

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

CAMPAIGN FOR TOBACCO-FREE KIDS, *et al.*,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Case No. 8:26-cv-02767-ABA

**BRIEF OF AMICUS CURIAE PUBLIC HEALTH LAW CENTER
IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Congress established an intentional and fundamental requirement in the Family Smoking Prevention and Tobacco Control Act (“TCA”) when it determined that new tobacco products must receive authorization from the U.S. Food and Drug Administration before they can be marketed lawfully. 21 U.S.C. § 387j(a)(2). Premarket review was a deliberate feature of the commercial tobacco control regulatory scheme Congress developed more than a decade before the TCA was enacted in 2009, and Congress affirmed its centrality in 2022, when regulating synthetic nicotine. That history reinforces the TCA’s statutory text: review ordinarily precedes market entry. An agency may not administer a statute in a manner inconsistent with the structure Congress enacted. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000). By allowing the marketing of new tobacco products prior to FDA review, the FDA’s recent guidance directly contravenes the regulatory sequence that Congress established.

Plaintiffs in this case challenge the FDA’s May 2026 guidance, “Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization.” 91 Fed. Reg. 25892 (May 12, 2026) (“Guidance”). The Guidance deprioritizes enforcement against unauthorized nicotine pouches and electronic nicotine delivery systems with pending applications that have been accepted and filed, subject to certain exceptions. This Guidance is antithetical to the TCA since, although the FDA acknowledges that unauthorized products remain unlawfully marketed, it offers manufacturers a policy under which sales may occur before the agency completes its review. The FDA concedes in the Guidance that the fact that an application has been filed has no bearing on whether the agency will authorize the sale of the product. Guidance at 5.

The Public Health Law Center (“Center”) submits this amicus brief in support of the Plaintiffs’ motion for summary judgment. Because the FDA’s Guidance contravenes both the plain

language of the TCA and the legislative intent behind its premarket review requirements, Plaintiffs' motion should be granted.

INTEREST OF THE AMICUS CURIAE

The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, and Tribal leaders strengthen public health policies. For more than twenty-five years, the Center has worked with public health professionals and community leaders to develop, implement, and defend effective public health laws, including laws regulating commercial tobacco. Through this work, the Center regularly addresses the relationship between federal commercial tobacco regulation and state and local public health policies. The Center offers its expertise on the legislative development of the TCA and the role Congress assigned to the FDA in premarket review.

ARGUMENT

I. In 2022, Congress Expressly Refused to Let Pending Applications Shield Unauthorized Products

The Defendants' Guidance is difficult to reconcile with the express statutory text of the TCA. In 2022, Congress revisited the role of premarket review in the Act when it chose to address products containing synthetic nicotine. Congress amended the TCA so that tobacco products were defined to include products made or derived from tobacco, "or containing nicotine from any source," including synthetic nicotine. 21 U.S.C. § 321(rr)(1).

Products containing synthetic nicotine were already on the market at the time, and Congress responded in awareness of that fact, choosing a circumscribed time frame that such products were allowed to remain on the market without authorization. *See* Compl. ¶¶ 49–50; Pls.'

Mot. for Summ. J., at 6–7. Products on the market when the law became effective could remain on the market for thirty days, and if an application for the product was submitted during that time, it could be marketed for ninety days after the effective date. *See* Consolidated Appropriations Act of 2022, Pub. L. 117–103, div. P, § 111(d), 136 Stat. 49, 789–90 (2022). Congress expressly provided, however, that once this transition period ended, a product lacking a marketing order violated Section 910, “including such a tobacco product that is the subject of a pending application.” *Id.* at 790. The Guidance is directly counter to this provision of the law: it uses a pending application as the basis for allowing unauthorized products to remain on the market.

