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Making It Easier to Leave Cigarettes Behind: Diverse Choices and a Transparent Market

By Jeffrey S. Smith



The test of reform is not simply faster review or a longer product list. It is whether reform makes it easier for adults to leave cigarettes behind without making it easier for young people and nonusers to start using nicotine.

Introduction

Reducing the harm caused by cigarettes requires changing smoking behavior, and regulation helps shape the conditions under which that change becomes possible. For an adult who continues to smoke, a lower-risk cigarette alternative must offer an acceptable experience, remain affordable and available, and provide a credible reason to stop smoking cigarettes. The stakes are substantial: The Centers for Disease Control and Prevention (CDC) estimates that smoking and secondhand smoke cause more than 480,000 deaths annually.[1]

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The U.S. Food and Drug Administration (FDA) recognizes that noncombustible tobacco products generally carry lower health risks than cigarettes, although they are not risk-free, and important uncertainties remain about their effects on long-term health outcomes.[2] Still, for adults who smoke, quitting combustible cigarettes completely is important to obtain the full health benefits of a lower-risk alternative; continuing to smoke poses substantial health risks.[3] Translating those differences into better health, however, depends on whether people actually replace cigarettes with lower-risk alternatives. The FDA's Center for Tobacco Products (CTP) is well positioned to advance that objective by authorizing a diverse range of lower-risk alternatives, but a September 2026 Government Accountability Office (GAO) assessment of the agency's application process found lengthy review times and gaps in review tracking.[4]

This paper focuses on key reforms the CTP should pursue to improve the authorization process and enable consumers and retailers to distinguish authorized products from unauthorized ones more easily. It also discusses how enforcement efforts and state policy can better align with and augment

The sources included in this paper were verified and active at the time of publication.

CTP efforts to ensure that the marketplace effectively supports adults seeking reduced-risk cigarette alternatives.

Meaningful Product Choices May Facilitate Smoking-Related Behavior Change

Continued smoking reflects more than a lack of interest in quitting. According to CDC data, about two-thirds of adults who smoke want to quit, but fewer than 40 percent use medication or counseling to support those efforts, and fewer than 10 percent successfully quit.[5] This gap between intention and success should prompt policymakers to consider what support people need to implement a change they already want to make.



The pervasive gap between wanting to quit smoking and succeeding should prompt policymakers to consider what support people need to implement a change they already want to make.

Innovative products offer new options for adults who may have found earlier lower-risk alternatives unsuitable or unappealing. Less harsh, easier-to-use, or more satisfying options can encourage those who smoke to try to quit again, and these trials of new products can serve as a first step toward long-term behavior change.[6] Innovative products can also have broader appeal (i.e., beyond people who currently smoke), so it is important that such products offer meaningful product choice and serve as sustained cigarette replacements for adult smokers while safeguards limit youth and nonuser uptake. Safeguards against that uptake include age-of-sale enforcement, restrictions on youth-directed marketing, and, where manufacturers propose them, product-specific access controls.[7]

Meaningful product choice means more than offering varieties of a single type of product; it also requires that products reflect differences in nicotine delivery method, ease of use, sensory experience, and price. E-cigarettes heat liquid into an inhaled aerosol, heated tobacco products warm tobacco without combusting it, and oral nicotine products deliver nicotine through the mouth. A single alternative product category will not appeal to all current adult smokers.

In addition, risk/benefit evidence differs across product types, and those differences should be clear when smokers compare reduced-risk products. For example, a 2026 Cochrane review found strong evidence that nicotine e-cigarettes improve quitting rates for at least six months compared with nicotine replacement therapy such as patches and gum, though evidence on long-term harms is less clear.[8] Regulatory agencies like the CTP should therefore be clear about what evidence supports each product type and which products have received authorization.

