



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

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

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

Dear Dr. Gottlieb:

We are grateful for the opportunity to submit this comment regarding the modified risk tobacco product (MRTP) application by Philip Morris Products S.A. cited above under section 911(g) of the Federal Food, Drug and Cosmetic Act on behalf of Reason Foundation.

Reason Foundation's nonpartisan public policy research promotes choice, competition and a dynamic market economy as the foundation for human dignity and progress. Reason produces rigorous, peer reviewed research and directly engages the policy process seeking strategies that emphasize cooperation, flexibility, local knowledge, transparency, accountability and results. Through practical and innovative approaches to complex problems, Reason seeks to change the way people think about issues, and promotes policies that allow and encourage individuals and voluntary institutions to flourish.

First, allow us to acknowledge and compliment the new course at FDA and the Center for Tobacco Products (CTP) upon which both you and CTP Director Mitch Zeller have referenced in public comments, public documents and your recent paper in the *New England Journal of Medicine*. This new course and your comments are welcome because following the same general course that has evolved over the last fifty years to reduce smoking-related death and disease is likely to leave us, according to the U.S. Centers for Disease Control (CDC), with an outcome where more than 480,000 Americans continue to die every year from smoking.

Specifically, we recognize and applaud the acknowledgement of a continuum of risk for tobacco and nicotine products, where combustible tobacco cigarettes fall at the high end of risk and nicotine replacement therapies fall at the low end of risk. We appreciate your acknowledgement that while addiction to nicotine as delivered through combustible tobacco cigarettes is at the center of this health crisis, the availability of nicotine in noncombustible forms (with product attributes that appeal as much or more to smokers as cigarettes) is part the solution to fighting disease and premature death. And, we appreciate your recent oft-stated commitment to approaching these opportunities by developing and implementing a standards-based regulatory process that fosters, or at least doesn't

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unduly restrict innovation that holds the key to preventing millions of people from suffering lung cancer, Chronic Obstructive Pulmonary Disease (COPD), heart disease and stroke as a result of inhaling the toxic products of combustion on a regular, long-term basis. You have indicated a desire to pursue actions that have the potential to save millions of lives and create a legacy of which you and all Americans can be proud. We welcome the opportunity to constructively engage in this process with you.

Since President Obama signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Act) into law in 2009, there are three pathways by which new products (or product claims) can find their way to market. The pathways are as follows: Pre-Market Tobacco Authorization (PMTA) for “new” products, Substantial Equivalence (SE) to existing predicate products and Modified Risk Tobacco Products (MRTP) that allow manufacturers an opportunity to be approved to make specific claims about specific products. This application, submitted by Philip Morris Products S.A. concerns the last of those three pathways.

The MRTP pathway is an important one given the well-established risks that combustible cigarettes pose to those who use the products. It is important that all Americans have access to honest, accurate, scientifically-valid information about different products upon which to make informed decisions. One can appreciate a cautious approach to these applications so to avoid misleading consumers into thinking alternative products are without any risks at all. However, it’s well-established scientifically and widely accepted that most noncombustible nicotine products can significantly mitigate potential risks of consuming nicotine through smoking.

It is important to note that an FDA order allowing a MRTP is not permanent and is set for a fixed period of time specified in the order. Upon the end of the set term, the company would need to seek renewal of the order. Additionally, if FDA later concludes that the determinations necessary to satisfy requirements cannot be made, they must withdraw the order. Given the known risks of death and disease that result from smoking combustible cigarettes and the temporary nature of the MRTP order, the FDA should exercise its wide discretion in liberally interpreting the requirements necessary for an MRTP.

Specifically, under Section 911(g) of the TCA, FDA is mandated to consider whether the use of the product by consumers will significantly reduce harm and the risk of tobacco-related disease to individuals who use the products and benefit the health of the population as a whole, considering both users of tobacco products and those who do not currently use them. Noting the temporary nature of the MRTP order, the current findings of the CDC that over 480,000 Americans die prematurely every year from smoking-related causes and the fact that no MRTP orders for reduced risk products are currently on the market and available to 30-40 million U.S. smokers, we strongly encourage you to avoid the most stringent burden of proof (i.e. “beyond a reasonable doubt”) and instead use a recognized and less rigorous standard (i.e. “a preponderance of the evidence” or “more likely than not”) to provide valuable information to inveterate smokers at risk of premature death and disease as a result of smoking.