The statute’s text shows that Congress anticipated that the FDA might not complete review of synthetic nicotine products before the transition period expired, and nevertheless it placed a definite endpoint on continued marketing. *Id.* In other words, beyond the evidence indicating congressional intent that new tobacco products must undergo premarket review and receive authorization before they can be sold, Congress also specifically addressed whether an exception should be allowed from that requirement for products that are already on the market. Congress chose a limited amount of time for a grace period, not an indefinite time frame. The Guidance grants by agency policy the indefinite time frame that Congress refused to provide.

II. Congress Deliberately Incorporated Premarket Review into the Precursors to the TCA

In addition to the express statutory text of the TCA, the Act’s legislative history also confirms that Congress intended for new tobacco products to undergo premarket review. The core components of the TCA developed over fifteen years of debates, negotiations, litigation, and judicial review about FDA regulation of tobacco products. Congress inserted premarket review for new tobacco products into the earliest precursor legislation to the TCA, which appeared in 1997.¹

¹ National Tobacco Policy and Youth Smoking Reduction Act, S. 1415, 105th Cong. (1997).

In addition, Congress consistently included premarket review in draft bills until the final passage of the TCA. This shows congressional intent that there should be FDA review *before* a new tobacco product can be lawfully marketed. 21 U.S.C. § 387j(a)(2).

A. Congress Added Premarket Review in 1997

The earliest legislative precursor to the regulatory architecture ultimately enacted in the TCA was the National Tobacco Policy and Youth Smoking Reduction Act, introduced in 1997. Two developments earlier in the 1990s were particularly relevant to the introduction of this legislation. First, the FDA Commissioner announced the agency's intention to regulate tobacco products as drugs or devices under the Federal Food, Drug, and Cosmetic Act ("FDCA") in 1994,² publishing a final rule to that end in 1996. 61 Fed. Reg. 44396 (Aug. 28, 1996). Second, in 1994, several states began suing the industry to recover Medicaid costs attributable to commercial tobacco-related disease. *See, e.g., In re Mike Moore, Attorney General, ex rel. State of Mississippi Tobacco Litigation*, No. 94-1429 (Chancery Ct., Jackson Cty., 1994); *State of Minnesota ex rel. Humphrey v. Philip Morris*, No. C1-94-8565 (Minn. Dist. Ct., Ramsey Cty., 1994).

Many states and the industry reached a tentative settlement of this litigation in 1997, the National Tobacco Settlement Proposal.³ This proposed settlement drew on many provisions in the FDA's 1996 rule while also adding substantive new elements. In addition to payments to states, one key provision provided the FDA with clear authority to regulate tobacco products as drugs or devices. The National Tobacco Settlement Proposal acknowledged that this could not be done

² Letter from David A. Kessler, Commissioner, Food and Drug Administration, to Scott D. Ballin, Chairman, Coalition on Smoking or Health (Feb. 25, 1994), UCSF Industry Documents Library, <https://www.industrydocuments.ucsf.edu/docs/qjnn0145/>.

³ Text of the Attorney General/Tobacco Industry Settlement. Proposed Resolution. Preamble, UCSF Industry Document Library, <https://www.industrydocuments.ucsf.edu/docs/fqmc0016/>.

without implementing legislation from Congress to give the agency such regulatory authority over tobacco products.⁴

Several congressional bills emerged within a year of the National Tobacco Settlement Proposal that sought to grant the FDA authority over tobacco products.⁵ The National Tobacco Policy and Youth Smoking Reduction Act progressed the furthest of these bills. This bill attempted to regulate tobacco products through a regulatory regime separate from drugs and devices. It also added further restrictions beyond those that were included in the settlement proposal, though this bill ultimately did not pass.

Nevertheless, between the National Tobacco Settlement Proposal and the National Tobacco Policy and Youth Smoking Reduction Act, many core aspects of what would become the TCA were already taking shape by 1997. For example, the National Tobacco Settlement Proposal included provisions giving the FDA oversight over health claims about “less hazardous tobacco products” (later known as modified risk tobacco products), requiring the industry to disclose smoke constituents, and giving the agency discretion to require the industry to reduce nicotine yields. The proposed settlement did not include a provision requiring premarket review of new tobacco products, however, relying instead primarily on postmarket mechanisms.

