United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
June 24, 2026
Lyle W. Cayce
Clerk

No. 24-60537

VDX Distro, Incorporated; Vapetastic, L.L.C.,

Petitioners,

versus

United States Food & Drug Administration; Marty Makary, *Commissioner, U.S. Food and Drug Administration*; United States Department of Health and Human Services; Robert F. Kennedy, Jr., *Secretary, U.S. Department of Health and Human Services*,

Respondents.

On Petition for Review
of an Order of the Food & Drug Administration
Agency No. PM0002351

Before Elrod, *Chief Judge*, Smith, and Wilson, *Circuit Judges*.

Cory T. Wilson, *Circuit Judge*:

Use of e-cigarettes has been on the rise in recent years, especially among young people. This case is one of numerous disputes between the United States Food & Drug Administration (FDA) and e-cigarette companies contesting the agency's efforts to balance between discouraging youth adoption of e-cigarettes and encouraging adult cigarette smokers to switch to relatively less harmful e-cigarettes—all in view of the public health

policy preferences enacted by Congress in the Family Smoking Prevention and Tobacco Control Act (TCA). Petitioner VDX Distro, Inc. (VDX) is one such company. It manufactures e-cigarette products and sells them to retailers including Vapetastic, LLC, also a petitioner here.

Under the TCA, e-cigarette manufacturers cannot market their products without FDA approval. So VDX applied to FDA to obtain marketing authorization for VDX's menthol-flavored e-cigarette products.

In FDA's view, non-tobacco-flavored e-cigarettes are especially dangerous for minors because those e-cigarettes are more enticing than tobacco-flavored ones. So under the agency's "comparative-efficacy standard," marketing applicants for non-tobacco-flavored e-cigarettes must show an advantage over tobacco-flavored e-cigarettes in encouraging adult cigarette smokers to "go digital"—*i.e.*, to switch to e-cigarettes—or to quit altogether. FDA denied VDX's application after determining that the benefits of VDX's menthol-flavored e-cigarette products to adult smokers did not outweigh the countervailing risks to youths. VDX and Vapetastic petition our court for review of that decision. We deny the petition.

I.

A.

Through the TCA, Congress gave FDA "the power to regulate the manufacturing, marketing, sale, and distribution of tobacco products." *FDA v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 551 (2024). The TCA granted FDA authority over "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," as well as any other product that FDA "by regulation deems" to be a tobacco product. *Id.* (citing 21 U.S.C. § 387a(b)). In 2016, FDA issued a rule deeming e-cigarettes to be tobacco products. *Id.* at 555; 81 Fed. Reg. 29028 (May 10, 2016).

The TCA prohibits manufacturers from marketing tobacco products without FDA authorization. 21 U.S.C. § 387j(a)(2)(A). A manufacturer can obtain authorization by submitting a premarket tobacco product application. *Id.* § 387j(c)(1)(A)(i).[1] The application process is "onerous, requiring manufacturers to gather significant amounts of information." *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 439 (5th Cir. 2020). There are a few ways that FDA can deny a premarket application, but only two are relevant here.

First, FDA can deny applications via the TCA's rulemaking provision. The TCA empowers FDA to promulgate "tobacco product standards." 21 U.S.C. § 387g(a)(3). And FDA "shall deny" a premarket application if the proposed product does not conform to any "tobacco product standard in effect under section 387g." 21 U.S.C. § 387j(c)(2)(D). The TCA itself contains two tobacco product standards: The statute bans cigarettes that contain "artificial or natural flavor[s] (other than tobacco or menthol)," and it prohibits manufacturers from using tobacco that "contains a chemical pesticide residue level greater than is specified by any tolerance applicable under Federal law." 21 U.S.C. § 387g(a)(1). Before adopting any other tobacco product standards, FDA must publish a notice of proposed rulemaking and invite comments. *Id.* § 387g(c).

The second mode is through the TCA's adjudicatory framework. FDA "shall deny" a premarket application that does not indicate that marketing the tobacco product would be "appropriate for the protection of the public health" (APPH). 21 U.S.C. § 387j(c)(2)(A). To determine whether a product is APPH, the TCA requires FDA to consider "the risks and benefits of the population as a whole, including users and nonusers of the

[1] The TCA "establishes a handful of other authorization pathways for new tobacco products," but those alternatives are irrelevant here. *Wages*, 604 U.S. at 551 n.1.

tobacco product." *Id.* § 387j(c)(4). The TCA further clarifies that FDA must consider "the increased or decreased likelihood that existing users of tobacco products will stop using such products and . . . [that] those who do not use tobacco products will start using such products." *Id.* In plain English, the TCA aims to maximize the chances that smokers will quit and minimize the risk that non-smokers will start.

