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for public health in America

TOBACCO HARM REDUCTION

follow the science. find the facts.

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No tobacco product is safe, all tobacco products containing nicotine are addictive. Youth should never use tobacco. Smokers who are concerned about their health should quit.

the opportunity before us



Priscilla Samuel, PhD

A Letter From Our
Executive Vice President
of Scientific Research
& Development

Tobacco Harm Reduction (THR) has been defined as “minimizing harms and decreasing total mortality and morbidity, without completely eliminating tobacco and nicotine use.”¹

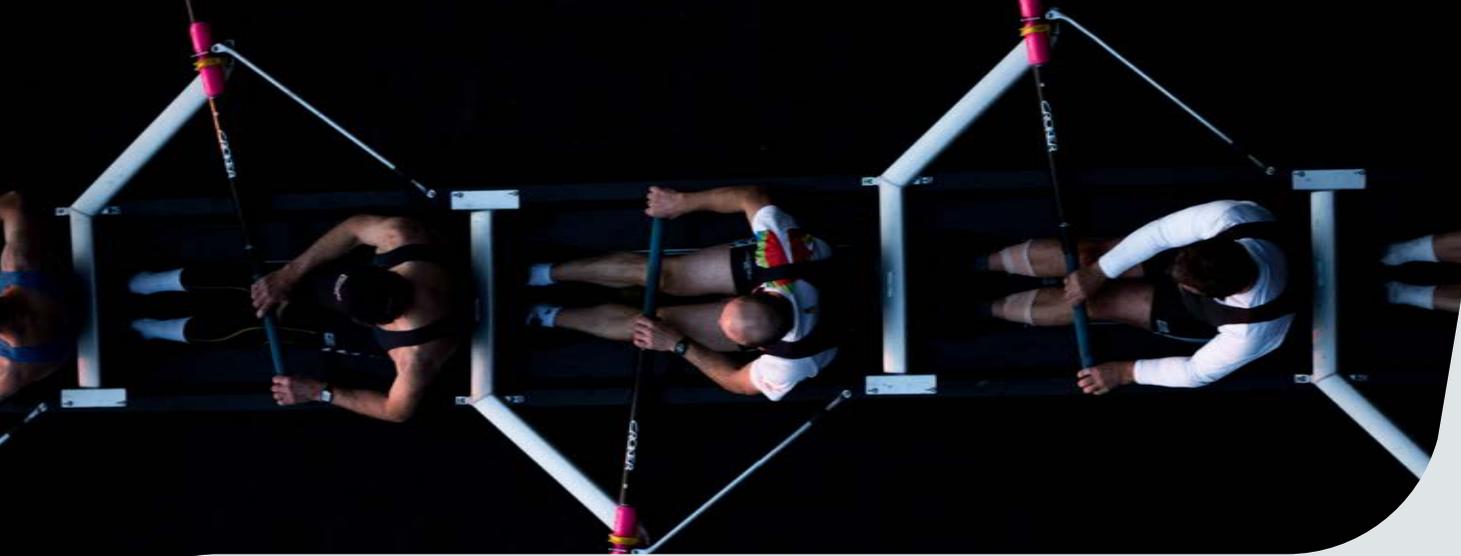
Conceptually, THR recognizes that while abstinence or never smoking tobacco is ideal, chasing zeros may not be realistic. Therefore, it accepts that there are alternate ways to reduce the harm caused by combustible tobacco use – by encouraging adult smokers who are uninterested in quitting tobacco altogether to switch to potentially less risky noncombustible alternative products. Whilst some skepticism exists, THR is a movement that is gaining meaningful momentum globally and can become a powerful public health strategy with the right support from all stakeholders. I believe it is one of the greatest public health opportunities we have worldwide because it is about reduced risk to the individual adult smoker and the impact on the community and society.

Public health has always been a top priority for me. When I obtained my doctorate in the Life Sciences arena, I minored in public health. Throughout my professional career, I have worked on a number of products and ingredients that have contributed to improved health and reduced the risk of disease. In the THR space, I remain fascinated by the impact that evolving science and innovation can have on public health as well as the critical task of educating and providing access to potentially less risky alternatives to those adult smokers who are uninterested in quitting tobacco altogether. Over the past 20 years, the industry, through science and innovation, has made progress on developing noncombustible product alternatives, including vapor products, tobacco heating products, and smokeless oral tobacco and nicotine products. Despite the progress of science and innovation,

there is much to be done. Although smoking rates are at historic lows, there are over 1 billion cigarette smokers globally and over 30 million cigarette smokers in the U.S. alone.^{2,3} Modeling suggests that under current patterns in the U.S. “[nicotine vaping products] use in the population will translate to [many]...deaths avoided...”⁴ Therefore, advancing THR could deliver one of the most monumental and sustainable public health achievements of our time.

