October 13, 2017

Dr. Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

The undersigned organizations are committed to a tobacco control mission that prevents initiation of all tobacco products, promotes cessation among users, and protects all from harmful secondhand exposure. Full implementation of the Food and Drug Administration's (FDA) authority under the Family Smoking Prevention and Tobacco Control Act is critical to achieving these goals and reducing disease and death from tobacco products.

In your speech on July 28, 2017, you proposed a sweeping new regulatory agenda for tobacco products. As you have recognized, one of the most important actions you can take is to make maximum use of the FDA's authority to drive down the use of the tobacco products that contribute to the premature death of nearly one-half million Americans every year—the nation's largest preventable cause of death. We support this goal. Annual smoking-attributable healthcare costs in the U.S. amount to $170 billion, with more than 60 percent paid for with public dollars, through programs like Medicare, Medicaid, Tricare, and Veterans Affairs health benefits. As you also noted, for the first time in history, between the authority that resides in the Center for Drug Evaluation and Research (CDER) and the authority that now resides in the Center for Tobacco Products (CTP), "the entire spectrum of nicotine-delivering products is now regulated."

Today the FDA is in a unique position to regulate products containing nicotine in a comprehensive manner. We support your proposal to conduct a public process to direct the "Center for Tobacco Products to develop a comprehensive nicotine regulatory plan premised on the need to confront and alter cigarette addiction." However, a comprehensive nicotine regulatory process must also, as you recognize, be agency-wide and not be limited to the Center for Tobacco Products. CDER's goal should be to enable every tobacco user to successfully quit.

In your speech, you stated "as we move forward, I also hope that we can all see the potential benefits to addicted cigarette smokers, in a properly regulated marketplace, of products capable of delivering nicotine without having to set tobacco on fire. The prospective benefit may be even greater for the subset of current cigarette smokers who find themselves unable or unwilling to quit."

You continued "we need to make sure we strike the right balance between FDA fulfilling its vital consumer protection role while also fostering innovation when it comes to potentially less harmful forms of nicotine delivery. This becomes especially true in a world where cigarettes are no longer capable of creating or sustaining addiction."

In your speech you spoke in broad terms. It is our understanding that your approach has two major components. 1) Accelerate the reduction in the use of tobacco products that cause death and disease including, but not limited to, your proposal to cut the level of nicotine in cigarettes to minimally addictive or non-addictive levels[1] and 2) Develop a more robust strategy to assist current smokers to quit the use of tobacco products entirely and, for the subset of smokers unable or unwilling to do so in the near term, to determine whether there are less harmful nicotine products that help smokers to switch completely to those products. The two components of your plan need to proceed together with the ultimate goal of ending all tobacco use.

If our understanding of your proposal is correct, we are supportive of this two-pronged agenda, as we explain in more detail below, and we are prepared to actively work with you to support the accomplishment of these objectives in the shortest possible time.

At the same time, we believe that the significant delay you announced in enforcing the statutory requirement that newly deemed products submit applications for pre-market review undermines your efforts to reduce the death and disease caused by tobacco use, especially among youth, and actually discourages the type of market-driven innovation you seek. We urge you to reconsider that decision.

The FDA has a historic opportunity to reduce the death and disease caused by tobacco and dramatically reduce government healthcare costs. It will take strong leadership to take the needed steps to drive down the use of cigarettes (and other combusted tobacco products) rapidly. It will also take thoughtful regulation to maximize any potential contribution e-cigarettes and other nicotine products[2] may make to reduce the number of people who die from tobacco use.

1) <u>The first key to the success of your plan is for the FDA to take decisive, concrete steps, such as those enumerated below, to reduce the use of cigarettes and all other combusted tobacco products as dramatically and as rapidly as possible.</u> This needs to be FDA's highest tobacco-specific priority. It will require a multi-faceted strategy using all the many tools Congress provided to the FDA. We support the objective of reducing the level of nicotine in cigarettes to

[1] Although your July 28 remarks focused on the need to reduce the use of cigarettes due to the particular harm of combustible products, FDA should not ignore the adverse public health impact of traditional smokeless tobacco products. Thus, the agency should move forward to finalize its proposed rule to sharply reduce the level of the carcinogen NNN in smokeless tobacco. *See* 82 Fed. Reg. 8004 (January 23, 2017) and Comments of Twenty-Nine Public Health Groups on Proposed Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products, Docket No. FDA-2016-N-2527 (July 10, 2017).

