



Robert Wood Johnson Foundation

Office of the President and CEO

July 12, 2018

The Honorable Scott Gottlieb, MD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

The Robert Wood Johnson Foundation (RWJF) is pleased to have the opportunity to comment on the Advanced Notice of Proposed Rulemaking (ANPRM) with respect to regulating flavors in tobacco products. By issuing this ANPRM, the U.S. Food and Drug Administration (FDA) has taken an important step toward developing a rule that has the potential to reduce tobacco-related disparities and youth uptake of tobacco products. We urge FDA to develop a proposed rule that prohibits the use of characterizing flavors in all combusted and smokeless tobacco products, including the use of menthol as a characterizing flavor in cigarettes, as quickly as possible. The proposed rule should prohibit characterizing flavors in e-cigarettes unless the manufacturer demonstrates, for a specific flavor in a specific product, that the presence of the flavor helps smokers quit tobacco products entirely or at least switch completely to an e-cigarette and that the benefits of the flavoring in helping smokers quit or switch outweigh the potential for youth initiation. Finally, we urge FDA and the National Institutes for Health (NIH) to support robust research, including randomized control trials, to determine whether flavored e-cigarettes can help smokers quit or completely switch to e-cigarettes. We look forward to working with FDA to ensure that the final rule reflects the best available evidence and protects everyone, especially those that are most harmed by tobacco.

Tobacco Use Among Youth and Other Vulnerable Populations is a Substantial Barrier to Achieving a Culture of Health

RWJF is the nation's largest philanthropy dedicated to improving health and health care in the United States. Since 1972, we have worked with public and private sector partners to advance the science of disease prevention and health promotion, train the next generation of health leaders, and support the development and implementation of policies and programs to foster better health across the country, including high-quality health care coverage for all. We are working alongside others to build a national Culture of Health that provides everyone in America a fair and just opportunity for health and well-being.

For more than 25 years, RWJF has been on the front lines of the battle against the harm caused by tobacco products, the largest cause of preventable death in the nation. Beginning in 1991, we joined forces with researchers, scientists, tobacco control advocates, and others to address smoking, one of the most intractable problems in the field of public health. Over the next two decades, RWJF invested significant resources, focusing on policy and systems changes, such as higher tobacco excise taxes, smoke-free indoor air laws, access to cessation treatment, and the federal regulation of tobacco.

Despite much success, tobacco continues to be a substantial barrier to our efforts to build a Culture of Health. Cigarettes and other combusted tobacco pose the greatest barrier. They are the overwhelming cause of tobacco-related death and disease¹ and disproportionately harm many marginalized populations. Groups with high smoking rates include people with lower incomes and less education; people with mental illness and substance use disorders; people who identify as lesbian, gay, bisexual, and/or transgender; Native Americans, and other ethnic minorities.² Smoking also has been found to contribute to disparities in life expectancies for African-Americans as compared to whites,³ some Hispanic subgroups as compared to whites,⁴ and people with less education.⁵

The impact of e-cigarettes on health and health disparities is less certain, but there is sufficient evidence to suggest they could threaten efforts to build a Culture of Health by increasing youth uptake of, and addiction to, tobacco. The 2018 National Academies of Science, Engineering, and Medicine (NASEM) found, “There is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”⁶ RWJF has long recognized the need to prevent tobacco use among youth. When we first began working on tobacco issues, the smoking rate among high school students was spiking upward, increasing from 28.3 percent in 1991 to 36.4 percent in 1997.⁷ Working with multiple collaborators, we focused many of our resources on reducing uptake among youth, and between 1997 and 2011, cigarette use among high school students dropped from 36.4 percent to 15.8 percent.^{8,9} Cigarette use among high school students has continued to decline, but e-cigarettes have become the most popular form of tobacco among youth. In 2017, 11.7 percent of high school students reported using e-cigarettes in the past 30 days.¹⁰ This is a similar rate to 2016, when 11.3 percent of high school students reported using e-cigarettes, and lower than 2015, when 16 percent of high school students reported using e-cigarettes.¹¹

Although e-cigarettes are generally considered less harmful than combustible tobacco cigarettes,⁶ they carry significant risks, including nicotine exposure and addiction.¹² The NASEM report also expressed concern about flavor additives, concluding that, “Independent of nicotine, exposure to particulates and flavorings in e-cigarette aerosols could also potentially impair lung function.”⁶ We are, therefore, concerned by the steep rise in e-cigarette use among youth in recent years and the possibility that this trend could undo the substantial progress we have made in reducing youth dependence on nicotine and tobacco.

To promote a Culture of Health in the United States, we must create conditions that make it easier for people to make healthy choices. Tobacco products do just the opposite: by addicting young people, including many adolescents who are particularly susceptible to addiction,¹³ these products make healthy choices harder. In addition, cigarettes disproportionately harm

marginalized populations and make it harder for many vulnerable people to live their healthiest life. The following recommendations reflect our desire to eliminate tobacco-related disparities and to reduce youth uptake.

