PMI US CORPORATE SERVICES

1399 NEW YORK AVENUE, NW, SUITE 400, WASHINGTON, DC 20005 TELEPHONE (202) 495-2661

Written Testimony on Rhode Island House Bill No. 5770

AN ACT RELATING TO TAXATION -- CIGARETTE, OTHER TOBACCO PRODUCTS, AND ELECTRONIC NICOTINE-DELIVERY SYSTEM PRODUCTS

Submitted to the Committee on Finance by Dr. Pritika Kumar, Director of Scientific Engagement, on behalf of PMI US Corporate Services Inc.

April 10, 2025

Good afternoon, Chair Abney and members of the Finance Committee. Thank you very much for the opportunity to testify in support of H 5770.

My name is Dr. Pritika Kumar. I have a PhD in Public Health and graduate degrees in community health and mental health, and over two decades of experience in harm reduction research, programs and policy. I am the Director of Scientific Engagement for PMI US Corporate Services Inc., a part of Philip Morris International (PMI for short) and its family of companies, which is at the forefront of developing reduced risk alternatives[1] in the United States. Today, smoke-free nicotine products represent 40% of our company's global net sales and we are committed to phasing out combustible cigarettes altogether. Of note, PMI has never sold, and will never sell, combustible cigarettes in the United States.

Here in the United States, 28 million adults continue to smoke today, including 9.5% of Rhode Islanders. While that rate is below the national average, it still represents real and considerable human costs; according to the Rhode Island Department of Health, 1,800 deaths in the state annually and 31.3% of cancer-related deaths are attributed to smoking combustible cigarettes. Concerningly, the effects of combustible cigarette use are felt most by some of Rhode Island's most vulnerable populations. Smoking prevalence—and the diagnosis rate of resultant smoking-related diseases, like COPD—is highest among Rhode Islanders of lowest income, limited education and more advanced age. Smoking significantly contributes to financial burdens on the state, amounting to $744 million in annual healthcare costs and $233 million in annual Medicaid expenses. Additionally, smoking leads to $1.1 billion in lost productivity in Rhode Island each year.

Public health authorities, including the U.S. Food and Drug Administration (FDA), have recognized that nicotine products exist on a continuum of risk, with smoke-free alternatives at the lower health risk end when compared to combustible cigarettes, the most harmful tobacco product. It is a fact that most

[1] Reduced-risk alternatives is the term PMI uses to refer to smoke-free products that present, are likely to present, or have the potential to present less risk of harm to smokers who switch to these products versus continued smoking.

adults who smoke in Rhode Island will not quit the use of nicotine, even if they no longer want to smoke combustible cigarettes—and these adults deserve access to affordable alternatives.

Although there are nicotine replacement therapies that are approved by FDA as smoking cessation-aids, their relatively low success rates and lack of appeal to smokers necessitate that the public health community consider expanding the portfolio of options to include innovative smoke free nicotine products.

Included in our portfolio is a product called IQOS, the nation's first authorized "heat-not-burn" tobacco product which replicates the experience of smoking at a much lower risk profile. Although no heat-not-burn product has been approved as a cessation aid, they can play a role in transitioning smokers away from the most harmful nicotine product in the marketplace. Although this product is just becoming available in the United States, data from countries where it has been sold such as Japan and Italy show that well over half of legal age smokers have transitioned from using combustible cigarettes to heated tobacco products since IQOS was introduced in these markets.

After a rigorous regulatory review, the FDA concluded that IQOS is both "appropriate for the protection of public health" as an authorized product and "appropriate for the promotion of public health" as a Modified Risk Tobacco Product (MRTP). To give you an idea of just how rigorous the application reviews are at the FDA, the review consolidates the interdisciplinary findings of the core review team, which is composed of an engineer, chemist, toxicologist, microbiologist, social scientist, epidemiologist, medical reviewer, behavioral clinical pharmacologist, and regulatory health project manager. Consultants from other disciplines, like statistics and the office of health communication and education, may also be involved in the review process, as needed. Before authorizing IQOS as a modified risk product, the FDA applied rigorous, independent, scientific review to determine that IQOS heats the tobacco and does not burn it. This lack of combustion significantly reduces the production of harmful and potentially harmful chemicals, and scientific studies have shown that "switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals." Our studies submitted to the FDA in support of our MRTP application demonstrated that, while not risk-free, IQOS emits 90% to 95% fewer harmful and potentially harmful constituents compared to combustible cigarettes.

