



PUBLIC HEALTH
LAW CENTER
at Mitchell Hamline School of Law

April 30, 2019

Commissioner Norman Sharpless M.D.
c/o Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20825

Re: Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry

Docket No. FDA-2019-D-0661

Dear Commissioner Sharpless:

The African American Tobacco Control Leadership Council, the National African American Tobacco Prevention Network, and the Public Health Law Center are pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the agency's draft guidance modifying the FDA's compliance policy for the premarket review of deemed tobacco products.

The African American Tobacco Control Leadership Council (AATCLC) was formed in California in 2008. AATCLC educates the public about the effects of tobacco on Black American and African Immigrant populations, the tobacco industry's predatory marketing tactics, and the need to regulate flavored tobacco products, including menthol cigarettes. To more effectively reach and save black lives, AATCLC also partners with community stakeholders and public serving agencies to inform and direct tobacco control policies, practices, and priorities.

NAATPN is a 20-year-old organization that exists to facilitate the implementation and promotion of comprehensive policies, community-led programs and culturally competent public health campaigns that benefit African Americans. NAATPN is committed to addressing the social and economic injustices that have marginalized our communities and led to deep health disparities. NAATPN is fortified by a network of community organizations, grassroots organizers, faith leaders, legislators, clinical service providers, researchers and media professionals who use their expertise to inform our policy work and amplify our educational campaigns.

The Public Health Law Center is the coordinating center of the Tobacco Control Legal Consortium, a national network of nonprofit legal centers providing legal

technical assistance to public health professionals and advocates concerning legal issues related to commercial¹ tobacco and public health.²

Since the passage of the Family Smoking Prevention and Tobacco Control Act (the “Tobacco Control Act”) in 2009, the FDA has not used its premarket review authority over tobacco products to the fullest extent possible to maximize the benefits to public health.³ In fact, over the course of the last ten years the FDA has made misstep after misstep, missing many opportunities to protect health from commercial tobacco products. With the promulgation of the Deeming Rule in 2016, the FDA had an opportunity to make improvements to the process or at least to begin taking steps in the right direction. One example is the agency’s failure to remove or restrict menthol in cigarettes, a mistake that the FDA seems committed to repeating in this proposed guidance. If the FDA had taken action on this issue in the ten years that the agency has been regulating tobacco products, many lives would have been saved and many of those would be African American lives.⁴

The enforcement of premarket review, as it was envisioned in the final Deeming Rule, was, to date, the most reasoned form of enforcement that the FDA’s Center for Tobacco Products (CTP) has outlined for newly-deemed products. The proposed version of the Deeming Rule had notable flaws and to the agency’s credit, the largest and most important flaws were addressed in the final rule after being identified by the public health community.⁵ Perplexingly, in July of 2017, the FDA announced

¹ This comment is addressed regulation of commercial tobacco products and should in no way be construed as advocating for heightened regulation of traditional and sacred tobacco use by indigenous communities. <http://keepitsacred.itcml.org/tobacco-and-tradition/traditional-v-commercial/>.

² The Tobacco Control Legal Consortium’s activities are coordinated by the Public Health Law Center, at Mitchell Hamline School of Law in St. Paul, Minnesota. The Consortium’s affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, both at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at the University of Michigan, Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

³ Desmond Jenson, Joelle Lester & Micah L. Berman, *FDA’s Misplaced Priorities: Premarket Review Under the Family Smoking Prevention and Tobacco Control Act*, 25 TOBACCO CONTROL 246 (2016).

⁴ A model of smoking in the United States predicts that a 10% quit rate among menthol smokers would save thousands of lives, preventing over 4,000 smoking-attributable deaths in the first ten years and 300,000 in forty years. David T. Levy et al., *Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths in the United States*, 101(7) ADDICTION 1236, 1239 tbl. 1 (2011); *id.* at 1237 (assuming that 10% of those who would have initiated with menthol cigarettes do not initiate as a result of a ban). Approximately 100,000 of those whose lives would be saved would be African American. *Id.* at 1239 tbl. 1.

⁵ Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28973, 28977, 29010–11 (May 10, 2016) (codified at 21 CFR 1100, 1140, 1143) (hereinafter “Deeming Tobacco Products”).

drastic changes to premarket review enforcement and these changes fully ignore the reasoning behind the important fixes in the final Deeming Rule. Not only do these changes double-down on the errors of the proposed Deeming Rule, but they also exacerbate them to an incredible degree.⁶ The public health community responded immediately, outlining the public health harms the changes would cause. Despite the best efforts of public health groups, the FDA never wavered.⁷ Public health groups had little choice but to file a lawsuit. Rather than resolving the lawsuit by addressing these legitimate concerns, the government decided to proceed in defending this harmful decision in court.⁸

The reworking of premarket review in 2017 is another example of an action that is entirely antithetical to the agency's mission to protect public health. Representatives of the FDA, from the highest levels to the lowest levels, consistently tout the agency's science-based, evidence-driven approach to regulation.⁹ Yet in this case, the FDA's sweeping action was justified by then-Commissioner Dr. Scott Gottlieb as preserving the potential role that e-cigarettes may play in reducing harm caused by combustible tobacco products,¹⁰ - that e-cigarettes could be an "off ramp" for adults who smoke - a benefit that is not supported by the evidence. The agency's decision to protect e-cigarettes in case some benefit is eventually demonstrated also ignores all of the real and potential *harms* for both youth and adults. Despite dozens of public health experts, many of whom have studied premarket review for years, warning the FDA that this decision would have a detrimental impact on public health, the agency stuck with its decision. When the evidence of the forewarned youth e-cigarette epidemic was finally available, the agency's hand was forced. This proposed draft guidance is an attempt to correct an egregious and entirely preventable error and without some significant changes to the guidance, it will fail to effectively correct the agency's mistake.

⁶ DEP'T OF HEALTH AND HUM. SERVS., FOOD AND DRUG ADMIN. CTR. FOR TOBACCO PRODUCTS, FDA-2017-D-2843, EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE: GUIDANCE FOR INDUSTRY (Aug. 2017), <https://www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2834-0005&attachmentNumber=1&contentType=pdf>.

⁷ Sheila Kaplan, *F.D.A. Delays Rules That Would Have Limited E-Cigarettes on Market*, N.Y. TIMES (Jul. 28, 2017), <https://www.nytimes.com/2017/07/28/health/electronic-cigarette-tobacco-nicotine-fda.html>.

⁸ See Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment and in Support of Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment, American Academy of Pediatrics, et al., v. United States Food and Drug Administration, (D. Md. 8:18-cv-883) August 7, 2018

⁹ U.S. Food & Drug Admin., *Tobacco Science & Research*, <https://www.fda.gov/tobacco-products/tobacco-science-research> (last visited Apr. 30, 2019).

¹⁰ Scott Gottlieb, Former Commissioner, Food and Drug Admin., *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco* (Jul. 28, 2017), <https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm>.

Since the agency adopted its new regulatory plan, then-Commissioner Gottlieb held several meetings with industry in attempts to persuade the industry to act voluntarily to address the youth e-cigarette epidemic. That effort did not yield any meaningful results. At the same time, the FDA has held members of the public health community at arms-length, neither soliciting input nor taking unsolicited input seriously. The public health community can no longer be treated as an outside interest without a stake in regulation that is equal to or greater than tobacco product manufacturers. Ignoring the vast commercial tobacco control policy expertise honed over fifty years at the state and local levels only weakens federal regulatory decision-making. Moreover, public health groups have demonstrated that when the FDA fails to uphold its mission, they will use the judicial system to force the agency to fulfill its mission. To produce better compliance procedures and avoid unnecessary litigation, the FDA must incorporate the comments and suggestions from public health groups in this guidance.

The suffering of humankind as a result of the commercially used tobacco epidemic at the hands of the tobacco industry can be measured in lives lost and dollars spent, most of which could have been avoided had there been tight controls on the marketplace. It took nearly fifty years after the first Surgeon General's report linking smoking to cancer for Congress to finally give the FDA authority to control the tobacco product market. With this authority, the FDA has incredible power to turn the tide of death, disease, and lost resources the tobacco industry has inflicted on society. As such, premarket review is an incredibly powerful tool the agency wields to control the market and protect public health. Unfortunately, the agency's lack of stringent enforcement has failed to live up to its potential.

Understanding that nicotine addiction is extremely hard to overcome, the tobacco industry has spent decades – and many millions of dollars – engineering the combustible cigarette so that it effectively and efficiently delivers nicotine to the user. Because combusted cigarettes present such a significant risk of serious health consequences and death, any non-combusted tobacco products are somewhat less harmful. Of course, being less harmful than the most dangerous product on the market is not the same thing being harmless. Therefore, it is a public health challenge to approach the regulation of e-cigarettes in a way that encourages those who smoke combusted cigarettes to completely transition to e-cigarettes as an interim step towards the ultimate goal of breaking their nicotine addiction entirely, while at the same time preventing the uptake of e-cigarette use for those, both adults and youth, who would have never tried tobacco products. Unfortunately, the FDA has prioritized the potential for those who smoke to transition to e-cigarettes over preventing youth and adult never-users from becoming addicted to nicotine. The problem with this approach is further compounded by the evidence showing that in addition to luring never-users, those who use combustible products are more likely to become dual-users of combustible products and e-cigarettes rather than

quitting combusted cigarettes entirely, prolonging their addiction and likely increasing their overall health harms.¹¹ This means that the FDA's strategy has entirely backfired. The purported beneficial health consequences have not manifested and instead the agency's actions have exacerbated the public health harms.

This guidance represents a small step in the right direction. However, in order to fully realize the agency's goal of protecting public health, the FDA must make changes to this guidance. Below we outline policies that, if adopted, would represent the improvements needed to maximize the public health benefits of this guidance. We will also outline several actions that the FDA must take in addition to this guidance because the use of enforcement discretion of premarket review of newly-deemed products will not reach cigarettes, smokeless tobacco, or any newly-deemed products that were grandfathered. We also note that the FDA has worked with the industry to develop this draft guidance, and it is obvious that the outcome aligns almost perfectly with public positions taken by Juul, a company that many, including the former Commissioner, have blamed for the current epidemic.¹² This draft guidance must, first and foremost, look at the root causes of the e-cigarette epidemic and the new wave of harm and death that will follow. The guidance must not just propose half-measures that the industry agrees to in an effort to prevent litigation. Instead, the FDA must take bold steps to resolve an unprecedented public health crisis.

1. Compliance Policy for E-Cigarettes

In September 2018, the preliminary results of the 2018 National Youth Tobacco Survey (NYTS) were released, showing a shocking increase in youth use of e-cigarettes. It took the agency another six months to propose this guidance, knowing that the guidance would not be finalized and implemented immediately. The final results of the 2018 NYTS confirmed that action should have been taken immediately to address the epidemic. According to the 2018 NYTS, current use of any tobacco product reported by high school students has skyrocketed to the highest levels since

¹¹ Sara Kalkhoran & Stanton A. Glantz, *E-Cigarettes and Smoking Cessation in Real-World and Clinical Settings: A Systematic Review and Meta-Analysis*, 4 *THE LANCET RESPIRATORY MED.* 116 (2016); Thomas A. Wills et al., *E-cigarette use and respiratory disorder in an adult sample*, 194 *DRUG AND ALCOHOL DEPENDENCE* 363–370 (2019); Talal Alzahrani et al., *Association Between Electronic Cigarette Use and Myocardial Infarction*, 55 *AMERICAN JOURNAL OF PREVENTIVE MEDICINE* 455–461 (2018); Albert D. Osei et al., *The association between e-cigarette use and cardiovascular disease among never and current combustible cigarette smokers: BRFSS 2016 & 2017*, *THE AMERICAN JOURNAL OF MEDICINE* 30211–30216 (2019).

