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GETTING SMART ON REDUCED HARM

WHITE PAPER

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THE TRUTH ABOUT NICOTINE: WHAT EVERYONE DESERVES TO KNOW

ADULTS AGED 21+ WHO WANT TO MOVE AWAY FROM CIGARETTES—AND THE MEDICAL PROFESSIONALS WHO ADVISE THEM—NEED ACCURATE INFORMATION ABOUT BETTER ALTERNATIVES TO SMOKING, ESPECIALLY FROM THE U.S. FDA.

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EXECUTIVE STATEMENT

Despite decades of research as part of tobacco control efforts, misperceptions about nicotine are pervasive among healthcare professionals and others. This is hurting efforts to help smokers leave cigarettes behind.

A survey of 1,565 U.S. medical professionals, commissioned by Philip Morris International's U.S. businesses (PMI U.S.) and conducted by independent researchers Povaddo LLC in March and April 2025, showed that around half of healthcare practitioners (47 percent)—and 59 percent of medical professionals who treat a significant number of cigarette smokers—mistakenly believed nicotine was a carcinogen. Another 19 percent were unsure.

This is a knowledge gap with potentially severe consequences, given the critical role nicotine can play in helping adults stop smoking. While quitting tobacco and nicotine entirely is best, evidence shows that those legal-age adults who choose not to quit can significantly reduce the harm they're exposed to by switching from combustible cigarettes to an FDA-authorized smoke-free alternative.[1]

1 https://www.fda.gov/news-events/press-announcements/fda-proposes-significant-step-toward-reducing-nicotine-minimally-or-nonaddictive-level-cigarettes

If medical professionals mistakenly believe nicotine is what makes smoking so harmful, they may be hesitant to suggest that patients who don't wish to quit at least switch to a nicotine-containing alternative that, although addictive and not risk-free, has been shown to be a far better choice for adults than continued cigarette use.

The survey results also reveal an urgent demand: Medical professionals want to know about the better alternatives to cigarettes that are now available. They want to know what the science says about these products. And they want that information to come from the nation's leading authority on tobacco and nicotine regulation: the U.S. Food and Drug Administration (FDA).

This points to two pressing needs in support of tobacco harm reduction:

First, healthcare regulators such as the FDA need to provide unbiased, science-backed information about nicotine and nicotine products to the healthcare community.

Second, medical professionals need to share accurate information about better alternatives—information that has been rigorously reviewed by the FDA—with patients aged 21+ who smoke. This requires that these professionals understand the facts about nicotine, including that nicotine in itself does not cause cancer.

This paper examines the essential steps all parties need to take to promote tobacco harm reduction and improve public health. Political leaders and policymakers must ensure the FDA delivers accurate information to medical professionals. Medical professionals need to be able to deliver this information and informed counsel to their legal-age patients who smoke and do not wish to quit nicotine completely. Legal-age smokers need to be able to consult with their doctors and other reliable sources, such as the FDA, to learn about the alternatives now available to them if they don't intend to quit nicotine altogether and why these products are a better choice than continuing to smoke. And the FDA needs to improve the process by which it reviews and, if appropriate, authorizes better alternatives and make them available and accessible to cigarette smokers 21+ while also continuing to protect those under the legal age from accessing any nicotine product.

THE SCIENTIFIC CONSENSUS ON SMOKING, NICOTINE, AND CIGARETTE CESSATION

THE DANGERS OF CIGARETTES

There is no longer any scientific debate about the risks associated with smoking tobacco: Smoking is harmful to your health. An estimated 480,000 Americans die each year from smoking-related illnesses such as lung cancer, cardiovascular disease, and emphysema, according to public health estimates.[2] Burning a cigarette produces high levels of toxic compounds that cause smoking-related diseases. Over time, the risks for cigarette smokers increase as smokers continue to expose themselves to the harmful chemicals emitted from cigarette smoke.

2 https://www.cancer.org/cancer/risk-prevention/tobacco/health-risks-of-smoking-tobacco.html#:~:text=Tobacco%20use%20remains%20the%20leading,those%20people%20die%20from%20cancer

NICOTINE

The science on nicotine is also settled: Nicotine is addictive. But nicotine, while not risk-free, is not the main cause of smoking-related disease. In 2017, the then-FDA Commissioner said, “Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung diseases, and heart disease that kills hundreds of thousands of Americans each year.”[3]

Elsewhere, the FDA has made the same point: “It’s the thousands of chemicals contained in tobacco and tobacco smoke that make tobacco use so deadly. […] This toxic mix of chemicals—not nicotine—cause serious health effects among those who use tobacco products.”[4]

ENDING CIGARETTE USE

Just over two-thirds of smokers in 2022 said they wanted to stop—and of those, more than half (53 percent) had tried in the previous year. Less than 9 percent succeeded.[5] Quitting may be hard for some people, but it is possible. As of 2021, two-thirds of U.S. adults who had ever smoked had stopped.[6]

Importantly, smokers seeking to quit cigarettes need education and support. Even a few minutes of informed guidance from a medical professional can be helpful to a smoker.[7] The problem is, they don’t always receive that advice. According to the U.S. Centers for Disease Control and Prevention (CDC), only half of adults who smoke cigarettes (51 percent) were advised to

3 Gottlieb S, Zeller M. 2017. A nicotine-focused framework for public health. N Engl. J. Med. 377(12):1111–14, https://www.nejm.org/doi/full/10.1056/NEJMp1707409
4 https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive
5 https://www.cdc.gov/tobacco/php/data-statistics/smoking-cessation/
6 Ibid.
7 https://pmc.ncbi.nlm.nih.gov/articles/PMC6395133/

quit by a healthcare practitioner in the previous year.[8] Moreover, fewer than 4 in 10 adults who smoke cigarettes used proven treatments—counseling or medication approved by the U.S. FDA—when trying to stop smoking.[9]

"The message is, if you don't smoke, you ought not start. If you do smoke, you ought to quit. Now, sadly, that's kind of where it has stopped from an education standpoint," said Dr. Tom Price, former U.S. Secretary of Health and Human Services (HHS) and current adviser to PMI U.S. For those who don't quit, Price advised, "You ought to change how you consume nicotine."[10]

REDUCED HARM STRATEGIES

Harm reduction is a pragmatic public health strategy focused on reducing risks associated with a range of behaviors—recognizing that not everyone is ready or able to cease engaging in the harmful behavior.[11]

Consider the use of bicycle helmets. Wearing one doesn't eliminate the risk of injury. But it reduces the likelihood of an injury to a vital part of the body so that people can continue to ride bicycles. We can see the same principle at play with car seatbelts, condoms (for the prevention of sexually transmitted diseases), and the medication-assisted treatment of drug addiction.

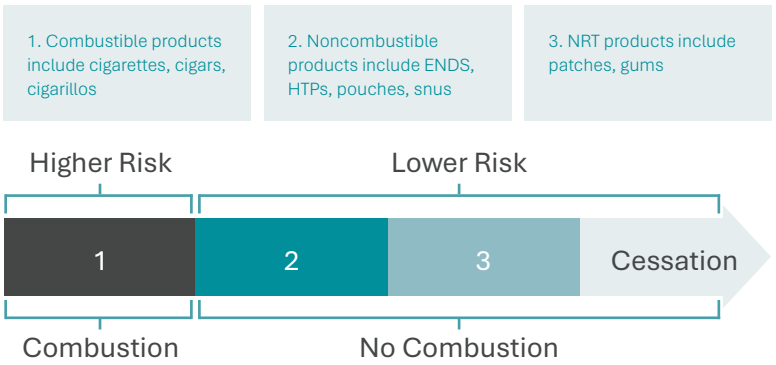
In the case of cigarette smoking, harm reduction involves complementing traditional tobacco control measures (e.g., strict labeling requirements, bans on sales to minors, restrictions on advertising and smoking in public places) with approaches that are likely to accelerate the decline in smoking frequency, intensity, and prevalence, thereby creating the potential for a reduction in smoking-related disease and death.

Tobacco harm reduction is supported by mounting scientific evidence on the harm reduction potential of smoke-free products compared with cigarettes.[12]

Why are smoke-free products a better choice than combustible cigarettes?

