pkg/FR-2017-01-09/pdf/2016-31950.pdf>. We are not referring to cessation or cessation aids.

<sup>9</sup> Centers for Disease Control and Prevention, Trends in Current Cigarette Smoking Among Adults in the U.S., available at [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/adult\\_data/cig\\_smoking/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm).

smokers who do not quit, non-combustible alternatives provide a less harmful way of consuming nicotine.

However, switching from cigarettes to a non-combustible alternative is a big change for smokers. Non-combustible products work differently than cigarettes, are more complex (particularly those involving electronics), and have different sensory characteristics. For example, the taste of e-cigarette vapor and heated tobacco product aerosol differs from cigarette smoke, and both e-cigarettes and heated tobacco products deliver a different user experience than combustible cigarettes. These factors create barriers to switching that flavors can help overcome. Commissioner Gottlieb recognized this when FDA announced the ANPRM:

I've talked to ex-smokers, who've told me that they quit cigarettes altogether and that they now vape. And they've also told me *it was the flavors that helped them make that transition off combustible cigarettes*. Now I know anecdotes aren't the same as data. And the ANPRM specifically seeks data on this issue. But these personal stories are important to me as we shape our overall approach to smoking cessation.<sup>10</sup>

Commissioner Gottlieb's statement is consistent with FDA's conclusions about the role of flavors in its proposed product standard for levels of N-nitrosornicotine (NNN) in smokeless tobacco products:

Smokeless tobacco products are heavily flavored and the presence of flavors is a significant driver of consumer acceptance of these products. The proposed standard does not prevent the addition of flavors to offset any changes in the taste of the product due to the methods used to reduce NNN to meet the proposed standard.<sup>11</sup>

Similarly, a number of studies have found that flavors are important for adult smokers' acceptance of non-combustible products and can help smokers switch to these better

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<sup>10</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to reduce tobacco use, especially among youth, by exploring options to address the role of flavors – including menthol – in tobacco products (Mar. 20, 2018) (emphasis added), available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm601690.htm>.

<sup>11</sup> Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products, 82 Fed. Reg. 8004, 8025 (Jan. 23, 2017), available at <https://www.gpo.gov/fdsys/pkg/FR-2017-01-23/pdf/2017-01030.pdf>.

alternatives.<sup>12</sup> For example, one study cited in the ANPRM, an international survey of more than 4,500 e-cigarette users, found that:

- e-cigarette users reported that a variety of e-cigarette flavors was very important “in their efforts to reduce or quit smoking;”
- 48.5% reported that restricting flavors would increase cravings for cigarettes; and
- 39.7% said that restricting flavors would have made it more difficult for them to “reduce or quit smoking.”<sup>13</sup>

As a result, the authors concluded that flavors:

are important contributors in reducing or eliminating smoking consumption ... [and] any proposed regulation should ensure that flavourings are available to [e-cigarette] consumers while at the same time restrictions to the use by youngsters (especially non-smokers) should be imposed in order to avoid future penetration of [e-cigarette] use to this population.<sup>14</sup>

More recent studies have confirmed that flavors can help smokers switch to non-combustible alternatives. For example, a 2017 study that examined the role of e-cigarettes in smoking cessation among youth and young adults found that those respondents who reported a preference for using e-cigarettes with a combination of flavors were more likely to use e-cigarettes for smoking cessation.<sup>15</sup>

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<sup>12</sup> See, e.g., Lehmann, K. et al., *Electronic Cigarettes in Germany: Patterns of Use & Perceived Health Improvement*, 23 EUR. ADDICTION RES. 136 (2017), available at <https://www.karger.com/Article/Abstract/475986>; Cooper, M. et al., *Comparing young adults to older adults in e-cigarette perceptions and motivations for use: implications for health communication*, 31 HEALTH EDUC. RES. 429 (2016), available at <https://academic.oup.com/her/article/31/4/429/2363245>; Dawkins, L. et al., ‘Vaping’ profiles and preferences: an online survey of electronic cigarette users, 108 ADDICTION 1115 (2013); Etter, J., *Electronic cigarettes: a survey of users*, 10 BMC PUBL. HEALTH 231 (2010), available at <https://bmcpublihealth.biomedcentral.com/articles/10.1186/1471-2458-10-231>.

