October 14, 2019

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

Re: Tobacco Products; Required Warnings for Cigarette Packages and Advertisements,
Docket Number: FDA-2019-N-3065

Dear Acting Commissioner Sharpless:

The Robert Wood Johnson Foundation (RWJF) is pleased to have the opportunity to comment on the proposed rule regarding required warnings for cigarette packages and advertisements as authorized by the Family Smoking Prevention and Tobacco Control Act.

The proposed rule requires graphic health warnings to be placed on cigarette packages and in advertisements, occupying the top 50 percent of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements. The 13 proposed warnings include a text-based description of the health harms of smoking and a color picture that depicts these harms. Based on robust scientific evidence, RWJF believes these warnings, if fully implemented and enforced, would increase knowledge of the health harms of smoking, particularly among people with low educational attainment and low literacy; reduce smoking initiation; and promote smoking cessation.

**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. 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. RWJF has long recognized the importance of reducing smoking rates for the health of our nation. For over 25 years, we have worked with scientists, tobacco control advocates, and policymakers to address smoking, investing significant resources in evidence building as well as policy and systems changes. These efforts have contributed to substantial reductions in smoking among youth and adults and have resulted in millions of lives saved.1

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1 The term “tobacco” in this document refers to commercial tobacco, not ceremonial or traditional tobacco. RWJF recognizes the important role that ceremonial and traditional tobacco play for many Tribal Nations, and our tobacco-related work focuses on eliminating the harms and inequities associated with commercial tobacco.
Despite this tremendous success, tobacco products continue to undermine our efforts to build a Culture of Health and advance health equity. Smoking remains the number one cause of preventable death in the United States and disproportionately harms many marginalized populations, including: African-Americans, American Indians, people with low incomes, people who identify as lesbian, gay, bisexual, or transgender, and people with behavioral health and substance use conditions. Smoking also has been found to contribute to lower life expectancies for African-Americans, some Hispanic subgroups, and people with less education.

In light of the enormous toll that smoking exacts on our society, additional bold measures are needed to reduce initiation among youth and young adults, promote cessation among current smokers, and eliminate social inequalities in tobacco use and its related health effects.

**Current Text-Only Warnings are Inadequate**

As noted by the Food and Drug Administration (FDA) in this proposed rule, existing text-only warnings on cigarette packages and advertisements are rarely noticed by people, are not remembered when seen, and do not enhance knowledge about the risks of smoking. Reasons for the ineffectiveness of these warnings include the fact that they have been unchanged for almost 35 years, are produced in small font, and do not contain images depicting the harms of smoking. Numerous authorities have confirmed FDA’s findings, including a 1994 Surgeon General’s report, a 1994 Institute of Medicine report, and a 2007 Institute of Medicine report. More recently, Wave 4 (2016–2017) of the Population Assessment of Tobacco and Health Study found that nearly three-quarters (73.5%) of people “never” or “rarely” noticed health warnings on cigarette packs.

**Public Understanding of the Health Impacts of Smoking is Still Limited**

In spite of decades of public education about the health risks of smoking, knowledge remains incomplete particularly for diseases other than lung cancer. Moreover, smokers continue to underestimate the severity and the magnitude of the health risks of smoking. For example, most smokers do not think cancer risk increases with the number of cigarettes smoked and more than half agree with myths such as exercise being able to undo most of the harmful effects of smoking. Knowledge is generally poorer among people with lower educational attainment, those with lower incomes, and people of color. In the past decade, scientific research has documented a number of additional diseases that are linked to smoking, including liver cancer, colorectal cancer, diabetes mellitus, and rheumatoid arthritis, which are likely even less well understood by smokers and potential smokers.
Graphic Warnings Can Increase Knowledge of Health Harms and Reduce the Toll of Smoking

As noted by the FDA, “Visual depictions of smoking-related disease in pictorial cigarette warnings help address gaps in public understanding of the negative health consequences of smoking by providing new information beyond what is in the text of the warnings through reinforcing and helping to depict and explain the health effect described in the text.” This has been confirmed by studies of graphic health warnings globally and experimental studies domestically. A systematic review of studies in 20 countries found that strengthening warnings is associated with increased knowledge about the risks of smoking along with increased quitline calls, reduced smoking consumption, increased quit attempts, increased short-term smoking cessation, and reduced smoking prevalence. A recent randomized clinical trial in the United States found that participants who received packs of cigarettes with text and pictorial warnings were more likely to forego cigarettes, more likely to try to quit, and more likely to successfully quit over a four-week period than participants who received cigarette packs with standard text warnings. Graphic warnings are also effective among youth in increasing knowledge about health effects, making smoking less attractive, and lowering intention to smoke.