THR is a global movement with many countries around the world implementing bespoke initiatives to decrease smoking rates. Data out of Sweden, Japan and the United Kingdom (UK) are promising as these countries have seen historic decreases in smoking rates.”^{5,6,7} These initiatives include publicly funded health education, reduced taxes for alternative products, and regulations that allowed for the accessibility and affordability of potentially less risky alternative products.

The future will be determined by public-private partnerships that can and should be forged across industry, scientists, policy makers, consumer advocates, public health community, healthcare professionals, and regulators who effectively galvanize towards one cohesive and collective goal – to reduce the harm from combustible tobacco use and improve public health. The stakes are too high to ignore and the task is too large for any stakeholder to tackle alone. We need to foster informed dialogue around scientific, evidence-based information and collectively define the standards and milestones that represent a clear improvement in public health. I am confident we can all work together towards achieving the common goal of benefiting public health.



building momentum

Since 1970, the rate of adult smoking has fallen more than 70 percent in the US.⁸ However, of those adults that still use tobacco products, including noncombustible products, more than 79% use combustible cigarettes.⁹ That number will likely remain high if there is a lack of access to potentially less risky product alternatives for those adult smokers who are uninterested in quitting tobacco altogether.

THR has existed for decades and started building momentum in 2001 when the Institute of Medicine, which is now the National Academy of Sciences, Engineering and Medicine, published its seminal publication “Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction.” The authors concluded that, “The potential for reduction in morbidity and mortality that could result from the use of less toxic products by those who do not stop using tobacco justifies inclusion of harm reduction as a component in a broad program of tobacco control.”¹⁰

Since 1970, the rate of adult smoking has fallen more than 70 percent in the US.

The combustion of tobacco, or more simply, the burning of a cigarette, is the major source of the burden of disease and death from tobacco use. While nicotine is not without risk, the longstanding scientific

consensus is that while nicotine is addictive, it is not the direct source of adverse health outcomes associated with combustible cigarette smoking. As former Food and Drug Administration (FDA) Commissioner Scott Gottlieb explained in 2017, “The nicotine in cigarettes does not directly cause tobacco-related cancer, lung disease or heart disease.”¹¹

If combustion, or burning of the tobacco, is the major source of harm from combustible cigarette smoking, how can we support adult smokers who are uninterested in quitting tobacco altogether?

A growing body of research and innovation supports the development and use of noncombustible technologies and products thus providing adult smokers acceptable alternatives to combustible cigarettes. Science-based evidence is continuously being gathered to support the reduced harm potential of these noncombustible alternative tobacco products.

It is time for all stakeholders to conduct an objective review of the literature and create the necessary framework of how we can better advance THR as a public health strategy.

harm reduction is a proven effective strategy

The concept of harm reduction is not new.

Harm reduction is the strategy of reducing negative consequences of inherently risky behavior.

Seat belts, for example, are a harm reduction strategy implemented to reduce the likelihood of death from car accidents. Safety goggles in the laboratory, personal protective equipment in healthcare settings, and hard hats on construction sites are just a few examples of harm reduction in our everyday lives.

Over the years harm reduction has served as an important counter in recurrent policy discussions regarding regulation governing potentially harmful behavior. Harm reduction is a better alternative to another prevailing yet ineffective public health philosophy regarding risky behavior — prohibition and government bans.



why harm reduction is better than prohibition

Prohibition follows the belief that by outlawing a particular substance or activity, one can effectively eliminate its negative societal impact. Policy makers and regulators have introduced and enacted hundreds of prohibitive policies in an attempt to curtail or eliminate harmful consumer behaviors. One major example of prohibition that proved to be unsuccessful was the prohibition of alcohol in the 1920s and 30s.