B.

In 2017, FDA noted an "alarming increase" in the use of e-cigarettes by "middle and high school students." FDA responded by investigating reports of e-cigarette sales to minors. FDA also issued warning letters to various manufacturers, distributors, and retailers that sold e-cigarette products with "advertising that resemble[d] kid-friendly food products, such as juice boxes, candy, or cookies." However, in 2018, "FDA continued to receive information underscoring the problem of youth use of [e-cigarettes]." By 2019, "two of the largest surveys of tobacco use among youth found that e-cigarette use ha[d] hit the highest levels ever recorded."

In April 2020, FDA published a guidance document laying out the agency's enforcement priorities for e-cigarettes (the 2020 Guidance). The 2020 Guidance stated that FDA would "exercise its enforcement authorities with respect to particular products . . . on a case-by-case basis, informed by the enforcement priorities described in this Final Guidance." FDA was especially concerned with the popularity of flavored e-cigarette products with youth because "[r]esearch has long shown that flavors increase youth appeal of tobacco products, including [e-cigarettes]." The 2020 Guidance noted that youth use of menthol-flavored e-cigarettes was not as high as youth use of other flavored e-cigarettes (such as mint- and fruit-flavored), and that young people preferred cartridge-based e-cigarettes as opposed to other types. Therefore, the 2020 Guidance stated that FDA would prioritize

enforcement against "[a]ny flavored, cartridge-based [e-cigarette] product (other than a tobacco- or menthol-flavored product)." In particular, FDA would prioritize e-cigarettes that were "targeted to minors or whose marketing is likely to promote use of [e-cigarettes] by minors."

By October 2022, internal memoranda indicate that FDA's approach to menthol-flavored e-cigarettes had shifted. The agency had hoped that menthol-flavored e-cigarettes would have less appeal to youth than other flavored e-cigarettes and would provide a suitable substitute for adults who smoke menthol-flavored combustible cigarettes. But after further study, FDA noted a "lack of robust evidence of the actual differential use of menthol-flavored [e-cigarettes]" in reducing cigarette use per day. For menthol cigarette smokers who sought to quit or switch to e-cigarettes, the "nationally representative data" had not shown that they preferred menthol-flavored e-cigarettes to tobacco-flavored ones. Therefore, FDA stated that its approach to menthol-flavored e-cigarettes should be the same as with other non-tobacco-flavored e-cigarettes "with respect to the evidence of adult benefit."[2]

C.

VDX Distro, Inc. manufactures e-cigarette products—specifically, nicotine-infused liquids that go inside of e-cigarettes— and sells them to e-cigarette retailers including Vapetastic, LLC. VDX submitted a premarket application to FDA requesting marketing authorization for its "Four

[2] According to FDA, the approach reflected in the internal memoranda was "formulated in the course of FDA's evaluation of the Logic menthol applications." *See Logic Tech. Dev. LLC v. FDA*, 8 F.4th 837 (3d Cir. 2023).

Seasons" e-cigarette products, many of which were menthol-flavored. FDA denied VDX's application as to the menthol-flavored e-cigarette products.[3]

FDA's written explanation for the denial is lengthy and technical, but the bottom line turns on FDA's application of a balancing test. While the evidence showed that non-tobacco-flavored e-cigarettes—including menthol—have a "known and substantial risk of youth initiation and use," *tobacco*-flavored e-cigarettes "have not been shown to present the same risks to youth." Therefore, FDA determined that the marketing of non-tobacco-flavored e-cigarettes is "APPH only if the evidence shows a benefit to adults who smoke as compared to tobacco-flavored [e-cigarettes]." In other words, to be APPH, a non-tobacco-flavored e-cigarette must have an advantage over tobacco-flavored ones when it comes to getting adult cigarette smokers to quit altogether or "go digital." Only then would a non-tobacco-flavored e-cigarette's benefit to adults outweigh its risk to minors. The parties call this the "comparative-efficacy standard."