Barriers to a Lawful, Transparent Market

The scale of unauthorized trade shows how far the market remains from functioning as current regulatory rules intend. As of Aug. 28, 2026, the FDA listed 48 authorized e-cigarette products.[9] However, in December 2025, unauthorized products accounted for nearly 70 percent of total tracked retail e-cigarette sales dollars and nearly 98 percent of disposables sales in tracked retail outlets.[10] These figures may underestimate the issue, as the study that reported them excluded vape shops, tobacco-specialty stores, and online sales; the study's researchers

also acknowledged difficulties matching changing product labels to authorization records.[11] With unauthorized products accounting for most measured sales, a product's availability on a shelf is not evidence that the FDA has authorized it.

Shrinking the unauthorized market depends in part on making the lawful route workable, which requires complete, reviewable applications as well as clear agency expectations. The GAO report noted that FDA officials identified missing required information as a source of delay, even though all five manufacturers interviewed sought clearer guidance on the evidence needed for authorization.[12] Enforcement shapes the market as well. The FDA acknowledges that it cannot pursue every unauthorized product, and its May 2026 guidance to industry indicated that certain products awaiting review would have a lower enforcement priority, despite not being authorized for sale.[13] Adult consumers and retailers therefore encounter a market in which products may be authorized, awaiting review, or denied authorization, with enforcement priorities (or lack thereof) adding another layer of complexity. To address these issues, the CTP must do more than increase the number and types of authorized products; it must also make authorization status understandable, identifiable, and enforceable.

Expand the Range of Authorized Alternatives

Expanding the variety of authorized alternatives to cigarettes requires two key improvements to the CTP's review process: using existing evidence to guide product authorization and making reviews predictable to support product development.

Use Existing Evidence to Guide Product Authorization



Determining whether existing findings should apply to a given product or whether product differences require additional evidence beyond what the CTP has already reviewed is complicated. It requires examining how product differences affect exposure and sustained cigarette replacement.

Completed CTP reviews provide a starting point for identifying product features that the CTP views positively in reduced-risk product applications. In heated tobacco and nicotine-pouch decisions, the FDA has considered both lower chemical exposure and whether products deliver nicotine in amounts that can help adults substitute them for cigarettes.[14] The May 2026 authorization of four flavored Glas e-cigarette products also illustrates how the FDA has treated age-related device-access controls and marketing restrictions designed to mitigate youth risk while preserving additional adult choices.[15]

Although these decisions highlight factors the CTP has considered when granting authorization, that does not mean that similar products will also gain authorization. FDA guidance does allow applicants to use relevant findings from research on earlier or similar products but requires them to explain why those findings are relevant to the product under review.[16] Even with data from similar products, CTP reviewers must consider whether subtle product differences introduce additional smoking-cessation benefits or heightened risks.

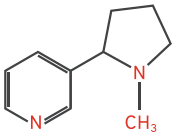
Determining whether existing findings should apply to a given product or whether product differences require additional evidence beyond what the CTP has already reviewed is complicated. It requires examining how product differences affect exposure and sustained cigarette replacement. Four product aspects should be considered to guide that assessment: toxicant exposure, nicotine delivery, sensory

experience, and usability. Assessing these factors draws on different kinds of evidence: Chemical testing characterizes toxicant levels, nicotine-delivery studies measure exposure to nicotine, and laboratory ratings or interviews describe sensory appeal and usability. None of these measures, by itself, demonstrates sustained cigarette replacement.[17]

