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January 3, 2018

Caryn Cohen
Office of Science, Center for Tobacco Products
Food and Drug Administration
Document Control Center, Bldg. 71, Rm. G335
10903 New Hampshire Ave., Silver Spring, MD 20993-0002

Re: Docket No. FDA-2017-N-5994

Tobacco Products Scientific Advisory Committee; Notice of Meeting

Dear Ms. Cohen,

Please find comments in regards to an upcoming hearing that the Tobacco Products Scientific Advisory Committee (TPSAC) will be holding at the end of this month, related to modified risk tobacco product applications for IQOS system.

The comments were previously submitted to the Food and Drug Administration (FDA) in September. The American Conservative Union believes it is critical that TPSAC do their job and take into account research done showing potential benefits for consumers in the marketplace. ACU supports allowing for the expansion of the market in the harm-reduction space and we hope that TPSAC will conduct a fair and substantive hearing, taking into account all the facts presented before them.

Respectfully,

Michi Iljazi
Director of Government Affairs
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September 15, 2017

Scott Gottlieb, M.D.
Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Docket No. FDA-2017-D-3001

Modified Risk Tobacco Product Applications for IQOS System, 82 Fed. Reg. 27487 (June 15, 2017)

Dear Dr. Gottlieb:

The American Conservative Union's mission includes advancing our nation's founding principles of political liberty and limited government. Because we know that Americans across all income levels and neighborhoods do better under a free enterprise system, ACU defends it from the overreach of the regulatory state as part of our mission. As our organization has repeatedly said: Free enterprise is the only economic system that offers the promise of widespread prosperity and the protection of individual rights. Building on that foundation of responsible, reasonable, and limited government combined with respect for the opportunity for prosperity and respect for the individual, ACU supports allowing for the expansion of the market in the harm-reduction space and urges the FDA to grant Modified Risk Tobacco Product (MRTP) application approval for the IQOS System.

Innovation spurs the free-market economy and the power of consumer choice drives innovation. ACU believes that there is a limited role for the government to ensure that certain products meet basic standards, regulators should not be in the business of preventing consumers from making their own choices when it comes to harm reduction products they prefer or want to try.

The IQOS System offers a new choice for Americans who may be seeking to make a change in their health, habits, and daily lives. The product is new to the United States, but it is becoming more recognized around the world as 32 countries (including Japan, Australia, and countries in the EU) have approved IQOS already. With many parts of the world allowing for this new choice on the marketplace, the answer for the FDA is a simple one: don't hinder innovation by overstepping the regulatory reach in contradiction of consumer choices.

In the past decade, the market for tobacco products has undergone a number of changes. New technologies are making it possible for innovation to move what was once a limited environment for consumer choice, into a brand new space altogether with harm-reduction now playing a significant

role in how the market looks.

On IQOS specifically, the product is giving consumers in other countries a new choice, and the initially numbers on IQOS are encouraging from a free-market, consumer-driven, and liberty-minded perspective. Since the product was introduced in 2014 (initially in Japan) nearly 3 million adult smokers worldwide have made the decision to stop smoking and switch to IQOS. Specifically, in Japan, the industry volume of cigarettes and other heated tobacco products has declined by 3% since IQOS hit the market. These trends are a great example of how innovation can help to expand markets, enhance consumer choice, and benefit public health; all things the FDA should work to advance here in the United States.

The precedent for seeing this shift in consumer choice, driven largely by innovation, has been evident with the growth of the E-Cigarette industry. Surveys from The BMJ of smoking-cessation rates from 2014 to 2015 showed that "65 percent of e-cigarette users had tried to quit smoking, versus 40 percent of people who smoked but didn't use e-cigs. About 8 percent of e-cig users succeeded in quitting for at least three months, compared to about 5 percent of non-users." The numbers from the survey show that overall, about 350,000 people have quit smoking due to the switch to e-cigarettes.

In closing, while there is certainly a legitimate role for the FDA to play in making sure that certain products coming onto the market are safe for use, the agency should never prevent an individual from being offered the chance to use a product that may in fact be a safer alternative than what is currently available. Innovation has driven consumers into new markets, with more choices that can reduce harm and broaden the amount of options individuals have available to them, this is a good thing and the FDA should continue to bolster efforts that build on innovation and expand free-markets for consumers. The IQOS represents a new alternative for individuals who smoke cigarettes but wish to change their habit (for whatever reason) and IQOS can be a safer option if health and harm reduction is a factor in the consumer's choice.

Sincerely,

Daniel Schneider
Executive Director

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