Prohibitive policies such as bans not only fail to stop consumers from using the prohibited substance, but they also lack the ability to benefit adult smokers who are uninterested in quitting tobacco products altogether. Prohibition can lead to a rise of illicit markets, increased smuggling, or product adulteration, all of which puts consumers at risk with more unregulated products and creates a strain on the criminal justice system. In 2020, Massachusetts banned the sale of flavored tobacco products, including menthol cigarettes, and there was an increase in cigarette sales in neighboring states in the four months following the ban, suggesting that consumers did not quit smoking, they likely just went elsewhere to purchase them.¹² In 2020, South Africa implemented a five-month ban on tobacco sales that resulted in an illicit market that accounted for 54% of the cigarette market after the ban ended, up from 30-35% in 2017.¹³

Harm reduction follows the logic that educating consumers and providing them with access to potentially less harmful products, promotes positive behavior changes, reduces individual risks, and ultimately yields genuine strides in public health.

Take for example the use of motorcycle helmets. Riding a motor vehicle, especially a motorcycle, is an inherently risky behavior. Instead of prohibiting or banning motorcycles, policies that advocated helmet use for operators helped reduce the risk. According to studies by the National Highway Traffic Safety Administration (NHTSA), helmet policies have been effective. NHTSA analyses “indicate that universal helmet use laws are effective in increasing helmet use, which reduces injuries, decreases hospital admissions and treatment costs, and lowers insurance claims. Studies in states that enacted universal helmet laws observed use rates of 90% or higher immediately after the laws became effective, compared to 50% or lower before the laws.”¹⁴

This approach is the basis for THR – instead of prohibiting or banning the risky product, it is important to provide access, through regulation and market authorization, to noncombustible alternatives so that individuals can make an informed choice.

Over the years harm reduction innovations and pragmatic approaches to policy have proved their value as a powerful counterweight to prohibition.

the misperceptions of nicotine

Advancements in THR are hampered by the public misunderstanding of the absolute and relative risks posed by different tobacco products, particularly when it comes to nicotine exposure. Researchers from Brown University recently observed —

“...misperceiving nicotine as a primary cause of smoking-related diseases may be associated with reduced cessation success and lower likelihood of using less harmful nicotine products.”¹⁵

A 2016 study using data from Health Informational National Trends Survey (HINTS-FDA 2015) found that three fourths of Americans incorrectly attribute nicotine as the root cause of the health risks associated with smoking.¹⁶ Evidence suggests that a majority of physicians also carry incorrect assumptions about nicotine. According to a 2021 survey of more than 1,000 doctors, “...the majority of physicians incorrectly ‘strongly agreed’ that

nicotine directly contributes to the development of cardiovascular disease (83.2%), COPD (80.9%), and cancer (80.5%).”¹⁷ The authors noted this study to be the first of its kind to document widespread nicotine misperceptions among physicians in the U.S. These results suggest a clear gap in science understanding that could result in health care providers not being adequately informed on the science of tobacco and nicotine, thereby lacking the ability to advise their patients on alternatives to combustible cigarettes.