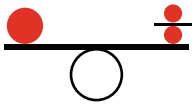
- **Toxicant Exposure.** Lower toxicant exposure provides the health rationale for switching to a reduced-risk product. Assessing the degree of exposure reduction requires chemical testing and evidence of manufacturing consistency, including a consideration of how toxicant levels change during storage or when the product comes into contact with packaging. Existing application requirements address these questions.[18] Toxicant exposure also varies with route of use. For example, the FDA recognizes that a flavoring that is safe to eat is not necessarily safe to inhale.[19]
- **Nicotine Delivery.** Different methods of nicotine delivery can influence how effective a reduced-risk product will be in relieving the cravings and withdrawal that impede smoking cessation. The FDA's reviews of nicotine-pouch products indicate that the amount and speed of nicotine delivery depend on the pouch's formulation and design, not just the nicotine amount on a label.[20] A randomized trial of 520 adults who wanted to reduce their smoking but did not plan to quit suggested that the amount of nicotine an e-cigarette delivers affects cigarette abstinence.[21] An exploratory analysis of the trial found that, at week 24, 10.8 percent of participants using an e-cigarette that delivered nicotine at levels similar to combustible cigarettes had not smoked in the previous seven days, as confirmed by biochemical testing. That compared with 0.8 percent of those using the same device without nicotine and 3.1 percent of those using a nonelectronic cigarette substitute. The trial tested only one device (with tobacco or menthol liquids), 36 percent of participants dropped out, and the study did not establish long-term continuous abstinence.[22] Thus, these findings inform the potential for adult cigarette replacement, not a product's net population-health effect. Reviewers must separately assess dependence, dual use, and the likelihood that youth and adults who do not use tobacco would start using the product.[23]
- **Sensory Experience.** Sensory experience affects whether an adult finds an alternative satisfying enough to continue abstaining from cigarettes. A randomized laboratory study found that participants rated e-cigarettes containing nicotine-salt formulations as smoother, less harsh, and more appealing than free-base nicotine formulations, though the study did not assess whether those ratings would support smoking cessation.[24] Similarly, although flavor preferences may matter in product selection, a flavor that makes a product appealing may not lead adults to replace cigarettes with it.[25] The FDA's March 2026 draft guidance acknowledges the potential adult benefits of flavored products while requiring evidence that those benefits outweigh youth risks.[26] CTP reviewers must therefore distinguish evidence of appeal from evidence of sustained switching while also weighing potential adult benefits against youth-uptake risks.



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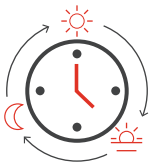


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- **Usability.** Usability is the ease with which adults can incorporate a reduced-risk product into their daily routines. Interviews with adults who had tried switching from cigarettes to another product describe how they experimented with different devices and settings after initially unsatisfying experiences, suggesting that product fit matters when adults seek a more satisfactory alternative to cigarettes.[27] Newer features designed to prevent underage access can also affect adult usability. For example, when the CTP reviewed Glas electronic nicotine delivery system product applications, it considered not only the benefits of such features in preventing youth use, but also adults' ability to easily complete age verification and operate the device.[28]



Newer features designed to prevent underage access can also affect adult usability.

The FDA's e-cigarette guidance already describes combining published longer-term studies with appropriate bridging information (data showing why findings from one product apply to another) and shorter-term studies.[29] The CTP should publish more specific examples of when such evidence is sufficient and when a product difference requires new testing. The agency could issue these examples as nonbinding guidance without creating a new exemption: Each product would still need the evidence and marketing authorization required by law, including an assessment of adult benefits and risks to youth and other nonusers.[30]

Make Review Predictable to Support Product Development



Uncertain review dates can make research budgets and financing more difficult to plan, and clearer evidence requirements and less duplicative testing could reduce these burdens, including for smaller applicants.

Developing new tobacco products requires that manufacturers plan for the cost of seeking authorization and the time it may take to reach the market. The FDA's 2021 regulatory impact analysis modeled the cost of preparing a complete original premarket tobacco product application (PMTA) bundle at about $840,000 for e-cigarettes and $1.22 million for e-liquids (in 2019 dollars); a bundle can cover several related products.[31] A 2025 FDA paperwork estimate puts preparation of a standard bundled submission at 1,713 hours—a measure of paperwork time rather than total research cost.[32] Applicants also face uncertainty about review timing. For applications submitted from 2018 through 2025, the GAO found that completed reviews across the three principal tobacco application pathways averaged 507 calendar days from submission to final determination.[33] As of Dec. 31, 2025, 131,915 applications still lacked a final determination and had been pending for an average of 1,266 days. Both figures measure elapsed time, not days of active scientific review.[34] Uncertain review dates can make research budgets and financing more difficult to plan, and clearer evidence requirements and less duplicative testing could reduce these burdens, including for smaller applicants.