The National Tobacco Policy and Youth Smoking Reduction Act introduced several additional components, including the public health standard, the substantial equivalence pathway, and a provision allowing preexisting tobacco products to remain on the market without undergoing review. Crucially, this bill introduced a provision requiring premarket review for *new* tobacco products, with the public health standard supplying the FDA with the standard for such review.

⁴ *Id.*

⁵ Healthy Kids Act, S. 1638, 105th Cong. (1998); Kids Deserve Freedom from Tobacco Act of 1998, S. 1889, 105th Cong. (1998); Healthy Kids Act, H.R. 3474, 105th Cong. (1998); Bipartisan No Tobacco for Kids Act of 1998, H.R. 3868, 105th Cong. (1998); National Tobacco Policy and Youth Smoking Reduction Act, S. 1415, 105th Cong. (1997).

The bill created Chapter IX in the FDCA for tobacco products and addressed premarket review in Section 910, the same place where the provisions on premarket review would later be found in the TCA. An amended version of the bill also gave the FDA authority to deem other products to be tobacco products in the future. It did not exempt such future products from the premarket review requirements of Section 910.

A Senate report about this bill explains that Congress drew on the premarket review requirements of the FDCA in developing a different public health standard specific to tobacco products. S. REP. NO. 105-180, at 23 (1998). The report notes that a new standard was necessary because “[t]obacco products raise different public health issues than medical devices regulated under Chapter V of the [FDCA].” *Id.* at 15. This “appropriate for the protection of the public health” standard served as an alternative to showing safety and effectiveness, a standard that tobacco products could not meet. *Cf.* 144 CONG. REC. S5012 (May 18, 1998) (“Well, clearly, tobacco is not safe or effective; we know that.”). Congress thus had three options: (1) ban tobacco products under the safety and effectiveness standard, (2) exempt them entirely, or (3) create a tobacco-specific review standard. While this bill exempted products that were on the market as of August 11, 1995 (a cutoff date changed in later legislation), it included a tobacco-specific standard of review for new tobacco products. By choosing premarket review, Congress placed the burden on manufacturers to establish that new tobacco products must meet the public health standard before they can be sold. *See* S. REP. NO. 105-180, at 23 (“the Secretary shall deny approval [if] there is a lack of a showing” that the product meets the public health standard).

Congress could have chosen to implement the proposed settlement with minimal changes. Instead, it added several new restrictions in the National Tobacco Policy and Youth Smoking Reduction Act, including premarket review for new tobacco products. Though that bill did not

become law, it advanced further than any similar bills during that congressional session. This bill also marked the earliest articulations by Congress of the core provisions of what would later become the TCA. Over the next decade, Congress continually returned to the basic structure found in the National Tobacco Policy and Youth Smoking Reduction Act.

B. Later Bills Retained Premarket Review in Subsequent Sessions, and Congress Enacted that Framework in 2009

While Congress debated legislation granting the FDA authority over tobacco products, the FDA was defending its rulemaking to regulate tobacco products as drugs or devices in court, as the industry challenged the rule soon after its publication. 61 Fed. Reg. 44396. In 2000, the Supreme Court invalidated the FDA's attempt to regulate tobacco products as drugs or devices because "Congress intended to exclude tobacco products from the FDA's jurisdiction." *Brown & Williamson*, 529 U.S. 120, 142.

After the Supreme Court's ruling in *Brown & Williamson*, Congress faced a choice between two approaches to tobacco product regulation: establishing the FDA's authority to regulate tobacco products through existing drug and device provisions or creating a tobacco-specific regime modeled on the National Tobacco Policy and Youth Smoking Reduction Act. Over the next few years, Congress introduced several bills that sought to delegate authority to the FDA to regulate tobacco products. Some bills aimed to give the agency authority to regulate them as drugs or devices,⁶ while others created a tobacco-specific regulatory regime.⁷ The tobacco-specific regime bills generally retained the core architecture of the National Tobacco Policy and Youth Smoking

⁶ Child Tobacco Use Prevention Act of 2001, H.R. 1044, 107th Cong. (2001); FDA Tobacco Authority Amendments Act, H.R. 1097, 107th Cong. (2001); Kids Deserve Freedom from Tobacco Act of 2001, S. 247, 107th Cong. (2001).