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The MRTP application in question was filed by Philip Morris Product N.A. for its IQOS heat-not-burn operating system.

How it works

PMI's Tobacco Heating System (THS), known as IQOS, uses a blade to heat a tobacco stick that is inserted into the battery powered device. The temperature of the tobacco stick is regulated to a maximum of 662 degrees Fahrenheit to ensure the tobacco doesn't burn. The temperature falls to 572 degrees Fahrenheit at 0.2 millimeters, with the tobacco heated at 482 degrees Fahrenheit. According to PMI Science, the tip of a burning cigarette, by contrast, exceeds 1300 degrees Fahrenheit.

This regulated heating process creates a tobacco flavored vapor containing nicotine but produces no smoke or ash because no combustion is taking place. Each tobacco stick generates 12-14 puffs lasting around six minutes, the typical time and puff amount of an average cigarette. Because the device uses real leaf tobacco and lasts the length of an average cigarette it mimics much of the ritual, taste and sensory experience of smoking.

Switching completely from cigarettes to the IQOS system significantly reduces exposure to harmful and potentially harmful chemicals

As indicated, the greatest harms from cigarettes come not from nicotine but from the combustion of tobacco. High temperatures from combustion expose cigarette users to high concentrations of hazardous chemicals, which when inhaled as intended have numerous ill effects on the user's health.

As the FDA has observed, it is not nicotine but exposure to these other constituents of cigarette smoke that is responsible for the negative health effects of smoking, which kills half of life-long users and major health problems for many of the remainder.

Smokers smoke for the large amounts of nicotine that are delivered to the brain in a matter of seconds, as well as the flavor and the ritual. But in so doing they are putting themselves at enormous risk. This problem was articulated by tobacco researcher Dr. Michael Russell who said "smokers smoke for the nicotine, but they die from the tar."

By using a process of heating instead of burning to give users a vapor instead of smoke, IQOS dramatically reduces exposure to the harmful constituents of cigarette smoke but still delivers levels of nicotine and a tobacco flavor that may be more satisfying to many smokers than many other noncombustible nicotine delivery products currently available on the market.

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The FDA has identified 18 harmful and potentially harmful constituents (HPHC) whose concentrations are fundamental to the evaluation of the relative safety of any tobacco product. Because there is no combustion in the THS, levels of HPHCs in the vapor generated by IQOS are, according to PMI researchers, on average 90% lower than a tested reference cigarette, across the three toxicity models tested by PMI.¹

“Similarly, the levels of chemicals classified by the International Agency for Research on Cancer (IARC) as Group 1 carcinogens are reduced on average by more than 95% compared to a reference cigarette,” according to PMI Science.

PMI Science, however, is not the only source of evaluation for the toxicity of IQOS. Dr. Konstantinos Farsalinos, a research fellow at the Onassis Cardiac Surgery Center in Athens, Greece, and at the Department of Pharmacy, University of Patras, has conducted independent research in a non-PMI lab.

According to Dr Farsalinos, IQOS produces “significantly lower toxic emissions than smoking.” Farsalinos found a reduction for most toxins of 90% or more compared to cigarette smoke.²

Furthermore, Farsalinos finds that IQOS delivers nicotine at levels higher than e-cigarettes but lower than a tobacco cigarette, suggesting IQOS could appeal to smokers looking to switch but who have found other reduced risk products unsatisfactory.³

Allowing smokers to access satisfactory amounts of nicotine through products that avoid the process of combustion, is a key ingredient to reducing smokers exposure to life threatening compounds and reducing tobacco related harms.

It is imperative that the process of switching away from combustible tobacco is made as easy and attractive as possible. By better mimicking the taste of tobacco as well as some of the ritual aspects of smoking, IQOS provides a new tool for smokers who may have attempted or wish to quit combustible tobacco but have been unable to do so.