<sup>13</sup> Farsalinos, K. et al., *Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey*, 10 INT’L J. ENVTL. RES. & PUB. HEALTH 7272, 7277 (2013), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3881166/>.

<sup>14</sup> *Id.* at 7279.

<sup>15</sup> Camenga, D. et al., *Current and Former Smokers’ User of Electronic Cigarettes for Quitting Smoking: An Exploratory Study of Adolescents and Young Adults*, 19 NICOTINE & TOB. RES. 1531 (2017), available at <https://academic.oup.com/ntr/article/19/12/1531/2629287>; see also Litt, M. et al., *Cigarette smoking and electronic cigarette vaping patterns as a function of e-cigarette flavourings*, 25 TOB. CONTROL ii67 (2016), available at [http://tobaccocontrol.bmj.com/content/25/Suppl\\_2/ii67](http://tobaccocontrol.bmj.com/content/25/Suppl_2/ii67).

After smokers switch to non-combustible products, flavors can also deter them from going back to cigarettes by creating a disassociation between cigarettes and non-combustible products.<sup>16</sup> In a recent study analyzing longitudinal data to assess the relationship between smoking behavior and the use of flavored e-cigarettes among 18-34 year olds, the authors found that e-cigarette users who used one or more flavors of e-cigarettes (other than tobacco or menthol flavors) were more likely to have reduced or quit smoking over the past year compared to non-e-cigarette users.<sup>17</sup> The authors offered several potential explanations for this finding, including the possibility that smokers “who successfully cut down on cigarettes are generally seeking a significant change in sensory experience and thus do not desire to use e-cigarette flavors similar to cigarette flavors.”<sup>18</sup>

Finally, banning flavors in non-combustible products may not only prevent smokers from switching to better alternatives, it could result in more cigarette smoking. A recent U.S. study analyzed the impact of potential FDA flavor restrictions on smokers’ decisions to use cigarettes or e-cigarettes.<sup>19</sup> A sample of 2,031 adult current and former smokers participated in a computer-based discreet choice experiment in which they made a series of choices between cigarettes and e-cigarettes with different attributes, including flavors (plain tobacco and menthol for cigarettes; and plain tobacco, menthol, fruit, and sweet for e-cigarettes). Data analysis allowed the researchers to predict the products smokers and former smokers would choose in various policy scenarios. Based on the study’s findings, the authors predict that banning menthol in cigarettes and all flavors in e-cigarettes (except plain tobacco flavor) would significantly reduce the number of people who choose e-cigarettes and would increase the number of people who choose cigarettes.

#### **IQOS U.S. ACTUAL USE STUDY DATA**

As part of PMI’s scientific assessment of *IQOS*,<sup>20</sup> a tobacco heating system, we conducted a study to assess how U.S. adult daily smokers use *IQOS* in near-to-real world conditions (the Actual Use

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<sup>16</sup> See, e.g., Russell, C. et al., *Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA*, 15 HARM REDUCTION J. 1 (2018), available at <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6>; New Nicotine Alliance Position Statement: Purpose of Flavors, available at <https://nnalliance.org/activities/resources/position-statements>.

<sup>17</sup> Chen, J., *Flavored E-cigarette Use and Cigarette Smoking Reduction and Cessation—A Large National Study among Young Adult Smokers*, SUBSTANCE USE & MISUSE (2018), available at <https://www.ncbi.nlm.nih.gov/pubmed/29624135>.

<sup>18</sup> *Id.* at 10.

