PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 22-3030

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LOGIC TECHNOLOGY DEVELOPMENT LLC,
Petitioner

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION

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On Petition from the United States Food & Drug Administration
(FDA-1: PM0000528.PD1, PM0000534.PD1, PM0000539.PD1)

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Argued May 9, 2023

Before: KRAUSE, PORTER, and AMBRO, *Circuit Judges*

(Filed: October 19, 2023)

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OPINION

KRAUSE, *Circuit Judge*.

New information and changes in the marketplace can alter consumers' decisions about the products they buy, and the same is true of the federal agencies that regulate the marketing of those products. Here, starting in early 2020, the Food and Drug Administration (FDA) began taking aggressive action to

remove fruit- and dessert-flavored e-cigarettes, also known as electronic nicotine delivery systems (ENDS), from the stream of commerce, leaving aside at that time tobacco- and menthol-flavored ENDS. More recently, based on additional studies and market data, the FDA has denied the applications of importers and manufacturers like Petitioner Logic Technology Development (Logic) to market menthol-flavored ENDS.

Logic now challenges that denial as a violation of the Administrative Procedure Act (APA), claiming it was arbitrary and capricious for the FDA (1) to apply the same regulatory framework to menthol that it used to assess the appropriateness of sweeter flavors, (2) to ultimately reject its applications for its menthol-flavored ENDS to remain on the market, and (3) to do so without granting Logic a transition period following that decision. For the reasons explained below, however, we find those arguments unpersuasive because the FDA applied a regulatory framework consistent with its statutory mandate, provided a reasoned explanation for its denial, and based its decision on scientific judgments that we may not second-guess. We will therefore deny Logic's petition for review.

I. Background

Because our resolution of Logic's petition requires an understanding of the highly reticulated scheme that Congress laid out in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), we review that framework before assessing its application to the menthol-flavored products at issue here.

A. Statutory framework

The Tobacco Control Act requires any tobacco product not on the market before February 15, 2007 to receive approval from the FDA. *See* 21 U.S.C. § 387j(a)(1)–(2). Only if the FDA concludes that "permitting such tobacco product to be marketed would be appropriate for the protection of the public health" (health-appropriate) can the product be approved.[1] *Id.* § 387j(c)(2). Manufacturers seeking advance permission to market one of these newer products can submit a "premarket tobacco product application" (PMTA or premarket application) to the agency. *See Liquid Labs LLC v. FDA*, 52 F.4th 533, 537 (3d Cir. 2022) (citations omitted).

When considering such an application, the FDA is statutorily required to conduct a balancing test to determine whether an ENDS is health-appropriate and, thus, whether it can remain on the market. The agency must assess:

> [T]he risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

[1] The FDA first deemed ENDS and their flavor cartridges "new tobacco products" and thus subject to the Tobacco Control Act in 2016. *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 28,976 (May 10, 2016). The D.C. Circuit upheld this rule in *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 281–82 (D.C. Cir. 2019).

> (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
> (B) the increased or decreased likelihood that those who do not use tobacco products will start using such tobacco products.

21 U.S.C. § 387j(c)(4)(A)–(B). This mandate in effect creates a sliding scale: the greater the risk of the new tobacco product to non-smokers, especially children, the greater the benefit to smokers that the manufacturer must demonstrate. *See Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1211 (11th Cir. 2022) (Rosenbaum, J., dissenting).

When applying that test, the FDA is to consult a wide range of evidence. The agency must deny a premarket application "if, upon the basis of the information submitted to the Secretary as part of the application *and any other information* . . . with respect to such tobacco product," it determines that the product is not health-appropriate. 21 U.S.C. § 387j(c)(2)(A) (emphasis added). And it "shall, when appropriate" make that determination "on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product." *Id.* § 387j(c)(5)(A). But if the agency "determines that there exists valid scientific evidence" beyond those studies that "is sufficient to evaluate the tobacco product, the Secretary may authorize that the [health-appropriateness] determination . . . be made on the basis of such evidence. *Id.* § 387j(c)(5)(B).

B. The FDA's previous regulation of vaping

Within the FDA, the Center for Tobacco Products (the Center) manages the premarket application evaluation process.[2] The Center, in turn, contains multiple divisions, including the Director's office, the Office of Science, and the Office of Compliance and Enforcement.[3] A manufacturer's premarket application passes through several discipline-specific reviews, including engineering, chemistry, epidemiology, and social sciences. The Technical Project Lead then synthesizes those teams' findings and ultimately determines whether the product is health-appropriate. Though the FDA has delegated authority to review premarket applications to the Office of Science, the Director retains supervisory authority over the Center's component offices. Thus, there is room for deliberation among the Center's teams, but the buck stops with the Director.

The Center's experts began to face a new challenge in the late 2010s as youth tobacco product use suddenly skyrocketed. Prior to 2017, high schoolers' e-cigarette use had been dropping. But from 2017 to 2019, "ENDS product use more than doubled among middle school and high school

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[2] U.S. Food & Drug Admin., *About the Center for Tobacco Products (CTP)* (July 21, 2023), https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp.

[3] *See* U.S. Food & Drug Admin., *Center for Tobacco Products Organization Chart* (Mar. 30, 2023), https://www.fda.gov/about-fda/fda-organization-charts/center-tobacco-products-organization-chart.

students." JA 1118. From 2017 to 2018, the proportion of twelfth graders who had smoked an e-cigarette in the past thirty days went from 16.6% to 26.7%. For tenth graders, that figure went from 13.1% to 21.7% in the same period. According to the National Youth Tobacco Survey (the Youth Survey), among high schoolers overall, e-cigarette use went from 11.7% to 20.8%. By 2018, the Surgeon General had deemed youth ENDS use an "epidemic." *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 10 (D.C. Cir. 2022).

Flavored e-cigarettes were the driving force behind this epidemic. Youth Survey data showed that in 2014, 65.1% of high schoolers and 55.1% of middle schoolers who were using ENDS said they were using a non-tobacco flavor (including menthol). By 2022, that figure had risen to 85.5% for high schoolers and 81.5% for middle schoolers, meaning approximately 2,110,000 of the 2,550,000 students using ENDS. Manufacturers were marketing ENDS with names and flavors that were more appropriate for a candy store than a smoke shop, such as "Brain Freeze Caramel Cone, Buncha Crunch . . . Crazy Bubble Grape, Giggle Juice," *id.* at 15, "Peanut Butter Milk Pie, Bad Monkey Giovanni, and Sunshine Vape Dragon Berry Balls," *Gripum LLC v. FDA*, 47 F.4th 553, 556 (7th Cir. 2022) (internal quotation marks omitted). The results were predictable. Flavors that most resembled fruit, candies, or desserts were more popular with kids than those that resembled combustible cigarettes. In a 2019 survey of kids who used JUUL e-cigarettes—then the most popular ENDS brand—the vast majority of respondents listed mango, mint, or fruit as the flavor they used most often. Tobacco and menthol barely registered with respondents.

The FDA had to figure out how it would address this crisis within the bounds of the Tobacco Control Act. The agency promulgated multiple guidance documents for manufacturers, the most relevant here being one published in June 2019 (Premarket Application Guidance),[4] which set out what the FDA was looking for in premarket applications for ENDS, and another, published in April 2020 (Enforcement Priorities),[5] which articulated the agency's priorities for enforcement actions against manufacturers whose products were not considered health-appropriate.

In the Premarket Application Guidance, the FDA said that "the finding of whether permitting the marketing of a product would be [health-appropriate] will be determined, when appropriate, on the basis of well-controlled investigations." JA 1027. "Nonclinical studies alone," on the other hand, "generally [would] not [be] sufficient to support [such] a determination." *Id.* The FDA also recommended that manufacturers "compare the health risks of its product to both products within the same category and subcategory" that "are most likely to [be] considered interchangeable." JA 1028. As applied to fruit-flavored ENDS, the Premarket Application Guidance meant that the FDA would not approve a product without evidence that it offered benefits "over an appropriate

[4] U.S. Food & Drug Admin., Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry (June 2019).

[5] U.S. Food & Drug Admin., Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry (Apr. 2020).

comparator tobacco-flavored ENDS" with randomized controlled trials, longitudinal cohort studies, or other similar evidence "that could potentially demonstrate the [relative health] benefit[s] of . . . flavored ENDS." *Liquid Labs*, 52 F.4th at 538 (citation omitted).

The Enforcement Priorities reflected recent trends in youth ENDS vaping. Highest priority would be given to non-tobacco, non-menthol flavors, along with other ENDS manufacturers with insufficient marketing restrictions or products marketed to kids. To support this approach, the agency cited survey data like that above, showing both middle- and high-school students using fruit flavors more often than mint or menthol. While survey data disaggregating mint from menthol ENDS was spotty at the time, the JUUL study had found that mint was much more popular than menthol. The FDA received, considered, and rejected comments arguing that menthol should be included among the flavors selected for aggressive enforcement. It noted that "[d]ata shows that tobacco- and menthol-flavored ENDS products are not as appealing to minors as other flavored ENDS products." JA 1145.

