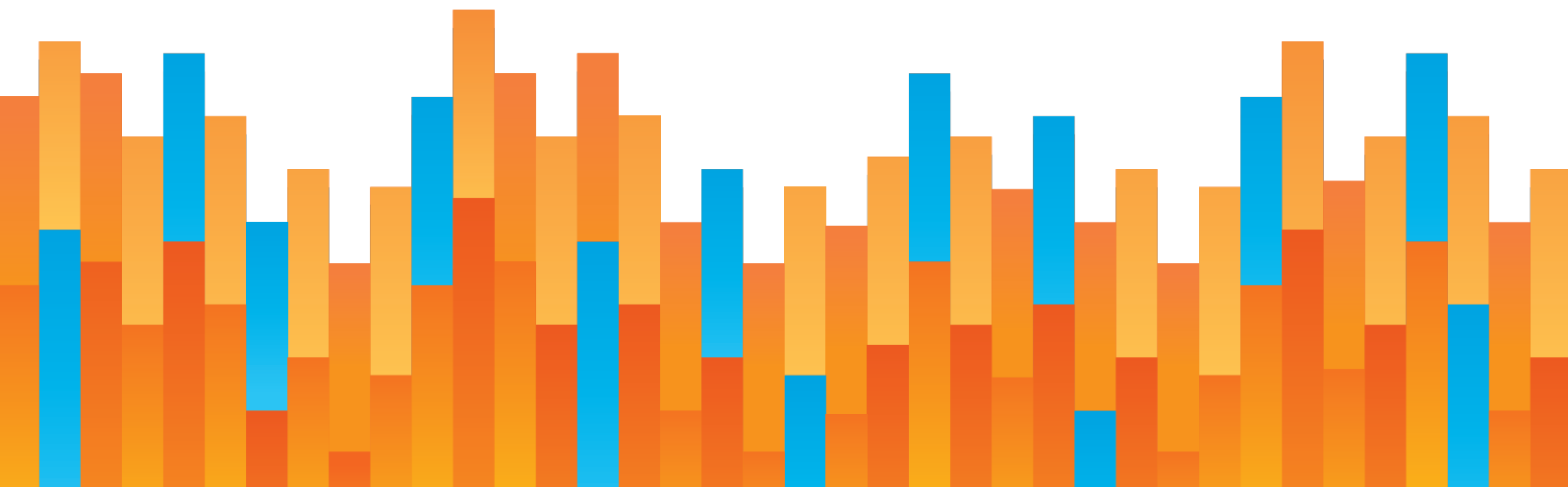




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HEATED TOBACCO PRODUCTS: FREQUENTLY ASKED QUESTIONS

by Guy Bentley
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FAQ 1

WHAT ARE HEATED TOBACCO PRODUCTS?

Heated tobacco products are part of a new generation of non-combusted products intended to give adult smokers the nicotine they desire without generating the smoke that may kill them. By heating instead of burning tobacco, these products emit much lower levels of harmful toxicants compared to cigarettes. Combustion at high temperatures causes emissions that expose cigarette smokers to complex and extremely hazardous chemicals, which when inhaled have numerous ill effects on the user's health. This problem was articulated by tobacco researcher Michael Russell who said: "People smoke for the nicotine, but they die from the tar."¹

The only heated tobacco product currently authorized for sale in the U.S. is Philip Morris International's (PMI) Tobacco Heating System (THS), sold under the brand IQOS. The battery-powered device uses a heating blade to warm a stick of leaf tobacco to a maximum temperature of 570 degrees Fahrenheit to ensure the tobacco doesn't burn. The tip of a burning cigarette, by contrast, exceeds 1300 degrees Fahrenheit.