¹² Julia Beluz, *Scott Gottlieb's Last Words as FDA Chief: Juul Drove a Youth Addiction Crisis*, *VOX* (Apr. 5, 2019, 7:10 AM), <https://www.vox.com/science-and-health/2019/4/5/18287073/vaping-juul-fda-scott-gottlieb>.

2004.¹³ This is almost entirely propelled by the increased use of e-cigarettes among high school youth, which, on its own, is higher than current high school use of all tobacco products in 2016 or 2017.¹⁴ And there are compelling reasons to believe that this is a significant underestimate of actual e-cigarette use among high school students today. First, NYTS survey questions about e-cigarette use included examples of some e-cigarette brands, but have not specifically included Juul. Many public health advocates have concluded that this epidemic is largely driven by Juul and it is reasonable to conclude that substantially more students would have reported e-cigarette use if Juul had specifically been referenced in the survey questions. Second, current use is likely higher today because Juul sales have increased significantly since the survey period ended. Juul sales data first signaled the potential for an increase in youth use that was later confirmed with the 2018 NYTS. Even more troubling, the 2018 survey was collected at the beginning of 2018. After the survey period ended in June of 2018, Juul sales have continued to soar – Juul’s sales increased 36.5% since June of 2018 according to Nielsen’s all-channel data (See Figure 1).¹⁵

Why do advocates and even the outgoing Commissioner believe that Juul has driven the epidemic? Little to no change in the prevalence of e-cigarette use among adults coupled with significantly increased e-cigarette use amongst youth correlates greatly with recent increases in monthly sales data for e-cigarettes. The recent spike in youth use seems clearly associated with the recent spike in e-cigarette sales overall – the latter being nearly exclusively driven by Juul and Juul-like products. Figure 1 depicts the e-cigarette market measuring in-person, convenience store sales since November of 2013. The market total (represented in blue) was consistently hovering around \$50 million in total sales each month. Red represents the proportion sales are attributed to Juul. As Juul sales continued to skyrocket, the total market rose. The light-colored boxes in Figure 1 depict the survey period and the reported prevalence of current high school e-cigarette use from NYTS data. Outgoing Commissioner Gottlieb recently noted that “[t]here’s no question the Juul product drove a lot of the youth use” and he attributed at least partial, if not all, responsibility to Juul for causing the epidemic.¹⁶ There are limitations to this

¹³ Centers for Disease Control and Prevention, *Tobacco Use, Access, and Exposure to Tobacco in Media Among Middle and High School Students – United States, 2004*, 54 MORBIDITY AND MORTALITY WKLY. REP. 297, 299 (Apr. 1, 2005); Centers for Disease Control and Prevention, *Tobacco Use Among Middle and High School Students – United States, 2000–2009*, 59 MORBIDITY AND MORTALITY WKLY. REP. 1063 (Aug. 27, 2010); Centers for Disease Control and Prevention, *Vital Signs: Tobacco Product Use Among Middle and High School Students – United States, 2011–2018*, 68 MORBIDITY AND MORTALITY WKLY. REP. 157 (Feb. 15, 2019).

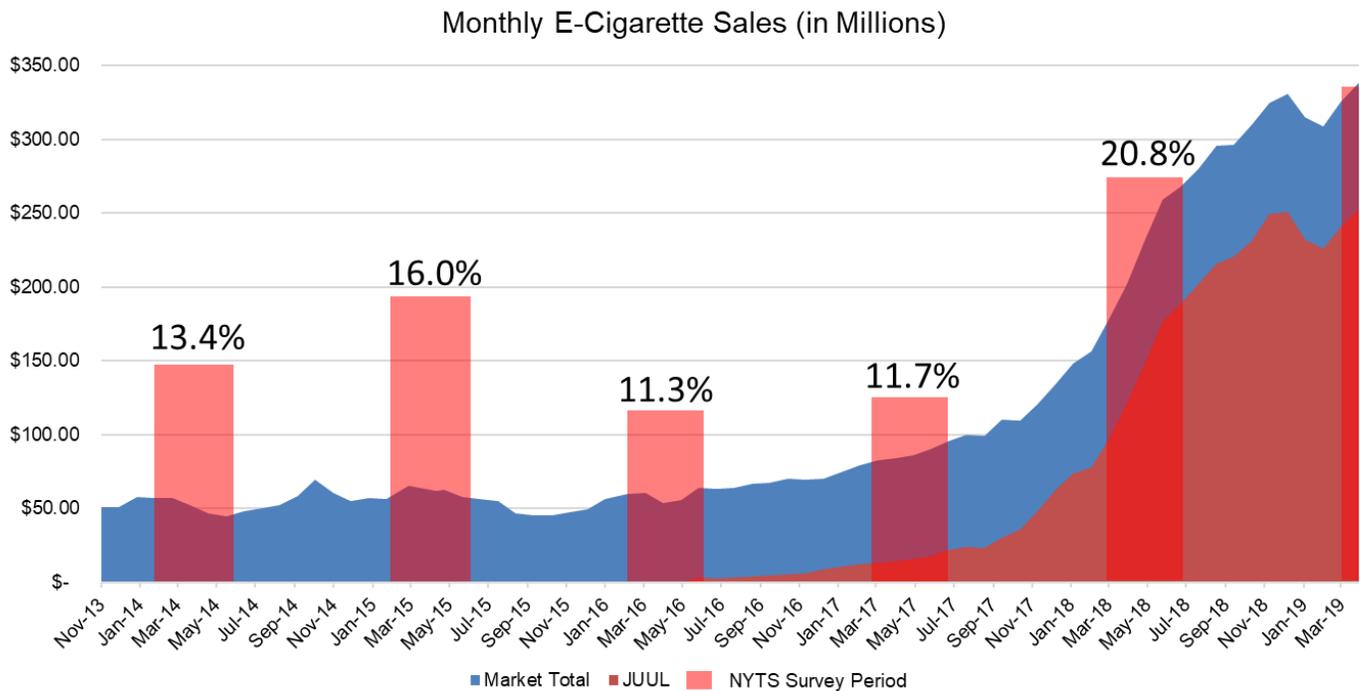
¹⁴ *Id.*

¹⁵ BONNIE HERZOG, NEILSEN: TOBACCO ALL CHANNEL DATA (Nov. 2013 – Apr. 2019).

¹⁶ Julia Beluz, *Scott Gottlieb’s Last Words as FDA Chief: Juul Drove a Youth Addiction Crisis*, VOX (Apr. 5, 2019, 7:10 AM), <https://www.vox.com/science-and-health/2019/4/5/18287073/vaping-juul-fda-scott-gottlieb>.

information, the data in Figure 1 fails to capture some stores and most importantly does not include online sales, of which we know very little. While the 2018 NYTS data should spur swift and immediate action, knowing that youth usage is certain to rise again in the 2019 survey data should persuade the FDA to take comprehensive and effective action address the epidemic.

Figure 1.



Even before the rise of Juul, the potential for youth to become addicted to nicotine through unregulated and easily accessible e-cigarettes was extremely concerning. Youth have consistently reported that the wide variety of flavors in e-cigarettes has been a primary reason for trying the products.¹⁷ Changing social norms and increased knowledge regarding the harms of cigarette use among youth, had undoubtedly contributed to the lowest levels of youth overall commercial tobacco use in recent years, but recent efforts by the e-cigarette industry and an unregulated market have successfully derailed this progress.

Lack of regulation has also contributed to the blatant targeting of youth through marketing and advertising. These marketing strategies have contributed to youth continuing to be woefully uninformed about the risks associated with use of e-

¹⁷ U.S. DEP'T OF HEALTH AND HUMAN SERV., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL (2016).

cigarettes, including Juul and Juul-like products. Juul has become popular among youth using marketing strategies to downplay the nicotine content and health risks for youth.¹⁸ Youth have revealed in survey data that they overwhelmingly believe that the e-cigarettes they are using do not always contain nicotine and that they mostly contain only flavoring.¹⁹ Additionally, Juul was able to convince youth that “Juuling”²⁰ was not really “vaping” or “using an e-cigarette,” instead they created a product that was so unlike other products that youth mistakenly believed they were not using an e-cigarette at all.²¹

While evidence is still emerging, research demonstrates that far from being “harmless water vapor,” e-cigarettes contain and produce hazardous substances similar to combustible cigarettes, and also have their own unique harms.²² For example, there are harms associated with the inhalation of flavoring aldehydes and heavy metals from the heating elements.²³ Furthermore, Juul and Juul-like products have created unique health harms by delivering such toxic levels of nicotine to the user that the FDA has released a “Special Announcement” warning parents and caregivers about several concerning reports of youth users experiencing seizures from abuse of the products.²⁴ Moreover, the potential for youth e-cigarette users to transition to combustible tobacco products raises even more concerns about the long-term health impacts for youth who initiate with e-cigarettes. The FDA cannot ignore the fact that, every single study of the topic has revealed that youth who initiate with e-cigarettes have an increased likelihood of transitioning to combustible tobacco products.²⁵

¹⁸ Jidong Huang et al., *Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market*, 28 TOBACCO CONTROL 146–151 (2018).

¹⁹ Jeffery G. Willett et al., *Recognition, Use, and Perceptions of JUUL Among Youth and Young Adults*, 28 TOBACCO CONTROL 115 (2018), <https://truthinitiative.org/sites/default/files/Recognition-use-and-perceptions-of-JUUL-among-youth-and-young-adults.pdf>.

²⁰ *Id.*

²¹ *Id.*

²² Elizabeth M. Martin et al., *E-cigarette use results in suppression of immune and inflammatory-response genes in nasal epithelial cells similar to cigarette smoke*, 311 AMERICAN JOURNAL OF PHYSIOLOGY-LUNG CELLULAR AND MOLECULAR PHYSIOLOGY L135–L144 (2016).

²³ Andrey Khystov & Vera Samburova, *Flavoring Compounds Dominate Toxic Aldehyde Production during E-Cigarette Vaping*, 50 ENVIRONMENTAL SCIENCE TECHNOLOGY 13080–13085 (2016); Pablo Olmedo et al., *Metal Concentrations in e-Cigarette Liquid and Aerosol Samples: The Contribution of Metallic Coils*, 126 ENVIRONMENTAL HEALTH PERSPECTIVES 027010–1–027010–11 (2018).

²⁴ U.S. Food & Drug Admin., *Statement from FDA Commissioner Scott Gottlieb, M.D., and Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D., on FDA’s Ongoing Scientific Investigation of Potential Safety Issue Related to Seizures Reported Following E-Cigarette Use, Particularly in Youth and Young Adults*, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-principal-deputy-commissioner-amy-abernethy-md-phd> (Apr. 3, 2019).