IQOS is an innovative, harm-reduction product that has helped over 35 million adults around the world reduce or eliminate their use of combustible cigarettes altogether. Importantly, our pre-market perception and behavior studies, submitted to the FDA, showed that this product is not likely to appeal to nonsmokers, including youth, but does appeal to those who have the intention to quit smoking, as stated by the FDA in its authorization determination.

To achieve positive outcomes in public health, the state should encourage adult smokers to switch to these FDA-authorized products by imposing risk-proportionate taxation. H 5770 would help achieve just that—by ensuring products like IQOS that have met the very high bar of being FDA-authorized as modified risk are taxed at a lower rate. This rate would better reflect the risk profile of the product. And it is prudent for the Committee to provide this tax reduction now as more innovative products with MRTP orders are or will be coming to market to offer adults who smoke with better options than smoking.

Consumer attitudes toward novel smoke-free products like IQOS are and will continue to be shaped, in large part, by government policies. As adult consumers see and use these products as they come to market, it is critical to have sound public policies in place, such as the language in H 5770, that affirm smokers are making a better choice. Seven states around the country, including Connecticut, have already enacted laws that provide for a similar tax differential for modified risk tobacco products.

We thank the sponsors of this legislation, Representatives Caldwell, Craven, McEntee, Casey, and Kazarian, for their commitment to tobacco harm reduction and urge the Committee to advance this legislation.

Thank you very much for your time today, and I am happy to answer any questions you might have.

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At PMI, we believe science and innovation can drive us toward achieving our vision of a smoke-free future, faster.

PMI LEADS THE WAY

2015: First ever FDA authorization - General Snus

2019: First ever modified risk order - General Snus

2019: First ever FDA-authorized heated tobacco products - IQOS

2020: First and only modified risk order for a heated tobacco product - IQOS

2024: First and only modified risk renewal - General Snus

2025: First and only FDA-authorized nicotine pouch - ZYN

OUR PRIORITY: HARM REDUCTION

Research shows smoke-free products, including PMI's ZYN and IQOS, provide legal-age adults who smoke with a better choice. While they aren't risk-free, they represent a better option for adults who would otherwise continue to smoke, which offers enormous potential benefits to public health.

Our smoke-free products are intended for and marketed only to current legal age adults who smoke cigarettes or use tobacco products. No one younger than 21 should use any tobacco/nicotine-containing products.

SMOKE-FREE ALTERNATIVES

ZYN

These FDA-authorized nicotine pouches, placed between the upper lip and gum, are spit-free and available in 2 nicotine concentrations and 10 flavored and unflavored varieties in the U.S.

IQOS

This FDA-authorized electronic device heats specially designed tobacco sticks - without burning - to deliver nicotine through a highly consistent aerosol. No smoke, no ash, no combustion.

For the past 10 years, PMI has been on a mission-filled purpose for a smoke-free world and has publicly said we want to end cigarette smoking because it causes harm.

—Stacey Kennedy
CEO, PMI US

CIGARETTES: THE MOST HARMFUL FORM OF TOBACCO USE

28.8 million[1]
That's how many adults still smoke cigarettes in the U.S. More than 90 percent continue to smoke each year. [2]

PMI BY THE NUMBERS

83,170
Global workforce

>$14 billion
Investment in smoke-free products since 2008

38.6 million
Estimated total legal-age users of PMI's smoke-free products

Information provided by PMI US Corporate Services Inc., on behalf of Philip Morris International and its family of companies (collectively referred to as "PMI", "we" or "our"). This information is intended for policy and regulatory discussions. It is not for advertising or promotional purposes and not intended for a consumer audience.

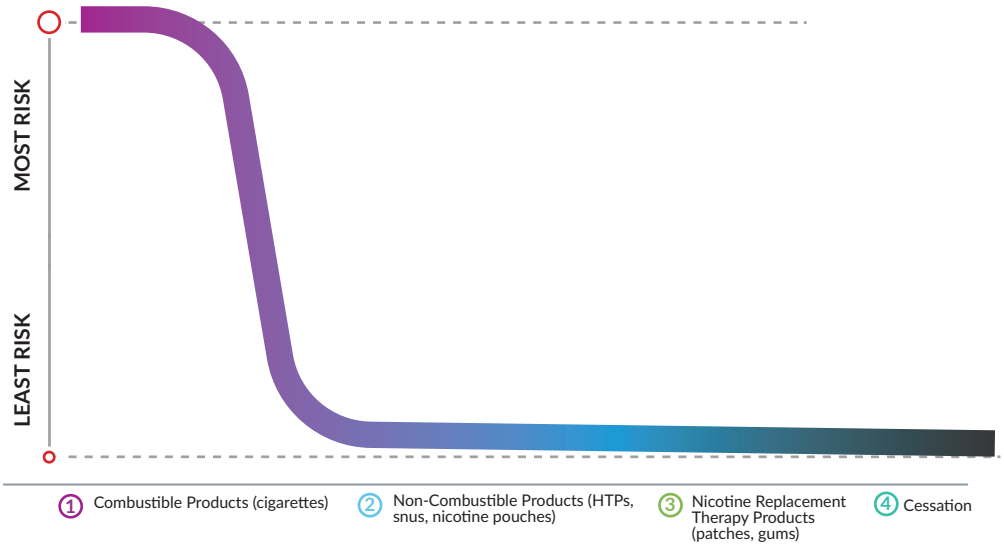
[1] CDC, Burden of Cigarette Use in the U.S. (October 8, 2024), https://tinyurl.com/4cxtf6w9