ENDS manufacturers attacked the FDA's application of the Premarket Application Guidance and Enforcement Priorities, with mixed results across the circuit courts.[6] We

[6] The Second, Fourth, Sixth, Seventh, Ninth, and D.C. Circuits all have denied petitions or stays. *Magellan Tech., Inc. v. FDA*, 70 F.4th 622, 625 (2d Cir. 2023); *Avail Vapor, LLC v. FDA*, 55 F.4th 409, 413 (4th Cir. 2022), *cert. denied*, No. 22-1112, 2023 WL 6558399 (Mem) (Oct. 10, 2023);

rebuffed that attack and upheld the FDA's approach in *Liquid Labs*. There, the company had received a marketing denial order for eighteen ENDS with non-tobacco, non-menthol "characterizing" flavors like "OG Summer Blue" and "Berry Au Lait." *Liquid Labs*, 54 F.4th at 537. To support its premarket applications, the manufacturer submitted a marketing plan, "an abuse liability study, a cross-sectional perception and intention study, a population modeling analysis, a clinical literature review, and well-controlled non-clinical analyses." *Id.* (internal quotation marks and citation omitted). The FDA found this evidence insufficient because Liquid Labs had failed to submit "randomized controlled trial[s] and/or longitudinal stud[ies]" or any other evidence that "reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on adult smokers' switching or cigarette reduction over time." *Id.* at 538 (internal quotation marks and citation omitted). The manufacturer petitioned for review, arguing that the FDA had "pull[ed] a surprise switcheroo" by changing the evidentiary standard for premarket applications. *Id.* at 539 (internal quotation marks and citation omitted).

Breeze Smoke, LLC v. FDA, 18 F.4th 499, 508 (6th Cir. 2021); *Gripum*, 47 F.4th at 553; *Lotus Vaping Techs., LLC v. FDA*, Nos. 21-71328, 21-71321, 2023 WL 4384447, at *2 (9th Cir. July 7, 2023); *Prohibition Juice*, 48 F.4th at 8. The Fifth and Eleventh Circuits have granted stays to manufacturers, albeit for different reasons. *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 187 (5th Cir. 2023); *Bidi Vapor*, 47 F.4th at 1191. The Fifth Circuit also has heard en banc argument to determine the validity of the FDA's comparative approach in *Wages and White Lion Invs., LLC v. FDA*, Nos. 21-60766, 21-60800 (5th Cir. May 16, 2023).

We sided with the FDA and sustained the marketing denial order. The Premarket Application Guidance, we determined, "nowhere guaranteed that unspecified other forms of evidence would necessarily be sufficient," *id.* at 540 (quoting *Prohibition Juice*, 45 F.4th at 21), and the text of the Tobacco Control Act "necessarily implie[d] a comparative analysis," *id.* at 543 (quoting *Wages and White Lion Invs., LLC v. FDA*, 41 F.4th 427, 434 (5th Cir. 2022), *vacated and reh'g en banc granted*, 58 F.4th 233 (5th Cir. 2023). Thus, we concluded that Liquid Labs had "fair notice of the analysis the agency would perform and the purpose of those comparisons," *id.* (quoting *Prohibition Juice*, 45 F.4th at 24), and the FDA's comparative evidentiary standard for fruit and similar flavors was not arbitrary or capricious.

C. Procedural background

While the courts were determining the legality of the FDA's approach to these flavors, the FDA made good on its comments in the Enforcement Priorities and turned its attention to menthol. Menthol posed an additional regulatory challenge because it had a legal substitute in menthol-flavored combustible cigarettes. With menthol making up about 37% of the combustible cigarette market, it was thought that ENDS offering a similar characterizing flavor might help millions of smokers ditch tobacco, potentially dramatically altering the health-appropriateness calculation and decreasing the showing that a manufacturer would need to make in terms of menthol's appeal to children. Thus, manufacturers, Logic among them, sought to make the case that the Tobacco Control Act's balancing test should produce a different result in the case of menthol-flavored ENDS.

1. *Logic's Premarket Application*

In August 2019, Logic submitted premarket applications[7] for over a dozen of its ENDS, including its menthol- and tobacco-flavored products.[8] To support its applications, Logic submitted hundreds of thousands of pages of data, including clinical studies to determine the products' risk of abuse, two sixty-day randomized controlled studies to determine the products' effects on smokers, and a marketing plan explaining how it would limit sales to children. As Logic saw things, this data offered "overwhelming scientific evidence" that its menthol-flavored ENDS were health-appropriate, Opening Br. at 12, because, among other things, the studies showed that its products helped adult menthol cigarette smokers reduce their daily cigarette intake, lowering their exposure to nicotine and helping them quit, and that these smokers preferred its menthol-flavored ENDS to its tobacco-flavored ones.

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[7] Manufacturers submit one premarket application per new tobacco product for which they are seeking agency approval. Logic submitted over a dozen premarket applications for ENDS with various characterizing flavors, three of them menthol-flavored. The Marketing Denial Order covers only these products. For ease of reference, we refer to Logic's applications for the at-issue ENDS as its Premarket Application.

[8] The history concerning some of Logic's other applications is recounted below, but only the FDA's rejection of its menthol-flavored ENDS is at issue in this appeal.

And on the other side of the health-appropriateness ledger, Logic provided survey data that it contended showed (1) that children do not use its products,[9] and (2) that menthol as a flavor was not nearly as popular among children as fruit or similar sweet flavors. In the same vein, Logic adopted many of the traditional marketing restrictions that other applicants have employed to keep its products out of children's hands, age-gating its website, quitting social media, and avoiding designs, flavors, and advertising campaigns directed at kids. With this combination, Logic believed it had made a strong case for its menthol-flavored ENDS to remain on the market.

2. *The Center's deliberations about menthol*

Logic's Premarket Application for menthol-flavored ENDS became something of a test case "because . . . it was one of the applications" for such a product "furthest along in review" when the Center began to assess how the same health-appropriateness balance should apply to that flavor. JA 908.

Because it believed there was a "potential benefit" to adults who smoked menthol-flavored cigarettes, the Office of Science's "preliminary" recommendation was to approve Logic's Premarket Application. *Id.* Menthol cigarette smokers' potential switch to a menthol-flavored ENDS like Logic's could alter the health-appropriateness balance by making the benefit to current smokers greater than in fruit-

[9] According to the 2019 Youth Survey, just 0.8% of high-school-aged respondents said that they used Logic's products. At the time, most high schoolers used JUUL or did not have a usual e-cigarette brand.

flavored ENDS. At the same time, the risk to non-smoking youth, while higher than for tobacco-flavored ENDS, appeared lower than for fruit-flavored ones.

But the Office of the Center Director was not so sure, and raised questions about the Office of Science's recommendation that "continued over the course of several months into 2022." JA 908. Director Brian King, who arrived at the Center in July 2022, shared this concern and continued to question whether Logic's menthol-flavored ENDS were appropriate for the protection of public health. JA 904, 909. According to a memorandum by Dr. Todd Cecil, then Acting Director of the Office of Science (the Cecil Memo), Dr. King "raised questions about the [Office of Science's] recommendation, including questions about the role and sufficiency of the general scientific literature on adult menthol smokers' differential preference for menthol ENDS in demonstrating likely behavioral change, and underscored [his] concerns about the substantial appeal of menthol to youth." JA 908. The Director ultimately concluded that "the approach to menthol-flavored ENDS should be the same as with other flavored ENDS with respect to the evidence of adult benefit." JA 904. Under that approach, as with fruit and similar characterizing flavors, the Center could only approve a menthol-flavored ENDS "if the evidence showed that the benefits . . . were greater than tobacco-flavored ENDS." JA 909.

The Director did not arrive at this conclusion in a vacuum. According to his memorandum (the King Memo), he solicited feedback from Office of Science staffers who may have disagreed with him "in a voluntary, confidential, and non-pressured environment" through the Center's Ombuds Team.

JA 905. King's team considered several competing approaches to these products, including:

> whether [the Center's] evaluation of ENDS products places too much emphasis on the risks to youth from ENDS use, is not adequately bearing in mind the dangers from conventional smoking, and is pursuing the elimination of youth ENDS use without adequate regard to the impact on potential benefits to adult smokers. [The Center's] review process [took] into account the magnitude and rigor of the data related to youth ENDS use, how [the Center] should consider these data . . ., and the critical need to weigh evidence among both youth and adults in deciding whether to grant or deny marketing authorization.

JA 904. Notably, as part of this process, the Center also considered whether its "approach to evaluating ENDS applications will result in the removal of all ENDS from the U.S. market except for tobacco-flavored ENDS . . . based on an assumption that no applicant would ever submit evidence sufficient to support authorization." *Id.* n.3.

Having completed that review, Director King concluded that "nationally representative data have not demonstrated that menthol combustible cigarette smokers are more likely to actually use menthol-flavored ENDS over tobacco-flavored ENDS to completely quit combustible cigarettes or significantly reduce their cigarette use." JA 905. On the other hand, "scientific evidence on the role of flavors in youth use of ENDS is significantly more rigorous and robust than the

preference data concerning menthol combustible cigarette smokers." *Id.* Drawing on this scientific literature, King concluded that the primary additional benefit that menthol-flavored ENDS could have brought relative to fruit-flavored ones was illusory, and the risks were higher than the Office of Science had thought.

The Office of Science "on its own initiative" ultimately agreed, concluding that "the literature did not demonstrate that menthol-flavored ENDS were differentially effective, relative to tobacco-flavored ENDS, in terms of promoting significant cigarette reduction or complete switching among adult smokers." JA 909.

3. *The FDA's review of Logic's Premarket Application*

The appropriate framework in hand and in agreement on the risks and benefits of menthol, Center staff assessed Logic's Premarket Applications, approving those for tobacco-flavored ENDS, but finding those for menthol-flavored ENDS lacking. On the benefits to current smokers, the agency looked for two things: (1) evidence that menthol cigarette smokers did not just prefer menthol-flavored ENDS to other flavors but in fact would switch to using them, and (2) statistically significant evidence that those benefits were greater than the ones that tobacco offered.

