United States Senate

WASHINGTON, DC 20510

October 5, 2017

The Honorable Scott Gottlieb, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

As the U.S. Food and Drug Administration (FDA) examines applications from Philip Morris International (PMI) for its new IQOS product, we write to underscore the importance of the criteria set by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) for modified risk tobacco product (MRTP) claims. This statute requires that applicants provide sufficient evidence to demonstrate that the product under review improves population health—that it is less harmful to the individual user and will not lead to an increase in the number of people using a tobacco product. In accordance with these statutory requirements, we urge you to conduct a thorough review of PMI's IQOS product to determine its impact on public health, especially in light of PMI's shameful history of deceiving the American public and government agencies about the harmful effects of tobacco use.

Despite gains in tobacco prevention and cessation efforts, cigarette smoking remains the leading cause of preventable disease and death in the United States, accounting for almost half a million deaths per year – or one out of every five deaths around the country. While we must continue to strive for safe and effective ways to help Americans quit smoking, it would be a grave misstep to rush an alternative tobacco product to market that has the potential to hook a new generation of Americans on nicotine without stringent scientific review. We have previously shared our views with you about the FDA's recent tobacco regulatory announcement, including our grave concerns that any actions to remove oversight or promote newer tobacco products may result in enhanced youth use.

The Tobacco Control Act requires an independent science-based review by FDA before a tobacco company can make a modified risk claim. This requirement is especially important because tobacco companies—including PMI—have a long history of making false claims about the risks their products pose. In 2006, a Federal District Court ruled that PMI's then-parent company and other major tobacco companies had:

> *Over the course of more than 50 years ... lied, misrepresented, and deceived the American public, including smokers and the young people they avidly sought as 'replacement smokers,' about the devastating health effects of smoking and environmental tobacco smoke, they suppressed research, they destroyed documents, they manipulated the use of nicotine so as to increase and perpetuate addiction, they distorted the truth about low tar and light cigarettes so as to discourage smokers from quitting, and they abused the legal system to achieve their goal – to make money with little, if any, regard for individual illness and suffering, soaring health costs, or the integrity of the legal system.*[1]

[1] Tobacco Control Legal Consortium, The Verdict Is In: Findings from United States v. Philip Morris, The Hazards of Smoking (2006). Retrieved from http://www.publichealthlawcenter.org/topics/special-collections/verdict-findings-united-states-v-philip-morris-collection.

PMI now claims to have a product in the IQOS that eliminates 90 to 95 percent of the toxic compounds found in regular cigarette smoke. Meanwhile, an independent study—recently featured in the Washington Post—found higher levels of toxic compounds produced by the device than Philip Morris has claimed, resulting in powerful pushback from the company that has effectively silenced the independent researchers.[2] PMI's use of intimidation tactics to influence the scientific process is shameful, and should not be tolerated.

Under the criteria set forth in the Tobacco Control Act, PMI will have to demonstrate in its MRTP application that IQOS will not only significantly reduce harm to individual tobacco users but that it also will benefit the health of the population as a whole. This statutory standard requires FDA to assess whether the product will increase the number of young people who use tobacco products or deter smokers from quitting, including maintaining current habits through dual use. Last year, the FDA set a strong precedent for the scope of scientific data required to adequately support an MRTP application when the agency determined that the Swedish Match tobacco company failed to provide sufficient scientific evidence to support its modified risk application to eliminate or weaken required health warnings for its snus smokeless tobacco products.[3] If PMI fails to provide sufficient evidence to demonstrate that it meets the criteria in the Tobacco Control Act, FDA must reject the IQOS application too.

Therefore, we ask that you apply a rigorous scientific review of PMI's IQOS application, as well as any other applications for modified risk claims that come before the FDA. The stakes could not be higher in this ongoing public health epidemic that is responsible for 1,200 deaths in America each day. We look forward to working with you to protect future generations – especially youth – from the grip of nicotine addiction.

Sincerely,

RICHARD BLUMENTHAL
United States Senator

RICHARD J. DURBIN
United States Senator

EDWARD J. MARKEY
United States Senator

JEFFREY A. MERKLEY
United States Senator

[2] Wan, William. "Big Tobacco's New Cigarette Is Sleek, Smokeless - but Is It Any Better for You?" The Washington Post, WP Company, 11 Aug. 2017. Retrieved from www.washingtonpost.com/national/health-science/big-tobaccos-new-cigarette-is-sleek-smokeless--but-is-it-actually-healthier/2017/08/11/60e9fe5a-763e-11e7-8839-ec48ec4cae25_story.html?utm_term=.b3947ca52c67.

[3] Myers, Matthew L. "FDA Is Right to Reject Swedish Match's Flawed Application to Remove Health Warnings on Its Smokeless Tobacco Products." Campaign for Tobacco-Free Kids, 14 Dec. 2016. Retrieved from www.tobaccofreekids.org/press_releases/post/2016_12_14_swedish_match.