Applying the comparative-efficacy standard, FDA determined that VDX's premarket application "lack[ed] sufficient evidence" to demonstrate that its menthol-flavored e-cigarette products will "provide a benefit to adult users that would be adequate to outweigh the risks to youth." On that basis, FDA concluded that allowing VDX to market its menthol-flavored e-cigarette products would not be APPH and therefore denied VDX's premarket application.

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[3] FDA also denied VDX's premarket application as to the flavored e-cigarette products that were neither tobacco- nor menthol-flavored, but the petition before us concerns only FDA's denial as to the menthol-flavored e-cigarette products.

II.

VDX and Vapetastic assert four challenges in their petition for review.[4] First, they argue that the major questions doctrine prohibits FDA's assertion of regulatory authority over e-cigarettes. Second, Petitioners contend that the TCA's APPH standard is unconstitutionally vague. Third, Petitioners maintain that FDA's comparative-efficacy standard is actually a tobacco product standard that FDA adopted in violation of the TCA's notice-and-comment rulemaking requirements. Finally, Petitioners insist that FDA arbitrarily and capriciously applied the APPH standard when adjudicating VDX's premarket application. We address each claim in turn.

A.

Petitioners' first claim ostensibly anchors itself to the major questions doctrine. They assert that "Congress's delegation of deeming authority violated the major questions doctrine" because the TCA allows FDA broad discretion to "deem" products to be "tobacco products," thus subjecting those products to the TCA's requirements. *See* 21 U.S.C. § 387a(b). Despite Petitioners' characterization, their argument in substance invokes not the major questions doctrine but the nondelegation doctrine. But the two doctrines are not interchangeable, and Petitioners' nondelegation challenge is squarely foreclosed.

The major questions and nondelegation doctrines are "closely related" but distinct. *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab.*, 595 U.S. 109, 124 (2025) (GORSUCH, J., concurring). While the major questions doctrine

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[4] Venue is proper in our court because Vapetastic is a Texas LLC. *See Shenzhen IVPS Tech. Co., Ltd. v. FDA*, 148 F.4th 306, 312 (5th Cir. 2025) ("[If] one of the Petitioners has its principal place of business within the Fifth Circuit, venue is proper under Section 387*l*(a)(1)(B).").

"guard[s] against unintentional, oblique, or otherwise unlikely delegations of legislative power," the nondelegation doctrine "ensures democratic accountability by preventing Congress from intentionally delegating its legislative powers to unelected officials." *Id.* at 124–25. Under the major questions doctrine, an agency must point to "clear congressional authorization" rather than "a merely plausible textual basis" when it asserts "[e]xtraordinary grants of regulatory authority." *West Virginia v. EPA*, 597 U.S. 697, 723 (2022) (quotation omitted). Under the nondelegation doctrine, Congress may vest discretion in executive agencies, but it cannot give away its legislative power; courts must ask "whether Congress has set out an 'intelligible principle' to guide what it has given the agency to do." *FCC v. Consumers' Rsch.*, 606 U.S. 656, 672 (2025) (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)).

Though Petitioners repeatedly reference the major questions doctrine, they do not really make a major questions argument. They assert that "Congress impermissibly delegated legislative authority to FDA to determine which products it would regulate." That is a textbook nondelegation argument, and our court has already rejected it. In *Big Time Vapes, Inc. v. FDA*, an e-cigarette manufacturer "sued the FDA, contending that the TCA unconstitutionally delegated to [FDA] the power to deem tobacco products subject to the Act's mandates." 963 F.3d at 440. This court disagreed, holding instead that "Congress plainly limited the authority that it delegated." *Id.* at 445. Petitioners' argument is on all fours with *Big Time Vapes*, so it is foreclosed, in whatever wrapping it is packaged.

B.

As explained earlier, the TCA requires FDA to deny premarket applications unless "permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C.

§ 387j(c)(2)(A). Petitioners contend that this standard is unconstitutionally vague. But a statute is open to a vagueness challenge only when it is arguably unclear as to what conduct it prohibits. The APPH standard does not run afoul of this guardrail.

