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Trusting Regulatory Science: Why FDA Determinations Should Inform State and Local Tobacco Policy

From PPI's Project to End Smoking

Why Congress Made the FDA the Scientific Regulator of Tobacco Products

In 2007, a coalition of leading tobacco control organizations testified before Congress in support of legislation granting the Food and Drug Administration authority to regulate tobacco products. Their support reflected a central problem in tobacco policy: Cigarettes remained legally available despite causing extraordinary disease and death, while tobacco companies had a long history of implying that some products were less harmful without adequate scientific proof.

With strong support from tobacco control advocacy, Congress created a public-health standard tailored to tobacco. The FDA would not decide whether tobacco products were "safe." Instead, the agency would determine whether their marketing, manufacture, sale, and claims were appropriate for the protection of public health, including effects on both users and nonusers. The Family Smoking Prevention and Tobacco Control Act[1] therefore made the FDA the federal agency responsible for independently evaluating industry claims, assessing product-specific risks, and determining which tobacco products may be lawfully marketed in the United States.

> "The FDA is the only government regulatory agency that combines the public health mission with the scientific and health expertise needed to effectively regulate the tobacco industry."
>
> **— American Cancer Society[2]**

That structure matters for state and local policy today. Policymakers now receive sharply different accounts of tobacco and nicotine product risks from industry and from tobacco control advocacy organizations. This brief explains why the FDA's regulatory science, grounded in the authority that the public health community helped establish, should receive serious weight when state and local governments consider tobacco-related legislation.

> "This legislation will provide the FDA with the authority it needs to appropriately oversee the marketing, manufacture, and sale of tobacco products. This authority will benefit public health by… ensuring that new products that purport to reduce harm actually do so, and by requiring tobacco companies to make changes in the products that make them less harmful to smokers unable to quit."
>
> **— Campaign for Tobacco-Free Kids[3]**

What the FDA has Determined

The FDA has formally concluded that, while no tobacco product is safe, the health risks for tobacco and nicotine products exist along a "continuum of risk." Cigarettes and other combusted products are the most harmful type of tobacco product, killing roughly 500,000 Americans every year. Non-combusted products – such as e-cigarettes, nicotine pouches, and other smokeless tobacco products – generally have lower health risks than cigarettes and other combustible tobacco products.[4]

This conclusion is not a marketing claim or an advocacy position. The FDA's "continuum of risk" framework was developed under the Obama, Biden, and Trump administrations as a science-based approach to reducing tobacco harms. It is the FDA's own scientific determination, reached through the same statutory authority that Congress granted the agency in 2009 and that the public health community championed at the time.

> "Instead of maintaining the status quo under which we do nothing to reduce the harm of tobacco products, the standard in the bill is based on what actions are 'appropriate to protect the public health,' taking into account the impact of any proposal on the health of the 'population as a whole, including users and non-users' of tobacco products. Thus, the bill gives the FDA the authority to take actions it believes will reduce the number of people who die from tobacco."
>
> **— Campaign for Tobacco-Free Kids[5]**

> ""Tobacco products can never be 'safe or effective,' and that is why a new public health standard is established in the proposed legislation to regulate tobacco products. FDA regulation of tobacco would allow tobacco companies to continue to develop new products, but would require that any health claim attached to a product is based on sound science."
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> **— American Cancer Society[6]**

FDA Authorizations

FDA authorizes new tobacco products for the U.S. market through two distinct pathways, each with its own evidentiary standard and purpose.

The **Premarket Tobacco Product Application (PMTA)** pathway is the baseline requirement for any new tobacco product to be lawfully marketed in the United States. FDA authorizes a PMTA when the applicant demonstrates that marketing the product would be "appropriate for the protection of public health" (APPH), a population-level standard that weighs the product's risks and benefits for both users and nonusers, including the likelihood of youth initiation, rather than evaluating the product in isolation.

The **Modified Risk Tobacco Product (MRTP**) pathway is a separate, additional authorization that a manufacturer may seek only after a product is already lawfully marketed. MRTP authorization permits a manufacturer to communicate specific, FDA-approved claims about reduced risk or reduced exposure relative to other tobacco products, claims that would otherwise be unlawful to make.

Together, these two pathways reflect the FDA's continuum-of-risk conclusion in regulatory practice: PMTA authorization controls what may be sold, while MRTP authorization controls what may be claimed about how that product compares to other tobacco products.