¹ Maurice R. Smith, Bruce Clark, Frank Lüdicke, Jean-Pierre Schaller, Patrick Vanscheeuwijck, Julia Hoeng and Manuel C. Peitsch, “Evaluation of the Tobacco Heating System 2.2. Part 1: Description of the system and the scientific assessment program,” *Regulatory Toxicology and Pharmacology*, Vol. 81, Supp. 2, pp. S17–S26, Nov. 30, 2016.

² Konstantinos Farsalinos, “Toxicant exposure Heated tobacco products vs. e-cigarettes,” Presentation at Global Forum on Nicotine, Warsaw, June 2017. Available at: https://gfn.net.co/downloads/Presentations_2017_/Dr%20Konstantinos%20Farsalinos.pdf

³ Farsalinos et al. “Nicotine delivery to the aerosol of a heat-not-burn tobacco product: comparison with a tobacco cigarette and e-cigarettes.” *Nicotine and Tobacco Research*, ntx 138, 2017, doi: 10.1093/ntr/ntx138.

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Switching completely from cigarettes to the IQOS system can reduce the risk of tobacco-related disease

By reducing levels of HPHCs, the THS allows smokers who exclusively switch to IQOS to dramatically lower their exposure to large concentrations of these lethal chemicals and therefore lessen their risk of smoking-related disease.

Toxicological studies conducted by PMI show the THS aerosol dramatically reduces the impact on “biological mechanisms and disease endpoints associated with chronic obstructive pulmonary disease and cardiovascular disease,” compared to cigarette smoke.⁴

Experiments conducted by PMI Science comparing exposure of IQOS vapor to cigarette smoke over an eight month period show IQOS use reduced exposure to HPHCs to the same degree as smoking cessation.

Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes

The reduction in exposure to HPHCs shows that smokers who switch exclusively to IQOS are significantly reducing their risk of smoking related disease. Clinical trials lasting 90-days carried out in Japan⁵ and the U.S.,⁶ show smokers who switched to exclusively to IQOS saw reductions in levels of 15 HPHCs similar to levels seen in smokers who ceased cigarette use for the duration of the study.

Substantial market potential for heat-not-burn products

Nicotine and how it is delivered to the brain is the principal appeal of combustible cigarettes. Smokers who are accustomed to regular cigarettes often find it extremely difficult to quit.

⁴ Phillips et al., “An 8-Month Systems Toxicology Inhalation/Cessation Study in Apoe^{-/-} Mice to Investigate Cardiovascular and Respiratory Exposure Effects of a Candidate Modified Risk Tobacco Product, THS 2.2, Compared with Conventional Cigarettes.” *Toxicological Sciences*, 149(2), pp. 411-432, 2016. doi: 10.1093/toxsci/kfv243.

⁵ Frank Luedicke, et al., “Reduced exposure to harmful and potentially harmful constituents after 90 days of use of tobacco heating system 2.2 in Japan: A comparison with continued combustible cigarette use or smoking abstinence,” PMI Science, March 2016.

⁶ Frank Luedicke, et al., “Reduced exposure to harmful and potentially harmful constituents after 90 days of use of tobacco heating system 2.2 Menthol in the U.S.: A comparison with continued cigarette use or smoking abstinence,” PMI Science, March 2016.

Nicotine replacement therapies and other reduced risk products have had some success in getting a minority of smokers to switch from the most lethal form of nicotine consumption but millions are still unwilling or unable to switch away from cigarettes to a safer product.

The number of smokers who have experimented with vaping in Europe and the U.S. for instance, far exceeds the number of regular vapers. This suggests there is substantial interest from smokers in switching to a reduced risk nicotine product but that vaping and other approaches for some smokers have been ineffective.

By more closely mimicking the smoking experience, IQOS has significant potential to draw smokers away from combustible cigarettes. In clinical trials, product satisfaction and measured nicotine uptake were comparable to a combustible cigarette, according to PMI.