<sup>19</sup> Buckell, J. et al., *Should flavors be banned in cigarettes and e-cigarettes? Evidence on adult smokers and recent quitters from a discreet choice experiment*, TOB. CONTROL (2018), available at <http://tobaccocontrol.bmj.com/content/early/2018/05/28/tobaccocontrol-2017-054165?paperoc>.

<sup>20</sup> The results of this assessment approach and the underlying data have been filed with FDA as part of PMI’s Premarket Tobacco Product and Modified Risk Tobacco Product Applications for *IQOS*. Study summaries and data

Study).<sup>21</sup> The study involved more than 1,300 adult daily smokers in eight U.S. cities.<sup>22</sup> Participants were shown hypothetical marketing materials for *IQOS* and were able to use *IQOS HeatSticks*<sup>23</sup> (regular (tobacco), menthol flavor, or a combination of the two, based on their preferences) *ad libitum* over the course of six weeks. Participants recorded their stick-by-stick consumption of both *HeatSticks* and cigarettes during that time period using an electronic diary.

The Actual Use Study data suggest that the availability of menthol can play an important role in encouraging adult smokers to try and to switch to a non-combustible tobacco product such as *IQOS*. For example, throughout the six-week observational period, the proportion of participants who started using<sup>24</sup> *IQOS* was highest among those who used both types of *HeatSticks* (menthol and regular). Fifty-one percent of those who chose menthol or a combination of menthol and regular-flavored *HeatSticks* started using *IQOS*, while only 31.5% of those who chose regular flavor *HeatSticks*, started using *IQOS*.

Furthermore, switching to *IQOS* was higher when using both menthol and regular *HeatSticks* compared to using regular or menthol *HeatSticks* only. Twenty-three percent of participants who used both regular and menthol *HeatSticks* were using *IQOS* predominantly<sup>25</sup> or exclusively<sup>26</sup> at the end of the six-week period compared to 14% of those who used menthol *HeatSticks* only and 12% of those who used regular *HeatSticks* only.

No combination of *HeatStick* use (*e.g.*, regular or menthol flavor) resulted in a meaningful increase in tobacco consumption over baseline daily cigarette smoking. For example, those who used only menthol *HeatSticks* used a total of 8.1 sticks per day on average (*HeatSticks* + cigarettes) versus an average of 9.1 cigarettes per day at baseline. Regular flavor *HeatStick* users consumed 10 sticks per day on average (*HeatSticks* + cigarettes) during the study compared to 11 cigarettes per day at baseline. Those who used both menthol and regular flavored *HeatSticks*

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can be found on [www.pmisceience.com](http://www.pmisceience.com) or FDA's web site at <https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm>.

<sup>21</sup> Designated as study THS-PBA-07-US. Available at <https://www.fda.gov/tobaccoproducts/labeling/marketingandadvertising/ucm546281.htm>.

<sup>22</sup> Sampling quotas approximated the distribution of U.S. adult smokers by sex, age, race, and income.

<sup>23</sup> "*HeatSticks*" refers to specially designed heated tobacco units that are intended for exclusive use in the *IQOS* heating tobacco system.

<sup>24</sup> Defined in the Actual Use Study protocol as consuming at least 100 *HeatSticks* during the observational period as reported by the study participant on a stick-by-stick basis in an electronic diary.

<sup>25</sup> Predominant *IQOS* use is defined as between 70% and 95% of an individual's total cigarettes + *HeatSticks* tobacco use in the form of *IQOS*.

<sup>26</sup> Exclusive *IQOS* use is defined as more than 95% of an individual's total cigarettes + *HeatSticks* tobacco use in the form of *IQOS*.

consumed 10.8 sticks per day on average (*HeatSticks* + cigarettes) versus 10.7 cigarettes per day at baseline.