The FDA's drug and device centers provide examples of how published expectations can put existing knowledge to work. The Center for Drug Evaluation and Research recommends methods for generic-drug developers to demonstrate equivalence to an existing medication.[35] Similarly, the Center for Devices and Radiological Health allows certain well-understood products, including some soft contact lenses, to use an expedited Safety and Performance Based Pathway by demonstrating performance against published criteria.[36] The CTP could draw on these examples by publicly specifying the evidence tobacco product applicants should submit, explaining which tests can provide that evidence, and focusing additional review on questions existing findings do not answer—all while retaining tobacco regulation's distinct requirement to assess population-level benefits and harms.

Federal law already sets a review deadline: It directs the FDA to issue a PMTA marketing decision as promptly as possible and no later than 180 days after receipt.[37] The FDA's regulation starts that clock when the agency receives an application that meets filing requirements, and the GAO explains that the agency applies the 180-day timeline to scientific review.[38] The GAO nevertheless found that the FDA did not collect the data needed to monitor whether it was meeting its scientific-review timeliness goals.[39] The Department of Health and Human Services agreed with the GAO's recommendation, stating that the FDA would upgrade its systems to track review milestones.[40]

Some process reforms are already underway. The GAO reported that the FDA groups similar applications, electronically validates submissions, and tested more direct applicant communication through a nicotine-pouch pilot carried out in September 2025.[41] As of May 11, 2026, six of the pilot's 158 product applications had been authorized, and 152 remained in scientific review. The FDA issued internal guidance in April 2026 to apply lessons from the pilot to e-cigarettes, but the GAO concluded it was too soon to know whether these efforts would improve review timeliness more broadly.[42]

To show whether these reforms are working, the CTP should implement the GAO's recommendation to track scientific-review milestones and publish performance against the applicable timelines.[43] It should also report total submission-to-decision times, distinguish agency review time from queueing and time awaiting applicant responses, and establish public targets for the full process. Reporting should separate application pathways and product categories and include both favorable and unfavorable decisions so that faster review is not confused with more authorizations.[44] That reporting would also let policymakers evaluate, rather than assume, whether clearer evidence requirements and faster reviews increase market entry, product variety, or sustained cigarette replacement.

Make Product Authorization Status Clear

Manufacturers need clear evidence requirements and predictable review expectations to navigate the application process successfully; consumers and retailers need an easy, reliable way to identify which products have received authorization and which have not. The FDA already publishes a list of authorized-e-cigarettes and a searchable tobacco-products database.[45] However, researchers found that changing product labels and differences between retail and regulatory names complicated matching retail products to authorization records, and that different package sizes could give one authorized product multiple universal product codes.[46]



Manufacturers need clear evidence requirements and predictable review expectations to navigate the application process successfully; consumers and retailers need an easy, reliable way to identify which products have received authorization and which have not.

The FDA should improve these existing resources by linking current retail names, package images, and identifiers to the exact authorized product and making them available at the point of sale.[47] For products that require premarket authorization, each record should state plainly whether the FDA has authorized the specific product. It should separately report any publicly verifiable application status, such as awaiting review or denied authorization, and any relevant enforcement-policy information. An application awaiting review or with a lower enforcement priority

does not itself grant permission for sale, and the lack of an authorization record does not establish that no application was ever submitted.[48] These records should also distinguish between authorized and unauthorized variants within a brand so that they do not imply that authorization covers an entire brand. The system should be easy to use—even for those with limited digital access or skills. Users should also be able to report mismatches or outdated records easily.

