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July 19, 2018

The Honorable Scott Gottlieb, MD
Commissioner
Food and Drug Administration
c/o Docket Management Staff
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA–2017–N–6565

Dear Commissioner Gottlieb:

The American Lung Association appreciates this opportunity share our comments on the Advance Notice of Proposed Rulemaking “Regulation of Flavors in Tobacco Products.”

The Lung Association works on behalf of the 33 million Americans living with lung diseases including lung cancer and COPD – which are primarily caused by tobacco use and exposure to secondhand smoke. Tobacco use remains the leading preventable cause of death and disease in the United States, killing 480,000 Americans each year. Another 16 million Americans live with tobacco-caused death and disease. The total estimated cost attributable to cigarette smoking is over \$332 billion annually. This includes over \$175 billion in direct medical expenses in 2013, and productivity losses from premature death of over \$150 billion among current and former smokers and over \$5.6 billion from secondhand smoke exposure among nonsmokers.

These comments include numerous citations to previous comments and supporting research, including links to the research for the benefit of FDA in reviewing our comments. We direct FDA to each of the studies and comments cited and made available to the agency through active hyperlinks, and we request that the full text of each of the studies cited, along with the full text of our comments, be considered part of the formal administrative record on this proposed rule for purposes of the Administrative Procedures Act.

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The American Lung Association is extremely disappointed with the glacial pace of the Food and Drug Administration's (FDA) regulatory approach to flavored tobacco products. Congress gave FDA a clear mandate in 2009 to act to protect the public health. Now, more than nine years later, the agency has released an advance notice of proposed rulemaking (ANPRM) instead of a proposed rule, continuing its failure to take meaningful action that would eliminate flavored tobacco products. Indeed, despite requests from the public health community to adhere to its original deadline for the submission of ANPRM comments, at the request of the tobacco industry, FDA extended the deadline for this and other ANPRMs.

FDA Must Act and Remove All Flavored Tobacco Products from the Market

The American Lung Association urges FDA to act immediately to prohibit the sale of all tobacco products with a characterizing flavor other than tobacco, and to eliminate all flavors and flavor additives in all e-cigarettes. Each day of delay benefits the purveyors of these products who continue to prey on our nation's children.

FDA Has Failed to Act on Menthol Cigarettes for More than Seven Years

Despite multiple robust scientific analyses conducted by FDA's own Tobacco Products Scientific Advisory Committee (TPSAC)¹, an [internal staff report](#)², and robust comments submitted in response to a 2013 ([ANPRM](#)) requesting information regarding the impact of menthol cigarettes on the public health (See Docket No. FDA-2013-N-0521), FDA has failed to even issue a proposed rule that would remove menthol cigarettes from the marketplace.

FDA's TPSAC first called for the removal of menthol cigarettes from the marketplace in 2011, a call the American Lung Association echoed. In April 2013, the American Lung Association and our partners submitted a formal [citizen petition](#) to the FDA, requesting that the Commissioner "prohibit menthol as a characterizing flavor of cigarettes."³ In it, our organizations cited the TPSAC report, which concluded:

1. Menthol cigarettes have an adverse impact on public health in the United States;
2. Menthol cigarettes offer no public health benefits.
3. Menthol cigarettes increase the likelihood of addiction and the degree of addiction in youth smokers.

The Lung Association and other public health and medical groups again called on the FDA to remove menthol cigarettes from the marketplace in comments submitted to the agency in November 2013 in response to FDA's ANPRM (Docket No. FDA-2013-N-0521).⁴ In it, our organizations concluded:

The weight of scientific evidence supports the conclusion that a product standard eliminating menthol as a characterizing flavor in cigarettes will reduce initiation of smoking among young people, increase cessation among current smokers, and save hundreds of thousands of lives over the next several decades. Such compelling public health benefits outweigh any conceivable countervailing effects of such a product standard. Given that both TPSAC and the FDA's own peer-reviewed Preliminary Scientific Evaluation have concluded that menthol

cigarettes likely have an adverse impact on public health, FDA should proceed, without further delay, to issue a Notice of Proposed Rulemaking prohibiting menthol as a characterizing flavor in cigarettes as the next step toward the final implementation of such a product standard. The price of undue delay will be paid in untold suffering and lost lives from tobacco-related disease.

Almost five years later, the Lung Association again urges the FDA to eliminate menthol as a characterizing flavor in cigarettes immediately, along with eliminating menthol as both a characterizing flavor and additive in all tobacco products.

All E-Cigarette Flavors are Additives

The overwhelming consensus in the public health community is that all tobacco products with characterizing flavors other than tobacco should be prohibited. The American Lung Association recognizes that all flavors in e-cigarettes are additives and there is no “tobacco” flavor inherent in e-cigarettes. Moreover, because of the increasing evidence that the chemicals in e-cigarettes – including propylene glycol and vegetable glycerin – are harmful to the lungs regardless of flavorings,⁵ FDA should use its full authority to make these products less attractive in general.