²⁵ NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (The National Academies Press, 2018); Konstantinos Farsalinos et al., *Comment on “Flavoring Compounds Dominate Toxic Aldehyde Production during E Cigarette Vaping,”* 51 ENVIRONMENTAL SCIENCE & TECHNOLOGY 2491–2492 (2017); Sarah Aleyan et al., *Risky*

The trend in youth e-cigarette use is not the only area where there are public health concerns with the FDA's approach to regulating e-cigarettes. A growing body of research indicates that e-cigarettes are not a viable cessation device for adults. The FDA's hope that a lack of stringent regulation would encourage adults who smoke to transition to e-cigarettes and eventually break their addiction is not supported by the evidence. In fact, several research studies found that using e-cigarettes does not lead to long-term smoking cessation for adults who smoke and that many adults who try switching to e-cigarettes actually become dual users, which increases the risk of certain serious diseases. A systematic meta-analysis of studies examining e-cigarettes as smoking cessation aids concluded that, overall, those that use e-cigarettes are less likely to quit smoking entirely.²⁶ While some recent research has shown that e-cigarette use in a more clinical setting, coupled with individual counseling, results in greater successful cessation over Nicotine Replacement Therapies (NRTs), these results do not mimic the daily usage patterns of the majority of e-cigarette users.²⁷

Rather than actually quitting smoking, a much more likely outcome is for an adult who smokes to become a dual user of e-cigarettes and other tobacco products. In 2015, according to the National Health Interview Survey, nearly 60% of adult e-cigarette users, also smoked cigarettes.²⁸ This is especially concerning because for some respiratory diseases and heart diseases, the evidence shows that dual use of e-cigarettes and other combustible products leads to greater health harms than just using one of the products exclusively.²⁹ This is supported by the recent study that

business: a longitudinal study examining cigarette smoking initiation among susceptible and non-susceptible e-cigarette users in Canada, 8 *BMJ OPEN* 1–7 (2018); Matthis Morgenstern et al., *E-Cigarettes and the Use of Conventional Cigarettes*, *DEUTSCHES AERZTEBLATT ONLINE* 243–248 (2018); Katherine East et al., *The Association Between Smoking and Electronic Cigarette Use in a Cohort of Young People*, 62 *JOURNAL OF ADOLESCENT HEALTH* 539–547 (2018).

²⁶ Sara Kalkhoran & Stanton A. Glantz, *E-Cigarettes and Smoking Cessation in Real-World and Clinical Settings: A Systematic Review and Meta-Analysis*, 4 *THE LANCET RESPIRATORY MED.* 116 (2016).

²⁷ Peter Hajek et al., *A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy*, *NEW ENGLAND JOURNAL OF MEDICINE* 629–637 (2019).

²⁸ Centers for Disease Control and Prevention, *QuickStats: Cigarette Smoking Status Among Current Adult E-cigarette Users, by Age Group — National Health Interview Survey, United States – 2015*, 65 *MORBIDITY AND MORTALITY WKLY. REP.* 1177 (Oct. 28, 2016).

²⁹ Talal Alzahrani et al., *Association Between Electronic Cigarette Use and Myocardial Infarction*, 55 *AM. J. PREVENTATIVE MED.* 455 (2018), <https://www.ncbi.nlm.nih.gov/pubmed/30166079>; Albert D. Osei et al., *The Association Between E-Cigarette Use and Cardiovascular Disease Among Never and Current Combustible Cigarette Smokers: BRFSS 2016 & 2017*, 132 *AM. J. OF MED.* (forthcoming 2019); Thomas A. Wills et al., *E-Cigarette Use and Respiratory Disorder in an Adult Sample*, 194 *DRUG AND ALCOHOL DEPENDENCE* 363 (2019).

shows that exposure to toxic chemicals is greater for the dual user than the exclusive user.³⁰

These results should not be surprising to the FDA as the e-cigarette marketplace was entirely unregulated prior to the finalization of the Deeming Rule in 2016 and since then, little regulation has actually been imposed on the products. Manufacturers are required to register with the FDA and provide lists of their products and warning labels were implemented in August 2018. Beyond this, little policy change has happened. The lack of regulation over the last ten years did not result in significant numbers of cigarette smokers moving to e-cigarettes, it seems very unlikely that a continued lack of regulation will produce different results. The FDA's dogged commitment to keeping the "off ramp" open to adults who smoke is increasingly at odds with the science and fails to protect public health. We commend the FDA for finally changing course but reiterate that there are still significant weaknesses in this guidance that must be changed.

The FDA proposes two sets of restrictions based on an e-cigarette's flavoring. In the proposal, tobacco, mint, and menthol e-cigarettes are the least stringently regulated and the FDA intends to prioritize all other flavored e-cigarettes (referred to in this comment as "other flavored e-cigarettes"). Failure to include menthol and mint flavored e-cigarettes will ensure a continued growth in tobacco-related disparities. Because of the immediate and potential long-term impacts of the youth e-cigarette epidemic, and the FDA's failure to adequately respond in a timely fashion, the agency must no longer take an incremental, drawn-out approach to e-cigarette regulation. In order to effectively address the youth e-cigarette market, the FDA must take comprehensive action that maximizes the public health benefits. To this end, the FDA must remove all Juul and Juul-like products from the market, remove all flavored e-cigarettes from the market, prohibit all online sales, and place heightened increase accessibility restrictions on the remaining e-cigarettes.

i. Targeting Juul and Juul-like products

On Commissioner Gottlieb's last day in office he observed that it is undeniable that the youth e-cigarette epidemic "was driven in part at the very least if not largely by Juul." There is no question that Juul's rise and dominance in the e-cigarette market has coincided with the youth e-cigarette epidemic (See figure 1). Along with the statistical correlation, there is significant evidence that Juul is the primary cause of the epidemic. In fact, many of Juul's practices look much like they took a page out of the tobacco industry playbook for luring and addicting youth as "replacement smokers" to offset profits lost from selling a lethal product.

³⁰ Maciej L. Goniewicz, Danielle M. Smith & Kathryn C. Edwards, *Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes*, 1 JAMA NETWORK OPEN (2018).

It is clear from Juul's unprecedented rise in popularity that the company was tapping into the market in way that was unlike all other e-cigarette products and its marketing specifically appealed to many aspects of youth and young adult attitudes and beliefs. Juul created a product that is small and easily concealed and also resembles a USB storage device, something a youth is likely to have for legitimate reasons. In fact, many parents report not being able to recognize that devices like Juul and Suorin are e-cigarettes.³¹ It is also small enough to conceal inside other objects for additional discretion. The use of nicotine salts in Juul products also makes using the product in public places easy to conceal, even in classrooms, because the exhaled aerosol is barely visible and an experienced user can conceal use entirely.³²

Additionally, Juul was deceptive in its labeling of nicotine on Juul packaging. While nearly all other e-cigarettes report nicotine levels in mg/mL, Juul reports nicotine as a percentage, 5% to be exact. To the uninformed youth, five is not a very large number and it certainly seems significantly lower than the 12-20 mg/ml of nicotine reported on other products. However, Juul's 5% solution delivers nearly 40 mg of nicotine to the user in a single pod – the equivalent of a pack of cigarettes.³³ Most other e-cigarettes have a maximum of 25 – 30 mg in a single pod or cartridge. Juul also offers price promotions for "starter kits," making them more affordable for youth, who are extremely price sensitive.³⁴ Survey data specific to youth use of Juul reveals that there is only a small difference in percentage of youth who ever try Juul and those who become habitual users; 80% of those who ever tried Juul were also current users.³⁵ This means that 8 in 10 kids who try Juul will become addicted to the products.

The formulation of the nicotine itself as nicotine salts is not only problematic because of easier concealment and confusion about nicotine content, but also from an abuse liability and addiction standpoint. Specifically, Juul uses benzoic acid to stabilize the nicotine salt.³⁶ Benzoic acid neutralizes the pH of the nicotine, which, in

³¹ Kristen Byrne, *Only 50 Percent of Parents Can Identify E-Cigarettes*, WTMJ-TV MILWAUKEE, (Apr. 9, 2019, 6:51 AM), <https://www.tmj4.com/news/local-news/only-50-of-parents-can-identify-e-cigarettes>.

³² Divya Ramamurthi, Cindy Chau & Robert K Jackler, *JUUL and other stealth vaporisers: hiding the habit from parents and teachers*, TOBACCO CONTROL 1–7 (2018).

³³ FAQs, JUULPOD BASICS, JUUL, <https://support.juul.com/home/learn/faqs/juulpod-basics> (last visited Apr. 24, 2019).

³⁴ ROBERT K. JACKLER ET AL., JUUL ADVERTISING OVER ITS FIRST THREE YEARS ON THE MARKET (2019), http://tobacco.stanford.edu/tobacco_main/publications/JUUL_Marketing_Stanford.pdf.

³⁵ Jeffery G. Willett et al., *Recognition, Use, and Perceptions of JUUL Among Youth and Young Adults*, 28 TOBACCO CONTROL 115 (2018), <https://truthinitiative.org/sites/default/files/Recognition-use-and-perceptions-of-JUUL-among-youth-and-young-adults.pdf>.

³⁶ U.S. Patent No. 9,215,895, (filed Oct. 10, 2014), <https://patents.justia.com/patent/20150020824>.

turn increases the palatability of the nicotine.³⁷ Free nicotine, which is commonly used in other e-cigarettes, has an acidic pH, which limits the amount of nicotine the user can inhale without discomfort, by using benzoic acid to neutralize the pH and creating a stable protonated form of nicotine, Juul has created a product that delivers incredible amounts of nicotine to the user.³⁸ Nicotine is unequivocally and irreparably harmful for the developing brain, the long-term effects of such an intense levels of nicotine is likely to be profound.³⁹

The most effective approach to addressing the youth e-cigarette epidemic would be for the FDA to immediately remove all Juul and Juul-like products from the market and require marketing authorization before those products may reenter the market. The inclusion of Juul-like products is important because recent research shows that as of September 2018, at least 39 Juul-like devices existed on the market; many of these products had nicotine levels similar to Juul, but some had even more nicotine.⁴⁰ The FDA could achieve this result several different ways, including removing all e-cigarettes that deliver over 20 mg/mL of nicotine to the user in a single pod, removing all products that use nicotine salts, or removing products that add benzoic acid to the e-liquid or nicotine. It is clear that Juul has caused this epidemic with its toxic mix of technology and marketing and the FDA must remove its products in order to effectively combat this public health problem.

ii. Youth-centered marketing and advertising

The FDA proposes to prioritize enforcement against companies that advertise or label their products that are especially enticing towards youth. To its credit, the FDA does not exempt any e-cigarette from this prioritization, however, this measure is unlikely to address the type of marketing that Juul used to drive this epidemic. The FDA specifically discusses marketing and labeling that resembles youth-centered products like labeling that is designed to resemble well-known sugary cereals and candy. However, Juul does not use this type of labeling, instead, Juul captured the market by using marketing that was particularly adept at luring youth through youth-centered social media platforms and paid social media “promoters.” These social media promoters work by acquiring thousands of followers, often youth and young adults, to their personal pages or content and then the promoters advertise

³⁷ Ilona Jaspers, ATS Tobacco Action Committee, Webinar: Perspectives on E-Cigarettes from an Inhalation Toxicologist Who Is Also a Mother of Teenagers (Apr. 11, 2019), <http://www.thoracic.org/advocacy/tobacco-action/perspectives-on-e-cigs.php>; Posting of Gregory Connolly, gregconn10@verizon.net, to smartalk@smartalk.org (Jan. 17, 2019) (attached and on file with author).

