



July 16, 2018

The Honorable Dr. Scott Gottlieb
Administrator
Food and Drug Administration
1717 Pennsylvania Ave NW #1025
Washington, DC 20006

Dear Administrator Gottlieb,

The Independent Women's Forum (IWF) is pleased to respond to the Food and Drug Administration's request for comments on docket number Docket No. FDA-2017-N-6189, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes. The Independent Women's Forum (IWF) is a non-partisan, 501(c)(3) research and educational institution that seeks to improve the lives of Americans by increasing the number of women that value free markets and personal liberty.

While we applaud the FDA's commitment to reducing smoking-related deaths, the FDA is, perhaps unwittingly, pursuing a policy that may further harm America's 37 million smokers. While the FDA is correct that "tobacco-related harms ultimately result from addiction to the nicotine," nicotine itself does not cause these harms (nor does tobacco itself). Rather, the harms come from the burning of the tobacco, releasing toxins, which then enter the lungs. This is the cause of smoking-related diseases. As Professor Michael Russell remarked in his landmark 1976 study on harm reduction, "People smoke for nicotine, but they die from the tar."

It therefore does not follow that reducing the level of nicotine in these products will work to curb people's use of traditional cigarettes. In fact, it could cause smokers to smoke *more*—in an effort to get the higher levels of nicotine exposure to which they are accustomed. This could accelerate tobacco harms as people will smoking more traditional cigarettes to get more nicotine, and as such, receiving higher levels of toxins.

In addition, the FDA should consider the potential for a black market to emerge due to these regulations. Federal law enforcement officials in the U.S. have already warned about the problems of illicit trade in cigarettes and the U.S. State Department has deemed it a "threat to national security." Because nicotine is so addictive, especially in cigarettes, smokers would find a way to get the cigarettes they prefer, even if it requires going to the black market fueled by countries that also produce tobacco crops, like China, India, Brazil, Indonesia, and Pakistan.

Instead of using agency resources to demand a reduction in nicotine, the FDA would be wise to recognize the established high risk of smoking traditional cigarettes as a nicotine delivery system from the lower risk of smoking e-cigarettes. The FDA should stop pursuing policies that can actually harm, and instead make it easier for products—like e-cigarettes—to enter the marketplace so that people have greater choice in the fight to quit smoking.

Sincerely,

Julie Gunlock

Director, Center for Progress and Innovation

Independent Women's Forum