The FDA agreed with Logic that its studies showed that menthol cigarette smokers "show a preference for menthol-flavored ENDS, relative to non-menthol-flavored ENDS." JA 914. It cautioned, however, that "evidence of preference is not evidence of behavior change, and these studies showing

preference for menthol-flavored ENDS were not designed to directly address the outcomes of complete switching or cigarette reduction. Actual product use is critical in the evaluation of product switching." *Id.* And when it came to evidence of switching, Logic came up short. The types of surveys Logic used were designed to "assess outcomes believed to be precursors to behavior, such as preferences or intentions . . . but [were] not designed to directly assess actual product use behavior." JA 951. This was consistent with the FDA's view of the broader scientific literature, which only showed that menthol smokers "prefer menthol-flavored ENDS," not that they actually promoted "complete switching or cigarette reduction." *Id.* As the FDA explained:

> [T]he ability of a product to promote switching among smokers arises from a combination of its product features . . . as well as the sensory and subjective experience of use (taste, throat hit, nicotine delivery), and can also be influenced by how the device itself looks and feels to the user. Moreover, uptake and transition to ENDS use is a behavioral pattern that requires assessment at more than one time point.

Id.

Logic's evidence that menthol offered any benefit beyond what tobacco presented was similarly lacking. Its randomized controlled studies did not demonstrate that its menthol-flavored ENDS generated a statistically greater reduction in cigarette smoking than its tobacco-flavored ENDS. This again tracked the more general literature, which did not show "that menthol-flavored ENDS *differentially*

facilitate switching or cigarette reduction." JA 944 (emphasis added). Thus, the potential benefit of menthol-flavored ENDS to current cigarette smokers remained just that—potential.

Turning to the flavor's appeal to non-smokers, menthol was not meaningfully less popular than fruit or dessert flavors such that it could escape comparison to tobacco. True, it remained less popular than fruit or sweets, but the gap was shrinking. By 2022, Youth Survey data showed that, among high schoolers who had used e-cigarettes in the previous thirty days, almost 27% had tried menthol, not far behind mint (about 30%) and sweets (about 38%). The National Institutes of Health (NIH) Population Assessment of Tobacco and Health longitudinal study had tracked long-term trends in youth vaping with stark results: across waves of this study, the vast majority of youth (12-17 year-olds) and young adults (18-24 year-olds) who started vaping did so with a flavor other than tobacco. A staggering 93.2% of youth in the NIH study's 2016-17 cohort said that their first ENDS product was not tobacco-flavored, while a relatively paltry 54.9% of adults twenty-five or older said the same. This was crucial because even a relatively small gap between tobacco and menthol can have important public health consequences for children. Studies have shown that "non-tobacco flavoring . . . make[s] them more palatable for novice users . . . which can lead to initiation, more frequent and repeated use, and eventually established regular use." JA 945. The key takeaway from the data, per the FDA, was not that menthol was less popular than fruit, but that it was more popular than tobacco.

In addition, the FDA had reason to believe that flavor preference data would trend in menthol's favor in the future. As enforcement actions had taken many cartridge-based

flavored ENDS devices off the market, high schoolers in one survey increased their use of disposable flavored ENDS over tenfold (2.4% to 26.5%) in just a year. As the FDA saw it, "[t]his trend underscores the fundamental role of flavor in driving appeal. . . . [T]he removal of one flavored product option prompted youth to migrate to another ENDS type that offered flavor options, even though it exhibited lower youth use prevalence historically." JA 935. For the time being, the FDA had turned its attention to fruit and dessert flavors that had especially strong appeal to kids. But as enforcement actions removed those flavors from the market, the FDA reasoned, other flavors like menthol could become yet more popular as kids turned to the remaining islands of flavor in the e-cigarette market.

Nor could Logic's marketing restrictions bridge the gap. The FDA already had assessed the efficacy of the types of restrictions that Logic had implemented in previous cases and concluded that they were "insufficient to mitigate the substantial risk to youth from flavored ENDS." JA 966. Indeed, evidence had consistently shown that these marketing restrictions were not responsive to children's actual purchasing patterns because "the majority of youth do not purchase e-cigarettes themselves from retail locations, but rather they obtain them from social sources, including from friends or family members, steal them, or use someone else's product." JA 940. While some new technologies, such as biometrics or geo-fencing, seemed promising to the Center, Logic did not offer them.

The FDA thus issued a Marketing Denial Order for Logic's menthol-flavored ENDS on October 26, 2022. Logic

successfully obtained a stay of that order and timely filed this petition for review.

II. Jurisdiction and Standard of Review

We have jurisdiction over Logic's petition under 28 U.S.C. § 1331 and 21 U.S.C. § 387l(a)(1)(B). The Tobacco Control Act directs petitioners to file in the D.C. Circuit or in the circuit encompassing their principal place of business. 21 U.S.C. § 387l(a)(1)(B). Logic's principal place of business is in Teaneck, New Jersey, so we may hear its petition.

The APA governs our review of the FDA's Marketing Denial Order. We must vacate the agency's decision if it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 702–03 (3d Cir. 2023) (quoting 5 U.S.C. § 706(2)(A)).

III. Discussion

Logic raises four principal challenges to the Marketing Denial Order. First, it contends that the FDA changed course and rejected its Premarket Application "pursuant to an undisclosed, illegal policy against all menthol ENDS." Opening Br. at 36. Second, and relatedly, it characterizes the Technical Project Lead Review as the product of a new evidentiary standard that unfairly surprised the company. Next, it characterizes the Marketing Denial Order as the product of the FDA's failure to examine important aspects of the regulatory problem and inconsistent with the evidence in its Premarket Application. Finally, it attacks as allegedly inconsistent with agency practice the FDA's decision to

require the immediate withdrawal of its menthol-flavored ENDS from the market rather than allow a transition period. In each instance, Logic's arguments are unavailing, so we will deny its petition for review.

A. Arbitrary and capricious review

When an agency acts, it "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.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted) (*State Farm*); *see Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). If it does not, the agency has failed to "engage in reasoned decisionmaking," and the APA requires the agency action be set aside. *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (internal quotation marks and citation omitted).

In addition, while the APA requires no "more detailed justification than what would suffice for a new policy created on a blank slate," when an agency revises or updates existing policies, it must at least "display awareness that it *is* changing position" and explain "that [it] *believes* [the new action] to be better." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). And when the new approach "rests upon factual findings that contradict those which underlay its prior policy; or when its policy has engendered serious reliance interests that must be taken to account," that extra explanation is necessary. *Id.*; *see also Encino Motorcars*, 579 U.S. at 222. Relatedly, an agency cannot say that it is going to approach a regulatory or licensing issue using one framework only to pull a "surprise switcheroo" on private parties and use a different framework instead. *Prohibition Juice*, 45 F.4th at 20; *see also Christopher*

v. SmithKline Beecham Corp., 567 U.S. 142, 156 (2012) (citation omitted) (noting that "agencies should provide regulated parties 'fair warning of the conduct [a regulation] prohibits or requires'").

We also are not free to sustain agency action based only on any *post hoc* reasoning that the parties offer up in litigation. Instead, we are limited to the justifications that were available to and relied upon by the agency at the time. *See DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) (citation omitted); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971) (citation omitted); *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943).

That said, arbitrary and capricious review is not meant to be an exacting standard. Because "a court is not to substitute its judgment for that of the agency," *Fox Television*, 556 U.S. at 513 (quoting *State Farm*, 463 U.S. at 43), we will uphold agency action even if its reasoning is "of less than ideal clarity" as long as "the agency's path may reasonably be discerned," *Garland v. Ming Dai*, 141 S. Ct. 1669, 1679 (2021) (quotation omitted). This is especially true in highly technical areas like public health, as "[w]e are 'particularly reluctant to second-guess agency choices involving scientific disputes that are in the agency's province of expertise.'" *N.J. Env't Fed'n v. U.S. Nuclear Regul. Comm'n*, 645 F.3d 220, 230 (3d Cir. 2011) (quotation omitted); *see also Fertilizer Inst. v. Browner*, 163 F.3d 774, 777 (3d Cir. 1998) ("[T]he court should not substitute its own judgment for the scientific expertise possessed by the agency.").

B. The alleged blanket anti-menthol policy

Logic paints the debate memorialized in the King and Cecil Memos as proof that Director King effectively imposed a blanket anti-menthol policy and overrode the Office of Science's determination that Logic's menthol-flavored ENDS were health-appropriate, violating both the APA and the Tobacco Control Act. Absent a more explicit explanation of why the agency viewed menthol as less dangerous to public health in the Enforcement Priorities and then considered the flavor to be essentially indistinguishable from fruit and sweets in the Technical Project Lead Review, Logic contends that the FDA's change in course was necessarily arbitrary and capricious.

Logic's view aligns in this respect with that recently articulated by the Fifth Circuit in *R.J. Reynolds Vapor*. There, the panel granted a stay to a much larger menthol ENDS manufacturer that had received a marketing denial order, reasoning that these memoranda showed that Director King "told" the Office of Science what the framework for menthol premarket applications would be and "are strong evidence that [the Center] developed and internally circulated new criteria for evaluating [premarket applications] for menthol-flavored ENDS." 65 F.4th at 192. As the Fifth Circuit saw it, the FDA's marketing denial order "rest[ed] upon factual findings that contradict those which underlay its prior policy," so the FDA was required to offer "a more detailed justification" of its decision. *Id.* (quoting *Fox Television*, 556 U.S. at 515).