There is even more evidence that flavor additives – especially those that are based on natural plant-based extracts, are menthol-based and food-related additives such as cinnamaldehyde – are particularly toxic to lungs when they are inhaled. One study found that these additives significantly affect the lung cell viability and the respiratory barrier integrity.⁶ Another study found that lower concentrations of these flavor additives in e-cigarettes caused inflammation and created symptoms consistent with endothelial dysfunction.⁷ And of course, the presence of chemicals such as diacetyl and acetyl propionyl, are associated with respiratory disease.⁸

While there are almost no studies on the long-term impact of e-cigarettes on lung health, almost all e-cigarettes contain chemicals that raise significant concerns about short-term health effects on lung health. Therefore, in order to meet its public health mandate, FDA must work to reduce the attractiveness of e-cigarettes as well as all other tobacco products, to mitigate the population-level health impacts on lung health. By prohibiting all flavors and flavor additives in e-cigarettes, FDA will make these products less attractive, and therefore minimize the impact on the public health.

FDA Has Already Concluded that Flavors Should be Prohibited

In its 2015 submission of the final “deeming” rule to the White House, the FDA proposed to remove newly deemed flavored tobacco products unless a manufacturer could prove its product was appropriate for the protection of the public health.⁹ The American Lung Association urges FDA to move forward with meaningful action by issuing a proposed rule that would prohibit flavors in all tobacco products, including e-cigarettes.

The science was clear in 2016 and is even more clear now: menthol and other flavored products attract youth to e-cigarettes, cigars and other tobacco products and should not be allowed.



Flavors Attract Youth

It is well established that flavors are attractive to children and young people. FDA's Federal Register notice cites part of the extensive body of scientific research that was summarized in the E-Cigarette Use Among Youth and Young Adults, Report of the Surgeon General 2016¹⁰ and the National Academy of Sciences, Engineering and Medicine.¹¹ The tobacco industry's decades long conspiracy to deceive the public includes many documents that demonstrate the industry's understanding the role flavors play in tobacco use initiation. Congress clearly understood the problem by prohibiting all characterizing flavors for cigarettes except menthol, and then requiring the FDA's TPSAC to release a report about the public health impacts of menthol cigarettes. Congress clearly vested FDA with the authority to prohibit all flavors or additives that are harmful to public health, including initiating tobacco use amongst non-users as part of the public health standard test.

The U.S. Food and Drug Administration has an affirmative responsibility to protect children, teens and all young people from the addiction, disease, disability and death caused by tobacco addiction. Congress repeatedly highlighted and prioritized this responsibility in the Family Smoking Prevention and Tobacco Control Act. Congress clearly understood this fact and the landmark law's first four findings are:

- (1) The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.*
- (2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.*
- (3) Nicotine is an addictive drug.*
- (4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.¹²*

Prohibiting flavored tobacco products, including menthol cigarettes, is a key step to reducing youth tobacco initiation.

FDA Must Prioritize Youth and Focus its Primary Efforts on Halting Initiation

The Lung Association is extremely disappointed that FDA has failed to prioritize protecting youth from the tobacco industry's predatory practices. Instead, FDA has fallen into the industry's trap and is following the industry's narrative that a mythical flavor that has yet to be discovered will prompt smokers to switch or end their addiction but not attract youth users. By delaying its action and failing to take meaningful steps to prevent children from initiating the use of tobacco products, FDA's actions are completely contrary to the clear public health mandate of the statute.

The tobacco industry has been using flavors to attract and addict youth for decades. While the Family Smoking Prevention and Tobacco Control Act prohibited the sale of flavored cigarettes other than menthol in 2009, it did not extend that prohibition to all other tobacco products -



instead leaving that authority to FDA. Once that flavored cigarette prohibition took effect in 2009, the sales of other flavored tobacco products proliferated – including cigars and e-cigarettes.

Recognizing that almost all tobacco users begin their use during their adolescence or young adulthood, tobacco companies have spent billions of dollars marketing their products and making them more attractive to young people. That has led to the industry using flavored tobacco products to lure youth, which has – tragically – been a successful strategy for the industry. The industry’s strategy has extended to targeting youth using e-cigarettes.

Youth now use e-cigarettes – including flavored e-cigarettes – more than any other tobacco products.¹³ In 2014, almost 3 in 4 high school students and over half of middle school students who used tobacco products report they used a flavored tobacco product during the last 30 days, and almost two-thirds of these students who used cigars reported using flavored cigars.¹⁴ FDA’s 2013-2014 Population Assessment of Tobacco and Health (PATH) study found that among 12-17-year olds who had ever smoked an e-cigarette, 81 percent tried a flavored e-cigarette the first time they used this product. PATH also found that over 4 in 5 current youth e-cigarette users use e-cigarettes “because they come in flavors I like.”¹⁵

After preventing youth initiation, the Lung Association urges FDA to next prioritize the almost 26 million American smokers who want to quit. We know approximately 70 percent of smokers say they want to quit but this is an incredibly powerful addiction.¹⁶ The Lung Association also believes that a significant portion of the remaining 30 percent of smokers who say they don’t want to quit would still like to do so – but they’re feeling defeated and worry they will fail at quitting. Quitting smoking is difficult. It takes an average of 8 or more quit attempts for most smokers to end their addiction for good, but the more than 54 million ex-smokers in the U.S. are proof that quitting is possible.