Smoke-free products don't burn tobacco, and so they don't release the high levels of harmful and potentially harmful chemicals (HPHCs) found in cigarette smoke. There is a growing body of independent research, including from numerous government agencies across the world, that demonstrates that smoke-free products can significantly reduce the average levels of HPHCs emitted compared with cigarettes, highlighting their potential to contribute to tobacco harm reduction.[13]

Risk cliff between combustible and noncombustible products[14]



ENDS: electronic nicotine delivery systems; HTPs: heated tobacco products; NRT: nicotine replacement therapy

8 https://www.cdc.gov/tobacco/php/data-statistics/smoking-cessation/
9 Ibid.
10 Transcript, Science Over Stigma: Rethinking Nicotine & Harm Reduction Conference, The Hill, May 21, 2025, Washington, D.C
11 https://harmreduction.org/about-us/principles-of-harm-reduction/
12 U.S. Food and Drug Administration (FDA), 2017; Public Health England (PHE), 2017; New Zealand
13 https://www.pmiscience.com/en/research/independent-studies/
14 https://www.pmiscience.com/en/smoke-free/harm-reduction/

Smoke-free products use a variety of technologies. For example, e-cigarettes heat a nicotine-containing liquid to produce an aerosol, which is inhaled. Snus and nicotine pouches contain nicotine (either through tobacco or a nicotine powder), which is absorbed when the user places the pouch between their upper lip and gums. Heated tobacco products heat tobacco instead of burning it, producing a nicotine-containing aerosol that is fundamentally different from cigarette smoke.

Why do smoke-free products contain nicotine?
Nicotine is an integral part of the tobacco harm reduction equation. People should be encouraged to quit, but not everyone does, and some legal-age consumers choose to continue using nicotine. To reduce harm, it's not enough to produce better alternatives to cigarettes. Adults who smoke need to be willing to switch to them, and that requires products that satisfy their preferences, including for nicotine.

Because nicotine is one of the reasons people smoke cigarettes, its presence in smoke-free alternatives can help adults switch to these products instead of continuing to smoke.

Do smoke-free alternatives help adults stop smoking?
Smoke-free alternatives are not intended as nicotine cessation aids, and people who wish to quit should be counseled by their healthcare providers on available options such as nicotine replacement therapies. Smoke-free products are only intended for those legal-age consumers who choose to continue using nicotine products and are looking for better alternatives to cigarettes.

Philip Morris International (PMI) studies the people who use its heated tobacco, also known as heat-not-burn (HnB), products over time to see whether they smoke fewer cigarettes or stop

smoking entirely. Studies in Italy, Japan, and Germany—markets where PMI has sold its heated tobacco products for many years—show that only 1–2 percent of current users of its HnB products "relapsed" or reinitiated cigarette use.[15] Most users no longer smoke cigarettes at all. As of December 31, 2024, there were 32.2 million users of PMI's heated tobacco products globally; of these, 23.2 million—or 72 percent—had switched completely and *stopped smoking*.

Are there independent studies of smoke-free alternatives to cigarettes? Who pays for these studies?

There have been many studies—more than 750, by our count—of smoke-free alternatives to cigarettes conducted by independent scientific or government agencies and organizations.[16] *Independent* means that they are not sponsored, supported, or subsidized by the industry, but PMI does provide data on its products when asked. Studies conducted by Public Health England, the Committee on Toxicity (U.K.), the Dutch National Institute for Public Health and the Environment, the German Federal Institute for Risk Assessment, the Superior Health Council of Belgium, and the U.S. Food and Drug Administration, to name a few, demonstrate that heated tobacco products, while not risk-free, expose users to significantly lower levels of harmful chemicals compared with cigarettes.[17]

Is there a stigma attached to alternatives to cigarettes that contain nicotine?

Definitely. Politicians and policymakers accept the notion of harm reduction in principle and typically acknowledge that smoke-free products are a better alternative than continuing to smoke. Nevertheless, long-standing skepticism toward the tobacco industry leads to resistance in some cases and to what some might characterize as an overreliance on the so-called "precautionary principle."