Finally, participants who used menthol *HeatSticks* during the study reported that they were more likely to buy *IQOS* than those who used only regular *HeatSticks*. At the end of the study, participants were asked, using a five-point scale, whether they would buy *HeatSticks* should they become available in the U.S.<sup>27</sup> Twenty-six percent of participants who used regular and menthol *HeatSticks* reported that they definitely or probably would buy *IQOS*, compared to 18% of those who used regular *HeatSticks* only. At the same time, 24% of those who used menthol *HeatSticks* only said they definitely or probably would buy *IQOS*, which demonstrates the importance of menthol in encouraging adult smokers to try, and ultimately switch to, non-combustible alternatives to cigarettes.

### **PMI *IQOS* COMMERCIALIZATION DATA**

PMI's *IQOS* commercialization data also demonstrate the important role that menthol plays in non-combustible products. In markets in which *IQOS* commercialization is most advanced, menthol *HeatStick* sales are significantly over-indexed relative to the menthol share of the cigarette market. For example, in Korea, menthol cigarettes account for about 4% of the total cigarette market, whereas menthol *HeatSticks* account for 57% of total *HeatStick* sales.<sup>28</sup> In Greece, Italy, and the Czech Republic, where there is virtually no menthol cigarette segment, menthol *HeatSticks* account for 20%, 25%, and 27% of total *HeatStick* sales, respectively.<sup>29</sup>

In Japan, where *IQOS* has a market share of 15.5%,<sup>30</sup> menthol cigarettes make up about 27% of the total cigarette market, whereas menthol *HeatSticks* account for 69% of total *HeatStick* sales.<sup>31</sup> At the same time, the age distribution of *IQOS* users is virtually identical between users of menthol and non-menthol *HeatSticks*.<sup>32</sup> This suggests that while menthol is likely helping smokers switch to *IQOS*, it is not a factor driving *IQOS* consumption among specific age groups, including young adults (20-29 years old). The share of young adults using menthol *HeatSticks* is comparable to the share of young adults smoking menthol cigarettes, suggesting that menthol

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<sup>27</sup> A rating of one indicated that the participant would definitely buy *IQOS*, while a rating of five indicated that they definitely would not buy *IQOS*.

<sup>28</sup> PMI estimates based on data for the first quarter of 2018.

<sup>29</sup> *Id.*

<sup>30</sup> PMI 2018 Second Quarter Results (July 19, 2018), available at <https://www.pmi.com/investor-relations/overview/event-details?EventId=5267398>.

<sup>31</sup> PMI estimates based on data for the first quarter of 2018.

<sup>32</sup> PMI estimates.

*HeatSticks* are not increasing interest in tobacco use among young adults.<sup>33</sup> Finally, the majority of *IQOS* users fall within the 30-49 year-old age group.<sup>34</sup>

#### **DEPRIVING SMOKERS OF ACCESS TO A RANGE OF FLAVORED NON-COMBUSTIBLE PRODUCTS WOULD UNDERMINE FDA’S OBJECTIVE OF REDUCING SMOKING PREVALENCE**

In July 2017, FDA announced its plan to regulate tobacco products pursuant to the continuum of risk in order to meaningfully shift smokers’ behavior by encouraging those who will not quit all tobacco and nicotine to switch to less harmful alternatives.<sup>35</sup> FDA’s plan involves establishing more effective regulation and product standards for combustible tobacco products, including a possible cigarette nicotine standard and potential regulation of flavors in addition to regulations already included in the Food, Drug, and Cosmetic Act (FDCA), as well as facilitating the development and availability of innovative non-combustible products so that existing smokers who will not quit can choose less harmful alternatives.<sup>36</sup>

FDA’s plan is promising, but its success necessarily depends on the existence of a robust and credible category of non-combustible products that are acceptable substitutes to cigarettes for adult smokers. Indeed, FDA’s assumptions about the public health benefits of a nicotine standard,<sup>37</sup> and its modeling of the magnitude of those benefits, relies on large-scale switching to less risky non-combustible products. FDA estimates that within five years of implementing a maximum nicotine standard, 3.25 to 8.45 million American men and women who smoke would switch completely to non-combustible products, largely e-cigarettes.<sup>38</sup> Notably, however, the public health experts who provided input for FDA’s model cautioned that these estimates “would

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

<sup>34</sup> *Id.*

<sup>35</sup> 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>36</sup> Gottlieb, S., Protecting American Families, *supra* note 3.