[2] CDC, Smoking Cessation: Fast Facts (September 17, 2024) https://tinyurl.com/4j4xswv2

IQOS:
A BETTER CHOICE

IQOS is an innovative electronic device that gives 28 million[1] American adults who smoke cigarettes a better option than continued smoking. It is the only Heated Tobacco Product (HTP) authorized as appropriate for the protection of public health by the FDA and the only HTP authorized as a Modified Risk Tobacco Product. These designations reflect rigorous scientific review that demonstrates IQOS, while not risk-free, is fundamentally different than a cigarette and gives legal-age adults who smoke a better choice.

COMBUSTION AND THE RISK CLIFF



CIGARETTES

Smoke. Fire. Ash.
Burns tobacco up to 900°C.
Combustion leads to thousands of toxic and carcinogenic chemicals.

IQOS

No smoke. No fire. No ash.
Electronically heats tobacco up to a maximum of 350°C.

Compared with cigarette smoke, IQOS aerosols contain considerably lower levels of potential carcinogens and toxic chemicals.

THE BOTTOM LINE:

IQOS is **fundamentally different** from a cigarette and a better option for adults who smoke cigarettes. That's why FDA concluded the sale of IQOS to adults who smoke is "appropriate for the protection of public health." Government policies on tobacco and nicotine use should be based on science, risk levels and common sense to ensure legal-age adults who smoke — who would otherwise continue to smoke cigarettes — have access to better options like IQOS.

2017

PMI submits IQOS premarket tobacco product application to FDA for review, which includes thousands of hours and millions of dollars performing scientific research.

2019

First, and only, HTP authorized by FDA: FDA completes rigorous review and concludes the sale of IQOS to adults who smoke is "appropriate for the protection of public health."[2]

2020

First (and still only) HTP authorized by FDA as a Modified Risk Tobacco Product: This FDA designation recognized that adults who smoke cigarettes who switch completely to IQOS will have significantly reduced toxic exposures that will benefit the health of the population as a whole.[3]

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1. CDC, Burden of Cigarette Use in the U.S. (October 8, 2024), https://tinyurl.com/4cxtf6w9
2. FDA, FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway (April 30, 2019), http://tinyurl.com/3cv8k2vs.
3. FDA, FDA Authorizes Reduced Exposure Claim for IQOS 3 System Holder and Charger (March 11, 2022), http://tinyurl.com/2tz7c7zx.

REASONABLE TAX POLICY MAKES SMOKE-FREE PRODUCTS MORE AFFORDABLE FOR ADULT SMOKERS

THERE IS AN URGENT PUBLIC HEALTH NEED TO MAKE SMOKE-FREE ALTERNATIVES AVAILABLE AND AFFORDABLE FOR RHODE ISLANDERS

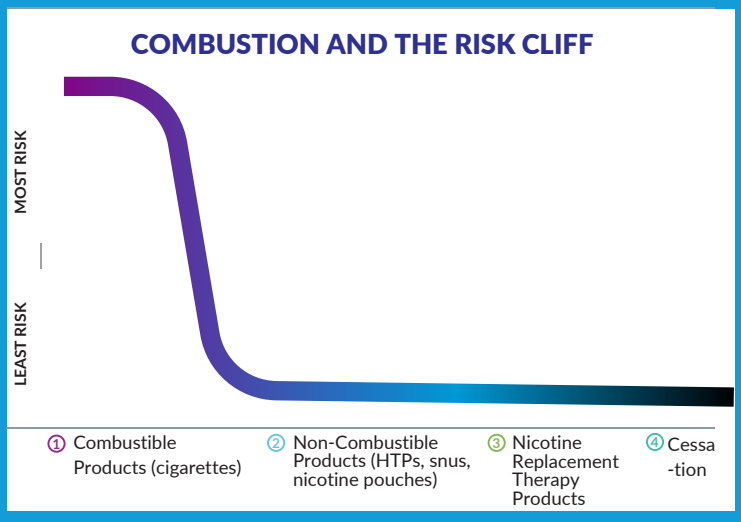
Smoking remains the leading preventable cause of death and disease in the United States. According to the Campaign for Tobacco-Free Kids:

- 9.5% of Rhode Islanders continue to smoke cigarettes.
- About 1,800 Rhode Islanders die each year from smoking-related causes.
- 31.3% of cancer deaths in Rhode Island are attributable to smoking.
- Annual smoking-related medical expenses in Rhode Island total $744 billion.
- The annual cost of lost productivity due to smoking in Rhode Island is an estimated $1.1 billion.

Source: Campaign for Tobacco-Free Kids, The Toll of Tobacco in Rhode Island, https://www.tobaccofreekids.org/problem/toll-us/rhode_island

POLICY SHOULD REFLECT RISK LEVELS

For adults who smoke, quitting all tobacco products is always the best choice. But many won't quit. While not risk-free, smoke-free alternatives like heated tobacco products give adults who smoke a better choice. Government policies on tobacco and nicotine use should be based on science, risk level, and common sense to ensure legal-age adults who smoke have access to FDA-authorized smoke-free products.

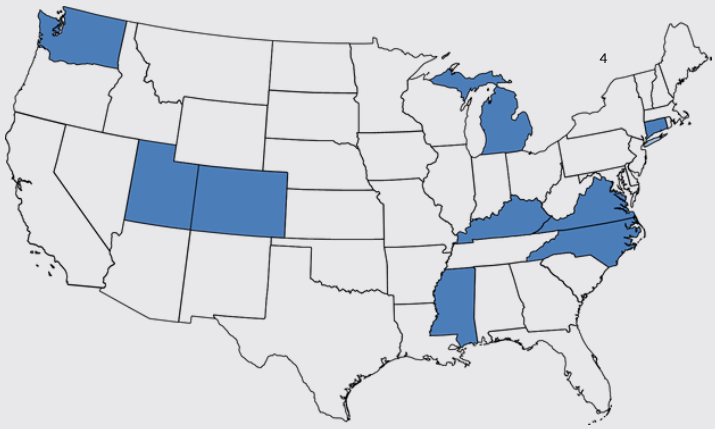


Adapted from Nutt, et. al. Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur. Addict Res 2014; 20:218-225.

HEATED TOBACCO PRODUCTS OFFER A SMOKE-FREE ALTERNATIVE TO COMBUSTIBLE CIGARETTES

Heated tobacco products (HTPs), also known as heat-not-burn products, do exactly what their name suggests: they are designed to heat tobacco instead of burning it. That is the fundamental difference between HTPs and combustible cigarettes. Because tobacco is heated and not burned, HTPs do not produce smoke, but instead, create aerosols with significantly reduced levels of harmful chemicals compared with cigarette smoke.

OTHER STATES HAVE ALREADY EMBRACED RISK-BASED TAXATION FOR TOBACCO PRODUCTS



A number of states have already used the legislative process to differentiate the tax rate for products that FDA has determined are appropriate to promote the public health and other states have or are working on creating a tax differential between combustible cigarettes, the most harmful form of tobacco, and heated tobacco products, which have a fundamentally different risk profile.

THE BOTTOM LINE:

Heated Tobacco Products are **fundamentally different** from combustible cigarettes and a better option for adults who smoke. Tax policy in Rhode Island should reflect this relative risk and incentivize adult smokers to switch to smoke-free alternatives.

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FDA NEWS RELEASE

FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information

Agency Will Closely Monitor Real-World Data to Assess if Marketing Continues to be Appropriate

More Press Announcements (/news-events/newsroom/press-announcements)

For Immediate Release:

July 07, 2020

Today, the U.S. Food and Drug Administration authorized the marketing of Philip Morris Products S.A.'s "IQOS Tobacco Heating System" as modified risk tobacco products (MRTPs). (/tobacco-products/advertising-and-promotion/modified-risk-granted-orders)This marks the second set of products ever to be authorized as MRTPs and the first tobacco products to receive "exposure modification" orders, which permits the marketing of a product as containing a reduced level of or presenting a reduced exposure to a substance or as being free of a substance when the issuance of the order is expected to benefit the health of the population. Importantly, the authorization for these products requires the company to conduct postmarket surveillance and studies to determine whether the MRTP orders continues to be appropriate, including assessing the potential for increased use among youth.