¹ Arnott, D. "There's no single endgame." *Tobacco Control* Vol 22. May, 2013. https://tobaccocontrol.bmj.com/content/22/suppl_1/i38

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 and lasts around five minutes, about the same as the typical time and puff amount of an ordinary cigarette. Because IQOS uses leaf tobacco and lasts the length of an average cigarette, it mimics much of the ritual, taste and sensory experience of smoking. Unlike e-cigarettes, IQOS flavors are limited to tobacco and menthol. The tobacco sticks meet the Food and Drug Administration’s (FDA) definition of a cigarette and are categorized as non-combusted cigarettes.²

² Center for Tobacco Products. “How are Non-Combusted Cigarettes, Sometimes Called Heat-Not-Burn Products, Different from E-Cigarettes and Cigarettes?” Food and Drug Administration. May 2019.
<https://www.fda.gov/tobacco-products/ctp-newsroom/how-are-non-combusted-cigarettes-sometimes-called-heat-not-burn-products-different-e-cigarettes-and>

FAQ 2

ARE HEATED TOBACCO PRODUCTS DANGEROUS?

Nicotine-containing products are not risk-free, but in a speech given on July 28, 2017, former FDA Commissioner Scott Gottlieb explained “there’s a continuum of risk for nicotine delivery. That continuum ranges from combustible cigarettes at one end, to medicinal nicotine products at the other.”³ IQOS, e-cigarettes and smokeless tobacco snus fall to the lower end of this spectrum as there is no combustion and no smoke.

Because there is no combustion in IQOS, levels of Harmful and Potentially Harmful Chemicals (HPHCs) in the vapor generated are, on average 54%–99.9% lower than reference cigarettes, according to an FDA review of independent and industry studies.⁴

On January 25, 2018, the FDA’s Tobacco Products Scientific Advisory Committee (TPSAC) unanimously endorsed the claim made by PMI that switching completely from cigarettes to

³ Gottlieb, Scott. “Protecting American Families: Comprehensive Approach to Nicotine and Tobacco.” Food and Drug Administration. White Oak, MD. July 28, 2017.
https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017?utm_campaign=ctp-728regplan&utm_content=speech&utm_medium=social&utm_source=CTPPartnerTwitter&utm_term=gov

⁴ Center for Tobacco Products. “Technical Project Lead Review of PMI IQOS Premarket Tobacco Application.” Food and Drug Administration. 2019.
<https://www.fda.gov/media/124247/download>

IQOS significantly reduces smokers' exposure to harmful and potentially harmful chemicals.⁵

Experiments conducted by PMI Science comparing the exposure of IQOS vapor to cigarette smoke over an eight-month period show IQOS uses reduced exposure of 15 HPHCs to the same degree as smoking cessation. A systematic review of the scientific literature on heated tobacco products concluded:⁶

Peer-reviewed evidence on heated tobacco products indicates that HnB are effective nicotine delivery devices that expose users and bystanders to substantially fewer harmful and potentially harmful compounds than smoking cigarettes.

Submitting evidence to the U.K. Parliament in 2018, the U.K.-based Centre for Tobacco and Alcohol Studies said:⁷

...an early evaluation of likely cancer risk places HNB products at about 10% that of tobacco cigarettes, while e-cigarettes were predominantly less than 1%.

On April 20 2019, the FDA explained its reasoning for approving IQOS for sale:

Following a rigorous science-based review through the premarket tobacco product application (PMTA) pathway, the agency determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes.

Heated tobacco products are not without risk, but it's clear from the available literature that they present significantly less harm than combustible cigarettes.

⁵ Food and Drug Administration. "Summary Minutes of the Tobacco Products Scientific Advisory Committee (TPSAC)." Center for Tobacco Products. January 24-25, 2018. <https://www.fda.gov/media/111455/download>

⁶ Simonavicius, E. A. McNeill and L. Shahab, et al. "Heat-not-burn tobacco products: a systematic literature review." *Tobacco Control*. September 4, 2018. <https://tobaccocontrol.bmj.com/content/early/2019/01/28/tobaccocontrol-2018-054419>

⁷ Written evidence submitted by the UK Centre for Tobacco and Alcohol Studies. December 2017. <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/ecigarettes/written/75176.html>

FAQ 3

CAN HEATED TOBACCO PRODUCTS REDUCE SMOKING?