"This is often true for innovative products, that people's worries and fears get in the way of adopting them," said Michael Mandel of the Progressive Policy Institute. "We're seeing a similar pattern right here, where we have these products which are clearly beneficial, which clearly can help move people from sort of high-risk activities towards lower-risk activities, and it's hard to make that case to people."[18]

Strict adherence to the precautionary principle can significantly delay progress. It helps to explain, for instance, why the U.S. is behind many other countries in introducing scientifically validated smoke-free products and encouraging their use by legal-age smokers as a better alternative to combustible cigarettes. Dr. Brad Rodu of the University of Louisville cites the consequences of this slow acceptance:

> In the United States, there are around 37 vaping products that have been authorized for sale, which means the FDA has reviewed the applications and said the benefits of these products outweigh what we think might be the potential risks. In the U.K., there are 50,000-plus vaping products on the Medicines and Healthcare products Regulatory Agency's registry. They can be legally sold. And the problem with the current system as we have it with FDA, the applications and so on, is that instead of being a path to innovation, as was originally envisaged in the Tobacco Control Act, to have new products come to market that can help people quit smoking, it's acted in reality far more as a bottleneck, really squeezing and tightening innovation, so only a very few products [receive authorization], often [ones] that are out of date and many people don't use.[19]

15 https://tobaccocontrol.bmj.com/content/29/4/381
16 https://www.fda.gov/tobacco-products/products-ingredients-components/how-are-non-combusted-cigarettes-sometimes-called-heat-not-burn-products-different-e-cigarettes-and
17 Ibid.
18 Transcript, Science Over Stigma: Rethinking Nicotine & Harm Reduction Conference, The Hill, May 21, 2025, Washington, D.C.
19 Ibid.

WHAT MEDICAL PROFESSIONALS KNOW AND BELIEVE

It's clear that healthcare providers in the U.S. have strong levels of familiarity with traditional tobacco products. Most express confidence in discussing these products with their patients—everyone knows smoking is harmful.

But do they have all the facts?

Our survey shows that they do not. In particular, far too many medical professionals misunderstand the risks of nicotine in isolation from the risks of smoking. They are also unaware of which new nicotine alternatives the FDA has authorized. Consequently, they are not in a position to share complete and accurate information with their adult patients who smoke.

The good news is that medical professionals are eager for change. They want to see real reform of the FDA and to receive science-based guidance that will allow them to have informed discussions with their patients.

Here's what our study found:

NICOTINE

The survey found that 47 percent of medical professionals incorrectly thought nicotine causes cancer, while 19 percent were unsure. Only 34 percent correctly indicated that nicotine is not a carcinogen.

Among the different types of medical professionals surveyed, primary care physicians were least likely to misidentify nicotine as a carcinogen, but even among these practitioners, 41 percent mistakenly believed nicotine causes cancer.

Members of every other medical profession surveyed—including general and mental health nurses, cardiologists, oncologists, pulmonologists, and licensed social workers, among others—were more likely than not to think that nicotine is a carcinogen.

Despite this confusion, medical professionals as a whole recognize that cigarettes are more harmful than noncombusted tobacco or nicotine products, such as heated tobacco products, e-cigarettes, nicotine pouches, and nicotine replacement therapies. However, their sense of the harm caused by certain nicotine products (e.g., heated tobacco products, nicotine pouches) versus cigarettes is far higher than the scientific data would suggest.[21]

> "For the hundreds of millions of adult smokers who don't stop smoking, proper understanding of the role of nicotine and of the smoke-free category is critical. Accurate and non-misleading communication, increased awareness, and better options for adults who would otherwise continue to smoke will help [accelerate] the end of cigarettes."[19]
>
> —Dr. Matthew Holman, Chief Scientific and Regulatory Strategy Officer, PMI U.S., and former Director of the Office of Science at the FDA's Center for Tobacco Products

Implication: *A significant majority of medical professionals don't know that nicotine is not the primary cause of smoking-related diseases and is not a carcinogen. That means they don't understand the reduced-harm potential of legal-age consumers switching to smoke-free alternatives if they choose not to quit nicotine altogether.*

WHAT MEDICAL PROFESSIONALS SHARE WITH THEIR PATIENTS WHO SMOKE

As noted, nearly half of medical professionals mistakenly characterized nicotine as a carcinogen, a cause of cancer. Even more troubling, this figure rose to nearly 6 in 10 (59 percent) among practitioners who see a lot of patients who smoke.

