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Client Alert Commentary

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Supreme Court Upholds FDA's Denial of Marketing Authorization for Flavored Tobacco Products

In a 9-0 decision, the Court held that FDA has broad discretion to interpret the standard for marketing authorizations of new tobacco products under the Tobacco Control Act.

Key Points:

- The Court also indicated that FDA must act consistently with the guidance it provides industry, but assumed, without deciding, that the change-in-position doctrine applies to an agency's divergence from a position articulated in nonbinding guidance.
- The Court declined to address whether FDA has imposed a de facto ban on flavored e-cigarettes that runs afoul of the statutory requirement to adopt tobacco product standards through notice-and-comment rulemaking.
- The Court's decision coincides with significant personnel and staffing changes at FDA and the Center for Tobacco Products (CTP), including the removal of CTP Director Brian King and agency-wide reductions in force (RIFs) affecting CTP.

On April 2, 2025, the Supreme Court unanimously held that the US Food and Drug Administration (FDA) lawfully denied marketing authorization for certain flavored e-liquids used in electronic nicotine delivery systems (ENDS), otherwise known as e-cigarettes or "vapes."[1] The Court vacated and remanded the Fifth Circuit's decision that FDA had acted arbitrarily and capriciously under the Administrative Procedure Act (APA) by issuing marketing denial orders (MDOs) to the respondents for their premarket tobacco product applications (PMTAs).[2]

In the 9-0 decision, the Court concluded that FDA's decision was sufficiently consistent with the guidance it had provided respondents before rejecting their PMTAs and thus did not run afoul of the Court's change-in-position doctrine.[3] Writing for the Court, Justice Alito emphasized that FDA has broad discretion under the Tobacco Control Act to decide what sort of scientific evidence a tobacco product manufacturer must submit with a PMTA to support marketing authorization.[4]

This Client Alert provides key takeaways on the ruling and outlines remaining uncertainties for tobacco and nicotine product manufacturers and distributors.

Background

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA) to grant FDA regulatory authority over tobacco products.[5] The TCA requires manufacturers seeking to commercially market a new tobacco product in the United States to first seek premarket authorization from FDA.[6] If FDA determines that authorizing the new tobacco product for marketing would not be appropriate for the protection of the public health (APPH), FDA must issue the applicant an MDO.[7] To determine whether authorizing a new tobacco product would be APPH, FDA must consider the risks and benefits to the population as a whole, taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using such products.[8]

Tobacco product manufacturers have repeatedly challenged FDA's APPH determinations in federal court. The Supreme Court's decision upholding FDA's determination comes in the wake of decisions from seven other circuit courts throughout the nation, which have similarly dismissed challenges to FDA's MDOs for flavored ENDS products as arbitrary and capricious.[9]

Key Takeaways

FDA has latitude under the TCA to determine whether manufacturers have provided sufficient scientific evidence to support marketing authorization of a new tobacco product

The Court's opinion stresses that the TCA provides FDA with broad discretion to determine whether the marketing of a new tobacco product would be APPH.[10] The Court notes that the TCA itself "imposes only basic requirements" for FDA to follow in making an APPH determination for a new tobacco product, specifying only that FDA's decision to grant marketing authorization be based on either "well-controlled investigations" or other "valid scientific evidence."[11] Although the Court acknowledged that FDA's guidance documents and oral presentations have lacked specific commitments about exactly what sorts of scientific evidence applicants should provide, the Court held that the TCA ultimately defers to FDA to decide what constitutes a well-controlled investigation or other valid scientific evidence sufficient to meet the statutory APPH standard.[12]

FDA's noncommittal approach to providing industry with guidance is consistent with the TCA and the APA

The Court reviewed the body of guidance documents, agency statements, and oral presentations FDA made to industry preceding the MDOs. Although the Court characterized this body of guidance as largely noncommittal, this lack of commitment weighed in FDA's favor. In the Court's view, FDA's "largely noncommittal guidance on scientific evidence and its specific reasons for rejecting respondents' applications" foreclosed any finding that FDA had violated the change-in-position doctrine by reversing course on statements it made to industry and failing to offer a sufficient explanation for such reversals.[13] To preserve this flexibility in interpreting and implementing the APPH standard under the TCA, FDA may continue to provide limited guidance on what qualifies as a well-controlled investigation or other valid scientific evidence.