In terms of health, the best thing a smoker can do is quit completely. Many smokers who want to quit, however, find total abstinence from nicotine too difficult or unattractive. While traditional nicotine replacement therapies (NRTs) have been on the market for many years, they've proved disappointing in helping smokers quit. Into this gap, e-cigarettes and heated tobacco products have emerged as a viable harm reduction alternative for smokers.

According to the Centers for Disease Control and Prevention (CDC), 480,000 Americans die every year from smoking-related diseases.⁸ There are currently 34 million adult smokers.⁹ For those smokers who can't or don't want to quit, supplying satisfactory levels of nicotine and the same tobacco taste with drastically reduced levels of harmful chemicals could

⁸ Centers for Disease Control and Prevention. "Fast Facts." Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion. February 6, 2019. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm

⁹ Centers for Disease Control and Prevention. "Current Cigarette Smoking Among Adults in the United States." Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion. February 4, 2019. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm

prove an attractive alternative. In its statement approving IQOS for sale, the FDA said, “IQOS delivers nicotine in levels close to combustible cigarettes suggesting a likelihood that IQOS users may be able to completely transition away from combustible cigarettes and use IQOS exclusively.”¹⁰

IQOS is currently sold in 49 countries including the United States, though its presence in most countries remains limited and has only recently become available. Japan was the first country where IQOS was sold nationwide.

A study conducted by the American Cancer Society (ACS) examined changes in Japan’s cigarette sales from the time IQOS was launched in 2014 to 2018. During this period there were no other major changes to Japan’s tobacco policy. Before the introduction of IQOS, cigarette sales were declining at 1.8% per year. After the introduction of IQOS, cigarette sales declined at 9.5% per year. The authors concluded that “The introduction of IQOS likely reduced cigarette sales in Japan.”¹¹

In the first seven months of 2015, before IQOS started taking significant market share, 104.84 billion cigarettes were sold in Japan. In the first seven months of 2019, 72.25 billion cigarettes were sold, a 31.1% decline relative to 2015. Notably, Japan differs from the U.S. in many respects, not least that e-cigarettes with nicotine are not allowed to be sold in Japan, so the success of IQOS in Japan might not be replicated in the U.S. and other countries that allow and/or encourage the sale of e-cigarettes. But in South Korea, where e-cigarettes are sold, IQOS achieved similar success.¹²

¹⁰ Food and Drug Administration. “FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway.” April 30, 2019.
<https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>

¹¹ Stoklosa, M., Z. Cahn and A. Liber, et al. “Effect of IQOS introduction on cigarette sales: evidence of decline and replacement.” *Tobacco Control*. 17 June 2019.
<https://tobaccocontrol.bmj.com/content/early/2019/06/11/tobaccocontrol-2019-054998>

¹² Korea Tobacco & Ginseng Corporation.
<http://en.ktng.com/report?cmsCd=CM0044>

In the second quarter of 2019, according to PMI, there were more than 11 million IQOS users globally, eight million of whom have switched completely from smoking to IQOS.¹³ The experience of IQOS to date suggests there is strong demand among smokers for heated tobacco products as a replacement for cigarettes.

¹³ Duprey, Rich. "Philip Morris International Gets a Big Boost From IQOS in Q2." Yahoo Finance. July 25, 2019.
<https://finance.yahoo.com/news/philip-morris-international-gets-big-220900387.html>

FAQ 4

ARE HEATED TOBACCO PRODUCTS A THREAT TO YOUTH?

There is no evidence to date from countries where IQOS is already sold to suggest that it appeals to youth.