[2] We use the term "e-cigarette" in the same way it is used by the Surgeon General to refer to the diverse group of devices that allow users to inhale a nicotine aerosol. *See* Department of Health and Human Services, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* (2016), at 3.

render them minimally or non-addictive, but pursuit of this goal should be a complement to, not a substitute for, both traditional tobacco control efforts and the exercise of the agency's broad authority to drive down the use of cigarettes and other tobacco products through other means.

There are a number of additional concrete steps the FDA can and should take in the short term, while it moves forward on reducing nicotine levels in cigarettes, including:

- Implementing the requirement for graphic warnings on all cigarette packs that, with the textual warnings also mandated by statute, cover at least 50% of the pack, far faster than the FDA has proposed to date.

- Prohibiting tobacco products with characterizing flavors because of their widespread appeal to youth. This issue has already been the subject of FDA examination and public comment. The evidence is clear that flavored products generally are detrimental to public health. The FDA should not start the process all over again with an Advance Notice of Proposed Rulemaking (ANPRM), but rather should move directly to a proposed rule. FDA's own Population Assessment of Tobacco and Health (PATH) study found that over 71% of cigar smokers aged 12-17 had used a flavored cigar in the past month and over 73% of those young cigar smokers said they smoked cigars "because they come in flavors I like."[3] The PATH study also found that over 85% of current e-cigarette users in that age group had used a flavored product in the past month and over 81% of those young users cited flavors as the reason for their use of the product.[4] As to flavored products, the FDA should be guided by the approach its staff proposed as part of the Deeming Rule.[5] Currently, the market is flooded with flavored e-cigarette products that appeal to youth but have not been demonstrated to help smokers quit. Products with characterizing flavors should be permitted only if the industry demonstrates, and FDA determines, that they meet the statutory public health standard. FDA must find that they do not attract youth, are not toxic or teratogenic and assist smokers to quit all tobacco products or switch completely to e-cigarettes as a pathway to quitting all tobacco products.[6]

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[3] Ambrose, BK et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015. Study cited by FDA at 81 Fed. Reg. at 29014.

[4] *Id.*

[5] In addressing concerns about the impact of flavored products on kids, the FDA should build on its previous work in developing the Deeming Rule. During that rulemaking, the FDA endorsed a policy of denying to flavored cigars and e-cigarettes the benefits of a compliance period for premarket review, requiring that newly deemed flavored products be taken off the market within 180 days of the May 8, 2016 publication of the Rule. Unfortunately, this policy was deleted from the rule during review by the OMB's Office of Information and Regulatory Affairs during the previous Administration. In addition, when it issued the final Deeming Rule, the agency indicated its intention to proceed with a rulemaking to prohibit characterizing flavors in cigars.

[6] As the FDA noted with respect to the Deeming Rule (in a discussion struck by OMB's Office of Information and Regulatory Affairs prior to issuance of the Final Rule), "if there were meaningful evidence that flavored ENDS actually make it more likely that smokers switch completely to ENDS, such evidence submitted as part of a PMTA

- Extend the prohibition on characterizing flavors in cigarettes to include prohibiting menthol as a characterizing flavor in cigarettes. FDA's own exhaustive study confirms that menthol as a characterizing flavor in cigarettes promotes youth initiation and increases long-term addiction to smoking. Indeed, more than half of youth smokers smoke menthol cigarettes. Young adults now smoke menthol cigarettes at higher rates than they smoke non-menthol cigarettes. Menthol is slowing the decline of cigarette smoking in the U.S. and is buoying smoking rates. If FDA is serious about cutting the use of combusted products, it must take this action.

- More effectively enforcing the prohibition on the introduction of new cigarette products that have not received an FDA marketing order. Numerous new cigarette products have been introduced with no apparent marketing order. We have written to the FDA repeatedly about the introduction of such new cigarette brands or brand variations. Such apparent violations of the statute undermine FDA's authority and frustrate its objectives.