⁷ Tobacco Livelihood and Economic Assistance for Our Farmers Act, H.R. 140, 108th Cong. (2003); Youth Smoking Prevention and Public Health Protection Act, S. 2626, 107th Cong. (2002); Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, S. 2764, 107th Cong. (2002); National Youth Smoking Reduction Act, S. 190, 107th Cong. (2001); National Youth Smoking Reduction Act, H.R. 2180, 107th Cong. (2001); Youth Smoking Prevention and Public Health Protection Act, S. 2568, 106th Cong. (2000).

Reduction Act. While these bills differed in various aspects, one constant was a provision requiring premarket review for new tobacco products. In contrast, bills that treated tobacco products as drugs or devices lacked an explicit provision on premarket review for such products. Congress ultimately opted for the tobacco-specific regime approach, which included the premarket review requirement modeled on the National Tobacco Policy and Youth Smoking Reduction Act.

With the basic architecture of the TCA settled, comparatively little changed between 2004 and 2009. In 2004, a pair of bills emerged that adopted the Family Smoking Prevention and Tobacco Control Act name that would reappear in subsequent congressional sessions until it was passed into law.⁸ In 2007, Congress proffered February 15, 2007 as the date for distinguishing between preexisting tobacco products that do not require premarket review and new tobacco products that require such review.⁹ That this date was eventually included in the final bill which was signed into law underscores the consistency in the drafters' intent that the harm level of the market be frozen at that point and no new harmful products be allowed on the market without prior authorization. Again, the central point is that premarket review remained unchallenged and was present in all these bills from 2004 to 2009.¹⁰

If Congress wanted to give the FDA discretion to dispense with premarket review of new tobacco products, it would have done so over the many years of debate about FDA regulation of tobacco products. It also could have given the FDA discretion to permit unauthorized newly deemed products to be marketed while review is pending. It did not grant such discretion. While

⁸ Family Smoking Prevention and Tobacco Control Act, S. 2461, 108th Cong. (2004); Family Smoking Prevention and Tobacco Control Act, H.R. 4433, 108th Cong. (2004).

⁹ Family Smoking Prevention and Tobacco Control Act, H.R. 1108, 110th Cong. (2007).

¹⁰ See Family Smoking Prevention and Tobacco Control Act, S. 982, 111th Cong. (2009); Family Smoking Prevention and Tobacco Control Act, H.R. 1256, 111th Cong. (2009); Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. (2007); Family Smoking Prevention and Tobacco Control Act, H.R. 1108, 110th Cong. (2007); Family Smoking Prevention and Tobacco Control Act, S. 666, 109th Cong. (2005); Family Smoking Prevention and Tobacco Control Act, H.R. 1376, 109th Cong. (2005); Family Smoking Prevention and Tobacco Control Act, S. 2461, 108th Cong. (2004); Family Smoking Prevention and Tobacco Control Act, H.R. 4433, 108th Cong. (2004).

Defendants have previewed an argument that the agency has inherent discretion unless Congress limits it, Defs.’ Mot. to Stay, at 9–10, it is clear here that Congress created some exceptions to premarket review (e.g., for preexisting products and those that meet the requirements of 21 U.S.C. § 387j(a)(2)(B)) but did not otherwise create discretion to allow exceptions for new tobacco products. *See Reyes v. Waples Mobile Home Park*, 903 F.3d 415, 432 (4th Cir. 2018) (quoting *Andrus v. Glover Construction Co.*, 446 U.S. 608, 616–17 (1980) (“Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied[.]”). The FDA’s Guidance allowing for a more relaxed premarket review requirement is contrary to the TCA.

