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 developing a product standard to set the maximum nicotine level for combusted tobacco products to a minimally or non-addictive level. 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 save millions of lives and reduce health disparities. To achieve the full benefits of the rule and minimize its risks, we urge FDA to develop regulations that set a single target to reduce nicotine to non-addictive levels in all combusted tobacco products as quickly as possible. We also offer our commitment and support to work with FDA and other partners to ensure that this rule protects everyone especially, those populations that are most harmed by tobacco.

Tobacco Use 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 health problems in the U.S. 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 promote a Culture of Health. To achieve our vision, we must create conditions that make it easier for people to make healthy choices. Tobacco products do just the opposite: by addicting users, often at a very young age, these products make healthy choices harder. In 2015, 68 percent of smokers wanted to stop smoking, 55 percent had attempted to quit within the past year, but only 7 percent had quit in the previous six to 12 months. Moreover, these products disproportionately harm 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. Smoking also has been found to contribute to disparities in life expectancies for African Americans as compared to whites, some Hispanic subgroups as compared to whites, and people with less education. The enormous toll that smoking exacts on our society in terms of preventable deaths and exacerbation of health disparities underscores the need to reduce tobacco use so that everyone has a fair and just opportunity for health and well-being.

Reducing Nicotine Levels in Combusted Tobacco Products Will Reduce Tobacco Use

A typical cigarette contains 10-15 mg of nicotine per gram of tobacco. Empirical and modeling studies of nicotine reduction have looked at a range of lower nicotine levels, including cigarettes with Very Low Nicotine Content (VLNC) at < 1-2 mg/g. More research is needed to determine the precise level of nicotine that would be non-addictive for the majority of the population, but extant research suggests that VCLC cigarettes are likely minimally addictive and those with 0.4 mg/g or less are possibly non-addictive.

By FDA’s own estimates, reducing nicotine in cigarettes to minimally-addictive levels would lead 5 million smokers to quit within the first year of policy implementation (5th to 95th percentile range, 110,000 to 19.7 million) and a total of 13 million to quit over the first five years (5th to 95th percentile range, 430,000 to 30.5 million). Notably, although dual use of combusted and non-combusted products might increase initially, it likely would drop to levels below that achieved without the nicotine reduction policy within nine years. Among individuals who are not interested in quitting, VLNC cigarettes with 0.4 mg/g have been associated with smoking fewer cigarettes per day, reduced nicotine exposure, reduced cigarette dependence, and increased likelihood of contemplating or making a quit attempt. Moreover, studies of VLNC cigarettes likely underestimate their impact since study participants can still access normal nicotine content (NNC) cigarettes outside of the study. Access to NNC alternatives would be substantially reduced, if not eliminated, if FDA applied nicotine reduction standards to all combusted tobacco products and if reasonable enforcement systems were put in place to limit illicit trade.

The impact of such a policy on smoking initiation is expected to be similarly dramatic. Although it is more difficult to study the impact of reduced nicotine cigarettes on initiation, we know that the majority of adults who smoke daily started smoking before the age of 18, well before their brains are fully developed. Adolescent onset smokers are more susceptible to addiction than adult-onset smokers and underestimate the addictiveness of cigarettes and the likelihood that
they will continue to smoke as adults.\textsuperscript{14,15} Moreover, according to the Surgeon General, “The evidence is sufficient to conclude that advertising and promotional activities by the tobacco companies cause the onset and continuation of smoking among adolescents and young adults.”\textsuperscript{16} Lowering nicotine content in cigarettes to non-addictive levels should dramatically reduce the number of youth who grow into adult smokers. Indeed, FDA estimates that lowering nicotine in cigarettes to minimally addictive levels would prevent 33 million youth and young adults from becoming smokers this century (5th to 95th percentile range, 8.0 to 64.1 million).\textsuperscript{17}

**FDA Should Reduce Nicotine to Non-Addictive Levels in All Combusted Tobacco Products in a Single Step and Within One Year of Issuing a Final Rule**

The potential public health benefits of reducing nicotine levels in combusted tobacco products underscore the need for FDA to issue a strong product standard across all tobacco products as quickly as possible.

To maximize the benefits of this rule, FDA should set the maximum nicotine level in combusted products to non-addictive levels. This standard should be set by determining the impact of lowering nicotine levels in cigarettes across multiple populations, including individuals with behavioral health disorders and other marginalized populations that are disproportionately harmed by tobacco. Only through a process that considers the impacts for the populations that are most harmed by tobacco will FDA ensure that everyone is fairly protected.