There is already evidence from locations where IQOS is being sold to suggest a large number of smokers would be willing to switch. In Japan, the only country where IQOS is sold nationwide, IQOS already accounts for 10% of the tobacco market and 72% of those using IQOS are doing so exclusively, after little more than a year on the market. IQOS is also being sold in cities in an additional 25 countries. According to PMI, 3 million adults so far have switched from cigarettes to IQOS.

Such rapid growth is extremely encouraging and highlights the potential benefits were the U.S. to permit the sale of IQOS and grant an MRTP. But it also highlights the danger of failing to do so, which would effectively prevent its citizens from benefiting, even while citizens in other countries have access to a product that is effectively helping them quit smoking.

No interest from never-smokers

There is no evidence to suggest IQOS would significantly appeal to never smokers. PMI's premarket Perception and Behavior Assessment research program found a range of interest in using IQOS among never-smokers aged 18-25 was between 0% and 1.1%. There was, however, substantial interest from current adult smokers, with between 20% and 39% saying they intended to use IQOS.

PMI surveys of adult smokers also suggests there is substantial demand from smokers to know the relative risks of different products so as to make an informed choice about how to reduce their risks from smoking-related harms. 98% of survey respondents said it is important adult smokers are informed about the benefits of a reduced risk product and 95% agreed the FDA has an obligation to

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allow these products onto the market. A further 89% said they would be more likely to switch to a potentially less harmful product if the government provided clarity on the relevant health benefits.

There is also significant support among healthcare providers for a tobacco harm reduction approach that allows smokers to switch to less harmful products. In a survey conducted on behalf of PMI, 82% of healthcare providers support communicating the relative risks of new tobacco products to adult smokers.

High interest from smokers to switch from combustible cigarettes to IQOS, and minimal interest from non-smokers suggests a large net gain to public health from allowing IQOS onto the market.

Summary

The new course being charted at FDA and discussed on various occasions by both FDA Director Gottlieb and CTP Director Zeller includes, among other things, emphasis on supporting and promoting product innovations that can provide long-term inveterate smokers with alternative nicotine products that appeal to them and dramatically reduce exposures to smokers from combustible cigarettes.

As it stands currently, many tobacco consumers fail to understand that it is not the consumption of nicotine, but rather exposure to the products of combustion through smoking that causes over 480,000 U.S. smokers to die prematurely every year. Information about tobacco and nicotine products provided by government that suggest noncombustible products might be as dangerous as cigarettes have contributed to these potentially deadly misunderstandings. The general public, tobacco consumers and even health professionals often fail to appreciate the significant differences in relative risks associated with different products. The failure to distinguish different risks results in smokers who are unable or unwilling to quit from moving from a deadly product to others that pose considerably less risk.

As it stands, there are limited pathways that allow innovative noncombustible tobacco products to come to market or to communicate to consumers that such products represent reduced risks. The MRTP pathway is critically important toward reducing the toll of smoking on the U.S. population and the record of success in utilizing this pathway is non-existent. This application is significant because of the size of the submission and the cost of compiling the materials necessary to make it. The FDA should encourage additional MRTP applications and work with applicants (Philip Morris Products N.A. in this case, Swedish Match in prior instances) to ensure that consumers have access to innovative noncombustible products and accurate information about reduced risks that such products offer as compared to traditional combustible cigarettes.

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We encourage you to approve the MRTP in this instance and where questions exist to work with the applicant reasonably to resolve those questions and thereby allow smokers in the U.S. the opportunity to explore less harmful product options and receive honest, accurate and scientifically valid information about relative risk so that they can make informed personal health choices. In a similar vein, we also encourage FDA and CTP to reconsider existing information available about noncombustible products currently on the market where required warning labels and other government information may confuse smokers into believing that those alternatives expose them to as much or even more risk than they are exposed to as a smoker.

In just a short time, you have already spoken and written eloquently about the need for innovation and the benefits that reduced risk, noncombustible nicotine products could provide to smokers. In no way do we want to minimize the significance of those welcome comments. Now it's time to put weight behind those words with demonstrated action toward those ends.

We respectfully request that you approve the MRTP application in regard to the specific claims included.

Sincerely,



Brian J. Fojtik
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