"Through the modified risk tobacco product application process, the FDA aims to ensure that information directed at consumers about reduced risk or reduced exposure from using a tobacco product is supported by scientific evidence and understandable," said Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products. "Data submitted by the company shows that marketing these particular products with the authorized information could help addicted adult smokers transition away from combusted cigarettes and reduce their exposure to harmful chemicals, but only if they completely switch. The FDA will closely monitor how IQOS is used by consumers to determine if these products meet this potential and do not cause increased use among youth. It is important to note that these products are not safe, so people, especially young people, who do not currently use tobacco products should not start using them or any other tobacco product."

The IQOS Tobacco Heating System includes the electronic IQOS device that generates a nicotine-containing aerosol by heating tobacco-filled sticks wrapped in paper, specifically Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks and Marlboro Fresh Menthol Heatsticks. The FDA previously authorized the marketing (/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway) of these products without modified risk information in April 2019 via the premarket tobacco application (PMTA) pathway.

Today's action pertains to the separate MRTP applications for these products and further authorizes the manufacturer to market these specific products with the following information:

"AVAILABLE EVIDENCE TO DATE:

- The IQOS system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.
- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."

Even with this action, these products are not safe nor "FDA approved." The exposure modification orders also do not permit the company to make any other modified risk claims or any express or implied statements that convey or could mislead consumers into believing that the products are endorsed or approved by the FDA, or that the FDA deems the products to be safe for use by consumers.

There are two types of MRTP orders the FDA may issue: a "risk modification" order or an "exposure modification" order. The company had requested both types of orders for the IQOS Tobacco Heating System. After reviewing the available scientific evidence, public comments and recommendations from the Tobacco Products Scientific Advisory Committee, the FDA determined that the evidence did not support issuing risk modification orders at this time but that it did support issuing exposure modification orders for these products. This determination included a finding that issuance of the exposure modifications orders is expected to benefit the health of the population as a whole.

In particular, the agency determined the company demonstrated that because the IQOS Tobacco Heating System heats tobacco and does not burn it, it significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke. Furthermore, studies showed switching completely from combusted cigarettes to the IQOS Tobacco Heating System significantly reduces the body's exposure to 15 specific harmful and

potentially harmful chemicals. The toxicological assessment also found that, compared with cigarette smoke, IQOS aerosols contain considerably lower levels of potential carcinogens and toxic chemicals that can harm the respiratory or reproductive systems. Additionally, the FDA found that the applications supported the required consumer understanding findings.

Today's authorization requires Philip Morris Products S.A. to conduct postmarket surveillance and studies to determine the impact of these orders on consumer perception, behavior and health, and to enable the FDA to review the accuracy of the determinations upon which the orders were based. These postmarket requirements include a rigorous toxicity study using computer models to help predict potential adverse effects in users. The orders also require the company to monitor youth awareness and use of the products to help ensure that the marketing of the MRTPs does not have unintended consequences for youth use. The company must also keep the FDA apprised of efforts to prevent youth access and exposure.

These requirements are in addition to the postmarket requirements and restrictions previously placed on these products in their April 2019 PMTA authorizations, such as reporting information to the FDA about consumer research studies, sales and advertising information and adverse experiences, among others. In particular, to limit youth access to the products and to limit youth exposure to IQOS advertising and promotion, the PMTA authorization placed stringent restrictions on how the products are marketed – particularly via websites and through social media platforms – by including requirements that advertising be targeted to adults of legal age to purchase tobacco products.

The company must request and receive authorization from the FDA to continue marketing the products with the same modified exposure information after the initial orders expire in 4 years. The FDA also may withdraw the initial and any potential subsequent exposure modification orders if the agency determines that, among other things, the orders are no longer expected to benefit the health of the population as a whole, for example as a result of an uptake in use of the products by youth or former smokers, or a decrease in the number of current smokers who completely switch to the products.

The MRTP pathway (/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products) outlined in the 2009 Family Smoking Prevention and Tobacco Control Act allows companies to submit applications for the FDA to evaluate whether a tobacco product may be sold or distributed for use to reduce harm or the risk of tobacco-related disease. By law, the FDA must also ensure that the advertising and labeling of modified risk products enables the public to understand the modified risk or modified exposure information and to understand the significance that information has in the context of total health and in relation to all tobacco-related diseases and health conditions.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Related Information

- Modified Risk Tobacco Products (/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products)
- Philip Morris Products S.A. Modified Risk Tobacco Product (MRTP) Applications (/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications)

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Inquiries

Media:

Alison Hunt (mailto:Alison.hunt@fda.hhs.gov)

202-308-5496

Consumer:

888-INFO-FDA