- Continuing the FDA's mass media campaigns that target youth and other vulnerable populations to reduce the use of tobacco products.

- Adopting a nationwide tracking and tracing system to proactively address any claims the tobacco industry and its allies make that reducing nicotine levels in cigarettes will lead to a black market.

- Adopting, as you suggested, strong new regulations for Substantial Equivalence, Modified Risk Tobacco Product and Pre-Market Tobacco Product Applications to accelerate the reduction in the use of cigarettes and other combusted tobacco products and prevent the introduction of new products that are inconsistent with the statute's public health standard.

- Strongly enforcing the minimum age verification requirement for the purchase of all tobacco products, including for internet and other non face-to-face sales.

2) <u>It is critical that FDA begin Action Promptly, and Set a Firm Deadline for Completing, a Final Rule to Reduce the Levels of Nicotine in Cigarettes</u>. As you explained, if nicotine were reduced to minimally addictive levels and such a product standard were actively enforced, we could save young people who experiment with cigarettes from a lifetime of addiction to these lethal products[7] and could dramatically reduce the number of current smokers who die from

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would help support that application, as part of the analysis of whether the marketing of the product is appropriate for the protection of public health."

[7] While reducing the nicotine content of cigarettes, the FDA must also take steps to ensure that youth do not initiate use of any tobacco products, including non-combustible products. Any tobacco product that contains nicotine is addictive and all tobacco products present risk.

tobacco use. However, this potential can be realized only if the FDA takes concrete steps to implement a nicotine standard as promptly as possible.

Recently conducted research supports the feasibility of a product standard reducing nicotine in cigarettes without unintended adverse consequences.[8] We urge the FDA to proceed promptly to issue its planned ANPRM addressing all the issues material to the development of such a product standard and to place the highest priority on doing all that is needed to put such a standard in place.

We also urge FDA to include, in this Advance Notice, consideration of a product standard reducing nicotine in all combustible tobacco products, including cigars. Although your July 28 remarks repeatedly referred to the addictiveness and toxicity of "combustible cigarettes," the science is clear that combustion of tobacco is a deadly delivery mechanism for nicotine in cigars and hookah as well.

3) <u>We agree that a comprehensive framework for nicotine reduction should be accompanied by a major new effort to assist current users to quit.</u> This will require an agency-wide effort that includes both CDER and CTP. The top priority should be for the agency to consider what actions it can take to enable more tobacco users to quit using tobacco products altogether, and for those who can't quit immediately, to switch completely to less hazardous products as a pathway to quitting all tobacco products.

For FDA to play a greater role in smoking cessation, it is vital for the FDA's CDER to take steps to address the performance of existing medicinal nicotine products and foster innovation that can help more smokers successfully use FDA-approved products to quit smoking.

In the last 50 years, the FDA has approved only three drugs (NRTs, buproprion and varenicline) as safe and effective in smoking cessation. It has approved no new medications in the last decade and it places restrictions on existing products and the use of those products that curtail their reach and efficacy. Although almost 70% of smokers want to stop smoking and more than half tried to stop within the past year, fewer than one-third who tried to stop used any FDA-approved medications and only about 7% of smokers actually stopped smoking successfully in the past year.[9] The FDA has not developed a regulatory framework that both fosters the development of high quality medications to assist America's 36 million smokers and

[8] *See, e.g.* Donny EC, et al., "Reducing the nicotine content of combusted tobacco products sold in New Zealand," *Tobacco Control* 26 e37-e42, 2017; Donny et al., "Randomized Trial of Reduced-Nicotine Standards for Cigarettes," *New Engl. J. Med* 373:1340-9, 2017; World Health Organization (WHO) Study Group on Tobacco Product Regulation (TobReg), Global Nicotine Reduction Strategy, 2015; Benowitz, Neal, et al., "Reduced nicotine content cigarettes, e-cigarettes and the cigarette end game," *Addiction* 112 6-7, 2016; U.S. v. Philip Morris, USA, Inc., 449 F. Supp. 2d 1, 309 (D.D.C. 2006).

[9] Babb, Stephen, et al.,"Quitting Smoking Among Adults, United States 2000-2015," MMWR 65(52) 1457-1464, 2017.

recognizes the urgency that is merited by the more than 480,000 avoidable deaths and billions of dollars in healthcare costs incurred per year.