³⁸ *Id.*

³⁹ U.S. DEP’T OF HEALTH AND HUMAN SERV., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL (2016).

⁴⁰ Robert K Jackler & Divya Ramamurthi, *Nicotine arms race: JUUL and the high-nicotine product market*, TOBACCO CONTROL 1–6 (2019).

products often without admitting that they were being paid to endorse these products.⁴¹ Youth that want to emulate the lifestyles of these influencers are hoodwinked into thinking that these products were “cool,” instead of highly addictive and harmful. When news of the epidemic broke and Juul’s role became obvious, Juul announced it would stop these deplorable schemes.⁴²

To maximize the public health benefit of the final guidance, any prioritization of enforcement against e-cigarette manufacturers that use youth-targeted marketing and labeling must identify these marketing schemes that often go unnoticed by adults but are undoubtedly contributing to the increases in youth e-cigarette use.

iii. Removing all flavors, including mint and menthol

The FDA proposes to regulate mint-, menthol-, and tobacco-flavored e-cigarettes less stringently than other flavors of e-cigarettes. Menthol in tobacco products has driven health disparities and comprehensive action by the FDA is overdue (see Section 5(i), below). The agency has proposed to prioritize enforcement against other flavored e-cigarettes that are sold in youth accessible ways – such as in youth accessible stores or in stores that have sold to youth in undercover buys. However, to maximize the public health benefit of the agency’s action, the FDA must remove all flavored e-cigarettes, including mint and menthol, from the market regardless of where and how they are sold and reentry should only be permitted after FDA authorization. All flavored e-cigarettes have contributed to this epidemic; no flavored e-cigarettes should be sold. In the absence of sweet and candy flavors, under the draft guidance youth will undoubtedly turn to mint and menthol flavored e-cigarettes to satiate their addiction.

As previously discussed, Juul’s role in the epidemic should prompt the agency to consider the best way to control the market that makes Juul the least accessible and appealing to youth and adult current and never users. One obvious flaw in the FDA’s exemption of mint and menthol flavors is that, while Juul comes in sweet flavors like “mango” and “crème,” it is also available in mint and menthol. If the FDA does not remove all Juul and Juul-like products from the market immediately, continuing to

⁴¹ JACKLER ET AL., *supra* note 34 ; Michael Nedelman, Roni Selig, & Arman Azad, #JUUL: How Social Media Hyped Nicotine for a New Generation, CNN, Dec. 19, 2018, <https://www.cnn.com/2018/12/17/health/juul-social-media-influencers/index.html?platform=hootsuite>.

⁴² Sheila Kaplan, *In Washington, Juul Vows to Curb Youth Vaping. It’s Lobbying in States Runs Counter to That Pledge*, N.Y. TIMES, Apr. 28, 2019, <https://www.nytimes.com/2019/04/28/health/juul-lobbying-states-ecigarettes.html>.

allow half the available flavors of Juul to be sold in kid-accessible ways will do little to actually address the epidemic.⁴³

Youth overwhelmingly and primarily initiate with and continue using flavored e-cigarettes. The 2018 NYTS data shows that between 2017 and 2018, current use of any flavored e-cigarettes rose significantly, from 60.9% to 67.8% among current high school e-cigarette users.⁴⁴ Population Assessment of Tobacco and Health (PATH) data reveals that among non-cigarette users, youth consistently reported product flavoring as a reason for use across all product types, including e-cigarettes (81.5%).⁴⁵ Additionally, the overwhelming majority of all youth ever-users of tobacco products report that the first product they used was flavored (81% of e-cigarette ever-users). Furthermore, the availability of flavors is, by far, the most common reason that youth e-cigarettes users report using e-cigarettes (59.6% of youth regular e-cigarette users – defined as youth who use e-cigarettes three or more times in the last thirty days).⁴⁶ This is also supported by 2016 NYTS data that suggests that current high school e-cigarette users most commonly use e-cigarettes is due to the available flavors.⁴⁷ Even more disconcerting, other survey data reveals that youth incorrectly perceive flavored e-cigarettes as less harmful than tobacco-flavored e-cigarettes.⁴⁸

The FDA has gone to great lengths to present a summary of the available research on the use of menthol and mint flavors in a way that justifies the agency's decision to subject those flavors to less stringent regulation. To support the conclusion that adults prefer mint or menthol flavors over youth, the FDA uses data from Wave 2 of the PATH study which was collected 2014-2015; at least a year before Juul was introduced to the market and long-before youth e-cigarette use was at epidemic levels. While some outdated data suggest that adults may find mint and menthol e-

⁴³ In addition to mint and menthol, Juul is available in “Virginia tobacco” and “classic tobacco.” These products would not be subject to stringent regulation under the FDA's proposal while Juul's other four flavors would. See JUUL, <https://www.juul.com/shop/pods> (last visited Apr. 30, 2019).

⁴⁴ Centers for Disease Control and Prevention, *Vital Signs: Tobacco Product Use Among Middle and High School Students – United States, 2011–2018*, 68 MORBIDITY AND MORTALITY WKLY. REP. 157 (Feb. 15, 2019).

⁴⁵ Bridget K. Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, 314 JAMA 1871 (2015).

⁴⁶ Megan E. Patrick et al., *Self-Reported Reason for Vaping Among 8th, 10th, and 12th Graders in the US: Nationally-Representative Results*, 165 Drug Alcohol Depend. 275 (2016).

⁴⁷ James Tsai et al., *Reasons for Electronic Cigarette Use Among Middle and High School Students - National Youth Tobacco Survey, United States, 2016*, 67 MORBIDITY AND MORTALITY WKLY. REP. 196 (2018).

⁴⁸ Jessica K. Pepper, Kurt M. Ribisl, Noel T. Brewer, *Adolescents' Interest in Trying Flavoured E-Cigarettes*, 25 TOBACCO CONTROL ii62 (2016).

cigarette flavors more appealing than youth do,⁴⁹ youth reported use of mint and menthol e-cigarettes is high enough to require the removal of mint and menthol e-cigarettes. As of 2018, the majority, 51.2%, of current high school students who use e-cigarettes, use menthol or mint flavored e-cigarettes.⁵⁰ Additionally, in Connecticut youth study that the FDA references, when combined, mint and menthol flavored e-cigarettes are reported as the second most popular flavors.⁵¹ Furthermore, the FDA failed to acknowledge that many youth report using combination flavors, which could hide the proportion of youth that are using mint or menthol flavored e-cigarettes combined with other flavors. Ultimately, the focus on whether adults or youth prefer mint and menthol flavors is meaningless in determining whether mint and menthol flavors should be exempted – to maximize the public health benefits of the final guidance, the FDA must remove all flavors of e-cigarettes that youth are using.

The evidence is undeniable that flavors lure youth, mask the harsh taste of nicotine, result in a deeper and longer addiction, and make quitting harder.⁵² This evidence-base has existed for decades and led to the prohibition of flavors other than menthol for cigarettes in the Tobacco Control Act. The FDA’s failure to prioritize menthol flavored e-cigarettes is deeply concerning. In the absence of other flavored cigarettes, youth predominately initiate with menthol flavored cigarettes,⁵³ and it is illogical for the FDA to conclude that the scenario would be any different for menthol and mint e-cigarettes. To maximize public health benefits and to effectively address the youth e-cigarette epidemic, the FDA must immediately remove all flavored e-cigarettes from the market, allowing them to return only after receiving marketing authorization. If the FDA does not immediately remove all flavored e-cigarettes, the FDA must not exclude mint and menthol flavors from the most stringent enforcement provisions in the final guidance.

⁴⁹ Liane M. Schneller et al., *Use of flavored electronic cigarette refill liquids among adults and youth in the US—Results from Wave 2 of the Population Assessment of Tobacco and Health Study (2014–2015)*, 13 PLOS ONE 1–9 (2018).

⁵⁰ Karen A. Cullen et al., *Notes From the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students – United States, 2011–2018*, 67 MORBIDITY AND MORTALITY WKLY. REP. 1276 (2018).

⁵¹ Grace Kong et al., *Sources of Electronic Cigarette Acquisition among Adolescents in Connecticut*, 3 TOBACCO REGULATORY SCIENCE 1–12 (2017).

⁵² U.S. DEP’T OF HEALTH AND HUMAN SERV., *E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL* (2016); Valerie B. Yerger, *Menthols Potential Effects on Nicotine Dependence: A Tobacco Industry Perspective*, 20 TOBACCO CONTROL 440–445 (2011); Valerie B. Yerger & Phyra M. McCandless, *Menthol Sensory Qualities and Smoking Topography: A Review of Tobacco Industry Documents*, 20 TOBACCO CONTROL ii37–ii43 (2011).

⁵³ Charles J. Courtemanche, Makayla K. Palmer & Michael F. Pesko, *Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use*, 52 AMERICAN JOURNAL OF PREVENTIVE MEDICINE 1–13 (2017).

iv. Prohibiting Online Sales

To maximize the protection of public health, the FDA must prohibit all online sales of all e-cigarettes, regardless of flavor. The FDA's current proposal, which appropriately tries to limit youth access to in-person sales is likely to drive youth to online sales, where oversight is essentially non-existent and even sales tracking is severely limited. Due to the unregulated nature of the internet, online sales are the easiest way for technology savvy youth to acquire e-cigarettes. The FDA's proposal to limit online sales to only those that use "heightened" age verification and limit quantity demonstrates a naiveté to the tenacity and ingenuity of youth who are deeply addicted to nicotine and the lack of effective methods for tracking compliance. To effectively address youth accessibility and to maximize the public health benefits of the final guidance, the FDA must prohibit all online sales of all newly-deemed tobacco products, instead of driving youth to these sales.

The only effective way to ensure that people are above the minimum legal sales age and using their own ID to purchase tobacco products is to require that all newly-deemed tobacco products be sold in face-to-face exchanges. In addition to the imperative face-to-face checking of an ID, in-person sales are the only sales where retailers are systematically inspected for compliance and routinely assessed penalties for underage sales.

As stated before, Juul has capitulated to the proposed guidance and has publicly supported flavor sales restrictions, as long as they apply only to in-person sales. The FDA should be highly suspicious of implementing any plan that the industry has acquiesced to, knowing that the industry would not support any restriction that has the potential to significantly jeopardize its profits. Only Juul knows how many e-cigarettes it sells online and in-person, if it agrees to sales restrictions for just in-person sales, the FDA should conclude that they intend to maintain profits through internet sales. The FDA should take caution knowing that only the industry has access to the record keeping for online sales.