"Vague statutes violate due process, because laws must 'give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly.'" *Ford Motor Co. v. Tex. Dep't of Transp.*, 264 F.3d 493, 509 (5th Cir. 2001) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)). But "[b]efore a penalty, whatever its nature, creates urgent need for notice, that penalty must attach to conduct." *Jones v. City of Lubbock*, 727 F.2d 364, 373 (5th Cir. 1984). If a law "imposes neither regulation of nor sanction for conduct," then "no necessity exists for guidance so that one may avoid the applicability of the law." *Boutilier v. INS*, 387 U.S. 118, 123 (1967). In short, "[a]bsent an effect on conduct, a statute's standard is not susceptible to attack as vague." *Jones*, 727 F.2d at 373.

The TCA's APPH standard does not, by itself, prohibit anything. It is instead an adjudicatory standard by which FDA must assess applications for marketing authorization. If FDA determines that marketing a proposed tobacco product would not be APPH, that determination does not mean that the product manufacturer has violated any laws; nor does it subject the manufacturer to any penalties. Rather, it is the TCA's prohibition of unauthorized marketing—not the APPH standard—that constrains a manufacturer's actions. And it is perfectly clear what a manufacturer must do to avoid violating the TCA: Do not market e-cigarettes without FDA preapproval. Because the APPH standard prohibits no conduct, it cannot be challenged as unconstitutionally vague.

C.

Under FDA's comparative-efficacy standard, the marketing of a non-tobacco-flavored e-cigarette will not be considered APPH unless the "evidence shows a benefit to adults who smoke as compared to tobacco-flavored [e-cigarettes]" because tobacco-flavored e-cigarettes do not pose the same risks to youths as non-tobacco-flavored ones. Petitioners assert that this is "a disguised tobacco product standard adopted contrary to the TCA" because FDA circumvented the TCA's notice-and-comment requirements for rulemaking. Petitioners are incorrect. The comparative-efficacy standard is not a "tobacco product standard" as the TCA delineates them; it is instead a methodology developed by FDA to apply the TCA's APPH standard.

As discussed, the TCA allows FDA to promulgate "tobacco product standards." 21 U.S.C. § 387g(a)(3). Before doing so, FDA must publish a notice of proposed rulemaking and invite public comment. *Id.* § 387g(c). FDA "shall deny" premarket applications for tobacco products that do not conform to any "tobacco product standard in effect under section 387g." *Id.* § 387j(c)(2)(D). The TCA does not define "tobacco product standard," but the rest of the statute provides illuminating context.

In 21 U.S.C. § 387g(a)(4), the TCA outlines the "[c]ontent of tobacco product standards," listing several "provisions" that a tobacco product standard might encompass. These provisions include various aspects of tobacco products, such as "nicotine yields"; "reduction or elimination of other constituents, including smoke constituents"; "testing," "measurement," and "sale and distribution"; and "the form and content of labeling for the proper use" of tobacco products. *Id.* The TCA further specifies that parties may submit specific evidence to FDA to contest a "determination, set forth in a proposed tobacco product standard in a

proposed rule," that it would be APPH to "require the reduction or elimination of an additive, constituent, or other component of a tobacco product." *Id.* § 387g(a)(3)(B)(iii). A consistent theme of these clauses is that tobacco product standards would draw hard-and-fast lines as to certain attributes of tobacco products, including their flavoring.

That reading gains support from the two tobacco product standards actually enumerated in the TCA.[5] The first is a "[s]pecial rule for cigarettes": They "shall not contain . . . an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, [&c.]." *Id.* § 387g(a)(1)(A). The second is an "[a]dditional special rule" providing that tobacco product manufacturers "shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco." *Id.* § 387g(a)(1)(B). In short, the TCA's two tobacco product standards (1) prohibit cigarettes from having any flavors except tobacco or menthol, and (2) set an upper limit on how much pesticide residue is allowed in tobacco products.

The Federal Register contains four proposed tobacco product standards propounded by FDA, all akin to the two Congress enacted in § 387g(a)(1). Each purports to derive its implementing authority from § 387g, and each bolsters our reading of what qualifies as a tobacco product standard under the statute. The first is a "tobacco product standard that would establish a limit of N-nitrosonornicotine (NNN) in finished smokeless

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[5] Under the TCA, the Secretary of the Department of Health and Human Services (or FDA, as the Secretary's designee) "may adopt tobacco product standards *in addition to those in paragraph (1)* if the Secretary finds that a tobacco product standard is [APPH]." 21 U.S.C. § 387g(a)(3)(A) (emphasis added).

