



August 12, 2017

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 FDA-2017-D-3001, Modified Risk Tobacco Product Applications for IQOS System.

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 IWF believes all issues are women's issues, when it comes to tobacco policy and smoking cessation products, women are a particularly important demographic.

Here's why. Each year, nearly a half-million Americans die of smoking-related diseases. Smoking-related healthcare costs exceed \$300 billion a year. Convincing people to stop smoking is both a public health and economic priority. Yet, studies show that women have a far more difficult time than men do quitting traditional, combustible cigarettes.

A **study** published in the April issue of Archives of General Psychiatry may shed some light on this gender difference. The study found that when men smoke, the number of nicotine receptors in the brain increased. But this wasn't true for women, who, while smoking, had the same number of nicotine receptors as nonsmokers.

This is significant because currently, the FDA only approves nicotine-replacement therapies—such as patches and gum—to help people quit smoking. Clearly, this study demonstrates that women need treatment options other than nicotine replacements, such as those that help replace other cravings—like the taste and smell of traditional cigarettes and the hand-to-mouth habits associated with smoking.

Similarly, researchers at the University of Montreal **found that women's menstruation cycle** increases neural activity related to cravings, which often hamper a female's attempt to quit traditional cigarettes. Other studies have shown women have much more severe symptoms of

withdrawal than men, and that women are more likely than men to begin smoking again when faced with stress and anxiety.

In an [interview with National Public Radio](#), Carolyn Mazure, a professor of psychology at Yale School of Medicine explained that, “Women often report smoking is helpful in reducing negative mood, even enhancing positive mood, managing the stress of daily life and also managing appetite and weight gain...” adding that they are “...looking to cigarettes to help them with those different situations, and as a consequence, it’s often more difficult for women [than for men] to give up their cigarettes.”

Clearly, the FDA doesn’t intend to punish women, simply for their gender. Yet, that’s precisely what’s going to happen if women are limited to smoking cessation products that biologically cannot provide them with the help they need to quit traditional cigarettes. For this reason, IWF strongly urges the FDA to approve new and innovative e-cigarette products, like the IQOS e-cigarette, which can provide users with the taste and smell of tobacco.

Products like IQOS have a far higher success rate in helping people permanently quit traditional cigarettes, and they are 95 percent less harmful than cigarettes. This innovative technology has already been embraced in the United Kingdom, where new government guidance encourages smokers to switch to less harmful alternatives—like e-cigarettes. The UK Department of Health even publicly stated that, “The evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco. The government will seek to support consumers in stopping smoking and adopting the use of less harmful nicotine products.”

Americans deserve the same commitment to harm-reduction products. When it comes to kicking the smoking habit, it’s clear the market is working. Private technological innovation has done what the government and public health advocates haven’t been able to do: give smokers effective tools that can help them quit smoking.

We urge the Food and Drug Administration to support these emerging technologies so that women have more choice in the marketplace.

Sincerely,

**Carrie Lukas**

*President*

*Independent Women’s Forum*

**Julie Gunlock**

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