Use Enforcement to Support the Lawful Market

As noted earlier, estimates suggest that unauthorized products accounted for nearly 70 percent of tracked retail e-cigarette sales dollars in December 2025.[49] Current enforcement strategies include issuing warning letters, levying financial penalties, blocking imports, and pursuing court orders against firms selling unauthorized products.[50] A September 2025 joint operation, for example, seized more than 2 million illicit vaping products from distributors and retailers across seven states.[51] These actions have not adequately reduced unauthorized sales.[52]

70%

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Manufacturers pursuing authorization incur research and application costs while competing with products sold without authorization. That uneven competition can weaken incentives to follow the lawful route, regardless of whether a competing seller has applied, been denied, or never sought authorization. Enforcement policy should not assume that every unauthorized seller is a prospective applicant, so the FDA and its enforcement partners should assess whether firms targeted by previous actions are continuing to produce or sell unauthorized products and then escalate enforcement if necessary. The goal should be to strengthen the lawful market while monitoring whether adults using affected products move to authorized alternatives, stop smoking, or return to cigarettes, as well as how enforcement affects youth uptake.

Protecting youth also depends on enforcing age-of-sale rules. Federal law prohibits tobacco sales to people younger than 21, and the FDA requires photo-identification checks for purchasers younger than 30.[53] Training, inspections, and effective penalties should support those rules, so that enforcement both discourages youth initiation and leaves adult smokers with realistic opportunities to choose less harmful products.

Make Authorized Alternatives Affordable and Accessible

State taxes and flavor restrictions can affect both vaping and cigarette use, but the observational evidence varies with what is restricted and who is studied. Massachusetts' June 2020 menthol-cigarette restriction, part of broader flavored-tobacco rules, was associated with a 1.0-percentage-point reduction in current smoking among adults aged 25 and older through 2021.[54] In contrast, a multistate study of 18- to 29-year-olds associated restrictions on flavored-e-cigarettes with a 2.2-percentage-point increase in daily smoking and a 3.6-percentage-point decline in daily vaping relative to comparison-state trends; Maryland's policy, which exempted menthol and open-system devices, was not associated with the same smoking increase.[55] States should therefore assess how their restrictions affect cigarette use rather than infer better health from reduced vaping alone.

Approaches to product taxation should follow the same logic. A retail study associated tax-driven e-cigarette price increases with higher combustible cigarette sales, though it did not track individual smoking or switching.[56] States should assess whether their taxes make lower-risk products more or less expensive than combustible cigarettes and use those findings to create a financial incentive to switch. Tracking actual retail prices and purchases can show whether tax policy maintains that incentive and how consumers respond.



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Even when authorized alternatives are available, some adults may need financial or other practical help to replace combustible cigarettes. The cost of trying a newer or more innovative product, difficulty obtaining supplies, or a need for personal device instruction can make switching more difficult for adults with limited money, transportation, or support.[57] Consistent with these barriers, recent quitting rates are lower among low-income adults, and uninsured adults are particularly unlikely to use quitting assistance.[58] States should also address barriers to quitting assistance, including gaps in Medicaid counseling coverage.[59]

Health systems and quitlines should train staff to answer adults' questions about FDA-authorized noncombustible tobacco products and explain what marketing authorization means. Counseling should distinguish these products from FDA-approved cessation medications and clarify that a separate modified risk tobacco product order is needed for specified reduced-risk or reduced-exposure marketing claims.[60]

Conclusion

A clearer and more timely application-review process could help adults leave cigarettes behind by bringing acceptable alternatives that could replace cigarettes completely into the authorized market. The CTP should implement the GAO's recommendation to collect and monitor scientific-review timing data, publish clearer evidence expectations, and assess whether faster, scientifically sound decisions improve the lawful market.[61] Authorization records linked to current retail names, images, and identifiers would help consumers and retailers identify authorized products, and consistent enforcement against unauthorized products would strengthen the lawful route to market. States should work to keep authorized products affordable relative to cigarettes, and health systems should offer practical support to adults who are trying to switch. The test of reform is not simply faster review or a longer product list. It is whether reform makes it easier for adults to leave cigarettes behind without making it easier for young people and nonusers to start using nicotine.

About the Author

Jeffrey S. Smith is a behavioral neuroscientist and former resident senior fellow in the R Street Institute's Healthier Communities program. His work at R Street has focused on tobacco harm reduction, reduced-risk nicotine products, substance use policy, and evidence-based approaches to public health regulation.

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