According to surveys of 64,000 Japanese students, conducted by Prof. Y Osaki of Tottori University, Medical School, youth use of heated tobacco is close to zero. The percentage of high schoolers who had used a heated tobacco product at least once in the past month between December 2017 and February 2018 was 0.9% and daily use was 0.1%.¹⁴ As part of its decision to approve IQOS for sale, FDA imposed stringent marketing restrictions to prevent youth access and exposure.¹⁵

¹⁴ Kumamaru, Hiroya. "Update on Current Status in Japan on Tobacco Harm Reduction." Global Nicotine Forum. June, 2019.
https://gfn.net.co/downloads/2019/presentations/Hiroya_Kumamaru.pdf

¹⁵ Food and Drug Administration. "FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway." April 30, 2019.
<https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>

“While the authorization of new tobacco products doesn’t mean they are safe, the review process makes certain that the marketing of the products is appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole,” said Mitch Zeller, director of the FDA’s Center for Tobacco Products. “This includes how the products may impact youth use of nicotine and tobacco and the potential for the products to completely move adult smokers away from use of combustible cigarettes.”¹⁶

The FDA added: “Available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using IQOS, including youth.” FDA is also requiring all IQOS package labels and advertisements to include warnings about the addictiveness of nicotine.¹⁷

With youth smoking at historic lows,¹⁸ it is extremely unlikely that non-smoking youth will find a product whose sole purpose is to mimic the taste and experience of tobacco appealing, especially with tightly controlled and monitored marketing.

Policymakers should, however, ensure these products are covered by the age of purchase laws which already apply to other tobacco products, and that IQOS stores or outlets where IQOS is sold comply with these laws. If IQOS is to be sold online, Altria—which has the exclusive rights to sell IQOS in the U.S.—should be compelled to introduce a system of strict age-verification prior to sale.

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Substance Abuse and Mental Health Services Administration. “Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health.” HHS Publication No. PEP19-5068, NSDUH Series H-54. Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. <https://www.samhsa.gov/data/>

FAQ 5

HOW SHOULD HEATED TOBACCO PRODUCTS BE TAXED?

When it comes to taxation, tobacco products should be treated according to the risk they pose to their users and the consequent negative impact they might have on public expenditures.¹⁹ Since heated tobacco products pose substantially less risk to their users than cigarettes, it follows that these products should not be taxed at the same rate as combustible cigarettes.

After an extensive review of the evidence around e-cigarettes and heated tobacco products, the House of Commons Science and Technology Committee told the U.K. government:

The level of taxation on smoking-related products should directly correspond to the health risks that they present, to encourage less harmful consumption. Applying that logic, e-cigarettes should remain the least-taxed and conventional cigarettes the most, with heat-not-burn products falling between the two.”

¹⁹ Fruits, Eric. “Vapor Products, Harm Reduction, and Taxation.” International Center for Law and Economics. Portland State University Group. Economics International Corps. October 1, 2018. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3384295

The government accepted these recommendations and imposed a level of excise duty that is the “lowest available for tobacco.”²⁰ Given their risk profile, heated tobacco products should be treated differently than cigarettes when it comes to taxation.

A 2019 Scientific Publication of the World Health Organization’s (WHO) International Agency for Research on Cancer (IARC) states:

*...as less harmful products have become more prevalent, and a continuum of risk or harm is present, it is appropriate to differentiate taxes according to relative risks (Chaloupka et al., 2015). The overriding focus remains the reduction of demand for the most harmful products.*²¹

Taxing low-risk and high-risk products at equivalent or similar rates would be tantamount to providing a fiscal protection to the most harmful products (i.e. cigarettes). A 2019 working paper published in the National Bureau of Economic Research (NBER) found that “traditional cigarette taxes appear to be less effective—in terms of reducing smoking—when a locality has also adopted an e-cigarette tax.”²² This indicates that a tax on less harmful alternatives will discourage smokers switching to these products.

Taxing products like IQOS at a lower rate than cigarettes can also provide a valuable financial incentive for smokers to switch away from cigarettes completely.

