May 30, 2017

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

Experimental Study on Warning Statements for Cigarette Graphic Health Warnings
Docket Number: FDA-2017-N-0932

Dear Commissioner Gottlieb:

The Robert Wood Johnson Foundation (RWJF) is pleased to have the opportunity to comment on the notice soliciting comments on the Experimental Study on Warning Statements for Cigarette Graphic Health Warnings that is being conducted in support of the graphic label provisions of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

There is compelling evidence that requiring graphic warnings on cigarette packages can reduce smoking rates in the United States. We believe that existing research can meaningfully inform decisions about the types of images and text to feature in such warnings. Researchers estimate that if the Food and Drug Administration (FDA) had implemented graphic health warnings in 2012, as initially planned, that regulatory action would have resulted in 5.3 to 8.6 million fewer smokers by 2013. Therefore, although the Foundation supports ongoing research on this important topic, we encourage FDA to develop new graphic warnings as quickly as possible to protect the public’s health.

Tobacco Use is a Substantial Barrier to Achieving a Culture of Health

RWJF is working with others to build a Culture of Health in the United States. We envision a society in which everyone—no matter who they are or where they are from—has the opportunity to live the healthiest life possible. As the nation’s largest philanthropy dedicated to improving health and health care in the United States, RWJF has long recognized the importance of reducing smoking rates. For over 25 years, we have worked with scientists, global health organizations, tobacco control advocates, and policymakers to address smoking, investing
significant resources in evidence building as well as policy and systems changes. These efforts have led to substantial and sustained reductions in smoking among youth and adults.

Nevertheless, smoking continues to place a heavy burden on our nation’s health. Smoking results in over $300 billion in direct health care expenditures and remains the number one cause of preventable death, resulting in about 480,000 premature deaths each year. These costs are disproportionately borne by 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, some Hispanic subgroups, and people with less education. The enormous toll that smoking exacts on our society in terms of preventable deaths, financial costs, and exacerbation of health disparities underscores the need to reduce smoking rates if we are to achieve a Culture of Health nationally.

**Graphic Warning Labels Can Reduce the Toll of Tobacco**

There is substantial evidence that graphic warning labels can reduce smoking rates. 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. Evidence from other countries focusing on both smoking rates and smoking-attributable deaths confirms these findings. Based on the impact of graphic warning labels in Canada, researchers estimate that adoption of graphic warning labels in 2012 would have reduced smoking rates in the United States by 2.87 - 4.68 percentage points, resulting in 5.3 to 8.6 million fewer smokers by 2013. A more recent study that used evidence from multiple countries to model the impact of graphic warning labels in the United States estimated that graphic warning labels would reduce smoking prevalence by 5 percent in just a few years, resulting in a reduction of almost 3000 smoking-attributable deaths per year by 2020 and 650,000 fewer deaths over 50 years. Other studies have demonstrated that graphic warnings are associated with numerous attitudes and behaviors likely to lead to lower smoking rates, including improved health knowledge and awareness of smoking risks, increased intention to not start smoking, increased intention to quit, increased quit attempts, and increased use of quitlines.

The positive impact of graphic warning labels appears to apply across sociodemographic groups. African-American smokers, Hispanic smokers, low-socioeconomic smokers, and low-education smokers have all been found to have similar responses to graphic warning labels as the general population of smokers. Therefore, they are expected to be as effective for marginalized and high-risk populations as they are for the general population.

Additionally, graphic warning labels have been shown to be effective in changing attitudes and behaviors among young smokers and young non-smokers. This is important both because young adults may be less aware of or concerned about the health consequences of smoking than older adults and because smokers who can quit by age 30 have a similar lifetime risk of tobacco-associated disease as people who never smoked.
FDA Should Develop New Warning Requirements as Quickly as Possible

Given the compelling evidence that graphic warning labels can substantially reduce smoking rates, we encourage the FDA to promptly develop new graphic warnings to accompany the textual warnings specified in the Tobacco Control Act, as mandated by that statute. It has been almost eight years since the Tobacco Control Act requiring graphic health warnings on all cigarette packs was signed into law. We supported the FDA’s previous attempt to require graphic warnings and recognize the challenges associated with that effort. Since that time, however, the case for requiring graphic warnings has grown even stronger, and it has become ever clearer that the longer we wait, the more lives will be lost.

Building a Culture of Health requires making the healthy choice the easy choice. Graphic warnings make it easier for non-smokers to make the healthy choice not to smoke and for current smokers to quit. Unfortunately, for people who are already addicted to nicotine, abstaining from smoking is rarely easy: in 2015, over 50 percent of smokers tried to quit, and less than 10 percent succeeded.21 Graphic warnings should be part of a comprehensive strategy to 1) prevent young people from starting smoking 2) support smokers’ efforts to quit and, 3) help our nation take one step closer to a Culture of Health.

Again, we appreciate the opportunity to comment on the importance of graphic health warnings on cigarette packages and address their importance to reducing smoking rates in the United States.

Sincerely,

Richard E. Besser, MD
President and CEO

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