Thus, a searching review of FDA's approach to nicotine-containing products regulated by CDER and tobacco products regulated by CTP should be an important component of your new comprehensive nicotine regulatory strategy. This review should address several critical policy issues and will require close coordination by CDER and CTP. Those issues include, for example: (1) ensuring that the evaluation of possible new indications or labeling changes for existing approved smoking cessation products are based on a risk/benefit analysis that uses, as the critical comparator, that the failure to use these products results in the continued use of a product that kills half of its long-term users;[10] (2) determining whether indications and labeling for existing approved smoking cessation products need to be revised to encourage greater consumer acceptance and more effective use of those products; (3) evaluating how FDA's current approaches should be revised to encourage greater innovation in the development and availability of new smoking cessation products; (4) examining, specifically, the speed with which nicotine is delivered by these products, as you suggested, as a factor in evaluating the effectiveness of those products as cessation tools; (5) implementing procedures for fast track, other accelerated approval authorities and post-market surveillance that can facilitate approval of new and effective treatments for tobacco dependence; and (6) establishing a division of responsibilities between CDER and CTP that best promotes innovation in the development of products that benefit public health.[11]

This is not the first time the need for CDER to revise how it handles tobacco cessation has been raised, but despite repeated requests, there has been little effective change. CDER has failed to take the steps necessary to motivate the industry to innovate and to produce the products to help the 36 million American smokers to stop smoking. Your proposal to reduce nicotine levels in cigarettes makes the need for more effective tobacco cessation products even more urgent. Such products will not be developed without a fundamental change from CDER and that change will occur only with decisive leadership. Your remarks suggest you are prepared to supply that leadership and we are supportive of the effort to implement an FDA-wide approach.

In addition, both CDER's and CTP's approach should be coordinated and consistent with each Center's respective statutory standards, and prioritize the goal of identifying which, if any, of those products may play a positive role in assisting smokers to quit, or switch completely as a pathway to quitting, and develop regulation of these products in a manner consistent with the public health goal of accelerating the reduction in the number of people who die from tobacco use.

4) <u>We strongly disagree with the decision to issue an ANPRM to determine if the FDA should exempt so-called premium cigars from its authority and urge you to reverse that decision</u>.

[10] While the FDA stated that it does so, in response to a Citizen Petition previously submitted by some of the undersigned organizations, the objective evidence suggests that its actions are inconsistent with that assertion.

[11] *See generally*, Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2016, Psychopharmacologic Drug Advisory Committee and Drug Safety and Risk Management Advisory Committee meeting of September 14, 2016 (August 30, 2016).

There is no need for the FDA to seek additional comments on this issue, since the agency specifically requested and received public comment in the Deeming Rule docket itself on the regulation of so-called premium cigars. In the Deeming Rule, the FDA rejected the option of exempting such cigars from its regulatory authority, finding that all cigars increase the risk of disease compared to their non-use, all cigars are potentially addictive, and all cigars produce secondhand smoke that can cause disease in nonusers.[12] The FDA also carefully considered, and rejected, the claim that patterns of use of so-called premium cigars – such as frequency of use and failure to inhale – avoid negative health effects for smokers of those cigars,[13] finding that "there are no data indicating that premium cigar users are not susceptible to [the] health risks [facing cigar smokers generally]."[14] No data developed since the Deeming Rule became final call for still another look at this issue or a contrary decision.

5) We strongly disagree with the decision to exempt cigars, e-cigarettes, hookah and pipe tobacco from statutory pre-market review requirements for several years to come. We believe this decision places our public health, including our nation's youth, at unnecessary risk, as well as depriving FDA and the public of information, currently available only to the industry, that would allow the agency to determine whether any e-cigarette products actually assist smokers in switching completely to those products, or quitting tobacco products altogether, and to establish science-based regulations to protect the public health.

