Tobacco Harm Reduction

Center Forward Basics
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Overview

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

Significantly, 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. 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 reduced-risk 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, heated tobacco products, or modern oral nicotine. 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 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 products to receive authorization and enter the market. In order to obtain authorization, applicants must submit scientific evidence demonstrating the new tobacco product is Appropriate for the Protection of Public Health (APPH) – a standard that considers, among other

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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.

For more information, please visit www.center-forward.org

Key Definitions:

- **Tobacco Harm Reduction:** A public health strategy that compliments traditional approaches by providing adults who would otherwise continue smoking combustible products with non-combustible alternatives that can reduce individual risk and help improve public health.

- **Smoke-free Products:** Non-ignitable products including chew, dip, dissolvables, snuff, and snus. E-cigarettes and heated

aspects, the risks and benefits to the population as a whole, including both users and nonusers. As of April 23rd, 2024, the FDA has issued forty-five 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. FDA's 2017 Comprehensive Plan - a multi-year initiative focused on youth prevention and helping adult smokers quit cigarettes - acknowledged the continuum of risk between different tobacco products, the need to move smokers down it, and the need to regulate against it. As former FDA Commissioner Gottlieb said, "A centerpiece of this comprehensive regulatory plan is acknowledging nicotine, while highly addictive, is delivered through products on a continuum of risk. And it's the delivery mechanism - not the nicotine itself - that is truly the issue at hand". As of April 23rd, 2024, the FDA has issued sixteen marketing 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 found in cigarette smoke that causes most of the tobacco-related deaths and diseases. That's why manufacturers are focused on smoke-free alternatives like e-cigarettes, heated tobacco products, and modern oral nicotine pouches.

According to the CDC, e-cigarettes come in various shapes and sizes and, typically, include a battery, heating element, and tank to hold the liquid. Also known as Electronic Nicotine Delivery Systems (ENDS) or vapes, 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 April 23rd, 2024, the FDA has issued twenty-three marketing granted orders for ENDS products. However, 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 unregulated 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 either an electric battery or a carbon ember. To date, the FDA has authorized one HTP product.

tobacco products (HTPs) are noncombustible because they heat tobacco and/or nicotine, but do not burn like traditional cigarettes. Noncombustible products may help reduce the risk of tobacco-related harms.

- **Heated Tobacco Products:** 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.

- **Modern Oral Nicotine (MON) Pouches:** Portioned, pouched products containing nicotine, flavorings, and other non-tobacco ingredients. MON pouches 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 the Appropriate for the Protection of Public Health standard (APPH).

Modern Oral Nicotine (MON) pouches are portioned, pouched products designed to be placed between the gum and upper lip. They do not contain tobacco and only include 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. To date, the FDA has not authorized any MON pouches.

Current Evidence

According to the CDC, smoking rates are at generational lows across demographics - 11.5% of U.S. adults (18+) are smokers – down from over 20% in 2005. These numbers show an encouraging trend and demonstrate traditional approaches, such as increasing cessation, decreasing initiation, and raising the minimum age of purchase to 21 have made some progress; however, nearly thirty million adults are still regular smokers in the United States. Many of these smokers cannot or will not quit smoking and are looking for reduced-risk alternatives.

- **Modified Risk Tobacco Product Application (MRTPA):** A regulatory pathway for manufacturers to communicate health risk information (i.e., reduced risk or reduced exposure) with adult consumers about an authorized product. Applicants must demonstrate the product will or is expected to benefit the health of the population as a whole.

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." Dr. Brian King, Director of the FDA's Center for Tobacco Products, 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."

While many smoke-free products are relatively new and long-term scientific data is still in process, tobacco harm reduction innovation has the potential to drastically impact public health. Other countries have reviewed the available science and, in some instances, promote smoke-free products as a better alternative to smoking. 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 long maintained vaping is 95% less risky than smoking cigarettes. Additionally, their latest "swap to stop" campaign, the first of its kind in the world, provides a million adult smokers (20% of the adult smoking population) with free vaping starter kits.
- Sweden embraced snus – a smoke-free oral product containing tobacco – for harm reduction many years ago. Sweden now has the lowest smoking rate and one of the lowest tobacco-related mortality rates in the European Union.
- 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

The FDA recently released a strategic plan outlining programmatic initiatives and objectives for the next five years 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 the FDA pursues these objectives and applies learnings from other countries successfully implementing similar policies, proponents of tobacco harm reduction believe it can reduce the burden of smoking and improve public health.

Links to Other Resources

- Associated Press: FDA Official on Vaping's "Promise or Peril"
- Centers for Disease Control: Adult Smoking Cessation - The Use of E-Cigarettes
- Centers for Disease Control: Electronic Cigarettes
- Centers for Disease Control: Smoking and Tobacco Use
- Centers for Disease Control: The Behavioral Risk Factor Surveillance System Survey
- 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: Premarket Tobacco Product Marketing Granted Orders
- 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