Currently, the only method for anyone outside of the industry to track online sales is through user surveys that ask where a product was purchased. This data is applicable, but only captures one segment of the landscape of online sales. These user surveys establish that youth are obtaining these products online. While youth Juul users mostly reported obtaining products in-person, 89% of underage youth that reported purchasing online were successful in their attempts to buy the products. Other surveys reveal that online purchasing is a common method for

purchasing e-cigarettes.⁵⁴ Additionally, international research reveals when banning in-person sales of e-cigarettes, online sales increase.⁵⁵

Online sales are particularly troubling not just because it is easy for youth to bypass age verification, but also because the market is dynamic and genuinely difficult to regulate. Research demonstrates that many online retailers are making illegal, harmful, and misleading claims.⁵⁶ Additionally, many online e-cigarette retailers are based off-shore and are removing and likely establishing new websites constantly.⁵⁷ The simplest answer to this fluid and difficult to regulate market is to draw a bright line and prohibit internet sales entirely.

If the FDA chooses not to prohibit online sales, the FDA should make other improvements to this provision in the guidance. First, because many youth do not have credit cards to purchase these products online, they have been known to purchase gift cards that can be used anywhere to purchase these products. Any regulation of online sales should restrict sales to credit cards that are issued in the name of the user. Additionally, as stated above, because no tracking of online sales currently exists, the FDA should require that all online sales be reported to the FDA so that the agency can sufficiently track sales trends and ensure that manufacturers and retailers are complying with heightened requirements for online sales.

v. Application and Review Deadlines

The FDA proposes a change in deadlines for marketing applications for other flavored e-cigarettes from August 8, 2022, to August 8, 2021. As mentioned above, we believe that the FDA should immediately remove all flavored e-cigarettes, including mint and menthol, from the market and prohibit reentry unless the products receive authorization from the FDA. However, for any products that the agency allows to remain on the market after the effective date of the guidance, the FDA must establish a new compliance deadline – August 2021 is still over 2 years from today's date and such a delay does nothing to address the epidemic happening now.

⁵⁴ Grace Kong et al., *Sources of Electronic Cigarette Acquisition among Adolescents in Connecticut*, 3 TOBACCO REGULATORY SCIENCE 1–12 (2017); Rebecca S. Williams, Jason Derrick & Kurt M. Ribisl, *Electronic Cigarette Sales to Minors via the Internet*, 169 JAMA PEDIATRICS 1–12 (2015).

⁵⁵ David Braak et al., *Where Do Vapers Buy Their Vaping Supplies? Findings from the International Tobacco Control (ITC) 4 Country Smoking and Vaping Survey*, 16 INTERNATIONAL JOURNAL OF ENVIRONMENTAL RESEARCH AND PUBLIC HEALTH 1–13 (2019).

⁵⁶ Kim Pulvers et al., *Internet-based Advertising Claims and Consumer Reasons for Using Electronic Cigarettes by Device Type in the US*, 3 TOBACCO REGULATORY SCIENCE 516–524 (2017).

⁵⁷ Greta Hsu et al., *A Comparison of E-Cigarette Use Patterns and Smoking Cessation Behavior among Vapers by Primary Place of Purchase*, 16 INTERNATIONAL JOURNAL OF ENVIRONMENTAL RESEARCH AND PUBLIC HEALTH 724–737 (2019).

The FDA's current approach to application deadlines for newly deemed products is extremely harmful to public health because unlike in the final Deeming Rule, the FDA no longer establishes a deadline for itself to review applications. This, in turn, incentivizes manufacturers to delay submitting applications until the last possible minute. If the FDA establishes a deadline for review, manufacturers that wait until the last possible minute to submit an application risk being removed from the market due to the deadline for product removal passing. To avoid this, manufacturers are likely to submit applications as soon as possible, before the deadline, because those applications will be the first reviewed and have the best chance of being reviewed by the FDA within the twelve month review period and thus allowing the products to stay on the market without ever being removed. If the FDA fails to establish a review deadline, much like the Provisional Substantial Equivalence Reports submitted in March 2011, the industry is likely to submit a flurry of applications at the last possible moment to comply with the law and maximize the longevity of product availability. This tactic will no doubt increase industry profits, because even if the marketing of a product is ultimately denied, the product has remained on the market and garnered profits until the FDA acts.

We suggest that the FDA take a similar approach to the final Deeming Rule in the final version of this guidance. The final Deeming Rule would have given manufacturers twelve months to submit Substantial Equivalence Exemption requests, eighteen months for reports of Substantial Equivalence, and twenty-four months for Premarket Tobacco Product Applications. Manufacturers would then have been given an additional twelve months to market products while applications were being reviewed by the FDA and the agency stated that it would then begin removing products from the market that had not received marketing orders. These timelines and the amount of notice afforded to manufacturers has been challenged in court and upheld.⁵⁸

We urge the FDA to establish similar deadlines in the final guidance. Starting on the effective date of the guidance (thirty days after it is finalized) manufacturers of all products that are being granted the benefit of additional enforcement discretion have twelve months to submit marketing applications. After the application deadline, products can be granted an additional twelve months to remain on the market while the FDA reviews applications. At that point, the FDA must commit to removing products from the market that have not been granted marketing orders. It cannot be overstated how important it is that the FDA establish a deadline after which products will be removed from the market without marketing orders. Erasing that deadline in the FDA's 2017 regulatory plan was potentially one of the most harmful decisions made with respect to premarket review.

⁵⁸ *Nicopure Labs LLC et al. v. U.S. Food and Drug Administration*, 226 F.Supp.3d 360 (D.D.C. 2017).

While we urge the FDA to adopt the shortest application timeline from the Deeming Rule, that rule has been in effect for two and a half years, and it is reasonable to expect that manufacturers have been spending some of that time preparing marketing applications. There is no legal reason for the FDA to defer to the industry for any longer than this, nor is there any public health justification for extending the timelines any further into the future (or allowing them to remain as they are). Therefore, these dates should be treated as a ceiling and the FDA should definitely consider shortening them further. Should the FDA decide not to move up the 2021 and 2022 application deadlines, there is a high likelihood that the lawsuit that the agency is defending in U.S. District Court for the District of Maryland will move forward and force the agency's hand.⁵⁹ That case is already addressing this issue but it is also possible that additional lawsuits could be filed challenging the FDA's mediocre and ineffective response to the youth e-cigarette epidemic. The agency may as well make the correct decision in its own right and not have the courts correct its error. We reiterate that these timelines need only be used for the products that will be allowed to stay on the market. We believe very strongly that certain categories of products, identified throughout this comment, including flavored e-cigarettes, must be removed from the market immediately and given no additional benefit of enforcement discretion.

vi. Youth Accessibility

The FDA proposes to address youth accessibility in two specific ways: (1) by limiting the sale of other flavored e-cigarettes to adult-only stores; and (2) prohibiting the sale of other flavored e-cigarettes in any store that fails a compliance check. Assuming the FDA removes all flavored e-cigarettes from the market, including mint and menthol, pending review, in order to maximize the public health benefits of a final guidance, the FDA must apply these restrictions to any e-cigarettes that remain on the market in the final guidance. However, to regulate any remaining e-cigarettes on the market in a stringent manner that addresses the potential for nicotine-addicted youth to increase usage of those products, the FDA should refine some of its proposed provisions regarding youth access from the draft guidance. Should the FDA exempt mint and menthol e-cigarettes, a move that flies in the face of reason and the best available scientific evidence, those products should also be subject to the heightened levels of regulation described below.

The FDA must limit the sale of any remaining e-cigarettes to adult-only establishments. In the proposal, the FDA proposes to limit other flavored e-cigarettes sales to "locations that minors are able to enter at any time (e.g. the entire establishment or an area within the establishment)." It is entirely unclear from this language whether the FDA is requiring the entire establishment to be adult-only,

⁵⁹ American Academy of Pediatrics et al. v. U.S. Food and Drug Administration, 8:18-cv-883 (D. Md. 2018).

with no portion where minors may enter or whether the FDA is requiring that any portion of a store that would sell other flavored e-cigarettes be limited to adults. When finalizing this provision, the FDA must adopt the former interpretation, that e-cigarettes that remain on the market can only be sold in establishments that are *entirely* adult-only and that no portion of the establishment is accessible to those under the minimum legal sales age.

In addition to heightened youth access controls to prevent youth from purchasing e-cigarettes, establishing that the entire establishment be inaccessible to youth, protects youth from some of the point-of-sale advertising and marketing of these harmful products. Research shows that point-of-sale advertising is more common near schools and where teens are likely to shop, like convenience stores.⁶⁰ Increased exposure to advertising leads to increased likelihood of initiation for youth and increased impulse buys for current users and recent quitters.⁶¹ Additionally, point-of-sale advertising is especially targeted in low-income and minority communities⁶² – limiting the sale of any tobacco products to adult-only facilities is likely to reduce this health inequity.

Furthermore, if given the option to only make a portion of the store adult-only, the industry will surely respond in a way that ensures that youth are still being exposed to the point-of-sale advertising of e-cigarettes. In many communities, where sales of all flavored tobacco products has been limited to adult-only stores, the industry, especially convenience stores, immediately responded by “dividing” the store with plastic, transparent partitions to create an “adult-only side” and a “youth accessible side.”⁶³ When renovations were completed, stores put up large signs outside

⁶⁰ See, e.g., E C Feighery et al., *An examination of trends in amount and type of cigarette advertising and sales promotions in California stores, 2002-2005*, 17 *TOBACCO CONTROL* 93–98 (2008); Rachel Widome et al., *The relationship of neighborhood demographic characteristics to point-of-sale tobacco advertising and marketing*, 18 *ETHNICITY & HEALTH* 136–151 (2013).

⁶¹ U.S. DEP’T OF HEALTH & HUMAN SERVS, *PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL* 543 (2012); see also Greta Hsu et al., *A Comparison of E-Cigarette Use Patterns and Smoking Cessation Behavior among Vapers by Primary Place of Purchase*, 16 *INTERNATIONAL JOURNAL OF ENVIRONMENTAL RESEARCH AND PUBLIC HEALTH* 724–737 (2019); William J. McCarthy et al., *Density of Tobacco Retailers Near Schools: Effects on Tobacco Use Among Students*, 99 *AMERICAN JOURNAL OF PUBLIC HEALTH* 2006–2013 (2009); Sandy J. Slater et al., *The Impact of Retail Cigarette Marketing Practices on Youth Smoking Uptake*, 161 *ARCHIVES OF PEDIATRICS & ADOLESCENT MEDICINE* 440–445 (2007); Nina C. Schleicher et al., *Tobacco outlet density near home and school: Associations with smoking and norms among US teens*, 91 *PREVENTIVE MEDICINE* 287–293 (2016).

⁶² U.S. DEP’T OF HEALTH & HUMAN SERVS, *PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL* 545 (2012).

⁶³ Brady Slater, *Duluth businesses circumvent flavored tobacco ban*, *GRAND FORKS HERALD*, March 20, 2019, <https://www.grandforksherald.com/news/government-and-politics/4587341-duluth-businesses-circumvent-flavored-tobacco-ban> (last visited Apr 30, 2019); Mukhtar M Ibrahim, *Minneapolis bans new tobacco shops for a year*, *STAR TRIBUNE*, August 31, 2018, <http://www.startribune.com/minneapolis-bans-new-tobacco-shops-for-a-year/492192721/> (last visited Apr 30, 2019).

establishments proclaiming, “FLAVORS ARE BACK!”⁶⁴The FDA can anticipate this industry response and protect youth as much as possible by requiring that the entire store be adult only, and not only a portion of the store.