The new policy you announced will allow newly-deemed products to remain on the market without FDA review for at least five years following the effective date of the Deeming Rule (cigars, hookah and pipe tobacco) or six years (e-cigarettes), despite the fact, as acknowledged by FDA, that many of those products are being marketed with fruit and candy flavors that are proving attractive to kids. Moreover, there has been no scientific demonstration that the e-cigarette products on the market benefit public health by helping smokers quit or switch completely; indeed, they are the subject of large-scale dual use. FDA's unnecessary decision to postpone the deadline for submission of product applications deprives the agency of the very information it needs to assess, in a timely fashion, whether any individual products currently on the market meet the public health standard. FDA must find that they assist smokers to quit using all tobacco products, or switch completely to less harmful products as a pathway to quitting, and they do not pose a threat to our efforts to prevent kids from becoming addicted to any tobacco products.

In addition, any possible need for promulgating additional rules does not justify allowing cigars (which, after all, are combustible products) with flavors like "Cherry Dynamite," "Wild Rush" and "Banana Smash" to avoid FDA review and remain on the market until 2021 and beyond, or e-cigarettes such as "Very Berry Slushie" or many of the other egregious flavored e-cigarette products, to remain on the market until 2022 and beyond.

[12] *See* 81 Fed. Reg. at 29020-22.

[13] *Id.* at 29024-25.

[14] *Id.* at 29020.

The FDA's decision also fails to recognize that the submission of applications for the FDA review of new products is a statutory requirement for new products to enter, or remain on, the market. Thus, FDA's decision to allow thousands of cigar, hookah, pipe tobacco and e-cigarette products to remain on the market for years without agency review raises serious legal issues.[15]

Finally, in your July 28 remarks, you stated that delayed enforcement of statutory mandates is needed to allow the FDA to "take the time to make sure we have in place the foundational elements of a robust and sustainable framework for regulating the non-combustible forms of nicotine delivery" and will promote innovation. In our view, it will have the opposite effect. It will postpone provision of the information the FDA needs to determine which, if any, such products actually meet the public health standard. Experience since the introduction of e-cigarettes demonstrates that a lack of meaningful regulation will not foster innovation consistent with your public health goals. FDA's decision creates an environment that discourages companies from spending money on scientific research, thus allowing highly flavored products that are widely appealing to youth and are cheap to manufacture to dominate the market.

CONCLUSION

Your vision of a comprehensive agency-wide regulatory program to drive down use of the tobacco products that cause the most disease and death, and to reduce excessive healthcare costs, has the potential to provide a pathway to historic change. Such a program must be aimed at eliminating the use of all combusted tobacco products and not only cigarettes. It must distinguish between products that have been shown to help smokers quit using any tobacco product, or for the subset of smokers who can't quit in the short run, switch completely to demonstrably less hazardous products, and those for which no such showing has been made. It should not permit the marketing of products that play no useful role in reducing the death and disease caused by current tobacco use. Products that do not meet these standards simply addict their users while providing no public health benefit. A comprehensive program properly designed to achieve these objectives could greatly accelerate the end of the tobacco disease epidemic in our country.

We look forward to fully participating in the opportunities for public input that FDA intends to provide, and working in other ways with you and your staff, to help fashion a comprehensive approach to nicotine that achieves the full potential of FDA's regulatory authority to end the scourge of tobacco-related disease and death.

[15] We also are concerned that the FDA's new policy of allowing products to stay on the market pending FDA review of applications for marketing orders will extend even further the marketing of many products that do not meet the statutory standards. In 2011, immediately before the deadline for the filing of substantial equivalence applications, the FDA received more than 3,000 applications. Despite the fact that the FDA has itself admitted that many of these applications were deficient, they functioned to keep products on the market despite repeated failures to provide information necessary to establish substantial equivalence. The large majority of the products covered by these thousands of applications remain on the market, without a decision by the FDA, more than six years after they were filed. As discussed below, the FDA now is reexamining whether to continue its review of these Provisional Substantial Equivalence applications. We are deeply concerned that permitting newly deemed products to remain on the market indefinitely pending FDA action will allow dangerous products to be marketed for many years to come.

Sincerely,

Christopher W. Hansen
President
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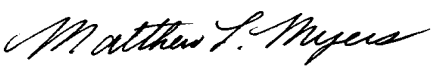
Nancy A. Brown
Chief Executive Officer
American Heart Association

Harold P. Wimmer
National President and CEO
American Lung Association



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CC: Mitch Zeller, Director, Center for Tobacco Products