



January 4, 2018

To: Caryn Cohen  
Office of Science, Center for Tobacco Products  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland, 20993

From: Brandon Arnold  
Executive Vice President  
National Taxpayers Union  
25 Massachusetts Ave, NW, Suite 140  
Washington, DC 20001

Subject: Modified Risk Tobacco Product Applications for the Philip Morris International Tobacco Heating System called IQOS

Dear Ms. Cohen,

I write to you on behalf of National Taxpayers Union (NTU), a Washington-based nonprofit research and taxpayer-advocacy organization dedicated to the protection of free-markets, limited government, and pro-taxpayer policies. Since 1969, NTU has been a leading voice against undue tax and regulatory burdens that hinder economic activity. While some level of regulation is often appropriate to protect the general public, excessive regulation increases costs to businesses, delays availability of new products, raises prices for consumers, and in the docket before you, could have a substantially detrimental impact on public health. It is for these reasons I urge the Food and Drug Administration (FDA) to allow the IQOS system be made available to the market as a Modified Risk Tobacco Product.

Unfortunately, for millions of smokers across the nation, delay of this product could have serious negative health consequences. Cigarette use is responsible for nearly 500,000 deaths a year, and remains the leading preventable causes of death in the United States. In fact, a government [study](#) found almost 70 percent of American smokers want to quit, yet, in 2016, only 6 percent were successful in doing so. Heat-not-burn (HNB) products have the potential to offer a new and more

appealing alternative for smokers who have been unsuccessful in quitting, or for those who might not have tried to quit smoking.

Smoking is the most common means to use nicotine, and the most harmful as well. In fact, combustion releases nearly 90 percent of the 7,000 chemicals that are inhaled. HNB products, on the other hand, [reduce](#) harmful carcinogenic chemicals by 90-95 percent, compared to cigarette smoke, thus reducing the risk of negative health effects. Without the availability of less harmful products, by the middle of the century, [over 17 million Americans](#) will suffer a premature and preventable death.

The absence of less harmful alternatives will also harm the health of the U.S. economy and strain taxpayer funds. Cigarette use leads to more than \$156 [billion](#) in lost annual productivity, including \$5.6 billion in lost productivity due to secondhand smoke exposure. Further, smokers [report](#) about 2.5 fewer work days each year compared, to their counterparts who do not smoke.

U.S. adults enrolled in Medicaid or who are uninsured smoke at [rates](#) more than double than that of people who have private insurance. Diseases and health implications from smoking increases Medicare [outlays](#) by \$45 billion, Medicaid by \$40 billion, and government-sponsored insurance programs by \$24 billion annually. In essence, taxpayers are subsidizing the use of cigarettes for those receiving health care from the government. Combined, private insurance and government programs [payout](#) nearly \$170 billion per year, or 8.7 percent of all health care costs, on tobacco-related illnesses and diseases.

However, people still smoke regardless of the known health consequences and monetary costs, and the best alternative for many current smokers are tobacco harm reduction products. The FDA plays a critical role in allowing certain types of products to be allowed to remain on, or enter into the marketplace. By regulating how products can be researched, developed, marketed, and sold in the U.S., any action the agency takes will determine the type of information available to consumers as well as their ability to purchase tobacco products that are less harmful.

The IQOS product developed by Philip Morris International (PMI) is an innovative product that heats tobacco opposed to burning it, like typical cigarettes. Cigarettes typically burn tobacco at 1600 degrees fahrenheit, causing the release of toxic chemicals that are inhaled by the smoker. IQOS heats tobacco to a temperature that is more than 1000 degrees fahrenheit lower than normal cigarettes. Instead of emitting a smoke, an aerosol is created that consists mainly of water vapor and glycerol. Importantly, many of the chemical reactions that result from combustion do not occur due to the considerably lower temperatures, creating a much safer experience than smoking cigarettes.

While a thorough review of the application is important, it is also important for the FDA to craft a ruling in an expeditious manner. To that end, it should be noted that this product has previously gone under intense review from governments across the globe. Today, IQOS is readily available for purchase in [30 nations around the world](#), including Germany, Japan, and the United Kingdom. According to PMI, over 3.7 million people have [switched](#) to the healthier alternative that is IQOS.

It is crucial that the examination of HNB products be evidence-based and demonstrate significant reductions in risk for cigarette-smokers making the transition. Clinical trials in both the United States and Japan have showed similar, positive results. Smokers who switched to heat-not-burn products were exposed to significantly lower carcinogenic and toxic chemicals than standard cigarettes. In one study, smokers who transitioned to heat-not-burn products for a three-month period had levels of harmful chemicals that were similar to those of smokers who quit for the same duration.

Bringing IQOS to the U.S. market could lead to dramatic improvements in public health. This promising new technology is backed by strong scientific evidence and clinical trials that suggest tobacco harm reduction products like heat-not-burn are an acceptable, less-harmful option for smokers. Thus, I respectfully ask that the FDA approve the IQOS Tobacco Heating System as a Modified Risk Tobacco Product available for sale in the United States.

Sincerely,

A handwritten signature in black ink, appearing to read "Brandon Arnold". The signature is fluid and cursive, with the first name "Brandon" being more prominent than the last name "Arnold".

Brandon Arnold  
Executive Vice President  
National Taxpayers Union