The new, non-addictive level should be set as a single target rather than implemented as a step-down approach. Smokers who switch to cigarettes with small to moderate reductions in nicotine content may smoke more cigarettes per day to compensate for the lower nicotine levels.\textsuperscript{18} By contrast, switching smokers to cigarettes with very low levels of nicotine for at least six weeks does not seem to result in compensatory smoking.\textsuperscript{19,20} Under either regime, the risk of compensatory tobacco use behaviors requires continued careful study. Another potential benefit of the single target approach is that it may lower tobacco use more quickly than the step-down method, reducing population exposure to tobacco-related harms.

The rule should apply to all combusted tobacco products, including premium cigars and hookahs. Premium cigars are addictive, toxic, and smoked by youth as well as adults.\textsuperscript{21} Hookahs carry similar risks to cigarettes and are used by an increasing percentage of high school students.\textsuperscript{22} Many users, however, misperceive hookahs to be safer and less addictive than cigarettes.\textsuperscript{23} Hookahs deliver large amounts of nicotine, and during a typical, hour-long hookah session, users inhale 150 to 180 times as much smoke compared to a single cigarette.\textsuperscript{24}

Tobacco companies should be required to comply with the rule within one year from the date the final rule is issued. FDA can require tobacco product manufacturers to comply with a new product standard one year after publication of the final rule unless meeting the standard requires “substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer,” in which case FDA must provide manufacturers two years to comply.\textsuperscript{17} Because manufacturers can reduce nicotine through genetic modification, which occurs prior to farming, and/or by chemical extraction, which occurs after farming, we believe FDA has authority to impose a one year compliance timeline. We recognize that tobacco product manufacturers will
likely argue that a one-year timeline would be too burdensome, and we note that it is commonplace for industries to overestimate the burden of regulations when submitting comments to federal agencies.\textsuperscript{25} It has been technologically feasible to manufacture low nicotine tobacco products for decades,\textsuperscript{20,26} and the tobacco industry is now on notice that it may be required to produce low-nicotine products in the near future. The tobacco industry has spent decades engineering cigarettes “to maximize the development and maintenance of chronic, dependent smoking,”\textsuperscript{18} and has profited enormously from doing so. In light of this history and of the enormous public health benefits this rule can bring, FDA should use the full extent of its authority to implement the strongest standard as quickly as possible.

**RWJF is Committed to Working with FDA to Ensure this Rule Benefits Everyone and, in Particular, Those Populations That Are Most Harmed by Tobacco**

Fair and effective implementation of this rule will require 1) closely monitoring the rule’s impact to understand whether and how it affects tobacco-related disparities and 2) improving access to cessation supports, especially for those populations most harmed by tobacco. Research on the impact that reducing nicotine levels in tobacco products would have on tobacco-related disparities has been limited, but a few studies do suggest the rule could differentially affect certain populations. For example, one study found that young men may experience less relief than young women from low-nicotine cigarettes.\textsuperscript{27} That could have implications beyond gender disparities because smoking rates among men and women differ across populations.\textsuperscript{28} There is also evidence that many smokers incorrectly perceive VLNC cigarettes to be less harmful than traditional cigarettes and that rates of misperception may vary by race, ethnicity, and education level.\textsuperscript{29} This initial research underscores the importance of identifying a maximum nicotine level that is determined to be non-addictive for diverse populations. It also highlights the need for FDA to monitor the impact of the rule on different populations and, especially, those most harmed by tobacco.

RWJF is committed to reducing tobacco-related disparities and will work with FDA and other partners to ensure fair and effective implementation of this rule. RWJF remains committed to increasing access to effective cessation treatments, especially for high-risk populations. We also encourage FDA to foster the development of new and effective products that will help more smokers quit.

**Conclusion: Reducing Addiction to Combusted Tobacco Products Promotes a Culture of Health by Supporting Those Who Are Most Vulnerable**

Our guiding principles dictate that we use our resources “to advance the public’s interest with a focus on helping the most vulnerable.” Reducing nicotine levels in combusted tobacco products to non-addictive levels would likely lower smoking rates across all groups and could be particularly beneficial for smokers in marginalized populations with lower quit rates. We applaud FDA for taking this important step toward developing a rule that will advance this principle by reducing dependence on combusted tobacco products. We look forward to working with FDA and other partners to ensure that a strong, evidence-informed final rule that protects everyone is developed and fairly implemented.
Sincerely,

Richard E. Besser, MD
President and CEO

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10 ANPRM (not sure how to cite this. Also, the model used was actually published in NEJM, so should we cite that study instead? That cite is: Apelberg, B.J., Shari P. Feirman, Esther Salazar, et al. “Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States.” N Eng J Med 378 (2018): 1725-1733.
29 Byron, M.J., Michelle Jeong, David B. Abrams, Noel T. Brewer. “Public Misperception that Very Low Nicotine Cigarettes Are Less Carcinogenic.” *Tob Control*