tobacco products." 82 Fed. Reg. 8004-1 (Jan. 23, 2017). The second "would prohibit characterizing flavors (other than tobacco) in all cigars and their components and parts." 87 Fed. Reg. 26396-01 (May 4, 2022). The third is a "tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes." 87 Fed. Reg. 26454-01 (May 4, 2022). And the fourth "would regulate nicotine yield by establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products." 90 Fed. Reg. 5032-01 (Jan. 16, 2025).[6] As with the standards denoted in the TCA itself, these four standards proposed by FDA all set objective, categorical limits on the tobacco products targeted by them (*e.g.*, smokeless tobacco, cigars, cigarettes). This means that, for instance, even if a manufacturer were to provide overwhelming evidence that marketing a strawberry-flavored cigarette would be APPH, the question is a non-starter; § 387g(a)(1)(A)'s tobacco product standard forecloses any question of FDA's approval.

FDA's comparative-efficacy standard is qualitatively different. It channels the flexible adjudicatory discretion that a tobacco product standard would usurp. With the comparative-efficacy standard, manufacturers can obtain marketing approval; as always, they need only show that marketing their product would be APPH. The difference is that for *non-tobacco-*

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[6] None of these four proposed rules has been finalized; the federal government's regulatory website indicates that all four remain open. *See* Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products (https://www.regulations.gov/docket/FDA-2016-N-2527) [https://perma.cc/26LS-GRZB]; Tobacco Product Standard for Characterizing Flavors in Cigars (https://www.regulations.gov/docket/FDA-2021-N-1309) [https://perma.cc/6JGW-EMCG]; Tobacco Product Standard for Menthol in Cigarettes (https://www.regulations.gov/docket/FDA-2021-N-1349) [https://perma.cc/752K-ZCKW]; Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products (https://www.regulations.gov/docket/FDA-2024-N-5471) [https://perma.cc/S6FP-3USW]; *but see* 90 Fed. Reg. 45515-01 (Sept. 22, 2025) (indicating that the latter two proposed rules have been withdrawn).

flavored e-cigarettes, FDA has decided to construe the APPH standard's pliable threshold more narrowly than for tobacco-flavored ones. In other words, the comparative-efficacy standard is simply a more exacting interpretation of the TCA's APPH standard as it pertains to non-tobacco-flavored e-cigarettes. True enough, FDA employs that interpretation across-the-board in its evaluation of applications for non-tobacco-flavored e-cigarette products. That uniformity may be tantamount to FDA's application of a rule—a question we do not address in today's case—but it does not render the comparative-efficacy standard a "tobacco product standard" within the meaning of the TCA. The comparative-efficacy standard is a balancing test, not a ban.[7]

Interpreting the TCA as allowing flavor-based comparisons is consistent with the Supreme Court's emphasis on the APPH standard's "inherently comparative judgment," one that "calls out for various types of comparisons, including comparisons between new tobacco products and those that are already available, as well as between different types of new tobacco products that may attract new smokers." *Wages*, 604 U.S. at 578–79. The TCA charges FDA with making those comparisons, and we see no reason why the APPH's comparative exercise cannot focus on flavor—especially given FDA's empirical findings about the different levels of risk posed by different flavors. As many of our sister circuits have concluded, FDA's choice to "compare[ ] the claimed cessation benefits of flavored and

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[7] Indeed, a few e-cigarette manufacturers *have* gotten marketing approval for menthol-flavored e-cigarettes even with the comparative-efficacy standard in play. This outcome, even if vanishingly rare, would not be possible at all under a tobacco product standard. *See* Food & Drug Administration, *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 [https://perma.cc/SY4U-PTH2].

non-flavored products . . . is precisely the type of analysis the statute calls for." *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 19 (D.C. Cir. 2022).[8] Accordingly, we reject Petitioners' suggestion that *any* flavored-based distinctions are tantamount to tobacco product standards. On the contrary, FDA's flavored-based comparative assessment flows from the TCA itself.