We do not share the Fifth Circuit's view of what happened within the Center or its legal impact. First, the pat story about Director King overriding the Office of Science's recommendation both oversimplifies and obscures. True, at first, the Office of Science thought that the health-

appropriateness balance might favor menthol and was therefore preliminarily inclined to recommend approval of Logic's Premarket Application. But at this early juncture, the Office of Science only considered the benefit of Logic's menthol-flavored ENDS to menthol cigarette smokers "potential," JA 908, and "did not find that the current literature support[ed] that use of menthol-flavored ENDS by adult smokers [was] associated with greater likelihood of complete switching or significant cigarette reduction relative to tobacco-flavored ENDS,"[10] JA 907–08. So even before any discussions with Director King, the Office of Science was at most lukewarm about treating menthol differently from other non-tobacco characterizing flavors.

And crucially, after discussions with Director King, the Office of Science "*on its own initiative*" went back to the evidence and "decided it was reasonable and consistent to treat menthol-flavored ENDS [premarket applications] in the same way as other non-tobacco-flavored ENDS [premarket applications]." JA 909 (emphasis added). It did so, moreover, after multiple opportunities for rigorous discussions about menthol with both the Director and the Center's Ombuds Team. Thus, the record does not support Logic's rendition of a political appointee parachuting in and dictating a new framework for the Office of Science to adopt.[11] *R.J. Reynolds*

[10] Of course, the agency eventually adopted this same view in Logic's Technical Project Lead review.

[11] Even if the Director were bringing political considerations to bear, that would not render the agency's action here arbitrary or capricious. As the Supreme Court has made clear, "a court may not set aside an agency's

Vapor, 65 F.4th at 192. Nor does it evince a blanket policy against menthol promulgated from on high. Instead, it reflects that the Office of Science's tenuous preliminary support for Logic's Premarket Application withered in the face of its own evolving understanding of the scientific evidence.

Second, and more fundamentally, the internal debates that the memoranda describe do not reflect a pre-existing agency policy or final agency action. The APA limits our jurisdiction to (1) "[a]gency action made reviewable by statute," and (2) "*final* agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704 (emphasis added). Agency action counts as "final" only if (1) it "mark[s] the 'consummation' of the agency's decisionmaking process," and (2) it is "one by which 'rights or obligations have been determined' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citations omitted); *see also* 5 U.S.C. § 551(13) (defining "agency action" for purposes of the APA). The consummation of the process here was the FDA's issuance of the Marketing Denial Order.[12]

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policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration's priorities. . . . Such decisions are routinely informed by unstated considerations of politics, the legislative process, public relations, interest group relations, foreign relations, and national security concerns (among others)." *Dep't of Com. v. New York*, 139 S. Ct. 2573, 2575 (2019).

[12] The Marketing Denial Order is reviewable pursuant to 21 U.S.C. § 387l(a)(1)(B).

In contrast to the Marketing Denial Order, however, the King and Cecil Memos are not—and therefore cannot be reviewed as—"final agency action" because they flunk the first finality requirement.[13] They show only that, to the extent that one component of the Center had developed a view of menthol at all by the second half of 2021, parts of it had arrived at a "preliminary recommendation" to approve Logic's Premarket Application. JA 908. This was nowhere close to a final decision—that would not come for almost a year while it determined what the right framework would be for menthol-flavored ENDS. As it internalized new information about menthol, the Center's understanding of the characterizing

[13] We may, of course, consider agency memos and other documents in the administrative record in determining whether an agency's change in existing policy was arbitrary and capricious, and whether its "sole stated reason" for its action is pretextual. *Dep't of Com.*, 139 S. Ct. at 2575 (considering agency documents in determining that the Secretary of Commerce's stated rationale for reversing prior policy and reinstating a citizenship question on the 2020 census questionnaire was "contrived"). Here, the King Memo and the Deficiency Letter do not reflect any prior agency policy, but merely its evolving understanding of the scientific evidence and the exchange of views among its different components. And the FDA's explanation for its final agency action in the Marketing Denial Order is entirely consistent with that evidence and exchange of views, i.e., "with what the record reveals about the agency's priorities and decisionmaking process." *Id.*

flavor crystallized into something more formal.[14] This is not the sort of "change[d] course" that can trigger a heightened burden for the FDA, *Regents*, 140 S. Ct. at 1913, nor does it expose some "secret" and nefarious anti-menthol policy, as Logic contends.[15] Crediting that argument would penalize the

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[14] Our dissenting colleague characterizes the FDA's preliminary discussions differently, insisting that the FDA's statements suggesting that menthol-flavored ENDS could be less harmful to public health reflected a "policy position," Dissent at 12, and that the FDA then "changed the agency's menthol policy 'out of Logic's sight,'" *id.* at 8. But the very portions of the record that the dissent has quoted contradict this characterization. *See id.* at 10 (citing agency's language in the Deficiency Letter indicating that menthol products "may have lower youth appeal"); *id.* at 11 (citing an internal FDA memo explaining that menthol-flavored ENDS offered a "potential means by which some adult smokers might seek to transition completely away from combusted tobacco products to potentially less harmful tobacco products"). These portions of the record underscore the tentative and preliminary nature of the agency's inconclusive inclinations before it issued the Marketing Denial Order.

[15] To be clear, Logic's advocacy is the lone source for the dissent's assertion that the FDA rejected Logic's applications as "a matter of policy, not science." Dissent at 6. The dissent cites a report outside the record for that proposition. *See id.* (citing Lauren Silvis et al., Reagan-Udall Found., Operational Evaluation of Certain Components of FDA's Tobacco Program ("Reagan-Udall Report") 15 (2022), https://perma.cc/NP3A-3QNJ). But that report does not

Center for engaging in the "ongoing dialogue" and deliberation that is supposed to be the hallmark of reasoned agency decision-making.[16] *See Avail Vapor*, 55 F.4th at 424.

It is also notable that these debates took place within the FDA, out of Logic's sight, and therefore could not have "engendered serious reliance interests that must be taken into account." *Regents*, 140 S. Ct. at 1913 (quoting *Encino Motorcars*, 579 U.S. at 222). The Fourth Circuit ably explained why deliberations like these cannot fall within the

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concern Logic's application. *See* Lauren Silvis et al., Reagan-Udall Found., Operational Evaluation of Certain Components of FDA's Tobacco Program ("Reagan-Udall Report") 15 (2022), https://perma.cc/NP3A-3QNJ. Instead, the report generally acknowledges that weighing an ENDS application's public health benefits to adult smokers (who may use the product to quit combustible tobacco products) against the risks to youth non-smokers (whom the product may appeal to) implicates policy questions as well as scientific ones. But that assertion is clearly irrelevant here, where the FDA determined, as a scientific matter, both that Logic's menthol-flavored ENDS posed a risk to youth non-smokers *and* that there was insufficient evidence of any benefits to adult smokers. JA 914, 945, 951. The FDA therefore did not need to engage in the weighing analysis that the Reagan-Udall Report characterizes as a policy decision.

[16] Nor was there anything untoward about the Center considering the possibility that the standard it was adopting amounted to a per se anti-flavoring rule. The Center is to be commended, not disparaged, for considering this possibility and taking pains to rule it out.

APA's reach in *Avail Vapor*, another case denying an ENDS manufacturer's petition. There, the petitioner raised concerns about internal FDA memoranda discussing the weight that the agency was going to accord certain evidence in premarket applications. *See Avail Vapor*, 55 F.4th at 423–24. Judge Wilkinson forcefully rejected the petitioner's assertions that these memoranda exposed a turnabout in FDA policy: "What Avail fails to recognize . . . is that these internal documents were just that: internal," and agencies merit "latitude in their internal discussions and debates" that "needs to be broad in the case of a statutory charge as general as this one, where internal discussions involve complex predictions within the [FDA's] area of special expertise." *Id.* at 424 (internal quotation marks and citations omitted); *see also Regents*, 140 S. Ct. at 1913–15. A contrary rule, he observed, would lead to "gridlock, an agency decisional process robbed of the value of ongoing dialogue." *Avail Vapor*, 55 F.4th at 424.

Echoing the Fourth Circuit, we will not "locate a point where agency deliberations become frozen in time." *Id.* We also will not acquiesce in binding the FDA to what were, by their own terms, the preliminary recommendations of one section of one of its divisions or require it to offer an additional explanation under *Regents* and *Fox Television* as a penalty for engaging in an iterative, deliberative discussion. *Id.*; *cf. Fertilizer Inst.*, 163 F.3d at 778 (holding that the EPA did not need to justify updating its definition of "chronic health effects" from the one it had put in an unpromulgated draft guideline); *but see R.J. Reynolds Vapor*, 65 F.4th at 192. Reasoned disagreement among civil servants is the stuff of good government, not APA violations.

C. Change in evidentiary standard for menthol

Stripped of the hyperbole that the FDA laid down a blanket anti-menthol policy, the record reflects nothing more than the application to menthol-flavored ENDS of the same regulatory framework and evidentiary standard that the agency had applied previously to other non-tobacco flavored ENDS and that we upheld in *Liquid Labs*. *See* 52 F.4th at 542–43. Analyzing new information under the same framework is no change at all as far as the APA is concerned.[17]

Here, too, we part ways with the Fifth Circuit, which accepted the argument that the FDA had changed course with respect to (1) the types of evidence that would be required for a premarket application to win approval, and (2) the appropriate comparator for menthol-flavored ENDS. *R.J. Reynolds Vapor*, 65 F.4th at 190. We already tread this ground in *Liquid Labs*, where we held that the FDA's evidentiary requirements did not constitute a "surprise switcheroo." 52 F.4th at 540. Even if *Liquid Labs* had not paved the way, however, we would reach the same conclusion here about the FDA's guidance for menthol premarket applications specifically.