Manufacturers' PMTAs can themselves serve as evidence that FDA provided sufficient notice of the agency's standards for marketing authorization

Respondents argued that FDA had failed to provide them with notice that they would need to compare their flavored ENDS products to tobacco-flavored products to receive MGOs.[14] The Court acknowledged that FDA did not provide this precise instruction in its pre-decisional guidance.[15] But in the Court's view, respondents' PMTAs reflected FDA's messaging because their PMTAs are "replete with statements

attempting ... to draw comparisons between dessert-, candy-, and fruit-flavored and tobacco-flavored products ... ."[16] The Court stated that the PMTAs served as evidence that "regulated entities had adequate notice of the sort of comparative analysis the FDA anticipated."[17] FDA may therefore argue that, even if a manufacturer asserts that relevant guidance is non-specific or ambiguous, their PMTA or response to a deficiency letter could reflect an understanding of FDA's expectations.

Beliefs about how FDA is likely to exercise its enforcement discretion are not a "serious reliance interest"

The Court rejected respondents' argument that FDA had changed course by subjecting its products to the same regulatory scrutiny as flavored, cartridge-based products.[18] In a 2020 guidance document, FDA indicated that it was prioritizing flavored, cartridge-based ENDS for enforcement, and the Court noted that the 2020 guidance "unmistakably emphasized cartridge-based products ... ."[19] In the Court's view, although the 2020 guidance may have led respondents to believe that FDA was more likely to authorize their open-system ENDs products than other manufacturers' cartridge-based products, "such a belief about how an agency is likely to exercise its enforcement discretion is not a 'serious reliance interest.'"[20]

Remaining Uncertainties

- The Court's decision stresses that FDA "*must* deny an application unless it is shown" that marketing a new product would meet the APPH standard, but does not offer industry with any additional and much-needed insight into *how* to meet the APPH standard.[21] Instead, the Court emphasizes that this decision is within FDA's broad discretion under the TCA. Manufacturers must therefore continue to rely on FDA's limited guidance on this front and may benefit from engagement with FDA throughout the process of developing a PMTA to build out the administrative record.

- Since granting certiorari in this case, FDA authorized the first non-tobacco-flavored ENDS products and the first oral nicotine pouch products, perhaps signaling the agency's loosening approach to its evaluation of new tobacco products under the APPH standard.[22] Last week, Brian King was removed as the director of the Center for Tobacco Products (CTP). Dr. King oversaw the denial of PMTAs for a wide variety of flavored ENDS products.[23] This personnel change and recent authorizations — coupled with the Court's holding that FDA has broad discretion to interpret the APPH standard under the TCA — may result in FDA continuing to exercise its discretion to authorize products it has historically held to stricter standards.

- Emphasizing that the only question before the Court was whether "FDA acted arbitrarily and capriciously in denying respondents' applications for premarket approval of their tobacco products," the Court did not address two key issues: (1) whether FDA has imposed a de facto ban on flavored ENDS by adopting a tobacco product standard without going through notice-and-comment rulemaking, and (2) whether the change-in-position doctrine under the APA applies to positions an agency articulates in nonbinding guidance documents.[24] Regarding the first issue, the Court stated that it "did not grant certiorari on that question, and without adequate briefing, it would not be prudent to decide it here."[25] The Fifth Circuit held that FDA "unquestionably failed to follow § 387g's notice-and-comment obligations before imposing its de facto ban on flavored e-cigarettes," but the Court refused to address this holding based on its narrow framing of the question presented.[26]

  With respect to the second issue, the Court noted that the change-in-position doctrine under the APA has traditionally applied in more formal settings.[27] But because neither party pressed the argument of whether it could apply to an agency's guidance documents, the Court assumed, without deciding, that the doctrine "could apply to an agency's divergence from a position articulated in nonbinding guidance documents."[28]

- Recent reporting indicates that the RIFs at FDA also affected Dr. Matthew Farrelly, the director of CTP's Office of Science, as well as offices at CTP responsible for enforcing tobacco regulations, drafting new tobacco regulations, and setting policy.[29] Such cuts will make it more challenging for FDA to provide industry with more guidance and to implement new regulatory policies. The impact of the RIFs on CTP's authorization of new tobacco products remains to be seen, but industry may face delays and complications in navigating the regulatory landscape.