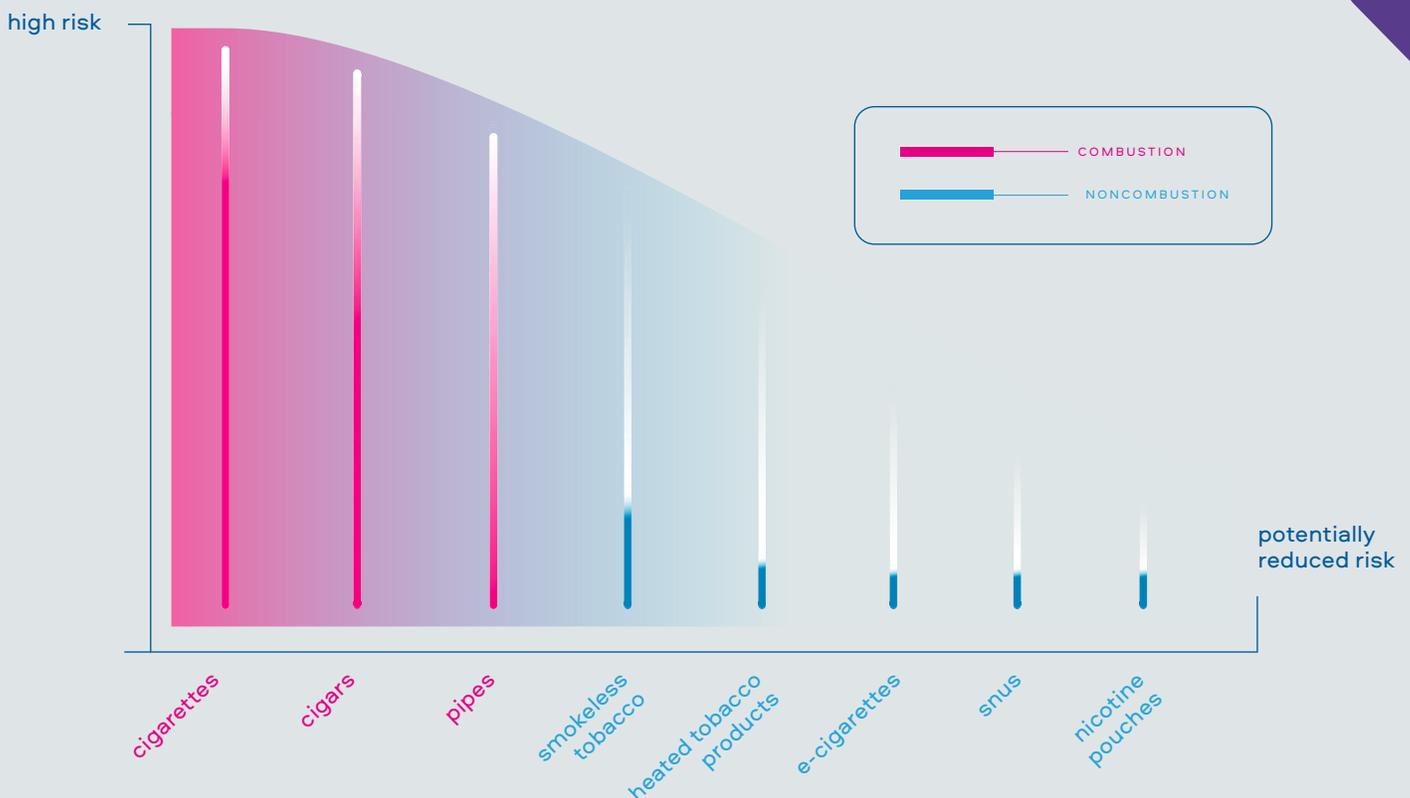
Nicotine is a naturally occurring compound. Tobacco plants contain the highest levels of naturally occurring nicotine, but it can also be found, at much lower levels, in potatoes, tomatoes and eggplants. Some research suggests that nicotine can stimulate the brain’s reward center, which can elevate mood, and improve cognitive function.^{18,19} But it’s important to note that nicotine is addictive and not risk-free.²⁰



noncombustible product alternatives

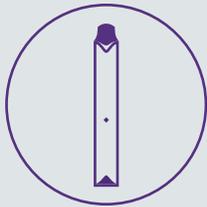
The FDA states that tobacco product categories containing nicotine pose different degrees of health risks to the consumer, referred to as the continuum of risk.²¹ Combustible products, or products that burn tobacco, are the most risky and other products, such as tobacco heating products, nicotine pouches, and e-cigarettes present potentially lower levels of risk. Adult smokers who are uninterested in quitting tobacco products altogether have the option to switch to potentially reduced risk product categories.

the risk continuum



*Image adapted from "Continuum of Risk for Nicotine Containing Products." Global State of Tobacco Harm Reduction, 2020

e-cigarettes



Electronic Nicotine Delivery Systems (ENDS), commonly known as vaping products, are battery-powered devices that heat e-liquid to produce an inhalable aerosol. E-liquid is drawn into the wick from a reservoir or tank and is then heated to form an aerosol when the consumer puffs on the product. The atomizer – the part that produces the vapor – consists of a tiny electric heater combined with a wick made from absorbent materials such as glass fiber, cotton, or ceramic. E-liquids either contain nicotine derived from tobacco or synthetic nicotine.

nicotine pouches



Nicotine pouches, often referred to as modern oral products, are smokeless, oral, tobacco leaf-free pouches that are placed between the gum and the lip to provide nicotine for absorption through the oral mucosa. The nicotine is often derived from tobacco and does not contain tobacco leaf. Adult nicotine consumers place the disposable pouch between their gum and lip during which nicotine and flavors are released.