Implication: *Most of the medical professionals best positioned to educate adult smokers about better alternatives don't understand that nicotine is not a carcinogen, negatively impacting their ability to provide fully informed counsel.*

20 Transcript, Science Over Stigma: Rethinking Nicotine & Harm Reduction Conference, The Hill, May 21, 2025, Washington, D.C.

21 https://www.accessdata.fda.gov/static/searchtobacco/ZYN/PMTA_TPL_PM593-PM612_Zyn_01_13_2025_Redacted.pdf

How often do medical professionals discuss better alternatives to cigarettes? Not often enough.

Only one in five medical practitioners (21 percent) said they "always" have conversations about smoke-free products with their cigarette-smoking patients, while one-third (35 percent) said these conversations happen "most of the time." The plurality (43 percent) only have these conversations "sometimes."

Implication: *Patients 21+ who smoke cigarettes don't hear enough from their medical providers about FDA-authorized smoke-free products that would be a far better choice than continued cigarette use.*

NEW PRIORITIES AT THE FDA

Medical professionals want the U.S. Food and Drug Administration to set new priorities, especially when it comes to helping legal-age cigarette smokers access and understand the better alternatives now available to them.

Nearly 9 in 10 practitioners (86 percent) said they consider the FDA a trusted source of information about tobacco and nicotine products and the science behind them.

Seventy-seven percent of medical professionals said that addressing smoking and tobacco use should be a "high priority" for the U.S. government, ranking it just below chronic diseases (90 percent) and mental health issues (79 percent).

Ninety-three percent of medical professionals surveyed agreed with the statement: "When the FDA began regulating tobacco products in 2009, e-cigarettes and nicotine pouches were not on the market. To better protect public health, reform of the FDA is needed so the agency can regulate these products appropriately."

An equal percentage (93 percent) believe the FDA has an obligation to convey information to medical professionals if it finds that a specific smoke-free product presents less risk of cancer, cardiovascular disease, or chronic obstructive pulmonary disease (COPD) compared with continued smoking. Among these medical professionals, nearly all (95 percent) indicated that they would convey this information to their patients.

> "[Physicians] have very limited bandwidth. Physicians don't really have the time to have the conversation unless they are given very clear and concrete guidelines [in formats they prefer]."[21]
>
> —Dr. Pritika Kumar, Director, Scientific Engagement, PMI U.S.

Sixty-seven percent of practitioners said the FDA should dedicate more time and resources to reviewing and authorizing new smoke-free alternatives to cigarettes; 66 percent said the FDA should do more to issue rules and guidance for making, distributing, importing, and selling tobacco and nicotine products.

Fifty-seven percent of practitioners said it would be helpful if the agency shared with them information about FDA-authorized smoke-free products, including the products' intended use and populations for whom they would be appropriate. A similar share (62 percent) said they want the FDA to share evidence-based comparisons of the relative risks of smoke-free products versus cigarettes, and 48 percent said they want the agency to create a centralized platform

22 Ibid.

or database with real-time updates on smoke-free product authorizations and research.

Implication: *Medical professionals trust the FDA and want more information and guidance from the agency regarding smoke-free alternatives to cigarettes.*

> Many [smoke-free products] were not even on the market when FDA started regulating tobacco products in 2009. The science has evolved, but the provider education, the public's understanding, and the regulation all have lagged."[22]
>
> —Dr. Pritika Kumar, Director, Scientific Engagement, PMI U.S.