Our conclusion is further bolstered by the Supreme Court's recent reiteration that "agencies may generally develop regulatory standards through either adjudication or rulemaking." *Wages*, 604 U.S. at 582 (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 202–03 (1947)). While FDA could have opted for rulemaking, "FDA had discretion to work out the meaning of the TCA's comparative standard when evaluating premarket tobacco product applications." *Id.* That is what FDA did with its comparative-efficacy standard; the agency chose adjudication as its preferred route for comparatively evaluating the distinctive dangers of non-tobacco-flavored e-cigarettes. And while FDA uniformly applies the standard across adjudications, nothing in the TCA prevents FDA from doing so. Because the comparative-efficacy standard is not a tobacco product standard, FDA's utilization of the comparative-efficacy standard did not violate the TCA's notice-and-comment requirements.[9]

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[8] *See also Magellan Tech., Inc. v. FDA*, 70 F.4th 622, 631 (2d Cir. 2023); *Liquid Labs LLC v. FDA*, 52 F.4th 533, 542 (3d Cir. 2022); *Avail Vapor, LLC v. FDA*, 55 F.4th 409, 427–28 (4th Cir. 2022); *Gripum, LLC v. FDA*, 47 F.4th 553, 559 (7th Cir. 2022); *Lotus Vaping Techs., LLC v. FDA*, 73 F.4th 657, 661 (9th Cir. 2023).

[9] Petitioners' TCA notice-and-comment attack on the comparative-efficacy standard is distinct from a claim based on the APA's notice-and-comment provisions. Amici curiae in support of Petitioners lodge both arguments, but Petitioners make only the former. We therefore leave for another day the merits of an APA notice-and-comment argument. *But see RJ. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 192–94 (5th Cir. 2022). As explained *supra*, the TCA's particular statutory framework and context drive our analysis of the TCA notice-and-comment issue before us.

D.

Turning to FDA's adjudication of VDX's premarket application, the TCA directs that we review FDA's denial of an application in accordance with § 706 of the Administrative Procedure Act (APA). 21 U.S.C. § 387*l*(b). The APA requires the court to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). An agency must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *BNSF Ry. Co. v. Fed. R.R. Admin.*, 62 F.4th 905, 910 (5th Cir. 2023) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

Petitioners contend that FDA arbitrarily applied the APPH standard to VDX's premarket application by: (1) basing its analysis on outdated data; (2) failing to adhere to the TCA's "population as a whole" requirement; and (3) arbitrarily applying the APPH standard to VDX's marketing plan. We consider each contention in turn.

1.

Petitioners first argue that FDA improperly relied on "stale youth use data" in denying VDX's application. True enough, more recent data show significant reductions in youth e-cigarette use. Yet, according to Petitioners, FDA nevertheless "continued to regulate as if it [was] still 2019 and the reductions in youth use never occurred." In short, Petitioners contend that FDA acted arbitrarily because it had no good reason to stay the course as the data changed.

Not so. The record shows that FDA was well aware that youth e-cigarette use had been declining since 2019; indeed, the agency affirmatively took credit for it. In FDA's view, its choice to prioritize non-tobacco-flavored e-cigarettes "contributed to the decline in youth use." Even then, FDA says, the problem persisted: Youth use of e-cigarettes remained at worryingly high levels. And of the youths who reported using e-cigarettes in 2022, about 27% used menthol-flavored ones. FDA therefore decided to stay the regulatory course.

"Black-letter administrative law instructs that when an agency makes . . . scientific judgments, . . . a reviewing court must be at its 'most deferential.'" *Seven Cnty. Infrastructure Coal. v. Eagle Cnty.*, 605 U.S. 168, 182 (2025) (quoting *Baltimore Gas & Elec. Co v. Nat'l Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983)). And an agency has "broad discretion" to choose among its regulatory priorities. *See Massachusetts v. EPA*, 549 U.S. 497, 527 (2007). We therefore decline Petitioners' invitation to second-guess FDA's continued prioritization of enforcement against non-tobacco-flavored e-cigarettes—though coincident with a decline in youth e-cigarette use—as the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action." *BNSF Ry. Co.*, 62 F.4th at 910.

2.

Petitioners also argue that FDA ignored the TCA's requirement that FDA must make its APPH determination based on "the risks and benefits to the population as a whole." 21 U.S.C. § 387j(c)(4). In Petitioners' telling, FDA improperly "focus[ed] wholly on two subpopulations and subfactors: the proven benefit in transitioning adult smokers versus the risks of youth access."