<sup>37</sup> FDA, Advance Notice of Proposed Rulemaking, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. 11818, 11835 (March 16, 2018) (“FDA expects that making cigarettes minimally addictive or non-addictive would reduce tobacco-related harms by smoking cessation or *complete migration to alternative, potentially less harmful non-combusted products and by reducing initiation.*”) (emphasis added), available at <https://www.gpo.gov/fdsys/pkg/FR-2018-03-16/pdf/2018-05345.pdf>.

<sup>38</sup> FDA’s model assumes that five million smokers will quit as a result of the policy in the first year, and that number would increase to 13 million after five years. Apelberg, B. et al., *Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States*, 378 N. ENGL. J. MED. 1725 (2018), available at <https://www.nejm.org/doi/full/10.1056/NEJMSr1714617>. In the expert elicitation study upon which FDA’s model is based, the experts estimate that 25%-65% of those who quit smoking in the first year following the implementation of a cigarette nicotine ceiling will switch to less risky non-combustible products, and switching rates would be comparable in the following years. Supplementary Appendix to Apelberg, B. et al., *supra*, at 19, available at [https://www.nejm.org/doi/suppl/10.1056/NEJMSr1714617/suppl\\_file/nejmsr1714617\\_appendix.pdf](https://www.nejm.org/doi/suppl/10.1056/NEJMSr1714617/suppl_file/nejmsr1714617_appendix.pdf).



be impacted by the degree to which e-cigarette use would become an *acceptable substitute* for cigarette smoking.”<sup>39</sup>

As discussed above, the data show that flavors are an important component of non-combustible product acceptability. For that reason, banning or severely restricting flavors in non-combustible alternatives would likely prevent many adult smokers from switching completely to less harmful alternatives, and therefore would undermine, rather than further, FDA’s comprehensive plan to change the trajectory of smoking in the U.S.

Finally, it is worth noting that the European Union recently banned all characterizing flavors in cigarettes and roll-your-own tobacco but chose not to do the same for e-cigarettes or novel non-combustible tobacco products.<sup>40</sup> In fact, the E.U. has encouraged its Member States to consider allowing flavored e-cigarettes to be marketed.<sup>41</sup> We urge FDA to take a similar approach and allow adult smokers to continue to have access to flavored non-combustible alternatives.<sup>42</sup>

#### **FDA HAS POWERFUL TOOLS TO MITIGATE THE RISK OF YOUTH USE OF FLAVORED NON-COMBUSTIBLE PRODUCTS**

In addition to manufacturers’ obligations to responsibly market their products, FDCA grants FDA various tools to ensure that tobacco products are not marketed to youth. FDA has shown that it can and will aggressively use these tools. As commissioner Gottlieb stated in his keynote address at the Food and Drug Law Institute Annual Meeting,

[W]e’re going to be continuing to take an escalating series of actions, including against the companies that market these products in ways that may be deliberately enticing to youth, and the retailers that are selling e-cigarettes to kids

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<sup>39</sup> Supplementary Appendix to Apelberg, B. et al., *supra* note 38, at 21 (emphasis added).

<sup>40</sup> Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0040&from=EN>.

<sup>41</sup> *Id.* (“This Directive does not harmonise all aspects of electronic cigarettes or refill containers. For example, the responsibility for adopting rules on flavours remains with the Member States. It could be useful for Member States to consider allowing the placing on the market of flavoured products.”).