% of healthcare providers believing this type of information would be helpful to receive from the FDA	
Clinical evidence that demonstrates the role of smoke-free products in harm reduction	**69%**
Clear guidelines on counseling patients about transitioning to smoke-free alternatives as part of a harm reduction strategy	**68%**
Evidence-based comparisons of the relative risks of smoke-free products versus cigarettes	**62%**
Public awareness campaigns for smokers about where different tobacco and nicotine products fall on the FDA's continuum of risk	**58%**
Information on FDA-authorized smoke-free products, including their intended use and populations for whom they may be appropriate	**57%**
Updates on the FDA's regulatory framework for assessing smoke-free products and their health impacts	**53%**
A centralized platform or database with real-time FDA updates on smoke-free product authorizations and research	**48%**
FAQs addressing common myths or misconceptions about smoke-free products and their risks	**45%**
Patient-friendly educational materials that healthcare providers can share in clinical settings	**39%**
Training modules or resources designed specifically for healthcare providers on tobacco harm reduction	**36%**

About the Survey: Povaddo LLC fielded the Tobacco Harm Reduction: U.S. Medical Professionals Survey among 1,565 medical professionals, including primary care physicians, cardiologists, oncologists, pulmonologists, social workers, dentists, psychiatrists, and general and mental health nurses, across the United States between March 10 and April 5, 2025. PMI U.S. funded the study.

23 Transcript, Science Over Stigma: Rethinking Nicotine & Harm Reduction Conference, The Hill, May 21, 2025, Washington, D.C.

OPPORTUNITIES FOR IMPROVED EDUCATION AND UNDERSTANDING

Medical professionals are eager to stay up to date on the latest science regarding tobacco and nicotine and to share that information with their patients who smoke. Time and again, we have seen that when there is a consistent and credible effort to inform providers about the best way to support public health, they become champions of good information and care.

WHAT MEDICAL PROFESSIONALS NEED TO KNOW

There are several core messages medical professionals need to learn to help their patients aged 21+ who smoke:

Combustion is the primary cause of smoking-related disease.
There are many ways to stop using cigarettes, and the best

choice is to quit tobacco and nicotine completely. Medical professionals already have a range of therapeutic options available to recommend to their patients for smoking cessation, such as nicotine patches, gums, lozenges, inhalers, behavioral counseling, and prescription medications. However, many smokers have attempted to stop or reduce smoking at least once, if not multiple times, without success using these therapeutic products. We understand everyone is different, and for adults 21+ who are not ready to stop using nicotine completely, practitioners should look to alternative products that provide nicotine without the burning of tobacco.

Nicotine is not a carcinogen ...

The most common smoking-related diseases are lung cancer, cardiovascular disease, and emphysema—and nicotine alone is not the main cause of any of them. These diseases are caused primarily by inhaling harmful compounds formed when tobacco is burned.

... but neither is it risk-free.

Nicotine is not risk-free, and it is addictive. It alters the brain's reward and stress systems, and repeated exposure over time can lead to temporary withdrawal symptoms such as feelings of anxiety, difficulty concentrating, and dysphoria (a feeling of unhappiness, dissatisfaction, or frustration).[24]

Certain people—including those who are pregnant or breastfeeding or who have heart disease, severe high blood pressure, or diabetes—should not use tobacco or nicotine-containing products. Minors, in particular, should not have access to nicotine-containing products.

Doctors and Other Medical Professionals Want to Share Accurate Information

Our survey, in line with the broader scientific literature[25], shows that, whatever misunderstandings doctors and other medical professionals have about nicotine, they want the facts. "My fellow colleagues out there who practice in medicine, they are clamoring for more information," said Dr. Tom Price, former U.S. Secretary of Health and Human Services and current adviser to PMI U.S., in reaction to the survey. "I think in their heart, they know that they haven't been brought up to speed on the kind of science that's out there right now and these new products. And they have said, explicitly, that if the FDA would actually give them the information, they would utilize it and let their patients know this information."[26]

Medical professionals deserve to have all the facts about nicotine, FDA-authorized alternatives to cigarettes, and anything else that will help their patients.

24 https://pmc.ncbi.nlm.nih.gov/articles/PMC6135092/

25 https://pubmed.ncbi.nlm.nih.gov/34300168/
26 Transcript, Science Over Stigma: Rethinking Nicotine & Harm Reduction Conference, The Hill, May 21, 2025, Washington, D.C.

