ppi radically pragmatic

FDA's Modified Risk Tobacco Product Authorization: What Policymakers Need to Know

From PPI's Project to End Smoking

INTRODUCTION

Policymakers are seeing a growing number of proposals — on taxation, retail access, and product regulation — that involve tobacco products the U.S. Food and Drug Administration (FDA) has authorized as Modified Risk Tobacco Products (MRTPs). As the nicotine marketplace continues to diversify, the number of products seeking and receiving MRTP authorization is likely to increase.

Policymakers are receiving sharply different advocacy accounts of what MRTP authorization means. This brief explains what the MRTP pathway is, why Congress created it, what evidentiary standards are required for an MRTP authorization, and why policymakers should give the FDA's MRTP determinations serious weight when evaluating tobacco-related legislation.

What this brief does — and does not — argue

This brief does not argue that any tobacco product is safe, or that youth nicotine use should be tolerated. It argues that the FDA's MRTP authorization process is credible and scientifically rigorous, that its determinations represent the best available federal science on comparative tobacco product risk, and that policymakers should give those determinations serious weight when considering tobacco-related legislation.

1. Why Congress Created the MRTP Pathway

The Tobacco Control Act was shaped in part by one of the most consequential episodes of consumer deception in American commercial history. For decades, cigarette manufacturers marketed cigarettes labeled "light," "mild," and "low tar" in ways that implied reduced risk compared with regular cigarettes. Those implied claims were not supported by evidence of meaningful health benefit.[1]

Congress determined that the only effective solution was to require advance FDA review of any reduced-risk or reduced-exposure claim before it reached consumers. The Act's findings are explicit:

"The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified." [2]

Congress identified the FDA as uniquely qualified for this role, citing the agency's "scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior."

That judgment was not controversial at the time. The American Cancer Society, American Heart Association, American Lung Association, and Campaign for Tobacco-Free Kids all supported the Tobacco Control Act and the FDA review authority it established. The principle they endorsed was straightforward: claims of reduced risk should not reach consumers unless the FDA has independently reviewed and authorized them.

2. What the MRTP Review Process Requires

Under federal law, a modified risk tobacco product is any tobacco product marketed with claims — explicit or implied — that it reduces harm or the risk of tobacco-related disease compared to other commercially marketed tobacco products.[3] No manufacturer may make such claims without a formal FDA authorization order.

The MRTP pathway permits two categories of authorization, each with its own evidentiary standard:

- **Risk modification orders** are issued when the FDA determines that the evidence supports claims that the product significantly reduces harm and the risk of tobacco-related disease for individual users and benefits the health of the population as a whole.

- **Exposure modification orders** are issued when the FDA determines that the evidence supports claims that the product or its smoke significantly reduces exposure to harmful or potentially harmful constituents, and that communicating the claim is expected to benefit population health.

In both cases, the FDA's review is comprehensive and multidisciplinary. A complete application must address:

- **Toxicology:** Analysis of harmful and potentially harmful constituents relative to comparator products;
- **Clinical and epidemiological evidence:** Data on disease risk for product users;
- **Behavioral research:** Evidence on how consumers actually use the product, including patterns of dual use and product switching;
- **Consumer-perception studies:** Research on whether the proposed marketing claims could mislead consumers about absolute or relative risk.

Applications are subject to public comment and are reviewed by the FDA's Tobacco Products Scientific Advisory Committee (TPSAC), an independent body of medical, scientific, and public-health experts.[4]

The population-level standard is the most demanding element of the review. FDA must conclude that authorizing the product's reduced-risk or reduced-exposure claims would benefit *the health of the population as a whole*, not merely that the product poses a lower risk for individual users. This requires the FDA to weigh the expected benefit for adults who switch away from cigarettes against the potential harm from youth initiation, continued dual use, and the possibility that the claims could discourage complete cessation. A product that reduces harm for individual users but is likely to attract large numbers of new young users fails this standard.

FDA's review process brings together toxicology, behavioral science, epidemiology, consumer-perception research, public comment, and regulatory judgment in a way no single advocacy organization, company, or academic study can replicate. Policymakers should consider MRTP determinations as uniquely relevant federal evidence, even when outside experts disagree about broader policy implications.

