

Tobacco Harm Reduction Products Should Be Widely Adopted



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According to the Centers for Disease Control and Prevention (CDC), smoking is responsible for more than 480,000 deaths annually in the United States and smokers die on average 10 years earlier than non-smokers.¹ If smoking in the U.S. continues at its current rate among youth, 5.6 million Americans currently younger than 18, or one in 13, are expected to die prematurely from a smoking-related illness. Yet, there is a way to mitigate these projected deaths, provided U.S. health officials adopt policies to help smokers quit or move to tobacco harm reduction (THR) products, like vaping, heat-not-burn technologies (HNB), and snus.

THR products can be an effective solution to help smokers transition away from something on which all health officials agree: smoking is deadly. It is the burning of tobacco that causes cancer, heart disease, lung diseases, diabetes, and chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis. But despite the well-documented positive impact of THR products, they are regulated and treated in very different ways worldwide.

In the U.S., public health agencies, Congress, and state governments have chosen to demonize THR products and make them difficult to buy and use with tough regulations and confiscatory taxes, like the proposed \$96.7 billion in new federal excise taxes in the monstrous “human infrastructure” budget reconciliation bill. The taxes break President Biden’s pledge that no one making less than \$400,000 will have their taxes raised.² Excise taxes are regressive, and, in this case, the Tax Foundation writes, “A large portion of this new tax burden will be paid by lower-income Americans.” After the excise tax is implemented, the lowest quintile of low-income smokers would pay about 12 percent of their income in cigarette taxes.³

The Food and Drug Administration (FDA), under the Tobacco Control Act of 2009, has been contradicting itself on THR products.⁴ On the one hand, it has made the application process of the Premarket Tobacco Product Application and the Modified Risk Tobacco Product Application for any novel tobacco product created after 2007 so complicated, time consuming, and expensive, that very few manufacturers will be able to achieve success. The FDA is also seeking to ban flavors for THR products, supposedly to stop them from being purchased by people younger than 21, even though it is already illegal for them to buy these products. The entire process is making it more difficult for adult smokers to switch from smoking to using e-cigarettes, as they depend on a variety of flavors to make the change.⁵

¹ Centers for Disease Control and Prevention (CDC), “Smoking & Tobacco Use, Fast Facts,” June 2, 2021, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm#beginning.

² The Joint Committee on Taxation, JCX-42.21, September 13, 2021, <https://www.jct.gov/publications/2021/jcx-42-21/>.

³ The Tax Foundation, “Analysis of Federal Proposal to Increase Tobacco and Nicotine Product Taxes,” August 31, 2021, <https://taxfoundation.org/federal-tobacco-tax-proposal/#Regressivity>.

⁴ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 111th Congress, (2009), <https://www.govinfo.gov/content/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>.

⁵ Christopher Russell, Neil McKeganey, Tiffany Dickson, Mitchell Nides, “Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA,” *Bio Med Central Harm Reduction Journal*, June 18, 2018, <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6>.

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On the other hand, the agency has authorized THR products for sale in the U.S., like Philip Morris's "IQOS" in April 2019.⁶ In July 2020, the FDA allowed it to be marketed as a modified risk tobacco product. FDA Center for Tobacco Products Director Mitch Zeller said, "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."⁷

On October 12, 2021, the FDA granted marketing orders to R.J. Reynolds' Vuse, the first vaping product to receive such a designation. Zeller said, "The manufacturer's data demonstrates its tobacco-flavored products could benefit addicted adult smokers who switch to these products – either completely or with a significant reduction in cigarette consumption – by reducing their exposure to harmful chemicals." At the same time, the agency issue denial orders for specific flavored products.⁸

Around the world, countries are taking varied approaches to using THR products as alternatives to smoking.

England is the global leader in analyzing, reviewing, and approving THR products. In July 2017, England's Department of Health and Social Care released a document, "Towards a Smokefree Generation – A Tobacco Control Plan for England."⁹ In addition to continued campaigns to educate citizens about the danger of smoking and promoting cessation; encouraging smoke-free places to protect people from second-hand smoke; gathering information on the effectiveness of various stop-smoking strategies, like ad campaigns, regulations, taxation, and reduced access to illicit tobacco products; the government also encourages the use of e-cigarettes. Public Health England (PHE) has recommended that anti-smoking laws neither include e-cigarettes nor be part of a smoke-free policy. PHE has regularly updated studies on e-cigarettes and alternative nicotine delivery devices, as the agency has found they "could play a crucial role in reducing the enormous health burden caused by cigarette smoking."¹⁰

Greece has a large smoking rate, about 39 percent in 2018, but according to some reports that is dropping thanks to e-cigarettes.¹¹ In 2020, Greece adopted law 4715 (Articles 35, 36),

⁶ FDA, "Pre-market Tobacco Product Marketing Granted Orders 2019," <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>.