<sup>42</sup> If FDA does decide to take further action on flavors in cigarettes, it should address the possible interplay between definitions in FDCA and FCLAA. In particular, certain non-combustible products could fall within the definition of “cigarette” under FCLAA, which defines a cigarette as “any roll of tobacco wrapped in paper or in any substance not containing tobacco.” 15 U.S.C. § 1332(1)(a). This definition could capture a variety of novel products that heat tobacco rather than burning it. Therefore, if FDA concludes that further action on flavors for cigarettes is “appropriate for the protection of public health,” it should draft the standard or regulations in a way that ensures that non-combustible products are not covered by the standard even if they meet the FCLAA definition of a cigarette. One way to make such a distinction would be to define the products that are subject to the cigarette nicotine standard as only those intended to be combusted.

... Companies that know children are using their products are on notice. If you target kids, then we're going to target you.<sup>43</sup>

As an initial matter, FDA controls whether, and if so under which conditions, new tobacco products can reach the market. It acts as a gatekeeper of the pathways to market that Sections 387j and 387k create.<sup>44</sup> Those provisions empower the Agency to propel the flow of innovations that provide better choices for consumers while minimizing the risk of new products that would undermine the objectives of its comprehensive plan.<sup>45</sup> Furthermore, they allow FDA to perform a case-by-case assessment of flavored non-combustible products to ensure that they are appropriate for the protection of public health.

Once a product has reached the market, FDA has a wealth of complementary tools at its disposal to gather critical information about consumption patterns, which can alert FDA to potential concerns regarding the use of flavored non-combustible products by unintended audiences, such as non-smokers and youth. In addition to *ad hoc* research, which is being produced at a rapid pace, a number of ongoing studies, including the National Youth Tobacco Survey, Monitoring the Future Survey, and Population Assessment of Tobacco and Health Survey, regularly provide insight into youth use of different tobacco and nicotine-containing products. Beyond this category-wide data, FDA can require manufacturers to provide data on the specific products they market. For example, FDA can seek:

Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.<sup>46</sup>

Similarly, upon authorization of a new tobacco product pursuant to Section 387j, FDA can require manufacturers to keep certain records necessary “to enable the Secretary to determine, or

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<sup>43</sup> Keynote Address by Commissioner Gottlieb to the 2018 FDLI Annual Conference (May 3, 2018), available at <https://www.fda.gov/NewsEvents/Speeches/ucm606541.htm>.

<sup>44</sup> See, e.g., Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, finding 44 (June 22, 2009) (“In connection with its mandate to promote health and reduce the risk of harm, the Food and Drug Administration routinely makes decisions about whether and how products may be marketed in the United States.”).

<sup>45</sup> In fact, FDA’s very mission is to take prompt, efficient, and appropriate actions with respect to regulated products, see 21 U.S.C. § 393(b) (“*Mission* The Administration shall— (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.”).

<sup>46</sup> 21 U.S.C. § 387d(b)(3).

facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending [a marketing authorization order].”<sup>47</sup>

Should FDA identify concerns, it has broad enforcement authority to address them. For example, FDA and the Federal Trade Commission (FTC) recently issued warning letters to 17 companies that marketed e-liquids that were misleadingly labeled or advertised as food products and, therefore, could be attractive to youth.<sup>48</sup> Many of the offending products mimicked candy, cookies, or other youth-oriented products.<sup>49</sup> PMI strongly agrees that tobacco and nicotine-containing products should never be branded, described, marketed, or sold in ways that mimic youth-oriented products.