3. Built-In Accountability: Why MRTP Authorizations Are Not Permanent

A common misunderstanding is that an MRTP authorization is a permanent seal of approval. It is not. The framework includes multiple accountability mechanisms designed to ensure that authorizations remain grounded in real-world public-health outcomes.

Time-limited orders. MRTP authorization orders are typically limited to five years. Manufacturers must submit renewal applications based on postmarket data demonstrating that the product continues to meet the statutory standard. A product that no longer satisfies the population-level benefit test at renewal cannot continue to market reduced-risk or reduced-exposure claims.

Ongoing postmarket surveillance. FDA requires authorized manufacturers to conduct and report postmarket surveillance studies. These studies monitor actual consumer behavior — including switching, dual use, cessation patterns, and youth uptake — and provide the agency with real-world evidence against which its original authorization can be evaluated.

Revocation authority. FDA retains full authority to revoke an MRTP authorization at any time if new evidence indicates the product no longer meets the public health standard.[5]

Product-specific determinations. Each authorization applies to a specific product with specifically defined permitted claims. An authorization for one snus product, one heated tobacco device, or one category of smokeless tobacco does not extend to other products in the same category. Each must earn its own authorization through the same process.

Taken together, these features mean that MRTP authorizations are not static endorsements. They are dynamic, evidence-based determinations that remain contingent on continued real-world performance.

4. What the FDA Has Authorized — and What That Means

To date, the FDA has authorized modified-risk claims for certain snus, moist snuff, nicotine pouch, heated tobacco, and low-nicotine cigarette products.[6] These authorizations are product-specific and define, with precision, which claims a manufacturer is permitted to make and under what conditions.

MRTP authorization does *not* mean that the product is safe. FDA is explicit on this point. The agency's continuum-of-risk framework — which distinguishes combusted cigarettes as the most harmful products while recognizing that noncombustible products generally carry lower, but not zero, risks — underlies every MRTP determination.[7] An MRTP authorization reflects the agency's science-based judgment that the specific permitted claim — whether about reduced exposure or reduced risk — is supported by evidence and is expected to benefit population health under the conditions of authorization. It does not establish the product as a cessation device or a medical treatment, and it imposes specific limits on how the manufacturer may describe the product to consumers.

What MRTP authorization does not mean

- It does not mean the product is safe.
- It does not mean the FDA has approved the product as a cessation treatment.
- It does not authorize claims beyond the specific language FDA permitted.
- It does not apply to an entire product category.
- It does not prevent the FDA from withdrawing the authorization if evidence changes.

5. Why MRTP Determinations Should Inform Policy

The MRTP pathway exists precisely to translate complex tobacco regulatory science into actionable, publicly communicated guidance. When the FDA issues an MRTP authorization, it is doing more than permitting a manufacturer to use specific claims. It is making a product-specific, evidence-based determination that communicating those claims is expected to benefit the health of the population as a whole when the product is available to adults who smoke.

Cigarette smoking remains the leading cause of preventable death in the United States, responsible for more than 490,000 deaths annually.[8] Existing cessation strategies, while valuable, leave millions of adults who want to quit unable to do so. For those adults, access to FDA-authorized lower-risk alternatives — at meaningful price differentials relative to cigarettes — is a practical public-health intervention grounded in the same federal regulatory science that policymakers routinely cite when supporting tobacco control.

Risk-proportionate policy — taxing FDA-authorized noncombustible products at lower rates than cigarettes and ensuring those products are available where adults who smoke already shop — is the mechanism by which the public-health benefits FDA has identified in the MRTP process can reach adults in the real world. Without a risk-proportionate policy, the federal investment in rigorous product review produces authorizations that have limited practical effect on adult smoking behavior.

How policymakers should use MRTP determinations

- Give the FDA's product-specific determinations serious weight.
- Preserve strong youth-access protections.
- Avoid tax and retail policies that treat MRTP-authorized noncombustible products as equivalent to cigarettes.

6. Questions Policymakers Should Ask

When evaluating testimony or written submissions regarding MRTP-authorized products, policymakers may find the following questions useful.