Prioritized enforcement of e-cigarettes sold in locations where minors are able to enter at any time and e-cigarettes sold in locations that have sold to minors after issuance of the final guidance may prove to be challenging provisions for the FDA to enforce. These particular policies are complicated by the fact that they potentially rely on not just the bad behavior of a tobacco product manufacturers, but also on the actions of third parties, in this case, retailers.

Where the FDA is able to target a specific product because of properties that are inherent to the product (e.g. it uses nicotine salts or it is a mint, menthol, or other flavored e-cigarette or flavored cigar), the agency can simply declare the product an adulterated and misbranded product and pursue enforcement actions against manufacturers who continue to introduce the offending product into interstate commerce and against retailers who continue to sell the product illegally. The situation is much more complicated when the agency’s prioritized enforcement is triggered by future events. It would be beneficial to the FDA to put as much of the onus of compliance onto tobacco product manufacturers as possible, while recognizing that even a manufacturer that attempts to fully comply with the law may see its product targeted through no fault of its own. Because of this possibility, we suggest that in the final guidance the FDA mandate that manufacturers be held responsible for the placement of their products in retail stores (e.g. products placed in stores where minors are able to enter at any time), unless they have a signed agreement with a retailer that indicates that the manufacturer has directed the retailer not to display its products in the store if youth can enter. This ought to be the manufacturer’s only defense to the possibility of its products being deemed adulterated and misbranded due to being sold in a location that minors are able to enter at any time. The result is that it becomes incumbent upon the manufacturer to secure a written agreement with every retailer that sells its products if the manufacturer wishes to avoid running afoul of the FDA’s enforcement discretion. Given how large the benefit is in this context (allowing products to remain on the market without authorization), this is not an unreasonable expectation.

However, the FDA must also ensure that manufacturers do not exploit this grant of immunity by separately urging retailers to continue their illegal activity outside of the agreement and then escaping liability for that action. To combat this possibility, we suggest that the FDA use its compliance and enforcement resources to target retailers who violate this policy for a significantly increased number of compliance

⁶⁴ Photos attached and on file with author (taken Mar. 23, 2019 in Minneapolis, MN and Saint Paul, MN).

checks. The agency should notify retailers that if they sell e-cigarettes in locations that minors are able to enter at any time violation of the FDA's compliance policy and the retailers' agreement with the e-cigarette manufacturer, it will be subject to at least monthly or even weekly compliance checks, significantly increasing the odds that the establishment is subject to civil monetary penalties. The FDA could also take this opportunity to seek Assurances of Voluntary Compliance (AVC) from these violating retailers, providing the agency with another tool to protect public health.⁶⁵

For the FDA's other enforcement priority that is triggered after the finalization of the guidance, e-cigarettes sold through retail establishments that have sold to minors after issuance of the guidance, there is a similar complication due to the actions of third parties. In order to avoid this problem, we suggest that the FDA restructure this policy. In order to put the onus of compliance onto manufacturers, we suggest that the FDA communicate directly with manufacturers of e-cigarettes on a monthly basis and provide them with a list of retail stores that have sold any tobacco product, not just e-cigarettes, to minors. Upon receipt of the list, tobacco product manufacturers would be prohibited from distributing their products to those stores. The FDA can allow for a 30-day sell-off period but after that, if e-cigarettes are found at that retailer, the product should be deemed adulterated and misbranded and removed from the market. In this situation, the manufacturer is most directly responsible for compliance.

Many of the FDA's proposed provisions in the draft guidance fail to effectively address the epidemic and protect youth. The agency must make significant improvements to this draft guidance to maximize the public health benefits. The FDA's delays have contributed to this epidemic and adopting the half-measures in the proposed guidance will not sufficiently rectify the FDA's role in the epidemic. To maximize the public health benefits of a final guidance, the FDA must remove all Juul and Juul-like products and all flavored e-cigarettes, including mint and menthol from the market immediately and only allow authorized products reentry. Additionally, the FDA must anticipate that youth will be driven to online sales by any restriction for in-person sales and because the internet is inherently difficult to regulate, the FDA must draw a bright line by prohibiting all online sales for newly-deemed products. The FDA must also address the abhorrent marketing practices of Juul and other similar products that have lured youth and contributed to this epidemic. Finally, the FDA should impose all proposed restrictions on e-cigarettes that remain on the market in the final guidance but should make significant improvements to those proposed restrictions to ensure effectiveness and compliance.

⁶⁵ Pub. Health L. Ctr., Using Retailer AVC's as a Tool in Tobacco Control (2015), <https://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-AVCs-tobacco-2015.pdf>.

2. Compliance Policy for Cigars

Although e-cigarettes have clearly received the most attention over the last few years, the FDA wisely decided to adjust its enforcement discretion for cigars as well. Importantly, the FDA has not exempted mint and menthol flavored cigars (as it proposed to do with e-cigarettes) in this draft guidance, instead treating them as it does any other flavor. There is no public health justification to exempt any flavor of cigar, of course, and we commend the FDA for recognizing that and acted accordingly.

While cigar use among high school students dropped slightly from 2017 to 2018, that change is not realized for all demographics. Importantly, usage rates for Black (from 7.8% to 9.2%) and Hispanic (from 6.7% to 7.3%) high school students went up. For both of these groups, and for high school males, rates of cigar use are higher than use of cigarettes. Also concerning, the 2018 NYTS data reveals that 13.3% of high school students that report dual-use, report that the second most common combination of products was “e-cigarettes + cigars.” The most common is “e-cigarettes + cigarettes.”⁶⁶ Additionally, data demonstrates that for youth who currently use cigars, the majority initiate with flavored cigars.⁶⁷

Even though the FDA has taken some significant steps forward in its proposal to regulate cigars, there is still room for improvement. First, while the FDA has proposed to remove flavored e-cigarettes from stores where youth can enter, it has exempted tobacco-flavored cigars from this provision. Removing all cigars from stores where youth can enter would also have a greater benefit to public health. The FDA has full authority to take this action and the ultimate goal should be to keep all tobacco products out of stores where youth can enter. Removing e-cigarettes, cigars, and other newly-deemed products leaves a notable loophole for cigarettes, smokeless tobacco, and roll-your-own tobacco. However, this availability does not justify any delay or the exemption the FDA would give for newly-deemed products. Instead, this problem should be addressed by the FDA acting swiftly to limit the sale of all tobacco products to adult-only facilities as well.

The FDA must also remove tobacco-flavored cigars from stores that have sold to minors after the issuance of the final guidance. The nuance of how best to implement this policy for e-cigarettes is discussed above. There is no difference in how this policy should be implemented with respect to tobacco-flavored cigars. The

⁶⁶ Andrea S. Gentzke et al., *Vital Signs: Tobacco Product Use Among Middle and High School Students – United States, 2011–2018*, 68 *MORBIDITY AND MORTALITY WKLY. REP.* 157 (2019); Teresa Wang et al., *Tobacco Product Use Among Middle and High School Students – United States, 2011–2017*, 67 *MORBIDITY AND MORTALITY WKLY REP.* 629 (2018).

⁶⁷ Andrea C. Villanti et al., *Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014)*, 53 *AM. J. PREVENTATIVE MED.* 139 (2017).

FDA must also implement the same restrictions on online sales of tobacco-flavored cigars that the agency has proposed for e-cigarettes. Those restrictions are also discussed above.

Because the cigar industry is similarly aware of the need for premarket authorization and should be preparing premarket applications, we recommend that the FDA adhere to the same deadlines we suggested in the e-cigarette section above and apply them to tobacco-flavored cigars as well. Starting on the effective date of the guidance (30 days after it is finalized) manufacturers of all products that are being granted the benefit of additional enforcement discretion have twelve months to submit marketing applications. After the application deadline, products can be granted an additional twelve months to remain on the market while the FDA reviews applications. At that point, the FDA must commit to removing products from the market that have not been granted marketing orders.

Finally, as the FDA has noted in its draft guidance, the agency's use of premarket review as a tool to improve public health will unfortunately only reach new tobacco products. The agency has acknowledged that there are some flavored cigars that have been determined to be grandfathered tobacco products, not subject to premarket review. Because the agency will be unable to remove these products from the market nor move them to adult only facilities through the use of enforcement discretion, the FDA must follow up this action with a formal rule-making prohibiting all flavors in all tobacco products, including menthol in cigarettes.

3. Compliance Policy for Waterpipe and Pipe Tobacco and Other Deemed Products

Another unfortunate gap in this draft guidance is the treatment of waterpipe and pipe tobacco and other deemed products. In a guidance document that is filled with far more scientific information than most other similar documents published by the Center for Tobacco Products, there is no evaluation of the health effects, abuse liability, usage patterns, or effect of flavors on these entire categories of products. The FDA's treatment of waterpipe tobacco is particularly embarrassing for the agency. Much is known about the harms of waterpipe tobacco and which populations are using it.

Use of waterpipe tobacco by high school students has gone up recently, increasing from 3.3% in 2017 to 4.1% in 2018.⁶⁸ While this is a small number compared to other tobacco products, the growth is concerning. It is also clear that flavors play an important role in youth experimentation of waterpipe tobacco, with 89% of users

⁶⁸ See Gentzke et al., *supra* note 66; see also Wang et al., *supra* note 66.

aged 12-17 reporting their first usage of waterpipe tobacco occurred with a flavored product.⁶⁹ We also know that younger adults, aged 18-24 make up more than half of the population that use waterpipe tobacco.⁷⁰ It is also clear that use of waterpipe tobacco is damaging to health. Consumption of the product causes respiratory and cardiovascular diseases as well as cancer, including oral and lung cancer.⁷¹ Waterpipe tobacco is harmful to health; it does not represent a less harmful alternative to cigarettes and should be regulated at least as stringently as cigarettes are regulated.

The FDA also made no attempt to curtail use of pipe tobacco and while pipe tobacco is the least used product by high school and middle school students according to the National Youth Tobacco Survey, usage did increase from 2017 to 2018, from 0.8% to 1.1%.⁷² It is also noteworthy that 30% of first time pipe tobacco users aged 12-17 also report using a flavored product.⁷³ This guidance creates an opportunity for the FDA to do a much better job protecting youth and young adults from the harms caused by waterpipe and pipe tobacco and other tobacco products.

Additionally, we know that when regulation leaves some products on the market but removes others, the industry often responds by altering current products to meet the definition of an unregulated product. This was evident when flavors were eliminated in cigarettes – the industry responded by flooding the market with flavored little cigars. Some of the same potential may exist for these other products. For example, a heated cigarette product, Vape Leaf uses PG/VG liquid, drawn through a cap containing processed, commercial tobacco leaf. Vape Leaf markets this product as “pipe tobacco.” Not regulating all newly-deemed products with the same stringency will only encourage the industry to exploit the FDA’s lack of foresight.