⁷ FDA News Release, "FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information," July 7, 2020, <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>.

⁸ FDA News Release, "FDA Permits Marketing of E-Cigarette Products, Marketing First Authorization of Its Kind by the Agency," <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency>.

⁹ Global and Public Health, United Kingdom, "Towards a Smokefree Generation: A Tobacco Control Plan for England," Department of Health, July 2017, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/630217/Towards_a_Smoke_free_Generation_-_A_Tobacco_Control_Plan_for_England_2017-2022_2_.pdf.

¹⁰ Public Health England, "Vaping in England: evidence update," February 2021, <https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021>.

¹¹ National Herald Staff, "E-Cigarettes Bring Big Drop In Greek Smoking Rate," *The National Herald*, January 17, 2019, <https://www.thenationalherald.com/e-cigarettes-bring-big-drop-in-greek>.

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which created a scientific assessment for novel tobacco products. The law adopted a variety of procedures required by manufacturers to market their products, like “including a risk/benefit analysis of the product, its expected effects on cessation of tobacco consumption, and its projected effects on consumers.” If the product is permitted in the Greek marketplace, the law allows manufacturers to communicate reduce risk messages to adult smokers.¹²

In September 2020, Scientific Adviser to the General Secretariat for Public Health of the Hellenic Ministry of Health Ioannis Faropoulos presented at the 3rd Scientific Summit on Tobacco Harm Reduction: Novel Products, Research, and Policy, that law 4715 legislated harm reduction and that the Greek government recognized that smokers have a right to have accurate information on and access to better novel tobacco harm reduction products.¹³

Other European countries are also making efforts to reduce smoking through harm reduction policies and strategies. According to Joe Nocera’s June 12, 2017, commentary in the *Chicago Tribune*, Bulgaria and France have smoking rates of 36 and 33 percent respectively, and Britain and Denmark are at 16 percent, and Sweden is at only 5 percent. Nocera wrote, “Why have Swedes stopped smoking? Because Sweden adopted a ‘harm reduction’ strategy: It has largely replaced deadly cigarettes with a product that supplies users with nicotine and tobacco yet doesn’t increase the odds of dying the way smoking does. That product is called snus (rhymes with goose).” Today, 15 percent of Swedes use snus, “a modern iteration of snuff” that consists of “little pouches of moist tobacco placed under the upper lip.” Nocera noted that Sweden has Europe’s lowest male lung cancer death rate, and that oral cancer is only slightly higher than non-users of snus.¹⁴

Nocera closed by stating, “The difference between the Swedish smoking rate and that of the next-lowest countries is enormous. If the West hopes to achieve a tobacco-free world by 2040, Sweden has pointed the way. Like it or not, harm reduction is the only answer.”¹⁵

Countries in Asia have either embraced or scorned THR products. Japan’s policies have led to a remarkable drop in cigarette smoking. In 2016, domestic combustible cigarette sales were at 43.6 billion, but by early 2021, that figure had dropped to 25 billion, a 43 percent decline over five years, mostly as a result of the popularity of heated tobacco products (HTP), or HNB electronic cigarettes, in which vapor is inhaled, not smoke. In 2018, Japan had the world’s largest HNB use at 85 percent of sales worldwide. Popular brands include Philip Morris’ IQOS and Japan’s Ploom Tech.¹⁶

¹² Greek Law 4715/2020 (Articles 35,36), <https://www.kodiko.gr/nomothesia/document/634794>.

¹³ Ioannis Faropoulos, “Tobacco Harm Reduction: Novel products, Research & Policy,” 3rd Scientific Summit, September 24 & 25, 2020, <https://2020.nosmokesummit.org/2020/09/25/new-legislation-on-smoking-control-in-greece>.

¹⁴ Joe Nocera, “Sweden figured out how to stop people from smoking,” *Chicago Tribune*, June 12, 2017, <https://www.chicagotribune.com/opinion/commentary/ct-perspec-smoking-0616-md-20170612-story.html>.

¹⁵ Ibid.

¹⁶ Alex Norcia, “Why Japan’s Huge Drop in Smoking Is a Story Prohibitionists Ignore,” *Filter*, May 13, 2021, <https://filtermag.org/why-japans-huge-drop-in-smoking-is-a-story-prohibitionists-ignore>.