smokeless tobacco products



Traditional oral products — also known as smokeless tobacco products — are those containing tobacco leaf and include portioned snus, loose moist, and portioned moist oral tobacco products, among others. Different from modern oral nicotine pouches, these pouches contain tobacco leaf. However, there is no combustion when using these products.

tobacco heating products



Tobacco heating products (THP) are products in which tobacco is heated and not burned to release nicotine and generate an aerosol. The burning of a normal cigarette can reach over 900°C but the heating chamber in an electronic THP heating chamber device reaches up to 260°C, which is not a high enough temperature to create combustion. The lower temperature can result in lower yields of harmful and potentially harmful constituents compared to combustible cigarette smoke.

Nicotine plays a role in helping adult smokers quit or switch to potentially less risky alternatives.²² The FDA has approved several nicotine replacement therapies (NRTs) that contain nicotine and are designed to help adults quit smoking. It is important for NRTs to exist in addition to noncombustible product alternatives particularly for those adult smokers who are uninterested in quitting tobacco products altogether. The UK's National Health Service (NHS) cites evidence that people who use e-cigarettes, together with expert face-to-face support, can be "up to twice as likely to succeed [at quitting] as people who used other nicotine replacement products, such as patches or gum."²³

challenges to tobacco harm reduction

In recent years misperception of THR, by adult smokers, regulators and the public health community has been one of the biggest obstacles to greater adoption of THR and noncombustible alternative products here in the U.S. In 2019 there was an outbreak of severe and fatal lung injuries that were initially linked to e-cigarette use. E-cigarette, or Vaping, product use-Associated Lung Injury (EVALI), resulted in 68 deaths. During the investigation, the Centers for Disease Control and Prevention (CDC) concluded that vitamin E acetate, used as an additive, in illegal tetrahydrocannabinol (THC) containing vaping products was “strongly linked to the EVALI outbreak”.²⁵ The CDC research analyzed lung samples from EVALI cases versus those without EVALI and identified vitamin E acetate in only those lung samples of EVALI patients.^{26,27} According to the CDC, “Vitamin E acetate usually does not cause harm when ingested as a vitamin supplement or applied to the skin. However, previous research suggests that when vitamin E acetate is inhaled, it may interfere with normal lung functioning.”²⁸ These illegal THC vaping products created widespread concerns and misperceptions and resulted in a 29% decline in e-cigarette sales across the United States according to Nielsen data.²⁹

Confusion around vaping, fueled by the EVALI outbreak, has caused many adult smokers to question whether to switch to vaping products. Following this outbreak, polling found that two thirds of adults viewed e-cigarettes as the culprit to the EVALI outbreak despite evidence stating otherwise.³⁰

“There is concern that the misleading EVALI name, coupled with the inaccurate communication surrounding it from the media and other sources, may be suppressing e-cigarette use by adult smokers who want to quit smoking, because of resulting fears of and/or stigma around using e-cigarettes.”

- From 2021 Letter to CDC Director signed by 75 experts²⁴

Misunderstanding the relative risks of noncombustible products, including vaping products, can lead to adult smokers continuing to use combustible cigarettes. Eliminating misperceptions requires following the science – science that was able to link EVALI to vitamin E acetate in illegal THC vaping products as the strongest potential cause for EVALI, as opposed to vaping nicotine.



preventing youth access and accelerating THR must be a priority

Youth should not use vapor or tobacco products of any kind, under any circumstances. Noncombustible alternative products should only be used by adult consumers. An adult that does not use any tobacco product should not start.

A continued focus on preventing youth access to tobacco and nicotine products must be a priority and as an industry, we are making progress on reducing youth tobacco access at retail locations. Data from the CDC's National Youth Tobacco Survey (NYTS) show rates of youth cigarette smoking is at an all-time low and youth vaping has declined from the historical high in 2019. The CDC data shows the rate of 'past 30-day youth vaping' has declined overall from 2019 to 2022. The percentage of high school students who reported vaping even one time in the prior 30 days was 14.1% in 2022. This is a decline in past 30-day vaping among high school students from 2019 (27.5%). CDC data for 2022 shows that among high school students overall, 4.2% report vaping daily as compared to 5.8% in 2019.^{30,31}

These CDC data suggest that youth cigarette prevalence has significantly declined without a corresponding increase in youth e-cigarette consumption. These data are encouraging, and it is critical for public health community and the industry to remain vigilant to keep these products out of the hands of youth.