FDA has also taken action against retailers who sell tobacco and nicotine-containing products to youth. On April 24, 2018, FDA announced that it had issued warning letters to 40 retailers for selling e-cigarettes to youth. FDA confirmed in its announcement that it has used its enforcement authority to “conduct[] 908,280 inspections of retail establishments that sell tobacco products, issue[] 70,350 warning letters to retailers for violating the law and initiated about 17,000 civil money penalty cases ... [and] more than 110 No-Tobacco-Sale Order Complaints.”<sup>50</sup>

FDA possesses other regulatory tools to mitigate the risk of youth initiation of flavored non-combustibles. For example, FDA can impose restrictions on advertising and promotion, or require labeling changes, if it determines that non-combustible products are being marketed and sold in ways that are particularly appealing to youth or nonsmokers and such changes would be appropriate for the protection of public health.<sup>51</sup>

#### **ADDRESSING CONCERNS ABOUT THE TOXICITY OF FLAVORS**

FDA also raises questions about the toxicity of certain flavors and flavoring ingredients that have been found in some e-liquids. FDA should exercise oversight over flavor additives in order to

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<sup>47</sup> 21 U.S.C. § 387j(f)(1).

<sup>48</sup> FDA, FTC take action against companies misleading kids with e-liquids that resemble children’s juice boxes, candies and cookies (May 1, 2018), available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605507.htm>;

<sup>49</sup> E-Liquids Misleadingly Labeled or Advertised as Food Products (May 2018), available at <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm605729.htm>.

<sup>50</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes (April 24, 2018), available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm>. In a recent speech, Commissioner Gottlieb announced that the number of warning letters sent to retailers for the sale of e-cigarettes to youth had increased to 56. Remarks by FDA Commissioner Scott Gottlieb, M.D., at Tobacco Regulatory Science Program Meeting (June 18, 2018), available at <https://www.fda.gov/NewsEvents/Speeches/UCM611033>.

<sup>51</sup> 21 U.S.C. § 387f(d)(1), (2).

ensure that non-combustible products are appropriate for the protection of public health. One way to address concerns about the toxicity of flavor additives is by establishing evidence-based product standards.

A number of countries outside the U.S. have implemented product standards that are instructive. For example, Article 20 of the European Tobacco Products Directive (TPD) requires Member States to ensure that nicotine-containing liquid in e-cigarettes and refill containers do not contain certain additives.<sup>52</sup> In addition to these requirements, some E.U. Member States have issued their own industry guidance or product standards that go beyond the E.U. requirements.<sup>53</sup>

FDA's forthcoming e-cigarette product standards<sup>54</sup> provide a ready-made platform to develop robust science-based standards in the U.S. context. While FDA has committed to "address the levels of toxicants and impurities found in nicotine, propylene glycol, and vegetable glycerin e-liquid"<sup>55</sup> through these standards, it should consider going further to address flavoring agents. FDA's pre-market review of new tobacco products also provides an opportunity to assess the overall toxicity of non-combustible products relative to cigarettes.

## CONCLUSION

American men and women who smoke deserve to have access to acceptable alternatives to cigarettes that are capable of moving them down the continuum of risk. Flavors play a critical role. Without them, smokers are less likely to switch to non-combustible products and more likely to continue smoking cigarettes. Valid concerns exist about the role of flavors in tobacco product consumption among unintended groups, particularly youth, and their impact on product toxicity. However, FDA has powerful tools to minimize these risks while still maximizing adult smokers' access to a range of less harmful alternatives.

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<sup>52</sup> Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0040&from=EN>.

<sup>53</sup> See, e.g., UK Discussion Paper on Submission of Notifications Under Article 20 of Directive 2014/40/EU, Chapter 6, Advice on Ingredients in Nicotine-Containing Liquids in Electronic Cigarettes and Refill Containers, available at [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/682739/ingredient\\_guidance\\_final\\_draft\\_011116.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/682739/ingredient_guidance_final_draft_011116.pdf).

<sup>54</sup> Gottlieb, S., Protecting American Families, *supra* note 3.

<sup>55</sup> Spring Unified Agenda: FDA's Anticipated Upcoming Regulatory Work (May 9, 2018), available at <https://blogs.fda.gov/fdavoices/index.php/tag/nicotine-addiction-crisis/>.