Recommendation 1: To Reduce Tobacco Related Disparities and Youth Update of Cigarettes, FDA Should Ban the Use of Menthol as a Characterizing Flavor in Cigarettes

Banning Menthol Cigarettes Will Reduce Tobacco-Related Disparities

There is substantial evidence that menthol cigarettes perpetuate tobacco-related disparities. Menthol cigarettes are disproportionately used by African-Americans, sexual minorities, and those with mental illness,¹⁴ all groups that are disproportionately harmed by tobacco.¹⁵ African-Americans have particularly high rates of menthol use and have long been targeted with ads for menthol cigarettes:¹⁶ 88.5 percent of African-American smokers report preferring menthol cigarettes.¹⁷ Moreover, FDA’s own scientific analysis found that “the weight of the evidence supports the conclusion that menthol cigarettes is likely associated with reduced success in smoking cessation, especially among African-American menthol smokers.”¹⁸

Research suggests that banning menthol cigarettes would lead many menthol smokers to stop smoking. One survey of menthol smokers in the United States found 38.9 percent reported they would quit if menthol cigarettes were banned; among African-American menthol smokers, 44.5 percent reported they would quit. We know of no evaluations of menthol bans in the United States, but early findings from an evaluation of a menthol ban in Ontario, Canada found menthol smokers in that province *underestimated* the likelihood that they would try to quit: only 14.5 percent indicated they would try to quit, but one month after the ban had been implemented, 30 percent of menthol smokers reported attempting to quit.¹⁹ Quit rates would likely be even higher if a menthol ban were implemented alongside a rule that set maximum nicotine levels in all combusted products to non-addictive levels.

Banning Menthol Cigarettes Will Reduce Tobacco-Related Disparities

Menthol cigarettes have been found to increase youth initiation. Over half of youth smokers use menthol cigarettes, and 70 percent of African-American youth smokers use menthol cigarettes. By the mid-1970s, the tobacco industry realized menthol cigarettes were popular among youth because they were perceived to be less harsh. Tobacco companies began to manipulate menthol levels in cigarettes and marketed them to be appealing to youth.²⁰ The marketing of menthol to younger consumers and other vulnerable populations, including African-Americans, continues as does the popularity of menthols among young smokers.²¹ Even as overall cigarette use by youth has declined in recent years, youth use of menthol cigarettes has stayed constant or increased. The continued popularity of menthol cigarettes among youth suggest that the sale and marketing of menthol cigarettes has impeded efforts to reduce youth smoking rates.^{1,22} Consistent with this observation, a 2014 survey of young adults in the United found 65.7 percent of menthol smokers reported they would quit if menthol cigarettes were no longer sold.²³ In 2011, the Tobacco Products Scientific Advisory Committee (TPSAC) estimated that banning menthol could prevent as many as 2.3 million people from initiating smoking by 2020.²⁴

Recommendation 2: To Reduce Youth Uptake of Other Combusted and Smokeless Tobacco Products, FDA Should Ban the Use of Characterizing Flavors in All Combusted and Smokeless Tobacco Products

There is strong evidence that a comprehensive ban of characterizing flavors in all combusted tobacco products will reduce smoking initiation among youth. When FDA banned all flavored cigarettes except menthol in 2009, cigarette smoking and overall tobacco use declined among adolescents.²⁵ These declines were, however, partially offset by increases among adolescents in the use of menthol cigarettes as well as cigars and pipes, which were not subject to the flavor ban.

This result underscores the importance of taking a more comprehensive approach to regulating tobacco flavorings and is consistent with other evidence suggesting that the availability of flavored combusted tobacco products increases smoking among youth. In a nationally representative survey of youth, a majority of respondents reported flavoring as a reason for use across multiple products, including hookahs (78.9 percent) and cigars (73.8 percent).²⁶ Consistent with this finding, most middle- and high-school tobacco users indicated they would stop using a product if it was not flavored, including 80.5 percent for cigar products, and 73.5 percent for hookahs.²⁷

As with combusted tobacco products, characterizing flavors in smokeless products can make them more appealing to youth. The 2013 - 2014 Population Assessment of Tobacco and Health (PATH) study found that 68.9 percent of 12 to 17 year olds who had ever used smokeless tobacco used flavored smokeless tobacco the first time they tried the product.²⁶ Mint flavoring, in particular, appears to make smokeless tobacco products more tolerable to new users.²⁸ And youth who continue to use smokeless tobacco products appear to use flavored smokeless tobacco products frequently: the 2014 National Youth Tobacco Survey found that 58.8 percent of middle and high school smokeless tobacco users had used flavored smokeless tobacco in the past month,²⁹ and the 2013-2014 found 81 percent of current smokeless tobacco users had used a flavored product in the past month.²⁶

Recommendation 3: Based on the Evidence that Characterizing Flavors in E-Cigarettes Increase Youth Uptake and Inconclusive Evidence that E-Cigarette Flavors Help Smokers Quit or Switch, FDA Should a) Develop a Proposed Rule that Requires Manufacturers to Demonstrate for Specific Flavors and Products that the Presence of the Flavor Helps Smokers Quit or Switch Completely to E-cigarettes and that the Benefits of the Flavoring Outweigh the Potential Harms from Youth Initiation and b) Fund Robust Research to Determine Whether the Availability of E-Cigarette Flavors Can Help Smokers Quit or Switch.