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[17] The record does not support the proposition, espoused by the dissent, that the framework the FDA applied to Logic's application was "previously reserved for non-menthol flavored ENDS." Dissent at 1. What it does reflect is that the agency established a framework that it determined was appropriate to assess whether the marketing of ENDS was health-appropriate, and it proceeded to apply that framework to ENDS products in descending order of enforcement priority, starting with fruit-flavored ENDS and eventually turning to menthol- and mint-flavored ENDS.

To review, the Premarket Application Guidance advised ENDS manufacturers in 2019 that "well-controlled investigations" would be necessary for their products to remain on the market, and that "[n]onclinical studies alone" probably would not be enough to win approval. JA 1027. The FDA made clear what it was looking for, recommending that applicants "compare the health risks of its product to . . . products within the same category and subcategory" that "are most likely to [be] considered interchangeable." JA 1028. For Logic's products, that meant menthol combustible cigarettes and tobacco-flavored ENDS.

Those expectations were not lost on Logic. Our dissenting colleague asserts that "Logic had no reason to compare menthol products to tobacco products." Dissent at 16. But the Premarket Application speaks for itself, as Logic made a point of providing those comparisons in the application. They included randomized controlled studies that juxtaposed the observed change in cigarette consumption for subjects who received Logic's menthol-flavored ENDS with the same effect for subjects who received Logic's tobacco-flavored ENDS. And at argument, Logic sought to persuade us that this comparison should have resulted in a favorable decision because its studies allegedly proved the decreases were attributable to the ENDS' menthol flavor alone.[18]

[18] Indeed, counsel argued that the FDA "overlooked" the aspects of Logic's submission that "do exactly what they claim to want to do, which is the comparison between the actual efficacy of switching between the menthol flavored ends and the tobacco flavored ends." Oral Arg. Tr. 18:10-14.

But that is not quite right. Logic included a comparison, but not one that was statistically significant. As the Technical Project Lead Review pointed out, these studies "were not designed to address direct comparisons between Logic's menthol-flavored ENDS and tobacco-flavored ENDS (or any other flavor combinations)." JA 949. So the problem was not that Logic had no reason to compare menthol products to tobacco products, but that it failed its statutory responsibility to present "well-controlled investigations." 21 U.S.C. § 387j(c)(5)(A).

No matter, Logic retorts, because the APA violation here was the FDA's "egregious" "bait-and-switch" in telling Logic in a Deficiency Letter that Logic should compare its menthol-flavored ENDS to other flavored ENDS, and then insisting that it compare those products to tobacco-flavored products instead. Opening Br. at 40. This argument might have traction if the FDA indeed had tacked on "an additional, previously undisclosed evidentiary requirement" for the approval of Logic's menthol-flavored ENDS, *id.* at 40–41, and failed to communicate it to the company. *See SmithKline Beecham*, 567 U.S. at 156–57. But that is not what happened here.

The part of the Deficiency Letter to which Logic refers concerned only its Premarket Applications for certain fruit flavors, not the menthol-flavored ENDS at issue in this case. *Cf. Fontem US, LLC v. FDA*, __F.4th__, 2023 WL 5536194, at

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According to counsel, the comparison between menthol-flavored ENDS and tobacco-flavored ENDS "was there in plain black and white in the submission." *Id.* at 20:19-20.

*9 (D.C. Cir. Aug. 29, 2023) (determining that the FDA "pull[ed] a surprise switcheroo" by representing in a deficiency letter that the information being requested "would be sufficient for the agency to approve Fontem's products" but later denying Fontem's application because Fontem failed to provide additional information). The FDA had made clear already both the appropriate comparators, including tobacco, and the types of data that would show their relative efficacy. *See Liquid Labs*, 52 F.4th at 539–40. Nothing in the Deficiency Letter changed those standards.[19]

[19] The Enforcement Priorities do not compel a different conclusion. That document did not modify the FDA's guidance about the evidentiary standards to which the agency would subject premarket applications for menthol-flavored ENDS. It only set the order in which the FDA would launch enforcement actions against "certain deemed tobacco products that do not have premarket authorization." JA 1108. Our dissenting colleague characterizes the Enforcement Priorities differently, suggesting that statements in that document are probative of a prior agency policy. But this characterization contradicts the FDA's own description of the document, which explained that it merely delineated the agency's enforcement priorities and was "not binding on FDA or the public." JA 1108. The dissent may disagree with the agency's description of its document or, like Logic, may disagree with the agency's scientific determination. But agree or disagree, on matters of science we may not "substitute [our] judgment for that of the agency." *See Sierra Club v. U.S. Env't Prot. Agency*, 972 F.3d 290, 298 (3d Cir. 2020) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)).

In sum, because the FDA's Marketing Denial Order applied the same standard it had been applying since 2019 to other non-tobacco flavors, Logic cannot rest its APA claim on any unfair surprise.

D. Conformity with the evidence before the agency

Logic next asserts that the Marketing Denial Order and Technical Project Lead Review "fall[] short of the 'reasoned decisionmaking' standard mandated by the APA," Opening Br. at 50 (quoting *Michigan*, 576 U.S. at 750), because the FDA incorrectly weighed the evidence it submitted, and improperly discounted its "product-specific" evidence, relying instead on "general claims concerning other menthol- and candy and fruit flavored ENDS products," *id.* at 49. The record tells a different story.

1. *Benefits to adults*

Logic challenges the FDA's conclusion that the potential benefit of menthol-flavored ENDS—their ability to serve as a substitute for menthol cigarette smokers—was largely illusory. Its menthol-flavored ENDS, it maintains, "are both preferred to and likely more effective than its tobacco-flavored ENDS in helping adult smokers reduce their combustible cigarette use or quit smoking altogether." Opening Br. at 48.

The Tobacco Control Act, however, requires the agency to assess whether "existing *users* of tobacco products will stop *using* such products." 21 U.S.C. § 387j(c)(4) (emphasis added). The lodestar is not what products smokers may prefer,

but what products they actually use. Yet Logic's data proved the former, not the latter. As the FDA explained at length in the Technical Project Lead Review, its Premarket Application "assess[ed] precursors to . . . product use behavior" like quitting, JA 951, and did not show a differential benefit for the menthol-flavored ENDS over and above its tobacco-flavored ones. While Logic may quarrel with the appropriateness of that standard, we already crossed that bridge in *Liquid Labs*. 52 F.4th at 542–43. That precedent controls.

So does the FDA's scientific judgment about the validity of Logic's studies. As Article III judges, "[w]e are 'particularly reluctant to second-guess agency choices involving scientific disputes that are in the agency's province of expertise.'" *N.J. Env't Fed'n*, 645 F.3d at 230 (quotation omitted); *Fertilizer Inst.*, 163 F.3d at 777. When asked to determine whether agency action was arbitrary or capricious, our job is only to (1) assess the sufficiency of the agency's review of the record, (2) ensure the agency offered a reasoned explanation for its decision, and (3) confirm the explanation accords with that record. *See State Farm*, 463 U.S. at 43. We overstep when we purport to substitute our judgment for the agency's as to the statistical validity or ultimate findings of clinical studies. *N.J. Env't Fed'n*, 645 F.3d at 230.

Yet that is precisely what Logic asks us to do. And Logic does not argue that the FDA ignored the evidence. Instead, it contends that the FDA did not weigh the evidence to Logic's liking. It objects that, after looking at the evidence that Logic's menthol-flavored ENDS would get smokers to stop smoking, the FDA found that evidence lacking and discounted the company's studies accordingly. So this is not a situation where the FDA failed to "address the potential benefits of [the

applicant's] products for the public at large" or to "consider the possibility that existing users of combustible tobacco products such as cigarettes would reap health benefits by transitioning to [Logic's] products." *Fontem US, LLC*, 2023 WL 5536194, at *7. This is instead a scientific debate, so the "fundamental principle of judicial restraint" dictates that we avoid it. *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 450 (2008).

It is enough for our purposes that the FDA's decision to deny Logic's Premarket Application was not "without substantial basis in fact" and was "within [the FDA's] area of competence." *N.J. Env't Fed'n*, 645 F.3d at 230 (quotation omitted).

2. *Risks to children*

Logic's arguments on the other side of the health-appropriateness scale fail for similar reasons. Logic contends it was arbitrary and capricious to issue a Marketing Denial Order to a company whose products were so unpopular with kids, taking particular exception to the FDA's reliance on "general statistics [that] do not account for Logic's particular products." Opening Br. at 51, 53. In Logic's view, the only way the agency could reject its Premarket Application was by "resort[ing] to improper speculation . . . further demonstrating that the FDA did not care at all about the evidence concerning Logic's particular product." *Id.* at 53.

Under the Tobacco Control Act, however, the FDA was well within its rights to rely on both Logic's product-specific evidence and broader scientific literature about the appeal of menthol. The Act permits the agency to look at "any . . .

information before the Secretary with respect to such tobacco product," 21 U.S.C. § 387j(c)(2)(A), including, "when appropriate, . . . well-controlled investigations, which may include . . . clinical investigations by experts," *id.* § 387j(c)(5)(A), or other "valid scientific evidence" that "is sufficient to evaluate the tobacco product," *id.* § 387j(c)(5)(B). Taken together, Congress set limitations on the quality of the evidence consulted by the agency— *i.e.*, whether the studies are "well-controlled," or whether the other evidence is "valid"—but not on the subject matter or scope of that evidence—*i.e.*, whether it only analyzed a specific applicant's ENDS. Of course, scientific evidence may be more persuasive when it evaluates the particular ENDS at issue, but that does not render otherwise "valid" general evidence irrelevant or incompetent.