However, the FDA should not focus its regulatory policy on a small group of select individuals who have chosen not to pursue evidence-based methods to end their use of all tobacco products. Furthermore, no tobacco product has been found by the FDA to be safe and effective for smoking cessation – therefore FDA should certainly not look to tobacco products that have not been found to be safe or effective in helping smokers to end their addiction as a panacea. And switching from one tobacco product (cigarettes) to another (e-cigarettes) is not quitting.

Indeed, in the fall of 2015 the US Preventive Services Task Force (USPSTF) updated its cessation interventions recommendation, reiterating that all three types of counseling and all seven FDA-approved medications are effective in helping tobacco users quit and *that there is not sufficient evidence to recommend e-cigarettes as a cessation device.*¹⁷

Instead, the preponderance of scientific evidence and studies are indicating that e-cigarettes do not help adult smokers quit. A recent study found that there is no evidence that e-cigarettes helped smokers quit at rates higher than smokers who did not use these products.¹⁸ Instead,



there are significant levels of dual use of cigarettes and e-cigarettes, with over half of adult current e-cigarette users continuing to be current cigarette smokers in 2016.¹⁹ Dual use of these products does not lower the risk of disease from smoking and needs to be discouraged by FDA to the extent possible under its authority.

Conclusion

The American Lung Association urges FDA to act immediately to prohibit the sale of all tobacco products with a characterizing flavor other than tobacco, and to eliminate all flavors and flavor additives in all e-cigarettes. The FDA must prioritize preventing youth and young adult initiation by prohibiting flavors. Congress has given FDA the clear mandate to act to protect the public health, FDA's failure to eliminate flavors perpetuates addiction, disease and ultimately death. We urge the FDA to promulgate a rule to eliminate all flavors in tobacco products immediately.

Sincerely,



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National President & CEO

¹ U.S. Department of Health and Human Services and Food and Drug Administration. (2011). Tobacco Products Scientific Advisory Committee, U.S. Food and Drug Administration, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations 220 (final as reviewed and approved by the TPSAC on July 21, 2011). Food and Drug Administration. Originally retrieved at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>.

² U.S. Department of Health and Human Services and Food and Drug Administration. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes. (2013). Food and Drug Administration. Retrieved from <https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM361598.pdf>

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- ⁵ Sleiman, M. et al. (2016). Emissions from Electronic Cigarettes: Key Parameters Affecting the Release of Harmful Chemicals. *Environmental Science Technology*. 50 (17), 9644-9651. Retrieved from <https://pubs.acs.org/doi/abs/10.1021/acs.est.6b01741>
- ⁶ Fetterman, J.L., et al. (2018). Flavorings in Tobacco Products Induce Endothelial Cell Dysfunction. *Arterioscler, Thrombosis, and Vascular Biology*. Retrieved from <http://atvb.ahajournals.org/content/early/2018/06/13/ATVBAHA.118.311156>
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- ⁹ U.S. Department of Health and Human Services and Food and Drug Administration. (2016). TAB B 2014-850 Deeming Final Rule Redline Changes. Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. 21 CFR Parts 1100, 1140, and 1143 [Docket No. FDA-2014-N-0189]. Retrieved from <https://www.regulations.gov/document?D=FDA-2014-N-0189-83193>
- ¹⁰ U.S. Department of Health and Human Services. (2016.) E-Cigarette Use Among Youth and Young Adults. Retrieved from https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf
- ¹¹ National Academies of Sciences. (2018). Public Health Consequences of E-Cigarettes. Retrieved from <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>
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- ¹³ Singh T., Kennedy S., Marynak K., Persoskie A., Melstrom P., King B.A. (2016). Characteristics of Electronic Cigarette Use Among Middle and High School Students – United States, 2015. *Morbidity and Mortality Weekly Report (MMWR)*. 65(5051);1425–1429. Retrieved from <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051a2.htm>
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¹⁸ Weaver S.R., Huang J., Pechacek T.F., Heath J.W., Ashley D.L., et al. (2018). Are electronic nicotine delivery systems helping cigarette smokers quit? Evidence from a prospective cohort study of U.S. adult smokers, 2015–2016. PLOS ONE. 13(7): e0198047. Retrieved from <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0198047>

¹⁹ Centers for Disease Control and Prevention. National Center for Health Statistics. National Health Interview Survey, 2016. Analysis performed by the American Lung Association Epidemiology and Statistics Unit using SPSS software.