III. The FDA’s Guidance Undermines Congress’s Intended Process of Premarket Review Before Product Entry into the Marketplace

Congress intended that new tobacco products should only be allowed to be sold if the FDA conducts premarket review and finds authorization to be appropriate for the protection of public health. 21 U.S.C. § 387j(c)(2)(A). It signaled this intention since the earliest legislative predecessor of the TCA in 1997 and retained the premarket review requirement from session to session until the eventual passage of the Act in 2009. Then, when given the opportunity to revisit premarket review in 2022, Congress again affirmed the requirement. As Plaintiffs note, “Congress has been explicit as to how and when new tobacco products may be marketed without premarket review.” Pls.’ Mot. for Summ. J., at 16.

The Guidance creates a different regime for regulating tobacco products than the one enacted by Congress. It does not create a temporary grace period but rather announces enforcement priorities that suggest a grace period without a definite end. This is contrary to declarations by the FDA that it will not allow the industry to flout premarket review requirements because doing so

would be “outside of its statutory authority.”¹¹ In addition, the agency’s decision to permit certain unauthorized products to remain on the market is not motivated by the need to accommodate a newly regulated product already on the market, as with synthetic nicotine. Rather, it applies to products that the FDA has been regulating for years.

Nothing in the TCA or its legislative history suggests that Congress intended to eliminate the FDA’s traditional discretion to prioritize enforcement against individual violations, but discretion over which violations to pursue is different from establishing a categorical policy under which entire classes of unauthorized products can remain on the market indefinitely. The Defendants argue that their “Guidance concerns just a single provision of the TCA, [and] only two types of products regulated under that provision.” Defs.’ Mot. to Stay, at 6. In reality, it concerns premarket review—a central pillar of the TCA, and the Guidance likely covers thousands of different products.¹²

The TCA’s legislative history reveals that premarket review for new tobacco products was always central to the Act. The Guidance cannot be reconciled with the regulatory sequence that Congress deliberately incorporated into the TCA. When Congress first inserted premarket review into legislation about FDA regulation of tobacco products in 1997, it sought to make the FDA the gatekeeper responsible for assessing the risks of new tobacco products before they are introduced to consumers. S. REP. NO. 105-180, at 23. The FDA’s recent Guidance effectively reverses that regulatory sequence by announcing that the agency will not prioritize enforcement against qualifying products while they remain on the market and while the FDA determines if they meet

¹¹ Response from FDA to Am. Vapor Mfrs., Docket No. FDA-2022-P-1211, at 3, <https://www.regulations.gov/document/FDA-2022-P-1211-0005>. The Guidance provides no explanation for the change in the FDA’s interpretation of its statutory authority, making it arbitrary and capricious. *See FCC v. Fox Television Stations*, 556 U.S. 502, 515 (2009).

¹² *See, e.g.,* Food & Drug Admin., *PMTA Metrics for Acceptance, Filing and Review/Action Phases* (2026), <https://www.fda.gov/media/169533/download?attachment>.

the public health standard. Reversing that timing is contrary to Section 910. In addition to this Court in *AAP v. FDA*, other courts have vacated guidance documents that are inconsistent with the premarket review requirements of the TCA. *See, e.g., Philip Morris v. FDA*, 202 F. Supp. 3d 31, 50 (D.D.C. 2016) (“the FDA’s interpretation of the TCA ... is foreclosed by the TCA itself”).

The FDA tried relaxing the premarket review process in 2017, but this Court stated that such agency action was incompatible with the TCA. *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 492 (D. Md. 2019) (“[The] Guidance defeats, rather than furthers, the purpose of the Tobacco Control Act by ... informing the manufacturers that the Tobacco Control Act requirements for premarket review will not be enforced.”). The agency is trying a similar approach through its 2026 Guidance. The Court should affirm Plaintiffs’ summary judgment motion and not allow the agency to shirk its clear premarket responsibilities under the TCA.

CONCLUSION

For these reasons, the Center respectfully requests that the Court grant the plaintiffs’ motion for summary judgment.

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Respectfully submitted,

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