

Overview

Modern tobacco policy is shaped by the passage of the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA), which was a watershed public health moment. The TCA gave the Food and Drug Administration (FDA) additional authority and the tools to tackle the leading cause of preventable death and disease in the United States – cigarette smoking. According to the Centers for Disease Control and Prevention (CDC) and the National Cancer Institute, nearly 480,000 Americans die from smoking-related causes each year, resulting in \$240 billion in direct healthcare costs and \$360 billion in lost productivity due to smoking-related illness and premature death.

Importantly, the TCA established the first common set of rules for tobacco product manufacturers, guidelines for accurate and scientifically based communications, and the opportunity to advance **tobacco harm reduction** by providing a framework for evaluating and authorizing reduced-risk products that meet the standard of being “appropriate for the protection of public health”. Given the known harms of smoking combustible products, non-combustible alternatives, often called **smoke-free products**, such as **heated tobacco products (HTPs)**, **electronic nicotine delivery systems (ENDS)**, and **modern oral nicotine pouches** have emerged as options for adult cigarette smokers interested in switching to a potentially less harmful product. This Basic will explore these alternatives as a form of harm reduction.

What is Harm Reduction?

Harm Reduction refers to a range of intentional public health policies and practices designed to lessen the negative social and/or physical consequences associated with various human behaviors, both legal and illegal. Harm reduction practices have been used for decades in a number of areas including opioid abuse, reproductive health, vaccinations, and more.

Methods of tobacco harm reduction vary for individuals but can include actions such as reducing or eliminating consumption and/or using smoke-free products like e-cigarettes (ENDS), heated tobacco products (HTPs), or oral nicotine pouches. All tobacco harm reduction strategies are complementary to traditional approaches for those looking to quit smoking, reduce their consumption, or switch to a smoke-free nicotine product. Harm reduction is particularly effective among smokers who otherwise can't or won't quit smoking cigarettes.

FDA Regulation

The FDA utilizes the **Premarket Tobacco Product Application (PMTA)** pathway as the primary avenue for new products to receive authorization and enter the market. In order to obtain authorization, applicants must submit

Center Forward Basics

Center Forward brings together members of Congress, not-for-profits, academic experts, trade associations, corporations and unions to find common ground. Our mission: to give centrist allies the information they need to craft common sense solutions, and provide those allies the support they need to turn those ideas into results.

In order to meet our challenges we need to put aside the partisan bickering that has gridlocked Washington and come together to find common sense solutions.

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Key Definitions:

- **Tobacco Harm Reduction:** A public health strategy that complements traditional prevention and cessation measures by providing adults who would otherwise continue smoking combustible products with non-combustible alternatives that, according to the FDA, can reduce health risks and help improve public health.
- **Smoke-free Products:** Non-combustible tobacco and nicotine products, including chew,

scientific evidence demonstrating the new tobacco product is Appropriate for the Protection of Public Health (APPH) – a standard that considers, among other aspects, the risks and benefits to the population as a whole, including both users and nonusers. As of June 5th, 2025, the FDA has issued [seventy-six](#) marketing granted orders through the PMTA pathway.

The **Modified Risk Tobacco Product Application (MRTPA)** pathway also plays a critical role in tobacco harm reduction because it's the only legal way for manufacturers of smoke-free products to communicate about the relative health risks of new products with adult tobacco consumers. Manufacturers can submit an MRTPA with evidence demonstrating (1) the product reduces individual risk or exposure and will benefit the population as a whole and (2) the proposed risk or exposure claim is scientifically accurate and comprehensible to consumers (e.g., “switching completely to this product from cigarettes reduces the risk of lung cancer”). MRTPA authorizations apply only to a single product, not an entire category of tobacco products, such as “all smokeless products.”

The creation of these pathways was intended to help facilitate tobacco harm reduction by providing a regulatory framework for the evaluation and authorization of smoke-free products and communications about their health risks to adult tobacco consumers. Previous FDA policy acknowledged a continuum of risk exists between different tobacco products, the need to move smokers down it, and the need to regulate against it. As of June 5th, 2025, the FDA has issued sixteen modified risk granted orders through the MRTPA pathway.