But Petitioners' position runs contrary to the TCA, which allows FDA to focus on particular subpopulations. The TCA requires FDA to

assess "the risks and benefits to the population as a whole, *including users and nonusers of the tobacco product*." *Id.* (emphasis added). Further, the TCA commands FDA specifically to consider "the increased or decreased likelihood" that "existing users of tobacco products will stop using such products" and that "those who do not use tobacco products will start using such products." *Id.* This indicates that Congress wanted to ensure that FDA considers both sides of the user/non-user equation when estimating a tobacco product's net impact, not that Congress wanted to block FDA from examining effects on subpopulations.

When it came to assessing the benefits and risks of flavored e-cigarettes, FDA made a reasonable decision as to which smokers are likely to stop and which non-smokers are likely to start. To gauge benefits to smokers, FDA's focus is on adults who smoke combustible cigarettes. And for risks to non-smokers, FDA focused on youth adoption as a particular concern. By focusing on these two subpopulations, FDA reasonably aimed to maximize the overall positive impact on the "population as a whole." On the record before us, that approach was not arbitrary and capricious.

3.

Petitioners last argue that FDA arbitrarily applied the APPH standard to VDX's marketing plan. Petitioners offer two reasons why, but neither is persuasive.

First, Petitioners assert that FDA "refused to review VPX's [*sic*] marketing plan for the sake of efficiency." Granted, FDA previously took this tack. In the agency's 2021 denial of VDX's earlier application for non-tobacco, non-menthol-flavored e-cigarette products, FDA stated that "for the sake of efficiency, the evaluation of the marketing plans in applications will not occur at this stage of review" because FDA had seen no "access

restrictions that, to date, have been successful in decreasing the ability of youth to obtain and use [e-cigarettes]."

But that is not what FDA did in this case. In FDA's denial of VDX's current application for menthol-flavored e-cigarette products, FDA noted that "given the concerns expressed by certain federal courts, . . . FDA is now reviewing all applicant-proposed marketing restrictions and mitigation measures." And FDA indeed reviewed VDX's marketing plan. Thus, Petitioners can challenge the substance of FDA's review of VDX's marketing plan, but they cannot challenge the fact that FDA reviewed it.

Second, Petitioners contend that FDA did not adequately explain its conclusion that VDX's marketing plan was insufficient. We disagree. FDA stated that VDX's marketing plan "did not propose any novel or materially different measures from those that FDA has previously considered and found insufficient." FDA further explained that while sales restrictions can help reduce youth access, youths obtain e-cigarettes despite sales restrictions because most youth e-cigarette users do not buy them; they often get e-cigarettes from friends or family, or steal them. Therefore, mere "sales access restrictions do not in themselves provide enough assurance of a sufficient reduction in youth use to mitigate the risk." Similarly, FDA explained that restrictions on advertising and promotion do "not directly prevent youth use," such that their utility is limited. "To date," the "only measures" that FDA has found to have provided sufficient safeguards from the risk of youth use are "device access restrictions" such as "identification by fingerprint or other biometric parameters in order to unlock and use a tobacco product." VDX's marketing plan did not include those safeguards.

FDA's rationale was not arbitrary and capricious. FDA explained that "point-of-sale restrictions and marketing changes did not sufficiently protect youth, as youth frequently accessed [e-cigarette] products after the

point of sale." *SWT Glob. Supply, Inc. v. FDA*, 139 F.4th 957, 964 (8th Cir. 2025). And FDA conveyed that "restrictions beyond the point of sale—for example, biometric use barriers—could combat the problem." *Id.* At bottom, FDA "articulate[d] a satisfactory explanation for its action." *BNSF Ry. Co.*, 62 F.4th at 910 (quotation omitted).

III.

In sum, all four of Petitioners' challenges are unsuccessful. First, Congress did not violate the nondelegation doctrine—or the major questions doctrine—by granting FDA the authority to deem products to be "tobacco products" for purposes of TCA regulations. Likewise, the TCA's APPH standard is not subject to a vagueness attack because it does not prohibit any conduct.

Nor did FDA's adoption of the comparative-efficacy standard violate the TCA's notice-and-comment rulemaking requirements. That is because the comparative-efficacy standard is not a "tobacco product standard" within the meaning of the TCA. Rather, it is a rubric for applying the APPH calculus's "inherently comparative judgment," *Wages*, 604 U.S. at 578–79, to non-tobacco-flavored e-cigarettes—a balancing test, not a ban.

Finally, FDA did not arbitrarily and capriciously apply the APPH standard to VDX's premarket application. The record indicates that FDA provided a reasoned explanation for its denial of that application.

PETITION DENIED.