²⁰ Secretary of State for Health and Social Care. “The Government Response to the Science and Technology Committee’s Seventh Report of the Session 2017-19 on E-cigarettes.” Department of Health and Social Care. December, 2018.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/762847/government-response-to-science-and-technology-committee_s-report-on-e-cig.pdf

²¹ World Health Organization. “Reducing Social Inequalities in Cancer: Evidence and Priorities for Research.” *International Agency for Research on Cancer, Scientific Publication No. 168*. 2019.
<http://publications.iarc.fr/Book-And-Report-Series/Iarc-Scientific-Publications/Reducing-Social-Inequalities-In-Cancer-Evidence-And-Priorities-For-Research-2019>

²² Pesko, Michael F., Charles J. Courtemanche and Johanna Catherine Maclean. “The Effects of Traditional Cigarette and E-cigarette Taxes on Adult Tobacco Product Use.” National Bureau of Economic Research. *Working Paper 26017*. June 2019.
<http://src.bna.com/JzT>

FAQ 6

SHOULD HEATED TOBACCO PRODUCTS BE INCLUDED IN SMOKE-FREE LAWS?

An obvious concern for policymakers when considering regulation of heated tobacco products is whether smoke-free laws apply or should be extended to these products. The principal reason for smoke-free laws is to protect bystanders from the harm that can arise from inhaling second-hand smoke in enclosed spaces. But what are the harms of inhaling second-hand IQOS vapor?

According to a study by Japan's National Institute of Public Health, the concentrations of Tobacco Specific Nitrosamines found in mainstream IQOS vapor was one fifth that of mainstream cigarette smoke.²³ The levels of carbon monoxide in IQOS vapor was one-hundredth of that found in cigarette smoke. With these substantial differences between

²³ Bekki, Kanae, Yohei Inaba, Shigehisa Uchiyama and Naoki Kunugita. "Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes." *Journal of UOEH* vol. 39. 2017.
<https://www.ncbi.nlm.nih.gov/pubmed/28904270>

mainstream IQOS vapor and cigarette smoke, the differences in toxicity between sidestream (second-hand) smoke and IQOS vapor will be equally or even more dramatic.

According to the 2018 systematic review of the heated tobacco products literature:

HnB exposed users and bystanders to toxicants, although at substantially lower levels than cigarettes.

The U.K. Committee on Toxicity concluded in their summary evaluating heated tobacco products:

A reduction in risk would be expected to be experienced by bystanders where smokers switch to heat-not-burn tobacco products.²⁴

As the second-hand vapor for both e-cigarettes and heated tobacco products has not been found to present significant harm to bystanders, it should stand that neither product should be treated in the same manner as cigarettes when it comes to smoke-free laws. However, it would be unwise to treat heated tobacco products favorably compared to other harm reduction products like e-cigarettes. For states and local authorities that have already extended smoke-free laws to e-cigarettes, it would be sensible to apply the same measures to heated tobacco products.

²⁴ Committee on Toxicity. "Toxicological evaluation of novel heat-not-burn tobacco products—non-technical summary." December 2017.
https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf

CONCLUSION

Critics of harm reduction products in general often argue that, because the long-term effect of these products is unknown, they should be treated the same as cigarettes until proven otherwise. The problem with this line of argument is that the dire effects of cigarette smoking are visible and known.

In the decades it will take to discover the exact effect IQOS will have on its users, millions of Americans will die from a smoking-related disease. Harvard law professor and former regulatory czar Cass Sunstein encapsulated the problem with this precautionary approach:²⁵

The precautionary principle, for all its rhetorical appeal, is deeply incoherent. It is of course true that we should take precautions against some speculative dangers. But there are always risks on both sides of a decision; inaction can bring danger, but so can action. Precautions, in other words, themselves create risks—and hence the principle bans what it simultaneously requires.

On the balance of the available evidence, the dangers of impeding IQOS as a tool to help smokers quit far outstrips any possible threat it could pose to public health.

²⁵ Sunstein, Cass R. “Throwing Precaution to the Wind: Why the ‘Safe’ Choice Can Be Dangerous.” *Boston Globe*. July 13, 2008.
http://archive.boston.com/bostonglobe/ideas/articles/2008/07/13/throwing_precaution_to_the_wind/

ABOUT THE AUTHOR

Guy Bentley is the director of consumer freedom at Reason Foundation. Guy's work focuses on the taxation and regulation of nicotine, tobacco, alcohol, food and gambling.