Nor was the Center's conclusion about menthol's appeal to children improperly "speculative." Opening Br. at 49. The agency was acting pursuant to Congress's express directive in the Tobacco Control Act. When making the health-appropriateness determination, the FDA must look at "the risks and benefits to the population as a whole." 21 U.S.C. § 387j(c)(4). "Risk" encompasses far more than facts currently known to an agency beyond a reasonable doubt—assessing risk requires looking to the future, *i.e.*, examining "the chance of injury, damage, or loss[, especially] the existence and extent of the possibility of harm." *Risk*, Black's Law Dictionary (11th ed. 2019). There is nothing improper under the APA about the Center prognosticating what will happen to children's menthol use as other flavored ENDS exit the market. It made reasoned projections based on market responses to previous enforcement actions, and it did so pursuant to a statute that not only permits it to forecast, but requires it to do so. *See Avail Vapor*, 55 F.4th

at 424. The conclusions the FDA reached as a result thus comport with its statutory mandate.

Logic seeks to change the calculus, touting its efforts to avoid marketing to children, but the FDA's skepticism on this score also had a reasoned basis. In *Liquid Labs*, we upheld the FDA's marketing denial order even though the agency had ignored the manufacturer's marketing plan because "there [was] no indication the plan would have made up for the deficiencies the FDA identified in Liquid Labs' applications." 52 F.4th at 543 (citations omitted). Here, the FDA did analyze Logic's marketing plan and found it lacking, clearing the low bar we set in *Liquid Labs*. The statute is not preoccupied with whether children are deterred from *buying* Logic's products; it focuses instead on the much broader question of whether they are deterred from *using* them. *See* 21 U.S.C. § 387j(c)(4). And the evidence has shown for years that marketing restrictions like Logic's do not cut down on youth use sufficiently to change the health-appropriateness balance.

E. Transition period

Finally, Logic complains that, in its treatment of its menthol-flavored ENDS, the FDA modified its purported "policy when removing marketing authorization for drugs, tobacco, or other products already on the market to give manufacturers a reasonable transition period before requiring that they remove their products completely from the market." Opening Br. at 57. But the products it identifies that received transition periods share little in common with Logic's menthol-

flavored ENDS.[20] *See, e.g.*, 85 Fed. Reg. 13,312, 13,349 (Mar. 6, 2020) (electrical stimulation devices "for self-injurious or aggressive behavior"); 83 Fed. Reg. 50,490, 50,502 (Oct. 9, 2018) (styrene for food flavoring); 81 Fed. Reg. 91,722, 91,728 (Dec. 19, 2016) (powdered surgeon's gloves). Nor do the few instances in which the FDA has issued ENDS manufacturers an administrative stay add up to an established agency policy. *See Bennett*, 520 U.S. at 177–78. And with approximately 2,110,000 students using flavored ends in 2022 and youth continuing to migrate to menthol-flavored ENDS in the absence of fruit-flavored ENDS, the FDA could reasonably conclude that immediate removal of these products from the marketplace was "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A).

IV. Conclusion

The FDA here fulfilled its statutory mandate in all respects. It saw a public health crisis—youth vaping—

[20] In its Reply Brief, Logic suggests that the dearth of tobacco-related transition periods supports its argument because the "FDA is admitting that it has treated tobacco products, including even some ENDS products, worse than non-tobacco products," which "itself violates the APA" because the FDA "provides no reasoned explanation as to why ENDS products should be treated more harshly than other types of products." Reply Br. at 27. Because this argument was not pressed in Logic's Opening Brief, it is forfeited. *See Barna v. Bd. of Sch. Dirs. of Panther Valley Sch. Dist.*, 877 F.3d 136, 146 (3d Cir. 2017) (citing *In re Grand Jury*, 635 F.3d 101, 105 n.4 (3d Cir. 2011)).

unfolding at the sweet spot of its expertise and the core of the jurisdiction it was given in the Tobacco Control Act. It reasonably prioritized among the products at issue, and when it reached menthol-flavored ENDS and Logic's Premarket Application, the scientific studies and market changes in the interim led it to conclude the marketing of that product was not "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). That was a reasoned decision, with substantial basis in fact, and thus did not run afoul of the APA or the Tobacco Control Act.

For the foregoing reasons, we will deny Logic's petition for review.

PORTER, *Circuit Judge*, dissenting.

The majority concludes that the FDA's secret, unexplained policy decision to treat menthol electronic delivery systems (ENDS) like fruit-and-dessert-flavored ENDS was not arbitrary and capricious but an example of "good government." Maj. Op. at 29. Logic Tech (Logic) was therefore foolish to rely on the agency's previous representations that (1) menthol and tobacco ENDS were different than flavored ENDS and (2) Logic needn't demonstrate that its menthol products are more likely to promote cigarette reduction compared to tobacco-flavored products. The majority says Logic has no ground to complain that the agency disregarded its own scientific conclusions and denied Logic's menthol ENDS applications using an evidentiary standard previously reserved for non-menthol flavored ENDS.

I view the FDA's actions differently. Before July 2022, it treated menthol ENDS like tobacco ENDS and told Logic that was its policy. According to the agency, menthol offered benefits to smokers wanting to transition from combustible cigarettes and posed less risk to youth, who prefer sweet and fruity flavors. But that month, unbeknownst to Logic, the agency abruptly changed its policy and lumped menthol together with fruit, candy, and dessert flavors. The FDA never informed Logic of the policy shift until after it denied Logic's menthol-product applications. Because the agency failed to give a reasoned analysis or detailed justification for the policy change, I respectfully dissent.

I

In July and August 2019, Logic submitted Premarket Tobacco Product Applications (PMTA) for fifteen ENDS. Three of the PMTAs were for menthol products.

While the applications were pending, the FDA twice communicated to Logic that it viewed menthol ENDS more like tobacco ENDS and not like flavored ENDS. In April 2020, the agency published guidance describing its ENDS enforcement priorities: It would target unlawfully marketed "flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored)." J.A. 1109. By targeting fruit and other flavored products but not tobacco or menthol products, the FDA said it sought to "strike[] an appropriate balance between restricting youth access to [fruit and mint products], while maintaining availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from combusted tobacco products." J.A. 1126.

In June 2020, the FDA issued a deficiency notice to Logic requesting additional information that was "needed for a marketing granted order determination." J.A. 3010. The FDA requested, among other things, additional data comparing the use of "products with fruit- or fruit-combination flavors," which "pose particular risks for youth initiation and progression to regular ENDS use," to "tobacco- or menthol-flavored products, which may have lower youth appeal." J.A. 3016. Pointedly, the notice did not request such data comparing menthol to tobacco products. This was the final correspondence that Logic received from the FDA until the MDO was issued.

By March 2022, every discipline within the Office of Science (OS) concluded that Logic's menthol products should be approved for marketing. At a PMTA Preliminary Assessment Meeting in May 2021, the Engineering, Chemistry, Microbiology, Behavioral and Clinical Pharmacology, and Medical Disciplines and the Office of Compliance and Enforcement identified no deficiencies with *any* Logic PMTA. The Toxicology and Environmental Science Disciplines joined their cohorts after a second review of Logic's PMTAs in March 2022. And that same month, the Social Science and Epidemiology Disciplines advised that Logic's menthol and tobacco products be approved for marketing but recommended that Logic's fruit and fruit-combination applications be denied. Social Science noted that the "menthol flavored new products . . . have lower youth appeal," J.A. 3097, and "may offer menthol cigarette smokers an appealing option to transition away from combusted cigarette smoking, an option particularly important given some menthol smokers' lower rates of combusted cigarette cessation," J.A. 3101. Epidemiology, similarly, distinguished menthol from other flavored ENDS by expressing its "concerns regarding the lack of evidence on the new products' with non-tobacco/non-menthol characterizing flavors ability to facilitate switching or cigarette reduction among adult combusted cigarette smokers." J.A. 3067.

Given these recommendations, the OS decided that Logic's menthol products merited approval. It found that that the "potential benefit" of adult menthol smokers switching from combustible cigarettes to menthol ENDS "amounted to a likelihood of greater cessation or significant reduction in smoking that would outweigh the known risks to youth from the marketing of the products, sufficient to meet the legal

standard for authorization." J.A. 908 (Cecil Memo). On March 24, 2022, FDA approved PMTAs for Logic's e-cigarette devices and tobacco-flavored products and denied the applications for fruit- and fruit-combination-flavored products, but it did not announce a decision on Logic's menthol products.

In July 2022, after each of the OS disciplines had cleared Logic's menthol applications, Brian King was appointed Office of the Center Director (OCD) of the Center for Tobacco Products (CTP). King immediately changed the FDA's approach to menthol ENDS, communicating to the OS, through his Senior Science Advisor, that for the first time, "the approach to menthol-flavored ENDS should be the same as for" fruit, candy, and dessert flavored ENDS. J.A. 909 (Cecil Memo).

Chastened by the new directive, OS leadership acquiesced to King's policy decision "to treat menthol-flavored ENDS PMTAs in the same way as other non-tobacco-flavored ENDS PMTAs regarding the evidence needed to show a potential benefit to adult smokers." J.A. 909.

King explained the agency's new menthol policy in an internal memo dated October 25, 2022. Without citing any scientific studies or published articles, he asserted that "scientific evidence on the role of flavors in youth use of ENDS is significantly more rigorous and robust than the preference data concerning menthol combustible cigarette smokers." J.A. 905 (King Memo). Therefore, "robust evidence of benefit is required to overcome the risk to youth and show that authorizing the marketing of a menthol-flavored ENDS would be appropriate for the protection of the public health." *Id.*

The majority insists that this decision was made, not "in a vacuum," but with "feedback from Office of Science staffers." Maj. Op. at 14. I read the Cecil and King memoranda very differently.