U.S. FOOD & DRUG ADMINISTRATION

THE FDA'S CRITICAL ROLE

Medical professionals are looking to the FDA and other public health authorities for the latest and best guidance on how to help their patients stop smoking cigarettes. They want more information about FDA-authorized products that have been shown to protect or promote public health for people aged 21+ who smoke. And they want more information about the relative risks of smoke-free products compared with continued smoking.

Medical professionals trust the FDA—and they want the agency to deliver against these expectations.

We agree: Adult smokers deserve a range of FDA-authorized smoke-free products that are acceptable, available, and affordable. Americans need a regulated market of authorized smoke-free products, accurate information for adults who currently smoke, and a continued focus on under-21 access prevention.

As former HHS Secretary and current adviser to PMI U.S. Dr. Tom Price has put it: "Science ought to be dictating our policy. And sadly, from a health standpoint, science hasn't dictated policy in the area of tobacco consumption, especially with smoke-free products."[27]

> Information is powerful, information is key, and we have to do everything we can to get it out there. And when we do so, I believe that the facts are going to stand for themselves. As we move from smoke-based to smokeless products [...] that's going to reduce the harm [caused by] tobacco across this country. And it's a meaningful step that we need to take, a gigantic step that we need to take for the American people."[27]
>
> —Representative Don Davis, Co-Chair, Congressional Tobacco Harm Reduction Caucus

PMI U.S. favors a strong FDA that regulates the tobacco industry and nicotine-containing products in a way that best reduces harm. We want the FDA to efficiently review new products for safety and efficacy and regularly authorize products that meet the agency's rigorous standards. We support any effort—especially at the FDA—to strike the right balance between sensible regulation and encouraging the availability of innovative nicotine products that have been shown to be less harmful than continuing to smoke.

"There's bipartisan support for this," said former U.S. Representative Larry Bucshon, who is a physician. "I don't think risk mitigation for combustible cigarette smoking is something that is a partisan issue. [...] You have to find champions and leadership—people willing to stick their neck out a little bit and say, 'OK, we have to address this.' And then we need to get the FDA and the leadership there to recognize that we need to do something about it."[29]

The American public agrees.

In 2024, PMI commissioned a poll of 2,000 American voters aged 21+,[30] which showed that Americans want more from the FDA, including in how it regulates the tobacco industry and new nicotine products. Strong majorities expressed support for FDA reform.

- Respondents said the government's top public health priorities should include improving mental health services (86 percent), encouraging healthier eating and more exercise (71 percent), and reducing cigarette smoking (61 percent).
- Only one-third (33 percent) said the FDA has been focused on what should be the nation's most important public health priorities.
- Nearly three-quarters (74 percent) agreed that real reform of the agency is needed to ensure it is focused on developing policies that will help Americans live longer, healthier lives.
- 68 percent agreed that American smokers should have access to a wide range of smoke-free, nicotine-containing alternatives to cigarettes to help them abandon cigarettes for good.
- Most medical providers (57 percent) agreed that FDA-authorized smoke-free alternative products should be

27 Transcript, Science Over Stigma: Rethinking Nicotine & Harm Reduction Conference, The Hill, May 21, 2025, Washington, D.C
28 Ibid.
29 Ibid.
30 Survey commissioned by PMI and conducted by RG Strategies and Peak Insights among 2,000 likely November 2024 voters aged 21 and older; https://www.pmi.com/us/voters-support-reforming-the-FDA

available in a range of flavors to encourage adult smokers to use these products instead of cigarettes. [In PMI's view, this should not extend to flavors (e.g., candy flavors) that are particularly appealing to youth, who should never access nicotine products.]

FDA reform that delivers against these expectations will do more to prevent youth use of tobacco and nicotine products, reduce access to illicit and potentially unsafe products, support research into the efficacy of products with the potential to reduce harm compared with continued cigarette use, and make smoke-free products more readily available to legal-age smokers looking for a better alternative to combustible cigarettes.

PMI U.S. also supports a U.S. FDA that serves as a central platform for real-time updates on smoke-free product authorizations and research. The agency should be an authority clinicians can go to with questions and receive care guidelines for treating cigarette smokers aged 21+ who want to make better choices.

OUR POSITION

Globally, Philip Morris International is focused on its mission to stop selling cigarettes. In the United States, the company has never sold combustible cigarettes and is working to move America's ~30 million adults who still smoke to FDA-authorized, smoke-free alternatives.