The FDA must treat waterpipe and pipe tobacco and other deemed products at least as stringently as it is treating cigars. The agency must remove all flavored products from the market immediately upon the effective date of this guidance. For the tobacco-flavored products that will remain on the market, the FDA must remove the products from locations that minors are able to enter at any time, implement the restrictions on online sales of products, and target products sold in locations that have sold to minors. The details of these proposals are discussed above.

⁶⁹ See Villanti et al., *supra* note 67.

⁷⁰ S. Sean Hu et al. *Tobacco Product Use Among Adults – United States, 2013–2014*, 65 MORBIDITY AND MORTALITY WKLY. REP. 685 (2016).

⁷¹ Reem Waziry et al., *The Effects of Waterpipe Tobacco Smoking on Health Outcomes: An Updated Systematic Review and Meta-Analysis*, 46 INT’L J. OF EPIDEMIOLOGY 32 (2017).

⁷² See Gentzke et al., *supra* note 66; *see also* Wang et al., *supra* note 66.

⁷³ See Villanti et al., *supra* note 67.

The FDA must also implement the marketing application deadlines that are discussed above for tobacco-flavored waterpipe and pipe tobacco and other deemed products not already discussed. Starting on the effective date of the guidance (30 days after it is finalized) manufacturers of all products that are being extended further enforcement discretion should be given twelve months to submit marketing applications. After that deadline expires, products can be granted an additional twelve months to remain on the market while the FDA reviews applications. At that point, the FDA must commit to removing products from the market that have not been granted marketing orders. These timelines and the amount of notice manufacturers would have has been challenged in court and upheld.⁷⁴ There is no legal reason for the FDA to defer to the industry for any longer than this nor is there any public health justification for extending the timelines any further into the future. Therefore, these dates should be treated as a ceiling and the FDA should consider shortening them. Not addressing this other category of products is a ridiculous loophole to leave open. While the FDA's enforcement resources are limited, this category of products is far smaller than e-cigarettes or cigars and allowing them to remain on the market unregulated is only likely to drive youth to these products to satiate their nicotine addiction and encourage the industry to look for ways to exploit this exception.

4. FDA's Prioritized Enforcement of Premarket Review

In addition to the product-specific changes to the guidance suggested above, the FDA must make one other crucial change. Throughout the document, the FDA states that it will "prioritize enforcement" of specific types of products or products marketed and sold in a particular way. However, at no point does the guidance discuss what the agency intends to do when it says that it will "prioritize enforcement." One would hope that the use of this phrase indicates that the FDA intends to order the immediate removal of products from the market but without explicitly stating that interpretation, one wonders if that is the case. Since Juul's significant escalation in popularity beginning in 2016, the FDA has been hesitant to take actions that would result in the removal of Juul or other e-cigarettes from the market. The agency has sent many letters to manufacturers requesting information about the marketing of various types of e-cigarettes and has also sent a handful of warning letters to some manufacturers for selling e-cigarette liquid clearly marketed to youth but the FDA has yet to take any additional actions or order the removal of products from the market, despite many offending products remaining available for sale. Given this history, the use of less than definitive language in this guidance to describe the FDA's current action is concerning. This must be fixed.

In the final version of this guidance, the FDA must expand on exactly how it will "prioritize enforcement" of premarket review for e-cigarettes, cigars, waterpipe

⁷⁴ Nicopure Labs LLC et al. v. U.S. Food and Drug Administration, 226 F.Supp.3d 360 (D.D.C. 2017).

tobacco, pipe tobacco, and other newly-deemed products. We suggest several additions to the guidance that will establish clear guidelines for tobacco product manufacturers to follow.

All of the product-specific guidance in the document can be separated into two categories: those provisions that take effect immediately (e.g. prioritized enforcement of flavored cigars), and those that are triggered by a future event (e.g. prioritized enforcement of products sold through a retail establishment that has sold to a minor after the issuance of the final guidance). While these two categories are treated slightly differently, they should both be subject to the strictest level of enforcement of which the FDA is capable.

We strongly suggest that in the final guidance, the FDA inform manufacturers that beginning on the day that the guidance becomes effective, the agency will fully enforce premarket review against any products that have not secured marketing orders and fall into one of the categories of prioritized enforcement that is effective immediately. Such products should be entirely removed from the stream of interstate commerce by manufacturers by the date that the guidance is effective. Any such products that are found in a retail store once the guidance is effective should be immediately deemed adulterated and misbranded tobacco products, the sale of which is prohibited by federal law.

For those provisions that are triggered by future events, when such an event occurs, the FDA should deem the product to be an adulterated and misbranded tobacco product and inform the manufacturer that they have thirty days to remove the product from the stream of interstate commerce. Because manufacturers of immediately prioritized products are given thirty days to remove products before enforcement, manufacturers of subsequently prioritized products should also be given only thirty days to remove products from stores.⁷⁵

Each subsequent time that an adulterated and misbranded tobacco product is found in a retail store, the FDA should seek civil monetary penalties against manufacturers and each product found in the stream of interstate commerce should be treated as a separate violation of the Tobacco Control Act.⁷⁶ The agency should also use its authority to seize adulterated and misbranded tobacco products to remove them from retail stores, as well as manufacturing and distribution facilities.⁷⁷

We further encourage the FDA to consider using its authority to seek criminal penalties against manufacturers who repeatedly violate the law. Should the FDA

⁷⁵ If the FDA adjust the timing of the effective date of the guidance, this portion of the compliance policy can similarly be adjusted.

⁷⁶ 21 U.S.C. § 333(f)(9).

⁷⁷ 21 U.S.C. § 334.

find adulterated and misbranded products that entered the stream of interstate commerce after adjudicating violations of the same, criminal penalties against those employees of tobacco product manufacturers who are responsible should be pursued.⁷⁸

Finally, the FDA should also undertake outreach to retailers to ensure that they are aware of the implications of the final guidance and provide a mechanism for notifying them of products that are adulterated and misbranded. Retailers who continue to sell such products in bad faith should also be subject to FDA enforcement. In addition, the FDA should establish a mechanism for communicating with the general public about the products that have been deemed adulterated and misbranded so that they can report the sale or offer for sale of such products by retailers.

5. Comprehensively Addressing Youth Use of Tobacco Products Requires Additional FDA Action

As acknowledged by the agency, the impact the FDA can have on youth use of tobacco products through final guidance is limited to newly-deemed products that are not grandfathered. This leaves significant gaps that the FDA can and should expeditiously fill with other supplementary action. Some of these require rulemaking: prohibiting all flavors - including menthol - in all tobacco products, and prohibiting all online sales of all tobacco products. Other actions require the FDA to more stringently enforce the law under the agency's existing regulation: addressing explicit and implicit drug and modified risk claims and establishing a reasonable approach to removing illegally marketed products that were introduced post-deeming. The fact that gaps exist should not prevent the FDA from finalizing strong and effective guidance, instead, the FDA should pursue immediate action on all fronts.

i. Prohibiting all flavors in all tobacco products.

Perhaps most importantly, the FDA must finalize a rule prohibiting all flavors in all tobacco products. The FDA has all the information and evidence the agency needs to pursue a prohibition of flavors. Even more compelling evidence exists for prohibiting menthol in all tobacco products. The FDA's delay in issuing this rule, most importantly addressing menthol, is unconscionable. This delay has cost thousands of lives and immeasurable health harms. There is a mountain of evidence to support the FDA's prompt action to remove menthol from all tobacco products including, 1) the FDA's commissioned scientific review from the Tobacco Products

⁷⁸ 21 U.S.C. § 333(a).

Scientific Advisory Committee (TPSAC) concluding that the “[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States”;⁷⁹ 2) the FDA’s own internal scientific review of menthol, which concludes that menthol plays a key role in youth and young adult initiation, that mentholated tobacco use is associated with a deeper level of addiction, and that these factors point to a greater overall health risk when compared to non-menthol cigarettes;⁸⁰ 3) a Citizen Petition from nineteen public health groups demonstrating tremendous support for the elimination of menthol to address the health harms imposed by mentholated cigarettes and to address the historic targeting of particular populations by the tobacco industry;⁸¹ and 4) a previous ANPRM, with over 170,000 submitted comments establishing overwhelming support for a prohibition on menthol in cigarettes.⁸² The FDA’s latest compilation of scientific research completed by the agency’s Tobacco Regulatory Science Research Program also echoes these past conclusions: that menthol increases initiation, facilitates addiction through suppressing the irritation of nicotine, decreases cessation, and affects vulnerable populations at higher rates.⁸³

Every day the FDA waits to propose a rule prohibiting menthol in all tobacco products costs lives; and research unequivocally establishes that this burden is borne disproportionately by African Americans. Studies have concluded that prohibiting menthol in combustible products could save thousands of lives, and that of those lives saved, one-third to one-half of those would be African American lives. Furthermore, many other communities are also disproportionately bearing the burden of the harm caused by mentholated combustible products, including those from other racial minorities, youth, those from the LGBTQ+ community, those with serious mental illness, and those of low socio-economic status (See Figure 2 below).

⁷⁹ TOBACCO PRODUCTS SCI. ADVISORY COMM., FOOD AND DRUG ADMIN., MENTHOL CIGARETTES AND PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND RECOMMENDATIONS (2011), <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>.

⁸⁰ FOOD AND DRUG ADMIN., PRELIMINARY SCIENTIFIC EVALUATION OF THE POSSIBLE PUBLIC HEALTH EFFECTS OF MENTHOL VERSUS NONMENTHOL CIGARETTES (2013), <https://www.fda.gov/downloads/ucm361598.pdf>.

⁸¹ TOBACCO CONTROL LEGAL CONSORTIUM, CITIZEN PETITION TO FOOD & DRUG ADMINISTRATION: PROHIBITING MENTHOL AS A CHARACTERIZING FLAVOR IN CIGARETTES (Apr. 12, 2013), <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fdacitizenpetition-menthol-2013.pdf>; *see also* FOOD AND DRUG ADMIN., PROHIBIT MENTHOL AS A CHARACTERIZING FLAVORING OF CIGARETTES AND CIGARETTE SMOKE (2013), <https://www.regulations.gov/docket?D=FDA-2013-P-0435>.

⁸² FOOD AND DRUG ADMIN., MENTHOL IN CIGARETTES, TOBACCO PRODUCTS; REQUEST FOR COMMENTS (2014), <https://www.regulations.gov/docket?D=FDA-2013-N-0521>.

⁸³ CTR. FOR TOBACCO PRODUCTS, FOOD AND DRUG ADMIN., TOBACCO REGULATORY SCIENCE RESEARCH PROGRAM AT FDA S CENTER FOR TOBACCO PRODUCTS: SUMMARY AND HIGHLIGHTS, <https://www.fda.gov/downloads/TobaccoProducts/PublicHealthScienceResearch/UCM613046.pdf>.

Figure 2. Prevalence of menthol cigarette users among current users of combustible cigarettes focusing on vulnerable populations.⁸⁴

Current Smokers	Menthol Cigarette Smoking Prevalence (%)
Female	43.5
Male	34.8
African American	84.6
Hispanic	46.9
White	28.9
Age	
12-17	53.9
18-25	50.0
26-34	43.9
35-49	32.3
50+	32.9
LGBTQ	36.3
Heterosexual	29.3
Serious mental illness	57.1
Household income (US\$)	
< \$10,000 - \$29,999	43.7
\$30,000 - \$74,999	37.2
\$75,000 or more	32.1

Menthol cigarettes and grandfathered flavored cigars will be a likely transition product for youth who are deeply addicted to nicotine and are unable to quit. Delaying a prohibition on all flavors, including menthol, will further exacerbate established and inequitable health harms and subject addicted youth to increased harm from transitioning to combustible products.