The decision to change the agency's menthol policy was made unilaterally by the new OCD after the OS divisions approved Logic's menthol applications and before consultation with OS. After the policy change was a *fait accompli*, OS leadership complied based on its "new awareness and understanding of the OCD position," as Cecil delicately wrote in his after-the-fact memo. J.A. 909. Still later, OS staff who had undertaken the menthol-flavored ENDS reviews—and whose scientific conclusions were overridden by the new policy—were given the opportunity to speak with the CTP Ombuds regarding the new approach. J.A. 905.

No one at the FDA informed Logic of the policy change. Nor did the agency give Logic an opportunity to amend the menthol-product PMTAs in response to the new policy. The agency simply relied on the new policy to deny Logic's applications on October 26, 2022—one day after King wrote his internal memo justifying the shift.

In the Marketing Denial Order (MDO), the FDA explained for the first time that under the new policy it required "a randomized controlled trial, longitudinal cohort study, or other evidence demonstrating the benefit of the new products to adult smokers relative to tobacco-flavored ENDS products." J.A. 2. Logic's PMTAs were deemed insufficient because—of course—they lacked the now-required evidence.

II

As the majority properly observes, "[w]e are particularly reluctant to second-guess agency choices involving scientific disputes that are in the agency's province of expertise." Maj. Op. at 22 (quoting *N.J. Env't Fed'n v. NRC*, 645 F.3d 220, 230 (3d Cir. 2011) (quotation marks omitted)). But the FDA's choice was a matter of policy, not science. *See* Lauren Silvis et al., *Operational Evaluation of Certain Components of FDA's Tobacco Program*, Reagan-Udall Found. 15 (2022), https://perma.cc/NP3A-3QNJ.[1] Indeed, OCD's policy change *overrode* the unanimous OS divisions' careful scientific analyses. *Id*. at 15 (observing that "a lack of clarity about the distinction between, and the intersection between, policy and science has created controversy within CTP and may lead to a perception that the Center's scientific integrity is being challenged *when, in fact, policy decisions that transcended the science are being made*") (emphasis added).

Because the FDA's decision to treat menthol ENDS like other flavored ENDS rather than tobacco was a policy change, the FDA was required to "supply a reasoned analysis."[2] *Motor*

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[1] The Reagan-Udall Foundation is an independent organization created by Congress to support the FDA. Silvis et al., *supra*, at 5. In 2022, the Foundation performed an independent evaluation of the CTP and PMTA review process upon the request of FDA Commissioner Robert Califf. *Id.*

[2] The majority emphasizes that the policy change was wholly internal. *See* Maj. Op. at 28 ("It is also notable that these debates took place within the FDA, out of Logic's sight."). But that's precisely the problem. As far as Logic knew, the FDA's previously communicated policy was that menthol ENDS offered benefits to menthol smokers and were less appealing to

Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 57 (1983) (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970)); *see also CBS Corp. v. FCC*, 663 F.3d 122, 138 (3d Cir. 2011) ("[An agency] cannot change a well-established course of action without supplying notice of and a reasoned explanation for its policy departure."). Although an agency "is not precluded from announcing new principles in an adjudicative proceeding," *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974), it "acts arbitrarily if it departs from its established precedents without 'announcing a principled reason' for the departure," *Johnson v. Ashcroft*, 286 F.3d 696, 700 (3d Cir. 2002) (quoting *Fertilizer Inst. v. Browner*, 163 F.3d 774, 778 (3d Cir. 1998).

At a minimum, the agency must "display awareness that it *is* changing position." *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2009). It cannot "depart from a prior policy *sub silentio*[.]" *Id.* An agency "fail[ing] to acknowledge that it has changed its policy . . . is unable to comply with the requirement under *State Farm* that an agency supply a reasoned explanation for its departure from prior policy." *CBS Corp.*, 663 F.3d at 151–52.

When a "new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account," the agency must "provide a more detailed justification than what would suffice for a new policy created on a blank slate." *Fox TV Stations, Inc.*, 556 U.S. at 515. As part of that "more detailed justification" the agency

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youth, so menthol, like tobacco, would be treated differently than other flavors.

"must consider the alternatives that are within the ambit of the existing policy" and the reliance interests at stake, their significance, and their weight against competing policy concerns. *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913, 1915 (2020) (quotation marks, citation, and brackets omitted); *see also Prohibition Juice Co. v. FDA*, 45 F.4th 8, 20 (D.C. Cir. 2022) ("Agencies must explain changes in position, particularly once a prior position has engendered regulated parties' reliance.").

To survive the arbitrary and capricious standard of review, the FDA must first have acknowledged that it changed its menthol policy and then provided a reasoned analysis for the change that addressed Logic's reliance interests and considered available alternatives. It did not do so. Instead, King overruled the OS divisions, changed the agency's menthol policy "out of Logic's sight," and then the agency denied Logic's menthol PMTAs because they failed to meet an undisclosed evidentiary standard. That is not "good government." Maj. Op. at 29.

The majority asserts that these "internal" debates do not reflect a policy change because, "fundamentally," they do not constitute "final agency action" under the APA. Maj. Op. at 25 (quoting 5 U.S.C. § 704). That is, the majority argues that the debates reflected in documents like the King Memo do not "trigger a heightened burden for the FDA" under *Regents* because they were "nowhere close to a final decision." Maj. Op. at 26, 27. Thus, it concludes that these portions of the record "cannot fall within the APA's reach" and should not control our arbitrary-and-capricious review. Maj. Op. at 29.

I disagree with the majority's description of judicial review under the APA. It's true that our review is limited to a

"final" agency action—the FDA's denial of Logic's PMTAs. We must determine whether that denial was "reasonable and reasonably explained." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2571 (2019). But under the APA and the Tobacco Control Act, our review is not limited to the FDA's proffered explanations for the denial, located in the MDO and the Technical Project Lead Review (TPL Review). We are required to "review the whole [administrative] record" in determining whether the FDA's denial was reasonably explained. 5 U.S.C. § 706. The FDA submitted the administrative record, as defined for PMTA proceedings in 21 U.S.C. § 387l(a)(2)(C), on December 6, 2022. *See* Opening Br. at 28. And the Cecil and King Memoranda were included in this submission. *See* Oral Arg. Tr. at 12:8–10 (noting that the "Cecil and King memos . . . were part of the administrative record").

Because these documents are a part of "the whole record," we must review them in determining whether the FDA's denial was reasonably explained. And because they show that the FDA "change[d] course," we must determine whether the FDA's explanation satisfied the requirements outlined in *Regents*. 140 S. Ct. at 1913. Neither the APA nor the Tobacco Control Act requires that these documents reflect any final agency actions to serve this purpose.

The Supreme Court's decision in *Dep't of Com. v. New York* supports this understanding of judicial review under the APA. There, the Court found that the Secretary of Commerce's decision to include a citizenship question on the decennial census failed the "reasoned explanation requirement of administrative law" under § 706. 139 S. Ct. at 2575. In reaching this conclusion, the Court did not limit its review to the Secretary's proffered "explanation for agency action." *Id.* It broadly considered "what the record reveal[ed] about the agency's priori-

ties and decisionmaking process." *Id.* This included several communications that were not "final" agency actions under § 704, including letters that the Secretary exchanged with the Department of Justice. *Id.* Accordingly, we may—indeed, we *should*—consider documents like the King Memo in determining whether the FDA's denial was reasonably explained. And because those documents reveal a policy change, the FDA's explanation must satisfy *Regents*' special requirements.

III

"Deciding whether agency action was adequately explained requires, first, knowing where to look for the agency's explanation." *Regents of the Univ. of Cal.*, 140 S. Ct. at 1907. For that we have the MDO and the TPL Review, which provides in-depth explanation of the FDA's reasons for denial. *See Liquid Labs LLC v. FDA*, 52 F.4th 533, 537–38 (3d Cir. 2022) (relying on the same).

The FDA did not provide a principled reason for the policy change in the MDO. The agency wrote, "There is substantial evidence that the use of menthol flavors in tobacco products, like the menthol flavors in the new products, has significant appeal to youth and is associated with youth initiation of such products." J.A. 2. But it did not explain why it adopted this position despite telling Logic in the deficiency notice that menthol products "may have lower youth appeal," J.A. 3016, or what had changed in the weeks following the Social Science discipline's March 18 conclusion that the "menthol flavored new products . . . have lower youth appeal," J.A. 3097.

The FDA also reported that it was "unable to determine whether or to what extent [Logic's] menthol-flavored new products facilitate complete switching or significant cigarette

reduction as compared to tobacco-flavored ENDS products." J.A. 2–3. Again, the FDA did not explain why it abandoned its earlier position that menthol ENDS offered a "potential means by which some adult smokers might seek to transition completely away from combusted tobacco products to potentially less harmful tobacco products." J.A. 1125.

Nor did the FDA explain why it never requested a comparison between menthol and tobacco products in the deficiency letter despite specifically asking Logic to compare its fruit and fruit-combination flavored ENDS to tobacco-flavored ENDS.

So we must look for a principled reason for the policy change in the TPL Review. The FDA acknowledged that it was applying a novel approach to menthol ENDS. J.A. 3174 ("The clear evidence of substantial use of menthol-flavored ENDS products among youth also reflects evidence beyond what was available at the time that FDA issued [the 2019 enforcement] guidance."), 3179 ("This grouping of tobacco and menthol together . . . reflected the perspective, at that time, that the menthol ENDS products might not necessitate the same strength of product-specific evidence of benefit that other flavored ENDS require relative to tobacco flavored ENDS."). But it failed to provide sufficient reasons for the departure.