Preventing youth access to tobacco products, including both combustible and noncombustible products is a major focus of THR, as is providing adult smokers who are uninterested in quitting access to potentially less risky products.

“With the reductions in [youth vaping] that we’ve seen, we’ve got an opportunity to ramp up our efforts related to the continuum of risk.”

Brian King, Director of the FDA's Center for Tobacco Products³²

Through education, enforcement of underage access laws, vigilance against unlawful products and continued collaboration among stakeholders, regulators, legislators and advocates, THR can accomplish both objectives for a better societal outcome.

THR around the world

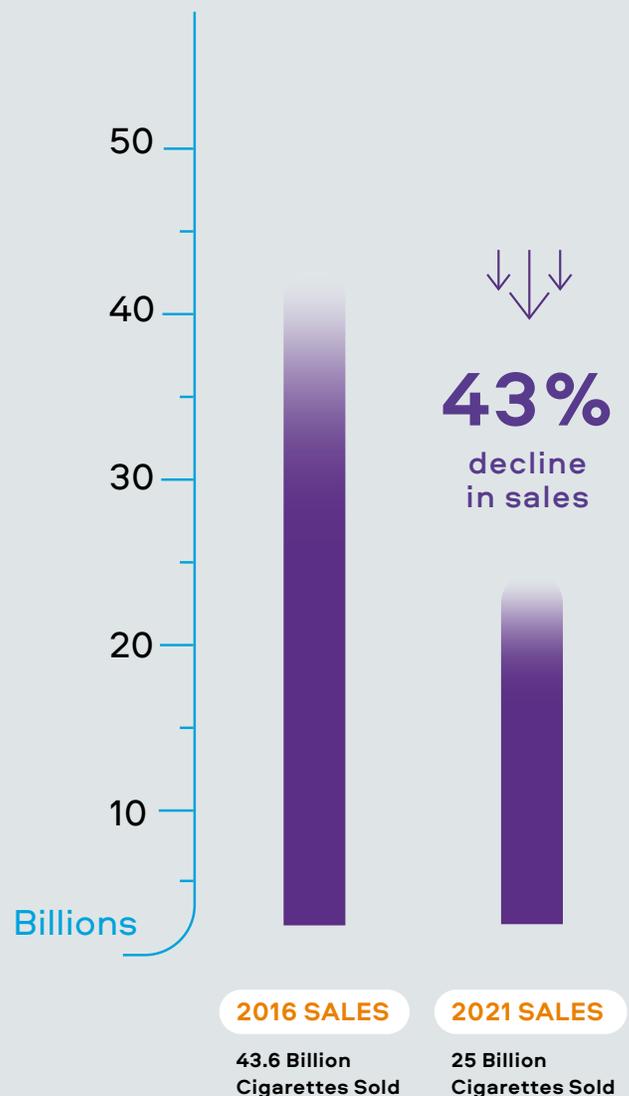
The opportunity to reduce the harm of combustible tobacco use is an international effort and there are many learnings from across the globe. Japan, the UK and Sweden are each on their own journey with THR and it is important to understand the specific policies that have led to their decreased smoking rates, while also noting that there is no one size fits all policy that addresses the specific circumstances of every country.

Japan

Japan has seen a rapid decline in combustible cigarette consumption due to the availability and access to tobacco heating products (THP), introduced in Japan in 2015. In the first quarter of 2016, domestic cigarette sales in Japan totaled 43.6 billion cigarettes. In that same quarter in 2021, total sales were 25 billion cigarettes, representing a 43 percent decline in five years. In that same year, THP held a 30 percent share of the total market.³³

Of those adult smokers who switched to THPs, 40% did so due to concern related to the health risks associated with second-hand smoke, 26% switched to reduce the numbers of combustible cigarettes smoked, and 26% switched in order to quit cigarettes.³⁴

Data out of Japan clearly shows that adult smokers, who were well-informed about the reduced risk potential of THPs versus combustible cigarettes, were able to make informed choices in regard to their health and noncombustible product alternatives.³⁵



