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April 22, 2020

The Honorable Lisa R. Barton

Secretary to the Commission

U.S. International Trade Commission

500 E Street S.W.

Washington, DC 20436

Re: Docket No. 337-3447

Certain Tobacco Heating Articles and Components Thereof

Dear Secretary Burton,

The American Conservative Union (ACU) believes in a strongly enforced Intellectual Property (IP) regime that respects innovators, and rewards creators for the fruits of their labor. ACU has worked hard to support positive reforms that strengthen the IP system in the United States and around the world. We believe IP rights are critical to innovating and incentivizing the engine of the American economy.

ACU is also in support of the U.S. International Trade Commission (USITC) following normal procedures that follow past precedent with regard to ongoing matters before the commission, which generally favor a gathering facts, examining patents, and adjudicating the legal process before any decision to implement an exclusionary rule is reached by the USITC. Therefore, we support allowing the importation of IQOS to continue as the USITC conducts its proceeding.

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Philip Morris Products, S.A.
Exhibit 1041



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Finally, ACU believes it is critical that the USITC take into account research done showing potential benefits for consumer choice in the harm reduction space as it relates to IQOS and its authorized sale in the United States. As such, please find attached comments ACU previously filed to the Food and Drug Administration (FDA). These publicly filed comments noted findings of strong compelling public interest in favor of allowing for the approval of IQOS system product applications in the United States.

Respectfully,

Daniel Schneider

Executive Director

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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.

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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.

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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.

Respectfully,

Daniel Schneider

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