> "A 'safe and effective' standard would thus dictate a total ban on tobacco products… virtually all public health experts recognize this as infeasible and unproductive."
>
> **— Campaign for Tobacco-Free Kids[7]**

FDA Science When Industry and Tobacco Control Advocacy Claims Diverge

Industry claims about the risks of its own products should not be accepted at face value. Companies that sell tobacco and nicotine products have financial interests in how those products are perceived, and a documented history of overstating or misrepresenting reduced-risk claims. Industry claims about product risk require independent verification, not public trust.

Tobacco control advocacy organizations tend to treat cigarettes and FDA-authorized noncombustible products as equivalent threats rather than distinguishing between them. This approach leads many advocacy organizations to support the prohibition of authorized products, tax parity between cigarettes and lower-risk alternatives, and other policies that flatten meaningful product-level risk distinctions.

Neither source can substitute for independent scientific judgment. FDA's review process is built to weigh the full population-level impact of a product, accounting for both youth uptake and adult cessation, regardless of industry's profit motive or advocacy organizations' opposition to continued nicotine use in any form. That is the standard policymakers should rely on when industry and advocacy organizations offer conflicting accounts of risk.

What FDA Authorization Means for State Policy

Federal law explicitly preserves state and local authority over tobacco taxation, sales restrictions, and other public health measures. States retain broad authority to regulate tobacco and nicotine products through taxation, flavor restrictions, retail licensing, and youth-access enforcement. That authority creates both an opportunity and a risk.

The opportunity is that states can design tax and retail policies that reflect the risk differences that the FDA's own scientific review has identified, taxing combustible cigarettes at higher rates than FDA-authorized noncombustible alternatives, for example, in ways that create financial incentive for adults who smoke to switch to lower-risk products.

The risk is that state policy disconnected from the FDA's scientific findings can unintentionally work against the very public health goals the policy is meant to advance. A flavor ban or tax structure that does not distinguish FDA-authorized reduced-risk products from unauthorized or combustible products may effectively treat FDA's product-specific scientific determinations as irrelevant to state policy design, even though FDA's determination represents the most rigorous available evidence on comparative product risk.

> "The capability of talented and skilled scientists and researchers currently employed by the FDA, who are able to conduct sophisticated analyses and evaluate complex scientific data, including an analysis of the impact of different products on the human body, is the best example of why the FDA is the right agency to regulate tobacco products."
>
> **— Campaign for Tobacco-Free Kids[8]**

Why FDA Scientific Determinations Should Inform Policy

Cigarette smoking remains the leading cause of preventable death in the United States, responsible for more than 490,000 deaths annually.[9] Existing cessation strategies, while valuable, leave millions of adults who want to quit unable to do so. For those adults, access to FDA-authorized noncombustible 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. To protect youth, risk-proportionate policy should be paired with strong age-verification requirements, retailer licensing, penalties for underage sales, restrictions on youth-oriented marketing, and strong enforcement against unauthorized products.

Conclusion

Before advancing tobacco-related legislation, state policymakers should ask whether the proposal accounts for the FDA's existing product-specific determinations. States retain broad authority to regulate tobacco and nicotine products, and they may have legitimate reasons to go beyond federal requirements. But when state policy departs from the FDA's scientific findings, that departure should be transparent, evidence-based, and attentive to whether the policy will reduce cigarette smoking or unintentionally preserve it.

FDA's determinations do not require policymakers to defer to industry, dismiss youth-use concerns, or treat any tobacco product as safe. They do require policymakers to recognize meaningful differences in product risk. Tobacco policy is most likely to improve public health when it protects youth, distinguishes authorized products from unauthorized products, and gives adults who smoke better incentives to move away from cigarettes. States that give serious weight to the FDA's scientific review will be better positioned to reduce smoking, preserve strong youth protections, and address the health disparities caused by combustible tobacco use.

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 tobacco regulatory science is credible and rigorous, that the FDA's 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.

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

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3 Campaign for Tobacco-Free Kids, Prepared Statement Submitted with Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions: Hearing on the Need for FDA Regulation of Tobacco, S. Hrg. 110-206, 110th Cong. 15 (2007), https://www.congress.gov/110/chrg/CHRG-110shrg33769/CHRG-110shrg33769.pdf.

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6 American Cancer Society, Written Responses to Questions for the Record, supra note 2, at 199.

7 Campaign for Tobacco-Free Kids, Prepared Statement Submitted with Testimony Before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health: Hearing on Legislation to Provide the Food and Drug Administration with Authority to Regulate Tobacco Products, H. Hrg. 110-74, 110th Cong. 118 (2007), https://www.congress.gov/110/chrg/CHRG-110hhrg44708/CHRG-110hhrg44708.pdf.

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