What Are Tobacco Harm-Reducing Products?

As the FDA and other public health agencies have recognized, it is the toxic mix of chemicals and carcinogens found in cigarette smoke that causes most of the tobacco-related deaths and diseases. Nicotine, while a highly addictive drug not suitable for those under 18, is not the primary driver of death and disease. As a result, manufacturers have shifted their focus to smoke-free alternatives like e-cigarettes (ENDS), heated tobacco products (HTPs), and oral nicotine pouches designed and marketed for adults looking for alternatives to cigarettes.

According to the CDC, ENDS, also called e-cigarettes or vapes, come in various shapes and sizes and typically include a battery, heating element, and tank to hold the liquid. These products heat the liquid, which typically includes nicotine and flavoring, so it can be inhaled as an aerosol, avoiding combustion and smoke. As of June 5th, 2025, the FDA has issued thirty-four marketing granted orders for ENDS products, parts or components. While a backlog of more than 486,000 PMTAs awaits decisions, thousands of illegal e-cigarettes remain in retail today as the FDA works through additional compliance and enforcement actions to clear the market of these unlawful products.

Heated Tobacco Products (HTPs) contain tobacco, but differ from traditional cigarettes because they don't burn the tobacco and don't produce smoke; rather, they heat the tobacco only until the nicotine can be inhaled as an aerosol. Various HTP designs exist, but most heat the tobacco using an electric device. As of June 5th, 2025, the FDA has authorized one type of HTP product through the

dip, dissolvables, snuff, oral nicotine and snus. ENDS and HTPs are noncombustible products including e-cigarettes and heated tobacco products that heat tobacco and/or nicotine, but do not burn like traditional cigarettes. Noncombustible products help reduce the risk of tobacco-related harms.

- **Heated Tobacco Products (HTPs):** Products that heat real tobacco instead of burning it. Heated tobacco products are smoke-free; since the tobacco does not burn, the quantity and levels of harmful chemicals are significantly reduced compared to cigarette smoke.
- **Electronic nicotine delivery systems (ENDS):** Vapes, vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes or e-cigs), and e-pipes are some of the many terms used to describe ENDS. They are noncombustible tobacco products.
- **Oral Nicotine Pouches (ONPs):** Portioned, pouched products containing nicotine, flavorings, and other non-tobacco ingredients. ONPs are placed between the gum and lip to deliver nicotine without smoke.
- **Premarket Tobacco Product Application (PMTA):** To receive authorization, a premarket tobacco product application must be submitted for any new tobacco product seeking an FDA marketing order. An application must provide scientific data that demonstrates the product meets

PMTA pathway.

Oral nicotine pouches are portioned, pouched products designed to be placed between the gum and upper lip. They do not contain tobacco leaf and only include pharmaceutical-grade nicotine, flavorings, and other non-tobacco ingredients that are pharmaceutical grade or used in foods. Nicotine is absorbed through the mucous membranes in the mouth, avoiding combustion. As of June 5th, 2025, the FDA has authorized twenty oral nicotine pouches.

Current Evidence

According to the CDC, smoking rates are at generational lows across demographics - 11.6% of U.S. adults (18+) are smokers, down from more than 20% in 2005. These numbers show an encouraging trend and demonstrate evidence-based approaches, such as increasing cessation, decreasing initiation, and raising the minimum age of purchase to twenty-one, have made some progress; however, nearly thirty million adults are still regular smokers in the United States. Many of these smokers will not simply quit smoking and are looking for potentially less harmful alternatives. For our youth, trends have been encouraging after spiking a few years ago, suggesting raising the age to twenty-one could be having positive effects. Unfortunately, the data shows that of youth who still vape, they do so regularly and overwhelmingly with flavors. In 2024, nearly 30% of high school e-cigarette users reported vaping every day. Furthermore, 90% of youth e-cigarette users report using flavored products.