The project leader wrote in the TPL Review, "I disagree with the social science reviewer's conclusion" that menthol ENDS are less appealing to youth than other flavors. J.A. 3180. An unsubstantiated personal opinion is an insufficient reason for a departure from agency policy.

The FDA cited several studies purporting to show that the use of flavored ENDS, including menthol, was rising

among student populations as cause to abandon its previous conclusion that menthol was less appealing to youth. These studies are unavailing for several reasons.

First, the studies predated the earlier policy position. *See* J.A. 3157 (studies from 2015 to 2020); 3171–72 (studies from 2004 to 2022). OS was still adhering to that policy as late as March 2022. *See* J.A. 3052–3156 (March 2022 OS Review of PMTAs, treating flavored ENDS differently than menthol and tobacco ENDS). So the July 2022 policy change was not based on fresh scientific data that OS hadn't already considered.

The National Youth Tobacco Surveys (NYTS), which the majority cites as evidence that "[f]lavored e-cigarettes were the driving force behind [the youth ENDS] epidemic," Maj. Op. at 7, show that ENDS use was relatively unchanged between 2014 and 2022. In 2014, NYTS published that "65.1% of high schoolers and 55.1% of middle schoolers who were using ENDS said they were using non-tobacco flavor (including menthol)." *Id.* In total, the NYTS estimated that 1,580,000 students used flavored ENDS in 2014. Corey et al., *Flavored Tobacco Use Among Middle and High School Students – United States, 2014*, Morbidity and Mortality Weekly Report (Oct. 2, 2015), https://perma.cc/99KK-MHUN. Because 63.3% of ENDS users reported flavored use, this means that roughly 2,496,000 students used ENDS of any kind in 2014. *See id.*

By 2022, the number of flavored ENDS users "had risen to 85.5% for high schoolers and 81.5% for middle schoolers" who were using ENDS of any kind. Maj. Op. at 7. But the data showed only that the number of flavored ENDS users increased, not the total number of ENDS users. NYTS esti-

mated that 2,110,000 students used flavored ENDS and that 2,550,000 students used ENDS of any kind in 2022. J.A. 1159. Compared with the 2,496,000 student ENDS users in 2014, there were only fifty thousand more in 2022.

These fifty thousand individuals may have been students who would not have used any tobacco products but for the availability of flavored ENDS. Or they may have been individuals who would have otherwise consumed a different tobacco product if not for the option of using ENDS—the NYTS estimated that, in 2014, 2,950,000 students used a tobacco product other than ENDS. Corey et al., *supra*. Because the 2022 NYTS only surveyed ENDS use, the majority doesn't know how the use of other tobacco products might have changed. *See* 21 U.S.C. § 387j(c)(4) (instructing the FDA to consider "the increased or decreased likelihood that existing users of tobacco products will stop using such products").

And because neither the NYTS nor any other survey independently assessed menthol ENDS use until 2022, the majority's confident assertion that the "gap [between menthol and flavored ENDS use] was shrinking" is baseless. Maj. Op. at 18. The 2014 NYTS grouped all flavors together and the 2019 NYTS grouped menthol and mint together. J.A. 3174; Corey et al., *supra*. Without any data comparing menthol use to other flavors, the majority cannot possibly know whether "the gap was shrinking." Maj. Op. at 18.

The majority seeks to bolster its assertion by reference to the TPL Review, dated October 26, 2022 (the same day that FDA sent Logic the MDO). *Id.* In particular, the majority focuses on the TPL Review's treatment of 2022 NYTS data. But the majority's discussion is misleading because it indulges the *post hoc ergo propter hoc* fallacy. The 2022 NYTS results

first appeared in the CDC's Morbidity and Mortality Weekly Report dated October 7, 2022. J.A. 1158. There is no evidence that King had or relied on them when he changed the policy three months earlier, but the majority inexplicably assumes that the October data informed the July decision.

In this and other instances, the majority omits too many inconvenient facts in its comforting narrative of apolitical, science-driven "good government," so I must demur. My skepticism is shared by a unanimous Fifth Circuit panel that considered a different manufacturer's challenge to FDA's rejection of its menthol-product PMTAs. *See R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 189 (5th Cir. 2023).

Oddly, the majority says the *R.J. Reynolds* decision rejects "Logic's rendition of a political appointee parachuting in and dictating a new framework for the Office of Science to adopt." Maj. Op. at 24 (citing *R.J. Reynolds*, 65 F.4th at 192). But that is precisely what the Fifth Circuit *did* find. Like me, our sister circuit perceives that shortly after OS recommended that the menthol-flavored PMTAs be granted "a new CTP director appeared on the scene and told OS that 'the approach to menthol-flavored ENDS should be the same as for other flavored ENDS . . . .' OS then changed its position." *Id*. at 192. The *R.J. Reynolds* court characterized this as "strong evidence that CTP developed and internally circulated new criteria for evaluating PMTAs for menthol-flavored ENDS in Summer 2022 . . . ." *Id*. The Fifth Circuit's analysis in *R.J. Reynolds* is clear-eyed and correct, but the majority barely engages it.[3]

[3] The majority brusquely dismisses the Fifth Circuit's decision, asserting that "we already tread this ground in *Liquid Labs*, where we held that the FDA's evidentiary requirements did not

Importantly, the majority fails to consider what the FDA did *not* say: The agency never discussed Logic's reliance interests or "the alternatives that are within the ambit of the existing policy." *See Regents of the Univ. of Cal.*, 140 S. Ct at 1913, 1915.

Neither the FDA nor the majority consider how Logic may have reasonably relied on the previous policy of grouping menthol and tobacco ENDS together. "Dealing with administrative agencies is all too often a complicated and expensive game, and players like [Logic] are entitled to know the rules." *R.J. Reynolds v. FDA*, 65 F.4th at 189 (citation and quotation marks omitted). "To keep things fair, agencies must give notice of conduct the agency 'prohibits or requires' and cannot 'sur-

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constitute a 'surprise switcheroo.'" Maj. Op. at 30. That is plainly wrong. Unlike this case and *R.J. Reynolds*, our decision in *Liquid Labs* addressed only fruit-and-dessert flavored ENDS and not menthol-flavored or tobacco-flavored ENDS. *Liquid Labs*, 65 F.4th at 537. The manufacturer's "surprise switcheroo" argument in *Liquid Labs* was different from Logic's argument here. In *Liquid Labs*, the petitioner challenged the FDA's requirement that it perform randomized control trials or longitudinal cohort studies after the agency had said in an industry guidance document that such studies would not be necessary. *Id.* at 540. Here, Logic is challenging the FDA's decision to treat menthol products like fruit, dessert, and candy flavored ENDS despite previously treating menthol like tobacco given its lower youth appeal and benefit as a combustible cigarette alternative for adult smokers. The analogous Fifth Circuit decision to *Liquid Labs* is not *R.J. Reynolds* but *Wages & White Lion Invs., LLC v. FDA*, 41 F.4th 427 (5th Cir. 2022), *reh'g granted*, 58 F.4th 233 (5th Cir. 2023), which the majority does not cite.

prise' a party by penalizing it for 'good-faith reliance' on the agency's prior positions." *Id.* (citing *Christopher v. Smithkline Beecham Corp.*, 567 U.S. 142, 156–57 (2012)).

The FDA dismissed Logic's randomized clinical trials as insufficient evidence that menthol encouraged switching from combustible cigarettes. But, as Logic explained, the goal of these studies was not to explore the benefits of menthol but "to assess biomarkers of tobacco exposure and effect during a 60-day controlled switch to [a Logic ENDS] compared with the continued use of combustible cigarettes or tobacco cessation." J.A. 1946, 2312. Logic had no reason to compare menthol products to tobacco products because FDA never said it required such information. The agency specifically instructed Logic to compare its fruit and fruit-combination flavored ENDS to tobacco ENDS in the deficiency notice, but "never told [Logic] that similar evidence would be required for its menthol . . . PMTA[s]." *R.J. Reynolds*, 65 F.4th at 190.

The FDA also failed to indicate that it considered alternatives to denying Logic's applications. *See Regents of the Univ. of Cal.*, 140 S. Ct at 1913. For one, the agency could have issued another deficiency notice asking Logic for data comparing menthol products to tobacco products. In the TPL Review, the FDA explained,

> One approach to evaluate whether the menthol-flavored varieties are more effective than tobacco-flavored varieties at increasing complete switching or significant reductions in [cigarettes per day], would have been to conduct a study that randomized smokers of menthol cigarettes to receive either the menthol- or tobacco-flavored variety.

J.A. 3177. But this was the first time that FDA made that recommendation to Logic, and it only came by way of explaining why the PMTAs were denied. FDA could have issued a second deficiency notice asking for more information regarding the benefits of menthol in light of its new menthol policy.[4] *See, e.g.*, *R.J. Reynolds*, 65 F.4th at 191 (noting that the FDA accepted thirteen amendments to R.J. Reynolds' non-menthol and non-tobacco PMTAs). That's not to say that the FDA had to issue a second deficiency notice, but it was at least required to take Logic's reliance interest into account.

IV

The FDA "cannot change a well-established course of action without supplying notice of and a reasoned explanation for its policy departure." *CBS Corp.*, 663 F.3d at 138. That is exactly what happened here. Without such explanation, the agency's action was arbitrary and capricious, so I respectfully dissent.

[4] The FDA is required to act on an application in 180 days. 21 U.S.C. § 387j(c)(1)(A). But that deadline had long since elapsed. Logic's PMTAs had been pending for three years. There would have been no harm in delaying a decision to permit Logic to perform a "long-term (i.e. six months or longer)" study on the benefits of menthol. J.A. 3175 n.15.