The best choice for anyone who smokes is to quit nicotine use altogether. However, those adults 21+ who do not quit deserve better alternatives.

OUR PARTICIPATION IN THE REGULATION OF NICOTINE PRODUCTS

Many countries have updated their regulatory frameworks to reflect the introduction of innovative smoke-free alternatives. Countries that do this typically differentiate these products from combustible tobacco products via different health warnings, flavor and packaging requirements, or similar measures. This is because not all tobacco products are equally harmful,[31] and regulatory bodies want their rules to regulate in proportion to risk.

In 2018, the U.S. Food and Drug Administration announced a strategic plan to address smoking by increasing restrictions on cigarettes and allowing "greater flexibility" for alternative noncombusted products.[32]

PMI participates in the FDA's processes that authorize new tobacco and nicotine products for marketing and sale in the

31 https://www.annualreviews.org/content/journals/10.1146/annurev-publhealth-040617-013849
32 https://www.fda.gov/about-fda/reports/healthy-innovation-safer-families-fdas-2018-strategic-policy-roadmap

U.S., and several of its products have been authorized. (As of June 1, 2025, PMI holds the distinction of having the most smoke-free products authorized by the agency.)

In addition, the FDA decides whether a particular nicotine product may be marketed with modified health risk claims. For example, in 2019, the FDA issued a decision regarding eight snus smokeless tobacco products marketed by Swedish Match USA—now a PMI company—under the *General* brand name.[33] The FDA authorized the marketing of these products with the claim, *"Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."*

And in 2022, the FDA authorized *IQOS 3.0* with the following reduced exposure information:

- *"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."* [34]

Also in 2022, the U.S. Congress passed a law clarifying the FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine. Similar to tobacco products, such as cigarettes and smokeless tobacco, such products can only be legally marketed in the U.S. if they are authorized by the FDA. Unfortunately, this has not prevented illicit products that ignore or evade FDA authority from reaching consumers.[35]

33 https://www.prnewswire.com/news-releases/fda-grants-first-ever-modified-risk-orders-to-eight-smokeless-tobacco-products-300943113.html#:~:text=In%20particular%2C%20the%20available%20scientific,%2C%20emphysema%2C%20and%20chronic%20bronchitis.

34 https://www.fda.gov/tobacco-products/ctp-newsroom/fda-authorizes-reduced-exposure-claim-iqos-3-system-holder-and-charger

35 https://www.reuters.com/business/retail-consumer/illegal-us-vape-sales-worth-least-24-billion-2024-data-shows-2025-02-24/

CONCLUSION

Philip Morris International has long viewed scientific innovation as critical to ending smoking and has spent billions of dollars developing smoke-free products that have demonstrated their value as potentially lower-risk alternatives to cigarettes.

In the United States, the next challenge is making sure the most important advisers to legal-age adults who smoke—their physicians or other medical providers—are aware of the facts about innovative, FDA-authorized nicotine alternatives. PMI U.S. will do its part to share the science behind these products, but the most trusted source of information is—and ought to be—the Food and Drug Administration.

Currently, the FDA isn't doing nearly enough to ensure that medical professionals have up-to-date and unbiased facts about smoke-free products. Consequently, far too many healthcare providers don't know the facts about nicotine and the role of combustion in disease. They don't know which products have been reviewed by regulators for safety and efficacy. They don't know that using a noncombustible product would be a far better choice than continuing to smoke for their patients aged 21+.

These are critical pieces of information in the fight to end the harm of cigarettes. It is urgent that the FDA get the word out so that medical professionals, in their role as trusted advisers, can offer fact-based guidance to their adult patients who smoke and help them move away from combustible cigarettes, which are by far the most harmful way to consume nicotine.

That is the future PMI U.S. is working toward and invested in. We call on the FDA to do its part, for the benefit of America's ~30 million legal-age smokers and public health.

"PMI U.S.," "we," "our," and "us" refer to Philip Morris International's U.S. family of businesses. References to "PMI" mean Philip Morris International Inc. and all its subsidiaries globally.

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