The New England Journal of Medicine recently published a study on the benefits of smoke-free products stating, “U.S. public health agencies and professional medical societies should reconsider their cautious positions on e-cigarettes for smoking cessation. The evidence has brought e-cigarettes to a tipping point. The burden of tobacco-related disease is too big for potential solutions such as e-cigarettes to be ignored.” Former Director of the FDA’s Center for Tobacco Products, Dr. Brian King, expressed a similar sentiment, “I’m fully aware of the misconceptions that are out there and aren’t consistent with the known science. We do know e-cigarettes – as a general class – have markedly less risk than a combustible cigarette product.”

In the United States, tobacco harm reduction innovation has the potential to drastically impact public health. In some cases, other countries have succeeded in curbing smoking rates among their adult populations by promoting smoke-free products. For example:

- The United Kingdom embraced e-cigarettes as a tobacco harm reduction strategy and now has record-low smoking rates. Public Health England (PHE), an executive agency of the UK Department of Health, has maintained that vaping is 95% less risky than smoking cigarettes.
- Sweden embraced snus – a smoke-free oral product containing tobacco – for harm reduction many years ago. Sweden is now considered a smoke-free country, as smoking rates have dropped below five %
- Japan embraced heated tobacco products as a part of its tobacco harm reduction strategy. Since their introduction, smoking rates have declined by 30%.

Looking Ahead

Under the Biden Administration and prior FDA leadership, the Agency released a strategic plan in 2023, outlining programmatic initiatives and objectives that include: (1) achieving product application review efficiencies; (2) pursuing timely enforcement strategies; (3) preventing youth use; and (4) educating adults who smoke about the relative risk of tobacco products. If pursued together, these tobacco harm reduction-focused objectives could help to reduce the burden of smoking and improve public health. Earlier this year, following Senate approval, the Trump Administration installed new leadership, including Dr. Marty Makary as the new FDA Commissioner and Bret Koplrow, PHD, JD as the Director of the Center for Tobacco Products. As of now, it is too early to know how tobacco harm reduction fits within the goals set by new leadership.

the Appropriate for the Protection of Public Health standard (APPH).

- **Modified Risk Tobacco Product Application (MRTPA):** A regulatory pathway for manufacturers to communicate health risk information with adult consumers about an authorized product. Applicants must demonstrate the product will significantly reduce harm and risk of tobacco related disease to individual tobacco users and advance general public health.

Links to Other Resources

- Associated Press: [Former FDA Official on Vaping's "Promise or Peril"](#)
- Centers for Disease Control: [Electronic Cigarettes](#)
- Centers for Disease Control: [The Behavioral Risk Factor Surveillance System Survey](#)
- Centers for Disease Control: [Tobacco Product Use Among Adults](#)
- Department of Health and Human Services: [The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for action in the US](#)
- Food and Drug Administration: [Family Smoking Prevention and Tobacco Control Act](#)
- Food and Drug Administration: [How are noncombustible products different than E-cigarettes and cigarettes](#)
- Food and Drug Administration: [Modified Risk Tobacco Products](#)
- Food and Drug Administration: [Premarket Tobacco Product Applications](#)
- Food and Drug Administration: [Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems](#)
- Food and Drug Administration: [Youth Tobacco Prevention Plan](#)
- New England Journal of Medicine: [A Nicotine-Focused Framework for Public Health](#)
- New England Journal of Medicine: [Electronic Cigarettes for Cessation: Have We Reached a Tipping Point?](#)
- New York University: [Do Less Harm: E-Cigarettes a Safer Option Than Smoking](#)
- Population Assessment of Tobacco Health: [About the Study](#)
- Public Health England: [Evidence review of e-cigarettes and heated tobacco products 2018: executive summary](#)
- Reagan-Udall Foundation: [Evaluation of the FDA's Tobacco Program](#)
- The National Academies of Sciences, Engineering, and Medicine: [2018 Public Health Consequences of E-Cigarettes](#)
- Tobacco Free Kids: [E-Cigarettes – Flavors Fuel a Youth Addiction Crisis](#)