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Ironically, while HTP is embraced, vaping products are “effectively banned,” according to Norcia. Japan is party to the World Health Organization’s (WHO) Framework Convention on Tobacco Control.¹⁷ While the framework includes harm reduction strategies, the WHO sets up roadblocks and does not favor vaping, HTP or other harm reduction products.¹⁸

The increased popularity of THR products in Japan has spilled over into South Korea. Between 2017 and 2018, cigarette sales declined by 8.9 percent, and HNB sales increased from 79 million packs to 332 million packs. David Sweanor, chair of the Advisory Board for the Centre for Health Law, Policy and Ethics at the University of Ottawa, said that THR products fit into other harm reduction tools like “seat belts and condoms” and show that substituting “safer alternatives works very well, and clearly does better than seeking abstinence rather via coercion.”¹⁹

Taiwan, however, is on the other side of the THR debate. For more than a year the country has been considering a package of amendments to its Tobacco Hazards Prevention and Control Act (THPCA). The Taiwan Ministry of Health worked on this legislation, which has the strictest regulation of THR in more than 13 years. Although work was originally delayed due to COVID-19 and there is supposedly strong support for the amendments in the legislature and the public, it has not been sent to the legislative branch for review. People familiar with the Taiwan situation say no one seems to know what is causing the continued delay.²⁰

The Taiwan legislation would raise the legal age to purchase tobacco products from 18 to 20, ban flavored tobacco products, increase the size of graphic health warnings, and expand the indoor smoking ban. Although the legislation would prohibit the sale of e-cigarettes, it would allow the commercialization of HTPs if authorized by a health risk assessment. The delay continues to leave many harm reduction products in limbo, including HTPs that have done so much to reduce the use of combustible cigarettes in other Asian countries.²¹

Taiwan government officials should be taking a hard second look at the success of HTP and recommend that e-cigarettes not be banned, since it would no doubt encourage the use of illicit products and create a thriving black market.²² There should be a more robust discussion around all THR products, including vaping, and the impact of HTPs on reducing smoking combustible cigarettes.

¹⁷ Ibid.

¹⁸ Elizabeth Wright, “The World Health Organization’s Misguided Effort to Stop Americans From Vaping,” *The Hill*, September 14, 2018, <https://thehill.com/opinion/healthcare/406609-the-world-health-organizations-misguided-effort-to-stop-americans-from>.

¹⁹ Filter Staff, “Rise of Heat-Not-Burn Products Coincides With Decrease in Cigarette Sales,” *Filter*, January 29, 2019, <https://filtermag.org/rise-of-heat-not-burn-products-correlates-with-decrease-in-cigarette-sales/>.

²⁰ Elizabeth Wright, “Tobacco Harm Reduction Products Help Smokers Quit,” *The Waste Watcher*, Citizens Against Government Waste, October 15, 2021, <https://www.cagw.org/thewastewatcher/tobacco-harm-reduction-products-help-smokers-quit>.

²¹ Ibid.

²² U.S. Customs and Border Protection, “Dulles CBP Seizes 50,000 Marijuana Atomizers from China,” September 24, 2021, <https://www.cbp.gov/newsroom/local-media-release/dulles-cbp-seizes-50000-marijuana-atomizers-china>; “CBP, FDA Seize Unapproved E-Cigarettes Worth \$719,453,” January 13, 2021, <https://www.cbp.gov/newsroom/local-media-release/cbp-fda-seize-unapproved-e-cigarettes-worth-719453>.

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In 2020, the Philippines was ready to adopt strict regulations on electronic nicotine delivery systems (ENDS), including permanently banning the use and importation of e-cigarettes, when it was discovered that an outside group, the Bloomberg Initiative to Reduce Tobacco Use, had funded the Philippine FDA to implement the National Tobacco Control Program. This conflict of interest led to a suspension of all efforts to regulating ENDS products.

In August 2021, the Philippine House of Representatives Committee on Good Government and Public Accountability presented to the full House a report that cited “the questionable receipt of private funding by the Food and Drug Administration (FDA) and other government agencies and institutions in exchange for the issuance of specific and predefined policies directed against a legitimate industry under Philippine laws and in complete disregard of the rights and welfare of consumers.” The report further noted that manufacturers of ENDS and HNB devices had been “unwittingly disadvantaged” and the FDA “failed to act judiciously.” As a result, a more reasonable approach has been taken toward regulating THR products.²³

The use of THR products has proven to be beneficial in numerous nations around the world. The success of these products in England and Sweden should encourage other countries to adopt the same policies. Yet in far too many countries, including the U.S., health officials are failing to truly help people to stop using combustible cigarettes, which are known to cause harm and death, by allowing THR products like e-cigarettes, HNB products, and snus to be widely available.

²³ Elizabeth Wright, “Good News Out of the Philippines on ENDS Products,” *The WasteWatcher*, Citizens Against Government Waste, August 26, 2021, <https://www.cagw.org/thewastewatcher/good-news-out-philippines-ends-products>.