Key to the effectiveness of graphic warnings are their size (taking up at least 50% or more of the cigarette package), text that clearly describes the health effects of smoking accompanied by a color picture that demonstrates such harms, and placement on the front of cigarette packages. FDA’s proposed graphic warnings meet all these conditions and will feature several lesser-known diseases caused by smoking such as bladder cancer, fetal growth restriction, type 2 diabetes, macular degeneration, and cataracts.

- WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
- WARNING: Smoking during pregnancy stunts fetal growth.
- WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
- WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.
- WARNING: Smoking causes cataracts, which can lead to blindness.

Notably, one-pack-per-day smokers would see these warnings approximately 7,000 times per year. A recent study modeling the impacts of graphic warnings in the United States estimated that they could reduce smoking prevalence by five percent in just a few years, resulting in a reduction of almost 3,000 smoking-attributable deaths per year and 650,000 fewer deaths over 50 years.

Graphic Warnings Can Advance Health Equity

Social gradients in smoking are stark. Among U.S. adults, smoking prevalence is significantly higher for those who did not graduate from high school (23.1%) and those with a GED (36.8%) compared to those with a college education (7.1%) or graduate degree (4.1%). Similarly, smoking is more common among those with household incomes less than $35,000 (21.4%) than among those with incomes above
$75,000 (11.8%) or above $100,000 (7.6%). Knowledge of the health risks of smoking is lower among these socially disadvantaged groups because of lower health literacy, limited access to information about the hazards of smoking, and targeted marketing of tobacco products.22, 23

Graphic warnings depicting the harms of smoking increase the accessibility of these warnings to people with low levels of literacy.24 Research from the International Tobacco Control project suggests: “Large, graphic warnings on cigarette packages are an effective means of increasing health knowledge among smokers [and] health warnings may also help to reduce the disparities in health knowledge by providing low-income smokers with regular access to health information.”25 For example, in Brazil, after the introduction of graphic warnings in 2002, 67 percent of smokers said the new warnings made them want to quit, with the impact particularly strong among less educated, lower income people.

**FDA’s Graphic Warnings Were Developed Using Rigorous Methods**

The FDA pursued a thoughtful, systematic process for developing the new text and pictures that appear in the 13 proposed graphic warnings. First, they identified health conditions to feature in the warnings based on the Surgeon General’s categorization of the strength of causal inference, which drew from guidance from the Institute of Medicine and the International Agency for Research on Cancer.26 Second, they developed and tested revised textual warnings with a large sample including adolescent smokers, adolescents at risk for smoking, and adult smokers, ensuring that the warnings chosen would increase knowledge and understanding among these key populations. Specifically, they looked at whether participants were provided new information by the warnings and learned something new from them. Third, they created and tested images that correspond to the textual warnings through interviews, focus groups, and experimental testing that included almost 10,000 adolescent and adult smokers and nonsmokers using validated measures of understanding, knowledge, and recall. The research demonstrated that the 13 proposed warnings all showed statistically significant higher levels of providing new information and self-reported learning compared to the current text-only warnings.27

**FDA Should Ensure Full and Equitable Implementation of the Graphic Warnings**

Effective implementation and enforcement of the graphic warning requirements will be essential for achieving the full benefits of this policy. FDA should ensure that tobacco companies submit a plan for the random and equal display and distribution of the warnings and then adopt the warnings in a timely manner. FDA should have robust compliance processes to assess whether tobacco companies are meeting these goals and whether tobacco retailers are displaying cigarette packages in a manner that does not obscure the warnings. Particular attention should be directed toward media and retailers serving people of color, people with low incomes, and LGBTQ populations. Research demonstrates that graphic warnings need to be rotated regularly with new text and images to avoid overexposure and loss of effectiveness.28 FDA should begin the process now of developing additional graphic warnings to deploy in the future.
Ensuring that everyone has a fair and just opportunity for health in this country will require bold, evidence-based strategies for reducing smoking and inequities in tobacco use and tobacco-related disease. FDA’s proposed graphic warnings represent a key tool for achieving this vision.

We appreciate the opportunity to comment on this proposed rule.

Sincerely,

Richard E. Besser, MD
President and CEO
Robert Wood Johnson Foundation

8. FDA, Center for Tobacco Products. “Memorandum of Summary of Data from Wave 4 of the Population Assessment of Tobacco and Health (PATH) Study.” 2019.