When considering testimony that challenges an MRTP authorization:

- **Scientific basis.** On what specific scientific grounds does your organization disagree with the FDA's MRTP determination? Does your analysis include the full range of evidence FDA reviewed — toxicological, clinical, behavioral, and consumer-perception data — and the population-level benefit assessment?
- **Consistency.** Your organization supported giving the FDA authority to evaluate modified risk tobacco products and to issue authorizations only after rigorous scientific review. Does your current position reflect disagreement with the agency's process, or with the specific evidence it evaluated?
- **Alternatives.** If an adult who smokes cigarettes switches completely to an MRTP-authorized product, does your organization believe that person has improved or worsened their health outlook? On what evidence is that view based?

When considering testimony that supports an MRTP-authorized product:

- **Authorization scope.** What specific claims has FDA authorized for this product, and are the claims being made in testimony consistent with those authorized claims?
- **Postmarket performance.** What does postmarket surveillance data show about actual patterns of use — switching, dual use, and youth uptake — since the product entered the market?
- **Youth safeguards.** What specific measures — in marketing, retail placement, and product design — does the manufacturer apply to minimize youth uptake, and how are those measures independently verified?

CONCLUSION

The MRTP authorization process was created to prevent unverified reduced-risk claims from reaching consumers. It requires multidisciplinary scientific review, public comment, product-specific claim authorization, postmarket surveillance, fixed authorization periods, and FDA authority to withdraw an order if the evidence changes.

When the FDA issues an MRTP authorization, policymakers should not treat it as a claim that the product is safe or as a blanket endorsement of an entire product category. They should treat it as a serious federal scientific determination that specific claims about a specific product have been reviewed and authorized under a population-health standard.

Policymakers who give appropriate weight to the FDA's MRTP determinations will be better positioned to design policies that distinguish products by risk, preserve strong youth protections, accelerate the decline of cigarette smoking, and reduce the health disparities that smoking continues to impose on the most vulnerable Americans.

For a complete list of authorized modified risk tobacco products and the specific claims FDA has permitted, visit the FDA Center for Tobacco Products MRTP page:
fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products

ABOUT THE AUTHOR

Jeff Willett is Director of the Progressive Policy Institute's Project to End Smoking, which advances people-centered, risk-proportionate tobacco policy strategies to accelerate the decline of cigarette smoking in the United States. Prior to joining PPI, Jeff held senior leadership roles at the American Heart Association, Truth Initiative, New York State Bureau of Tobacco Control, and Ohio Tobacco Prevention Foundation.

ABOUT PPI'S PROJECT TO END SMOKING

The **Project to End Smoking** is designed to accelerate the decline in cigarette smoking in the United States. We believe it is possible to both protect youth from nicotine product use and dramatically accelerate adult smoking cessation. Achieving this requires better aligning public health policy with scientific evidence on nicotine risk and smoking cessation.

The Project to End Smoking advances people-centered, risk-proportionate policy strategies that align smoking cessation goals with real-world nicotine use patterns, particularly among populations for whom existing smoking cessation approaches have fallen short.

ABOUT PPI

Founded in 1989, the Progressive Policy Institute is a catalyst for policy innovation and political reform based in Washington, D.C. Its mission is to create radically pragmatic ideas for moving America beyond ideological and partisan deadlock.

Notes and References

1 *Family Smoking Prevention and Tobacco Control Act,* Public Law No. 111-31, 123 Stat. 1776 (2009), https://www.congress.gov/bill/111th-congress/house-bill/1256.

2 *Family Smoking Prevention and Tobacco Control Act*, § 2(43).

3 "Modified Risk Tobacco Products," 21 U.S.C. § 387k, U.S. Food and Drug Administration, last updated May 18, 2026, https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products.

4 "Modified Risk Tobacco Products."

5 FDA retains authority under 21 U.S.C. § 387k(j) to withdraw a modified risk tobacco product authorization order upon a determination that the order is no longer consistent with the protection of public health.

6 "Modified Risk Tobacco Products," U.S. Food and Drug Administration, accessed June 2026, https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products. For a summary of each authorized MRTP and the permitted claims, see the product-specific authorization pages linked from that page.

7 "The Relative Risks of Tobacco Products," U.S. Food and Drug Administration, last updated March 12, 2026, https://www.fda.gov/tobacco-products/health-effects-tobacco-use/relative-risks-tobacco-products.

8 *Eliminating Tobacco-Related Disease and Death: Addressing Disparities–A Report of the Surgeon General*, U.S. Department of Health and Human Services (Atlanta, 2024), https://www.ncbi.nlm.nih.gov/books/NBK614484/.