Sweden

As of 2022, Sweden is approaching the designation “smoke free,” with less than 6 percent of adults smoking.³⁶ As part of an event announcing these findings, Dr. Delon Human, president of Health Diplomats, a specialized health, nutrition and wellness consulting group, pointed to the far-reaching implications of Sweden’s success saying, “If all smokers in the world, some 1.1 billion people, would switch to one of less harmful alternative smoke-free, nicotine-based products, it could prevent disease and save millions of lives worldwide.”³⁷

Sweden’s rate of adult smoking has fallen sharply since the 1970s. In 1976, 40% of men and 34% of women smoked. In 2002, the rate had fallen to 15% of men and 20% of women. Rates have fallen much further in the past two decades, primarily because of the use of the smokeless tobacco product snus. Aside from public funded education and tax incentives, it is hypothesized that the availability of snus, especially among Swedish men, offered an alternative resulting in Swedish male smokers choosing this nicotine product.³⁸

As Dr. Karl Erick Lund, a senior researcher at the Norwegian Institute of Public Health has observed:

“Swedish men consume as much tobacco as their male counterparts in Europe, but more in the form of snus than in cigarettes. Having worked within the tobacco control community for 36 years, my impression is that it has been difficult to accept that availability of snus may have greater impacts in reducing smoking than the regulations we have spent a lifetime fighting for.”³⁹

While Sweden is close to becoming the first country to achieve the “smoke free” designation, other nations striving for the same goal will not achieve that status for a few more decades. For example, the European Union, having banned the sale of snus in early 1990s, currently has approximately 18.4% of people who smoked cigarettes daily with the hopes of reaching smoke free designation by 2040.⁴⁰ The availability and acceptability of snus has helped Sweden see success in THR and contributed to the decline in smoking rates.⁴¹



The United Kingdom

The UK is also seeing decreases in smoking rates due to the availability of potentially less risky alternatives, including vaping products, and the support of regulatory agencies and healthcare professional societies such as the Royal College of Physicians. The Royal College of Physicians is a British healthcare professional membership body dedicated to improving health and healthcare. Between 2014 and 2020, smoking rates have fallen in the UK by 20%.⁴² In their statement on “Nicotine without Smoke: Tobacco Harm Reduction,” the Royal College of Physicians stated that vaping products appear to be effective when used by smokers as an aid to quit smoking and that the hazard to health arising from long-term vapor inhalation from the vaping products available today is unlikely to exceed 5% of the harm from smoking combustible cigarettes.⁴³ The declines of smoking rates in Sweden, the UK and Japan are real world examples of how having access to less risky alternatives is important for adult smokers who are uninterested in quitting tobacco products altogether.

The U.S. can take learnings from across the globe and create public policy and a comprehensive

framework that provides access to noncombustible products for adult smokers who are uninterested in quitting tobacco while keeping those products out of the hands of youth.

Agencies such as the FDA have a critical role to play on multiple levels. In 2019, the FDA introduced their Comprehensive Plan for Tobacco and Nicotine Regulation, which includes the science-based review of tobacco products and educating the public and correcting the misperceptions about nicotine.⁴⁴

The U.S. is often looked at as a leader and this is the time for us to make up for lost time and lead a THR program that not only affects individuals, but the population at large. THR can dramatically decrease smoking rates not only in the U.S., but globally, and represents a tremendous opportunity for public health.





a brighter future for public health in America

Effective THR policies have the possibility to make strides in public health and reduce the burden of combustible tobacco use.⁴⁵ With real world examples of the successes of acceptable and accessible noncombustible alternative products in Japan, the UK and Sweden, there is a reason for optimism and urgency. Advances in science call us to reexamine many of the tobacco control policies and approaches that are over two decades old.⁴⁶

We hope this information will spark renewed conversation on THR among all stakeholders. It is time to study the facts and pursue unified, science-based policies that best serve public health. From providing accurate information about nicotine's health effects

and alternatives available to adult cigarette smokers, to replacing ideologies with pragmatic, real world solutions, the time is now to advance one of the most consequential movements in public health.

Succeeding in reducing the health-related illnesses due to combustible cigarette smoking is a challenge that is larger than any single organization. The public health community, regulators, legislators, consumers, scientists, healthcare professionals and industry all have a voice and role to play in developing a more informed THR strategy that will result in a brighter future for millions of adult smokers in America and society at large.



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