Flavored E-Cigarettes Likely Increase Youth Uptake

Flavoring likely induces many youth to initiate use of e-cigarettes. According to the Surgeon General, “E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults.”¹² This is concerning, especially in light of the fact that in

2016 an estimated 78.2 percent of middle and high school students had been exposed to e-cigarette advertisements, up from 68.8 percent in 2014.³⁰ Adolescents are also more likely to report interest in trying a fruit-, candy-, or menthol-flavored e-cigarette offered by a friend than a tobacco-flavored e-cigarette, and adolescents perceive fruit e-cigarettes to be less harmful than tobacco-flavored e-cigarettes.³¹

Among a nationally representative sample of youth (12 to 17 years) who had ever used an e-cigarette, 81 percent reported using a flavored e-cigarette the first time they tried the product. Among Texas youth who had used e-cigarettes, 98.6 percent “started with an e-cigarette flavored with something other than tobacco.”³² Seventy-eight percent of Texas youth who used flavored e-cigarettes reported that they would stop using e-cigarette if flavors were not available.³³

The Evidence that Flavored E-Cigarettes Help Smokers Quit is Inconclusive

The evidence that *flavored* e-cigarettes help smokers quit or switch from combusted tobacco products, however, is inconclusive, as a recent systematic review by Zare et al. found.³⁴ Because of limitations in research design, the two studies cited in the ANPRM for the proposition that “flavors in some non-combusted tobacco products... may help some adult users decrease their cigarette use and transition away from combusted products to potentially less harmful products” do not provide helpful evidence for determining whether flavors can help with cessation or switching to e-cigarettes. One study involved findings from two focus groups of a convenience sample of e-cigarette users (n=11).³⁵ The other reported findings from an online convenience sample, and the authors acknowledged, it “was not designed to evaluate whether variability of flavors may promote smoking cessation in the general population; moreover our sample is not representative of the general population of smokers, who are generally less educated compared to the population evaluated here.”³⁶ We think it is notable that Zare et al.’s systematic review did not include either of the studies that were cited in the ANPRM, despite the fact that both fell within the date range of articles that were included in the review.

In light of the risks associated with e-cigarette use, the evidence that e-cigarette flavors increase youth uptake, and the lack of evidence that flavors help smokers’ quit, we believe FDA should develop a rule that prohibits characterizing flavors in e-cigarettes unless the manufacturer demonstrates, for a specific flavor in a specific product, that the presence of the flavor helps smokers quit tobacco products entirely or at least switch completely to an e-cigarette and that the benefits of the flavoring in helping smokers quit or switch outweigh the potential for youth initiation. This rule should not be a *de facto* ban on all e-cigarette flavors and should provide a clear and feasible pathway for e-cigarette manufacturers to obtain approval for products that can help smokers quit.

As FDA develops this proposed rule, it should coordinate with NIH to fund robust research, including randomized control trials, to determine whether and to what extent the availability of flavored e-cigarette products help smokers quit or switch to e-cigarette use, so that the final rule is grounded in strong evidence.

RWJF Will Work with FDA to Ensure the Final Rule Benefits Everyone and, in Particular, those Populations that Are Most Harmed by Tobacco

Fair and effective implementation of this rule will be necessary to ensure maximum impact and to protect the populations most harmed by tobacco. Although there is strong evidence that banning menthol cigarettes will reduce tobacco-related disparities, FDA and NIH should fund additional research to understand whether and how prohibiting flavors in other tobacco products could differentially affect marginalized populations. Moreover, evidence from menthol bans in Canada suggest that tobacco manufacturers may try to find ways to circumvent a flavor prohibition.³⁷ FDA should be careful to close all potential loopholes in the rule and to closely monitor compliance.

Conclusion: Prohibiting Flavored Tobacco Products Will Promote a Culture of Health by Reducing Tobacco-Related Disparities Protecting Our Youth

RWJF is committed to using our resources to help the most vulnerable improve their health and well-being. As discussed above, we believe prohibiting flavored tobacco products will protect vulnerable groups by reducing tobacco-related disparities and decreasing youth uptake. We applaud FDA for taking this important step toward developing a rule that promises to reduce tobacco-related disparities and protect youth from tobacco and nicotine dependence. This will require ensuring all smokers—and, especially, those from the populations most harmed by tobacco—have adequate access to evidence-based cessation services. We look forward to working with FDA and other partners to ensure that a strong, evidence-based final rule that protects everyone is developed and fairly implemented.

Sincerely,



Richard E. Besser, MD
President and CEO

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