⁸⁴ See Amanda Fallin et al., *Menthol Cigarette Smoking Among Lesbian, Gay, Bisexual, and Transgender Adults*, 48 AM. J. PREVENTIVE MED. 93 (2015); Andrea C. Villanti et al., *Changes in the Prevalence and Correlates of Menthol Cigarette Use in the USA, 2004–2014*, 25 TOBACCO CONTROL ii14 (2016); Kelly C. Young-Wolff et al., *Correlates and Prevalence of Menthol Cigarette Use Among Adults with Serious Mental Illness*, 17 NICOTINE & TOBACCO RES. 285 (2015).

ii. The FDA must prohibit the online sale of any tobacco product.

As stated above, addicted youth with limited access to e-cigarettes are likely to turn to the internet to buy products. The online market is inherently difficult to regulate because of its dynamic nature and the FDA's attempts to somewhat limit online sales are unlikely to be effective. The best way to prevent online sales of tobacco products to youth is to prohibit online sales entirely. In addition to removing e-cigarettes that are sold online through the FDA's premarket review authority, the FDA must promptly finalize a rule prohibiting the sale of all tobacco products online. This ensures that as e-cigarettes are authorized for sale, they are not being sold online.

iii. FDA enforcement of illegally marketed products.

While the FDA has made clear that this new guidance adjusts the agency's 2017 compliance policy for the enforcement of premarket review for newly-deemed products that were on the market as of August 8, 2016, nowhere in the guidance does the FDA discuss its treatment of products that entered the market after August 8, 2016. These illegally marketed products are numerous and the FDA has done little to stop their marketing or the introduction of additional illegal products.⁸⁵

Twice the FDA has sent letters to manufacturers of suspected illegally marketed products, merely requesting information, not warning any of them to stop their illegal activity.⁸⁶ The agency has yet to take enforcement actions against any such products and most of the products that the FDA suspected were being marketed illegally are still readily available. In many cases, manufacturers carelessly market products as "new" and in other cases similar statements are made by third parties, often in trade magazines and media coverage of the tobacco industry.

The FDA has long struggled to prevent new products from entering the market illegally, without the required authorization from the agency.⁸⁷ One important cause of this problem is that the FDA has yet to develop a system to monitor the marketplace for new tobacco products that enter illegally or otherwise. According to then-Commissioner, Scott Gottlieb, "FDA does not have a list distinguishing deemed

⁸⁵ Letter from American Academy of Pediatrics et al. to Dr. Scott Gottlieb, Commissioner, Food and Drug Administration (Aug. 7, 2018) https://www.tobaccofreekids.org/assets/content/press_office/2018/2018_08_07_new_ecig_products.pdf.

⁸⁶ U.S. DEP'T OF HEALTH AND HUM. SERVS., FOOD AND DRUG ADMIN., CTR. FOR TOBACCO PRODUCTS, CTP LETTERS TO INDUSTRY, <https://www.fda.gov/TobaccoProducts/ucm281784.htm>.

⁸⁷ Desmond Jenson, Joelle Lester & Micah L. Berman, *FDA's Misplaced Priorities: Premarket Review Under the Family Smoking Prevention and Tobacco Control Act*, 25 TOBACCO CONTROL 246 (2016).

products that were on the market prior to August 8, 2016.”⁸⁸ Such a tool would provide the FDA with an important opportunity to oversee the introduction of illegally marketed products. Knowing what is happening in the marketplace is foundational to the agency’s role as gatekeeper.

FDA action on this issue is long overdue. In the decade since the agency was tasked with controlling the commercial tobacco market, it has warned exactly one manufacturer for marketing products illegally.⁸⁹ Public health groups have informed the FDA of dozens of illegally marketed products.⁹⁰ None of these products has been subject to any enforcement action beyond a warning letter. In investigating the marketing of these products and similar products such as those seeking a grandfather determination, the FDA suggests that firms provide evidence of marketing, the FDA’s guidance on grandfathered products does not prevent a firm from providing merely a self-certifying statement.⁹¹ Giving tobacco product manufacturers the benefit of the doubt seems unwise given the tobacco industry’s long history of lying to government agencies and to the public.⁹² We have also been told that the FDA conducts no independent investigations to verify the veracity of these statements, at least in the context of grandfathered products. This is a much larger problem.

Because it accepts self-certifying statements as inherently true with little or no additional evidence, the FDA has an incredible challenge in establishing that such a statement is false. There are two important facets to this problem. First, if the industry has merely provided a certifying statement it is likely because there is no actual evidence related to the timing or nature of the marketing of a product (this is certainly true if the statement is false and the marketing is illegal). If no evidence of marketing exists, the FDA cannot manifest this same non-existent evidence to refute the false claim. So, if the product is illegally marketed and the manufacturer lied, there is no possible way for the agency to rebut the lie. The second important oversight with this process is the inherent difficulty of proving a negative. While it is relatively simple to prove the existence of something, it is almost impossible to

⁸⁸ Letter from Scott Gottlieb M.D., Commissioner of Food and Drugs, to the Honorable Richard J. Durbin, Senator (October 5, 2018).

⁸⁹ Warning Letter from Ann Simoneau, Director, Office of Compliance and Enforcement, Ctr. for Tobacco Products, to Mark Cassar, CEO, Kretek Int’l, Inc. (Jul. 11, 2017), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm566373.htm>.

⁹⁰ See Letter from American Academy of Pediatrics et al., *supra* note 85.

⁹¹ Joanna Weitershausen, Director, Division of Enforcement and Manufacturing, Office of Compliance and Enforcement, Ctr. for Tobacco Products, Presentation in FDA’s “Break the Chain” Retailer Education Program: Grandfathered Tobacco Products (Oct. 29, 2014) (Slides available at: <http://www.fda.gov/downloads/TobaccoProducts/ResourcesforYou/BreakTheChain/UCM420769.pdf>).

⁹² U.S. v. Philip Morris, Inc., 449 F. Supp. 2d 1 (D.D.C. 2006), *aff’d* in relevant part, 566 F.2d 1095 (D.C. Cir. 2009), cert. denied, 130 S.Ct. 3501 (2010).

prove the non-existence of something. Things that do not exist tend not to leave evidence behind. The FDA has placed an impossible burden on itself but it need not be that way.

The simplest solution to the agency's problem is for the FDA to shift the burden of evidence to the tobacco product manufacturers. Rather than accepting self-certifying statements, the FDA should require actual evidence of marketing with clear dates that establish that a product entered the market when the manufacturer alleges that it did. If no such evidence exists, the FDA must remove the product from the market because it violates the agency's compliance policy for premarket review. In the context of products that are subject to the Deeming Rule, and in particular, e-cigarettes, it is much easier for the FDA to remove these products from the market entirely because none of them are eligible for grandfathered status. All such products are marketed illegally and subject to the FDA's overly generous enforcement discretion. If a manufacturer cannot unambiguously establish that its product entered the market prior to August 8, 2016, the agency can remove the offending product from the market and force the manufacturer to file a marketing application in order to begin the process of entering the market legally. The consequence of not having records that adequately establish a marketing timeline is that a manufacturer must merely avail itself of the process that Congress intended to be used in that very situation.

iv. Modified risk claims and cessation claims

Another driver of the youth e-cigarette epidemic that requires FDA action is stringently enforcing the Federal Food, Drug, and Cosmetic Act's (FDCA) prohibitions on unauthorized drug claims and the Tobacco Control Act's prohibition on unauthorized reduced risk or exposure claims. Data demonstrates that e-cigarette manufacturers continually make both explicit and implicit claims that e-cigarettes can be used for cessation and have other health benefits. The FDA is aware of these issues, but no public action has been taken to enforce either law against e-cigarette manufacturers. A 2017 study demonstrated that 77% of e-cigarette manufacturer websites and 65% of retailer websites make at least one health-related claim.⁹³ Modified Risk claims were prevalent, averaging at least two claims per website.⁹⁴ These claims are harmful; a 2018 study revealed that adolescents who are exposed to modified risk claims incorrectly believe that those products have fewer chemicals and reduced risk of harm.⁹⁵

⁹³ Elizabeth G. Klein et al., *Online E-cigarette Marketing Claims: A Systematic Content and Legal Analysis*, 2 TOBACCO REGULATORY SCIENCE 252–262 (2016).

⁹⁴ *Id.*

⁹⁵ Sherine El-Toukhy et al., *Impact of Modified Risk Tobacco Product Claims on Beliefs of US Adults and Adolescents*, 27 TOBACCO CONTROL s62–s69 (2018).

Moreover, Juul specifically has crossed the line into illegal drug marketing without the FDA doing anything to stop these actions to protect consumers. Juul has taken out full-page ads in many newspapers and on radio stations suggesting that adults who smoke should “switch.” Additionally, in at least one presentation to a Tribal Council, which the FDA has been made aware of, Juul representatives “disclaimed” any of the assertions they were making by acknowledging that it was illegal to make cessation claims when the product was not authorized as a drug or delivery device by the FDA and then proceeded to make explicit claims that Juul could be used to help Tribal members quit smoking. In that scenario, the company attempted to use the Tribal community as guinea pigs in their pursuit of cessation claims, without establishing any of the criteria for an informed clinical trial.⁹⁶ Juul has also recently established an “enterprise markets team” which is focused on “striking deals with health plans, providers, and self-insured employers and the public sector” to offer Juul as a cessation aid.⁹⁷

That the FDA does not act quickly to address this illegal behavior is even more bewildering in light of the FDA’s concurrent jurisdiction over drug-delivery devices. There is a legal way for Juul and other e-cigarettes to make these claims; that is to conduct the appropriate research and file the appropriate applications and obtain authorization. The FDA could even prioritize such applications, but instead, they allow the industry to blatantly disregard the law and genuinely mislead consumers. The FDA does not have to wait for the finalization of its draft guidance to address this illegal behavior. The FDA should take immediate action now to ensure that consumers are protected from these harmful and misleading practices.

6. Conclusion

We welcome comprehensive action by the FDA to address the youth e-cigarette epidemic. In order to end that epidemic and best protect public health, the agency must improve the final version of this guidance. There is no excuse for additional delays and incremental measures. The FDA must act now.

Respectfully,

The African American Tobacco Control Leadership Council
The National African American Tobacco Prevention Network
The Public Health Law Center

⁹⁶ Rae O’Leary & Natalie Hemmerich, Presentation to the National Indian Health Board: Juul’s Threat to Youth and Tribal Communities (Feb. 26, 2019).

⁹⁷ Angelica LaVito & Christina Farr, *Juul is pitching its e-cigarette as an anti-smoking tool to employers and insurers*, CNBC, March 7, 2019, <https://www.cnbc.com/2019/03/07/juul-e-cigarette-maker-pitches-employers-insurers.html> (last visited Apr 30, 2019).