- The Court remanded to the Fifth Circuit the issue of whether FDA's decision not to consider respondents' marketing plan was a harmless error under the APA.[30] FDA declined to consider the marketing plan because it had found that marketing and access restrictions on flavored ENDS products cannot remedy an otherwise insufficient PMTA lacking the necessary scientific evidence.[31] The Court clarified for the Fifth Circuit that remand — here, requiring FDA to review the marketing plan — would be pointless if, for example, it is clear that "the agency's error 'had no bearing on the procedure used or the substance of [the] decision reached ... ."[32] On remand, the Fifth Circuit may nonetheless require FDA to review the marketing plan.

Latham & Watkins will continue to monitor developments in this space.

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Endnotes

1 *FDA v. Wages & White Lion Invs., L.L.C.*, No. 23-1038, 604 U.S. 1, 46 slip op.

2 *Id.*

3 *Id.* at 25.

4 *Id.* at 25-26.

5 Pub. L. No. 111-31, 123 Stat. 1776 (June 22, 2009).

6 21 U.S.C. § 387j(a)(2).

7 *Id.* § 387j(c)(2).

8 *Id.*

9 See *Magellan Tech., Inc. v. FDA*, 70 F.4th 622, 629-630 (2d Cir. 2023); *Liquid Labs LLC v. FDA*, 52 F.4th 533, 539-545 (3d Cir. 2022); *Avail Vapor, LLC v. FDA*, 55 F.4th 409, 419-427 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023); *Gripum, LLC v. FDA*, 47 F.4th 553, 558-561 (7th Cir. 2022), cert. denied, 143 S. Ct. 2458 (2023); *Lotus Vaping Techs*., *LLC v. FDA*, 73 F.4th 657, 668-673 (9th Cir. 2023); *Electric Clouds, Inc. v. FDA*, No. 21-9577, 2024 WL 795952, at *2-*13 (10th Cir. Feb. 27, 2024); *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 20-26 (D.C. Cir. 2022); see also *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 503-507 (6th Cir.) (rejecting challenge at the stay stage), stay denied, 142 S. Ct. 638 (2021).

10 *FDA v. Wages & White Lion*, at 26.

11 *Id.*

12 *Id.*

13 *Id.* at 29.

14 *Id.* at 32.

15 *Id.* at 35.

16 *Id.* at 36.

17 *Id.*

18 *Id.* at 37.

19 *Id.* at 39.

20 *Id.* at 39-40.

21 *Id.* at 5 (emphasis in original).

22 FDA, FDA News Release, *FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review* (June 21, 2024), https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-four-menthol-flavored-e-cigarette-products-after-extensive-scientific; FDA, FDA News Release, *FDA Authorizes Marketing of 20 ZYN Nicotine Pouch Products after Extensive Scientific Review* (Jan. 16, 2025), https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-20-zyn-nicotine-pouch-products-after-extensive-scientific-review.

23 Matthew Perrone, AP, *FDA tobacco official is removed from post in latest blow to health agency's leadership* (Apr. 1, 2025), https://apnews.com/article/fda-tobacco-rfk-brian-king-cf2d5657e5d55410073aece19592be09;

24 *FDA v. Wages & White Lion,* at 19.

25 *Id.*

26 See *FDA v. Wages and White Lion Invs., L.L.C.*, No. 21-60800, at 41 n.5 (5th Cir. 2024).

27 *Id.* at 23 n.5.

28 *Id.*

29 Lizzy Lawrence and Sarah Todd, STAT+, *FDA Commissioner Marty Makary gets off to a bruising start as agency is wracked by layoffs* (Apr. 1, 2025), https://www.statnews.com/2025/04/01/fda-rif-3500-layoff-notices-under-rfk-jr-hhs-reorganization/.

30 *FDA v. Wages & White Lion*, at 46.

31 *Id.* at 43.

32 *Id.* at 45.