Food and Drug Administration
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In The Matter of Modified Risk Tobacco Product Application: Renewal Application for IQOS 3.0 System Holder and Charger, Heated Tobacco Product, Submitted by Philip Morris Products S.A.

The American Consumer Institute is an independent 501(c)(3) education and research organization. Its mission is to identify, analyze, and protect the interests of consumers in selected legislative and rulemaking proceedings in information technology, health care, insurance, and other matters.

We are writing in support of re-authorizing Philip Morris Products S.A.'s modified risk tobacco products.[1] According to the CDC, "smoking kills more than 480,000 Americans each year."[2] Evidence shows that heated tobacco products (HTPs) reduce smokers' exposure to harmful toxins compared to cigarettes.[3] HTPs—like other harm reduction and smoking cessation tools—are useful tools for reducing suffering from smoking-related disease and lowering healthcare expenditures for patients, as well as Medicare and Medicaid. Re-authorizing these products would advance the Food and Drug Administration's (FDA's) public-health mandate by continuing to provide adult smokers with a less harmful alternative.

1. Marlboro Amber HeatSticks, Marlboro Green Menthol HeatSticks, Marlboro Blue Menthol HeatSticks, IQOS 2.4 System Holder and Charger, and IQOS 3.0 System Holder and Charger
2. "Burden of Cigarette Use in the U.S.," Center for Disease Control, Reviewed October 8, 2024, https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html.
3. Haziza, et al., "Reduction in Exposure to Selected Harmful and Potentially Harmful Constituents Approaching Those Observed Upon Smoking Abstinence in Smokers Switching to the Menthol Tobacco Heating System 2.2 for 3 Months (Part 1)," Nicotine and Tobacco Research, Vol. 22, Issue 4, Pages 539—548, April 2020, https://pmc.ncbi.nlm.nih.gov/articles/PMC7164581/; Gale, et al., "Changes in Biomarkers of Exposure on Switching From a Conventional Cigarette to Tobacco Heating Products: A Randomized, Controlled Study in Healthy Japanese Subjects," Nicotine and Tobacco Research, Vol. 21, Issue 9, Pages 1220—1227, September 2019, https://pmc.ncbi.nlm.nih.gov/articles/PMC6698948/.

When these products were first authorized in 2019 the FDA specifically noted the substantial reduction in harmful and potentially harmful chemicals (HPHCs):

> "In particular, through the FDA's scientific evaluation of the company's applications, peer-reviewed published literature and other sources, the agency found that the aerosol produced by the IQOS Tobacco Heating System contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke. For example, the carbon monoxide exposure from IQOS aerosol is comparable to environmental exposure, and levels of acrolein and formaldehyde are 89% to 95% and 66% to 91% lower than from combustible cigarettes, respectively."[4]

The evidence that HTPs reduce risk compared to cigarettes has grown stronger since the FDA first authorized these products for sale. A review of the health effects of HTPs reports HPHC levels were 90 percent lower, and levels of Group 1 carcinogens—as defined by the International Agency for Research on Cancer[5]—were 95 percent lower compared to smoking.[6] Smokers who switched show reduced exposure to HPHCs across 15 biomarkers. There is evidence of reduced impact from in vitro[7] and in vivo (mice) studies,[8] as well as studies of smokers.[9]

A randomly controlled study on the effectiveness of HTPs as a smoking-cessation tool found that among smokers who did not intend to quit, HTPs had smoking-reduction rates to comparable to vaping,[10] which has been shown to be an effective means for quitting. [11]

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4. "FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway," United States Food and Drug Administration, April 30, 2019, https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway.
5. "Agents Classified by the IARC Monographs, Volumes 1–139," International Agency for Research on Cancer, Updated June 27, 2025, https://monographs.iarc.who.int/agents-classified-by-the-iarc/.
6. Reuven Zimlichman, Elena Scotti, and Giuseppe Plebani, "Heated Tobacco Products and Cardiovascular Disease: A Narrative Review of Peer-Reviewed Publications," American Medical Journal, September 15, 2022, https://www.emjreviews.com/en-us/amj/cardiology/symposium/heated-tobacco-products-and-cardiovascular-disease-a-narrative-review-of-peer-reviewed-publications-s02622/.
7. Schaller, et al., "Evaluation of the Tobacco Heating System 2.2. Part 2: Chemical composition, genotoxicity, cytotoxicity, and physical properties of the aerosol," Regulatory Toxicology and Pharmacology, Vol. 81, Supplement 2, Pages S27–S47, November 30, 2016, https://www.sciencedirect.com/science/article/pii/S0273230016302902.
8. 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, Vol 149, Issue 2, Pages 41–432, February 2016, https://pubmed.ncbi.nlm.nih.gov/26609137/.
9. Lüdicke, et al., "Effects of Switching to a Heat-Not-Burn Tobacco Product on Biologically Relevant Biomarkers to Assess a Candidate Modified Risk Tobacco Product: A Randomized Trial," Cancer Epidemiology Biomarkers and Prevention, Vol. 28, Issue 11, Pages 1934–1943, 2019, https://pubmed.ncbi.nlm.nih.gov/31270101/.
10. Caponnetto, et al., "Comparing the Effectiveness, Tolerability, and Acceptability of Heated Tobacco Products and Refillable Electronic Cigarettes for Cigarette Substitution (CEASEFIRE): Randomized Controlled Trial," JMIR Public Health and Surveillance, Vol. 9, 2023, https://pubmed.ncbi.nlm.nih.gov/37014673/.
11. "Vaping to quit smoking," United Kingdom National Health Service, accessed September 18, 2025, https://www.nhs.uk/better-health/quit-smoking/ready-to-quit-smoking/vaping-to-quit-smoking/.

Smokers are a diverse population and need different tools when they choose to quit. Yet the FDA currently offers far more choice to people who continue to smoke than those trying to stop. Between 2018 and 2022 the FDA approved 892 new cigarette products, giving consumers a wide array of more harmful options.[12] By comparison, the FDA has approved 45 reduced-risk products in total—only eight of which are heated tobacco products (formerly "noncombusted cigarettes").[13] Smokers need options when attempting to quit, and there are very few authorized alternatives relative to the number of cigarette products the FDA has authorized.

While there are no risk-free ways to consume nicotine, some methods are far less harmful than others. HTPs significantly reduce the risks associated with tobacco use. These products can help ensure fewer people suffer from smoking-related illnesses and can reduce avoidable costs borne by patients and by Medicare and Medicaid. Re-authorizing these products will help ensure Americans have viable, less harmful options when trying to quit smoking.

Respectfully,

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12. "FDA Approves More Than 1200 Combustibles and 900 New Cigarettes," Vapor Technology Association, March 2023, https://vaportechnology.org/wp-content/uploads/2023/04/VTA-Report-%E2%80%93-FDA-Approves-Combustibles.pdf.
13. "Premarket Tobacco Product Marketing Granted Orders," United States Food and Drug Administration, Updated March 28, 2024, https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders.