No. 23-1038

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, PETITIONER
v.
WAGES AND WHITE LION INVESTMENTS, L.L.C.,
DBA TRITON DISTRIBUTION, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRIEF OF LOGIC TECHNOLOGY DEVELOPMENT LLC AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether the Food and Drug Administration's retroactive application of a new comparative-efficacy standard for evaluating already-pending premarket tobacco product applications for certain electronic nicotine delivery systems products was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Logic Technology Development LLC imports and sells electronic nicotine delivery systems ("ENDS"), and has sold its ENDS devices lawfully in the United States for over a decade. *Amicus*' ENDS feature a rechargeable, battery-operated device that is used with cartridges of e-liquid. These products offer a viable and safer alternative to combustible cigarettes, and can help adults seeking to reduce or quit smoking combustibles.

Like many other ENDS companies, *Amicus* submitted premarket tobacco product applications ("PMTAs") to the Food and Drug Administration ("FDA") to obtain marketing authorization for its ENDS products in fruit, menthol, and tobacco flavors. Also like many other ENDS companies, *Amicus* invested millions of dollars to prepare these PMTAs, including for its menthol-flavored ENDS products. *Amicus* undertook substantial efforts to put together thorough PMTAs designed to show that the benefits of its ENDS products outweigh the risks. *Amicus* hired dozens of professionals and contracted with

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[1] Pursuant to this Court's Rule 37.6, *Amicus* states that no counsel for any party authored this brief in whole or in part, and that no entity or person, aside from *Amicus* or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

several scientific research companies. It proactively set up a meeting with FDA to discuss and plan the content of its PMTAs, including the design of *Amicus*' clinical and nonclinical studies. These submissions demonstrated that *Amicus*' products benefit current adult smokers, including by offering a safer alternative to combustible cigarettes. *Amicus*' PMTAs further showed that its ENDS products are not used by youth in any appreciable amounts, and so pose little risk to youth.

With respect to *Amicus*' menthol-flavored ENDS PMTAs, in particular, the evidence supporting these applications was so strong that FDA's Center for Tobacco Products' Office of Science recommended granting marketing authorization for these products, only for FDA's newly appointed leadership to reverse course. As would later be revealed, FDA's leadership decided, in secret, to impose upon menthol-flavored ENDS applicants—many of whose PMTAs had by that point been pending for years—a new evidentiary standard. Contrary to FDA's prior representations concerning the evidence necessary to support an ENDS marketing application, the agency would now require that ENDS companies provide comparative-efficacy evidence showing that their menthol-flavored ENDS have an added benefit over tobacco-flavored ENDS in helping current adult smokers switch from combustible cigarettes. This was the same heightened and vague evidentiary standard that the agency had initially imposed on fruit-, candy-, and dessert-flavored ENDS PMTAs, like those at issue in

this case. At no point did FDA disclose this new comparative-efficacy standard prior to denying ENDS manufacturers' PMTAs, despite the fact that many of these companies—like *Amicus* here—relied in good faith on FDA's prior guidance and communications in designing their evidentiary submissions. Using this new comparative-efficacy standard, FDA issued a Marketing Denial Order ("MDO") for *Amicus*' menthol-flavored ENDS.

Amicus files this brief to explain that FDA's denial of non-tobacco-flavored ENDS applications pursuant to a new, retroactively applied comparative-efficacy standard is unlawful. *Amicus* further files this brief to underscore the critical distinctions between FDA's treatment of menthol-flavored ENDS, on the one hand, and fruit-, candy-, and dessert-flavored ENDS, on the other hand.

INTRODUCTION AND SUMMARY OF ARGUMENT

Manufacturers sell ENDS products in different flavors, including the fruit, candy, and dessert flavors at issue in this case. Tobacco- and menthol-flavored ENDS are especially critical for the public health. These products offer a key resource for adult smokers hoping to stop or reduce their consumption of combustible cigarettes, which are lawfully sold only in tobacco and menthol flavors. Menthol-flavored cigarettes, in particular, make up approximately 37% of all cigarette sales in the United States. *See*

Menthol Tobacco Products, CDC (May 15, 2024).[2] To that end, menthol-flavored ENDS "may be important to adult smokers looking to transition away from cigarettes" because "combustible cigarettes are still sold in menthol flavor," as former FDA Commissioner Scott Gottlieb has correctly explained. *See* Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps to Protect Youth (Nov. 15, 2018) ("Statement from Commissioner Gottlieb").[3]

FDA has undertaken an unlawful, two-step strategy to deny marketing authorization for almost all non-tobacco-flavored ENDS. The lynchpin of this strategy is FDA's retroactive imposition of a comparative-efficacy standard found nowhere in the Tobacco Control Act's statutory text. For the first step of this scheme, in the summer of 2021 and after the deadline for submitting PMTAs for marketed ENDS products had passed, FDA circulated an internal memorandum directing that PMTAs for "flavored" ENDS—then defined not to include menthol- or tobacco-flavored ENDS—must have submitted evidence showing that their products have some undefined added benefit over tobacco-flavored ENDS

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[2] Available at https://www.cdc.gov/tobacco/menthol-tobacco/?CDC_AAref_Val=https://www.cdc.gov/tobacco/basic_information/menthol/index.html (all websites last visited Oct 14, 2024).

[3] Available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access.

in helping current adult smokers stop smoking. Although FDA later purported to rescind that memorandum, FDA applied its new comparative-efficacy requirement to deny every PMTA for fruit-, candy-, and dessert-flavored ENDS. In the second step of this scheme, FDA worked an even more egregious bait-and-switch on menthol-flavored ENDS companies. After issuing public guidance and deficiency letters that expressly distinguished menthol from fruit, candy, and dessert flavors, FDA reversed course. The agency overruled its own Office of Science and extended the same unlawful, comparative-efficacy standard to menthol-flavored ENDS applications without providing applicants any notice—and, indeed, after telling those applicants that the new standard would apply only to fruit-, candy-, and dessert-flavored ENDS.

Although FDA's retroactive imposition of a non-statutory comparative-efficacy standard on fruit-, candy-, and dessert-flavored ENDS is the core legal defect here, FDA's Petitioner's Brief before this Court says next to nothing about it. FDA instead pretends that it determined only that Respondents' evidence was not sufficiently "robust and reliable." Pet.Br.21 (quoting Pet.App.167a, 227a, 279a). Contrary to FDA's revisionist history, the agency did not merely require Respondents to provide "robust and reliable" evidence of their products' benefits as compared to their risks. FDA instead expressly required Respondents to have provided evidence "reliably and robustly evaluat[ing] the impact of the new flavored

vs. Tobacco-flavored products on adult smokers' switching or cigarette reduction over time," Pet.App.167a–68a, 209a, 227a–28a, 263a—a new evidentiary burden found nowhere in the Tobacco Control Act or any prior FDA rule or guidance document.

The reason that FDA now pretends that its non-statutory, retroactive comparative-efficacy standard does not exist is that it has no legal defense as to what it did with regard to Respondents' PMTAs, or the millions of other PMTAs that FDA has denied under that same unlawful standard. It may be that FDA can deny some or maybe even most ENDS PMTAs because they included "insufficient evidence of [the product's] benefits." Pet.Br.20. But FDA cannot invent a non-statutory comparative-efficacy standard and then apply that standard retroactively to pending PMTAs.

Finally, even if this Court decides that FDA lawfully applied its comparative-efficacy standard to PMTAs for fruit-, candy-, and dessert-flavored products, it should make clear that this holding in no way blesses FDA's application of that standard to the multibillion-dollar menthol-flavored ENDS industry. FDA's treatment of menthol-flavored ENDS was far more egregious, including because FDA eventually told manufacturers that its comparative-efficacy standard would apply to fruit-, candy-, and dessert-flavored ENDS PMTAs and not to menthol-flavored PMTAs. Further, it makes no sense to place the same

burden on menthol-flavored ENDS as on fruit-, candy-, and dessert-flavored ENDS, where menthol-flavored ENDS provide a critical resource for current adult menthol smokers seeking to reduce or quit smoking, and all the evidence shows that fruit-, candy-, and dessert-flavored ENDS, as a category, appeal far more to youth than menthol-flavored ENDS.

ARGUMENT

I. FDA Imposed A New Comparative-Efficacy Evidentiary Standard Upon Already-Pending PMTAs, In Violation Of The APA

A. FDA retroactively imposed a non-statutory comparative-efficacy standard on Respondents' ENDS applications, just as it did with millions of other PMTAs. Contrary to the fair notice principles that govern agency action, *see Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020), FDA's public guidance never previewed that the agency would invent and retroactively impose this new evidentiary burden on ENDS companies. The agency instead induced those companies to spend millions of dollars preparing submissions in reliance on FDA's prior representations, which FDA then discarded as soon as it began reviewing those applicants' submissions. The Fifth Circuit thus properly "set aside" FDA's orders as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Nowhere in FDA's public guidance on PMTAs did the agency suggest that ENDS companies must provide studies comparing the efficacy of fruit-, candy-, and dessert-flavored ENDS as against tobacco-flavored ENDS to obtain marketing authorization. In 2019, for example, FDA released a guidance document on ENDS PMTAs that advised applicants to compare their products' physiological health risks against the health risks posed by other ENDS and combustibles, without ever indicating that an ENDS company would need to compare the switching efficacy of fruit-, candy-, and dessert-flavored ENDS as against tobacco-flavored ENDS. *See* Joint App.1–109. FDA's 2019 proposed rule on ENDS PMTAs similarly stated that FDA did "not expect that long-term clinical studies (*i.e.*, those lasting approximately 6 months or longer) [would] need to be conducted for each" application. *See* 84 Fed. Reg. 50,566, 50,619 (proposed Sept. 25, 2019).

But then FDA adopted in secret a different approach to fruit-, candy-, and dessert-flavored ENDS, one found nowhere in the statutory text, FDA rule, or even any FDA guidance. In July 2021, well after many ENDS manufacturers had already submitted PMTAs, the agency circulated an internal memorandum explaining that it would now apply a new "standard for evidence" to analyze PMTAs for "flavored" ENDS products, which term FDA then used to refer only to fruit-, candy-, and dessert-flavored ENDS. *See* Joint App.242. Under this new approach, PMTAs with a "fatal flaw"—namely, a lack

of long-term studies showing that the applicant's ENDS have some undefined added benefit over tobacco-flavored ENDS in reducing or stopping combustible cigarette use among current adult smokers—would "likely" be denied. Joint App.243. FDA privately reiterated that same standard on August 17, 2021, circulating another internal memorandum requiring that "flavored" ENDS applicants provide long-term studies showing that the flavored product at issue was more effective in helping current smokers stop smoking than an "appropriate comparator" tobacco-flavored ENDS product. Joint App.267.

Although FDA purported to rescind this memorandum on August 25, 2021, it applied its substance the very next day, denying *en masse* thousands of fruit-, candy-, and dessert-flavored ENDS applications based on their failure to satisfy the agency's new comparative-efficacy standard. *See* Joint App.281; Press Release, FDA, *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products* (Aug. 26, 2021).[4] Shortly thereafter, FDA denied Respondents' PMTAs, concluding that Respondents failed to provide evidence "reliably and robustly evaluat[ing] the impact of the new flavored vs. Tobacco-flavored products on adult smokers' switching or cigarette

[4] Available at https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence.

reduction over time." Pet.App.167a–68a, 227a–28a, 280a; *see Wages & White Lion Invs., LLC v. FDA*, 90 F.4th 357, 370–71 (5th Cir. 2024).

As the Fifth Circuit correctly explained, FDA's basis for denying Respondents' PMTAs was their failure to provide data showing that "*flavored* e-cigarettes promote more switching than *unflavored* ones." *Wages*, 90 F.4th at 377. FDA had never previewed such a non-statutory requirement to Respondents or other ENDS companies prior to their deadline for submitting PMTAs for marketed ENDS products. Indeed, "[t]here is not a single sentence anywhere in the voluminous record . . . that says: 'manufacturers should submit long-term scientific studies on the differences between their new flavored e-cigarette products and other non-flavored e-cigarette products.'" *Id.* at 385 (citation omitted). The only support that FDA could point to below for its new standard was a single sentence in its June 2019 Guidance stating that "[w]e recommend an applicant compare the health risks of its product to both products within the same category and subcategory, as well as products in different categories as appropriate." *Id.* at 377.

Further, FDA cannot lawfully adopt non-statutory standards found nowhere in the Tobacco Control Act and impose them retroactively on pending PMTAs. The Tobacco Control Act outlines a specific risk-benefit analysis, requiring FDA to consider "the risks and benefits to the population as a whole, including

users and nonusers of the tobacco product," taking into account the "increased or decreased likelihood that existing users of tobacco products will stop using such products" and the "increased or decreased likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. § 387j(c)(4). It does not condition marketing authorization upon a showing that the applicant's product has some unspecified added benefit over a comparator product in helping current adult smokers reduce or quit smoking. *See id.*; *see also Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2261 (2024) (courts must "set aside any [agency] action inconsistent with the law as they interpret it"). At a very minimum, FDA needed to engage in rulemaking before attempting to impose its new comparative-efficacy standard, which it did not do here. *See* Resp.Br.47–49. And, of course, even if FDA had undergone that type of notice-and-comment process, it could not impose any rule under that standard retroactively to already-pending PMTAs. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156–57 (2012); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

B. In its brief before this Court, FDA takes a head-in-the-sand approach to the core legal issue in this case: the legality of FDA's retroactive imposition of a non-statutory comparative-efficacy standard on already-pending PMTAs. FDA now claims that it merely sought any type of "'evidence' that 'reliably and robustly evaluated the impact'" of Respondents' flavored products. Pet.Br.21 at 21 (quoting

Pet.App.167a–68a, 227a–28a, 280a). FDA omits entirely the key conclusion in its MDOs: the agency expressly required Respondents to submit either "a randomized controlled trial and/or longitudinal cohort study that demonstrated *the benefit of [their] flavored ends products over an appropriate comparator tobacco-flavored ends*" or 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*." Pet.App.167a–68a, 227a–28a, 280a (emphasis added); *see Wages*, 90 F.4th at 370. Nor does FDA even discuss its "fatal flaw" memoranda. While FDA tries to shield its new comparative-efficacy standard from this Court's view, Respondents' failure to meet the agency's new comparative-efficacy standard was the primary basis upon which FDA denied their PMTAs. *See* Pet.App.167a–68a, 227a–28a, 280a.

C. Finally, although FDA now pretends that it did not create and then retroactively apply any new comparative-efficacy standard—and suggests instead that it undertook a holistic evaluation of each individual PMTA—two aspects of FDA's later application of that standard to menthol-flavored ENDS further undermine this revisionist history, showing that this standard is what has done the work in FDA's anti-"flavored"-ENDS campaign.

First, as two extraordinary internal memoranda would later reveal, FDA's career experts in the Office of Science unanimously recommended granting

marketing authorization to *Amicus*' menthol-flavored ENDS, before FDA's new political leadership directed them to extend the agency's comparative-efficacy standard for fruit-, candy-, and dessert-flavored ENDS to menthol-flavored ENDS. The Office of Science's non-partisan, expert staff concluded that, "as long as menthol-flavored cigarettes remain on the market, menthol-flavored ENDS could be a direct substitute for them, providing a less harmful alternative for menthol-flavored cigarette smokers, who are less likely to successfully quit smoking than smokers of non-menthol-flavored cigarettes." Joint App., Vol. III at 908, *Logic Tech. Dev. LLC v. FDA*, No.22-3030, Doc.41 (3d Cir. Jan. 5, 2023). Given menthol smokers' "documented preference" for menthol and *Amicus*' "product-specific evidence," the benefits of *Amicus*' menthol-flavored ENDS outweighed any risk to youth, satisfying the "legal standard for authorization." *Id.*

Countermanding the Office of Science's evidence-based conclusions, FDA's new political leadership went on to overrule its career experts and impose upon menthol-flavored ENDS the very same comparative-efficacy evidentiary standard originally devised in the "fatal flaw" memorandum to deny PMTAs for fruit-, candy-, and dessert-flavored ENDS. According to FDA's new leadership, "in light of the substantial risk to youth and the lack of robust evidence of actual differential use to quit or significantly reduce cigarettes per day, the approach to menthol-flavored ENDS should be the same as for

other flavored ENDS." *Id.* at 909. Put another way, the agency now intended to deny every menthol-flavored ENDS PMTA that did not include "robust, product-specific evidence showing that the[ ] menthol-flavored products facilitate complete switching or significant reduction in smoking . . . among adults greater than that facilitated by tobacco-flavored ENDS." *Id.*

Had FDA not devised this comparative-efficacy standard, as FDA now pretends in its briefing before this Court, it could not have retroactively imposed it upon menthol-flavored ENDS PMTAs.

Second, while FDA now touts its recent grant of marketing authorization to a handful of menthol-flavored ENDS products manufactured by NJOY, Pet.Br.47, FDA's grant orders in those cases make clear that the *only* difference between those PMTAs and others that FDA previously denied is that NJOY —now having learned about FDA's comparative efficacy standard and its new application to menthol-flavored ENDS after the high profile release of the memoranda in *Amicus*' case—submitted studies to try to meet that new standard. *See* FDA, Technical Project Lead (TPL) Review of PMTAs (June 21, 2024).[5] ***Indeed, NJOY had to amend its PMTAs in December 2022—two months after FDA denied marketing authorization for* Amicus' *menthol-***

[5] Available at https://www.fda.gov/media/179501/download?attachment.

flavored ENDS—to provide evidence that would satisfy FDA's new comparative-efficacy standard. *See id.* at 42. FDA then went on to apply the same comparative-efficacy evidentiary standard in the NJOY marketing granted order, requiring that NJOY demonstrate that its menthol-flavored ENDS help adult smokers switch from smoking cigarettes to some unspecified greater degree than do tobacco-flavored ENDS. *See id.* at 44–45.

That FDA clearly applied its comparative-efficacy standard to NJOY's marketing applications further refutes the agency's present attempt to pretend that standard does not exist.

II. If This Court Upholds FDA's Comparative-Efficacy Standard As To Fruit-, Candy-, And Dessert-Flavored ENDS, It Should Make Clear That Its Decision Does Not Bless FDA's Treatment Of Menthol-Flavored ENDS

Even if this Court decides that FDA acted lawfully in retroactively imposing its comparative-efficacy standard with respect to fruit-, candy-, and dessert-flavored ENDS, *Amicus* respectfully requests that this Court make clear that its holding does not bless FDA's treatment of menthol-flavored ENDS. FDA's decision to apply its non-statutory comparative-efficacy standard to menthol-flavored ENDS, in particular, worked a distinct and even more egregious bait-and-switch on the menthol-flavored ENDS industry. Moreover, FDA lacked any reasoned basis

to impose its new comparative-efficacy standard on menthol-flavored ENDS, where menthol—like tobacco—is a lawful characterizing flavor in combustible cigarettes and menthol-flavored ENDS provide a critical resource for current adult menthol smokers hoping to switch, without appealing to youth.

A. As explained above, FDA acted unlawfully by imposing a non-statutory comparative-efficacy standard on pending applications for fruit-, candy-, and dessert-flavored ENDS. *See supra* Part I. The agency then performed a separate and even more egregious bait-and-switch with respect to menthol-flavored ENDS, despite FDA itself distinguishing between menthol, on the one hand, and fruit, candy, and dessert flavors, on the other hand, in communications and deficiency letters. Thus, any holding that FDA acted lawfully in this case should be limited to the specific fruit-, candy-, and dessert-flavored ENDS applications at issue here.

FDA has long made clear to ENDS companies that it distinguished between menthol and tobacco flavors, on the one hand, and fruit, candy, and dessert flavors, on the other, such that companies had no reason to provide evidence in their PMTAs comparing the efficacy of their menthol- and tobacco-flavored ENDS. *See* Joint App.160 (defining "flavored" ENDS not to include menthol or tobacco); Joint App.170 ("Menthol is unique compared to other available ENDS product flavors as it is the only characterizing flavor available in cigarettes, and may reduce the irritation and

harshness of smoking."). After *Amicus* and other ENDS companies had already submitted their PMTAs for ENDS products in fruit, tobacco, and menthol flavors, the agency delivered deficiency letters articulating further information that the agency now required to authorize these companies' ENDS products. *See Logic Tech. Dev. LLC v. FDA*, 84 F.4th 537, 558 (3d Cir. 2023) (Porter, J., dissenting); *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 188 (5th Cir. 2023). As to *Amicus*' fruit-flavored ENDS, FDA told *Amicus* to submit a new category of evidence, namely, comparative-efficacy evidence showing that *Amicus*' fruit-flavored ENDS have some added benefit over tobacco- or menthol-flavored ENDS in helping current adult smokers reduce or quit smoking. Joint App., Vol. VII at 3033, *Logic*, No.22-3030, Doc.45 (3d Cir. Jan. 5, 2023) (requiring "scientific evidence and rationale to demonstrate whether these flavor variants may facilitate adult smokers switching to [*Amicus*'] products at a rate beyond that of tobacco- or menthol-flavored products"). Although the deficiency letter that FDA delivered to *Amicus* also addressed *Amicus*' menthol-flavored ENDS PMTAs and requested comparative-efficacy evidence for *Amicus*' fruit-flavored ENDS, *id.*, it did not ask *Amicus* to submit data showing comparative switching efficacy as between menthol- and tobacco-flavored ENDS.

Only later did FDA upend its approach to menthol-flavored ENDS, as revealed in the agency's extraordinary internal memoranda. *Supra* pp.12–14.

Again, although FDA's career experts unanimously recommended granting marketing authorization to *Amicus*' menthol-flavored ENDS, the agency reversed course after FDA's leadership decided to extend the comparative-efficacy standard to menthol-flavored ENDS applications. Like fruit-, candy-, and dessert-flavored applications, pending menthol-flavored ENDS applications would now be denied if the agency failed to credit "robust, product-specific evidence showing that the[ ] menthol-flavored products facilitate complete switching or significant reduction in smoking . . . among adults greater than that facilitated by tobacco-flavored ENDS," Joint App., Vol. III at 908, *Logic*, No.22-3030, Doc.41 (3d Cir. Jan. 5, 2023)—evidence that FDA had never before asked menthol-flavored ENDS applicants to provide.

This is the very abuse that this Court should put a halt to. If *Amicus* had the fortune, like NJOY, of being last in line and learning of the previously secret comparative-efficacy standard in time, it would have shown the same findings as the handful of recent successful menthol-flavored ENDS products that FDA spotlights in its briefing (assuming FDA is going to apply its amorphous comparative-efficacy standard consistently as between applicants). *See* Pet.Br.46–47; *see supra* pp.14–15. But because of FDA's failure to articulate this new and heightened standard in a timely manner, *Amicus* is now threatened with a product-destroying MDO that will require *Amicus* to remove its menthol-flavored ENDS from the market, likely for years, as it prepares, submits, and waits for

FDA to review new PMTAs. During these years, the few companies that were last in line will benefit from an unprecedented commercial windfall, destroying any hope that a competing product can recover several years down the line. This is precisely the sort of conduct that this Court's fair-notice principles are designed to prevent. *See SmithKline Beecham*, 567 U.S. at 156–57.

B. Not only was FDA's bait-and-switch with respect to menthol-flavored ENDS even more egregious than the one it pulled on fruit-, candy-, and dessert-flavored ENDS, FDA's justification for adopting the non-statutory comparative-efficacy standard for menthol-flavored ENDS—whether retroactively imposed or not—is even more indefensible.

FDA itself has consistently recognized the importance of menthol-flavored ENDS to current menthol smokers hoping to reduce or quit smoking combustible cigarettes. *See, e.g.*, Statement of Commissioner Gottlieb, *supra*. Menthol-flavored cigarettes also make up a significant percentage of the combustible cigarette market, comprising 37% of cigarette sales in the United States. *See Menthol Tobacco Products*, *supra*. FDA's own former leadership has acknowledged the importance of menthol-flavored ENDS, *see* Statement of Commissioner Gottlieb, *supra*, as did the agency's career experts in the context of reviewing *Amicus*' PMTAs, concluding that menthol-flavored ENDS may

assist current menthol smokers looking to transition away from combustibles, *see supra* pp.12–13.

Moreover, the evidence demonstrates that the menthol flavor is far less popular among youth than fruit, candy, and dessert flavors. *See* Joint App., Vol. III at 1158–59, *Logic*, No.22-3030, Doc.41 (3d Cir. Jan. 5, 2023). Indeed, the evidence that FDA considered in deciding *Amicus*' menthol-flavored ENDS PMTAs showed that menthol-flavored ENDS were used by 26.6% of middle- and high-school ENDS users in 2020, a figure that was significantly lower than the use rates for fruit (69.1%) and candy/desserts/other sweets (38.3%). *Id.* at 1158–59. Such evidence in no way supports FDA's effort to apply the same evidentiary burden to menthol-flavored ENDS that it applies to fruit-, candy-, and dessert-flavored ENDS; indeed, it simply makes no sense to lump menthol-flavored ENDS together with other non-tobacco-flavored ENDS.

C. In all, if this Court reverses the Fifth Circuit's judgment below, it should clarify that its holding applies only to the FDA's conduct with respect to the specific fruit-, candy-, and dessert-flavored PMTAs here for the additional and related reason that the menthol flavor is fundamentally distinct from the fruit, candy, and dessert flavors at issue here. Menthol-flavored ENDS comprise an important, multibillion-dollar industry, and this Court should not allow the disposition of this case to be misused by FDA to further attack responsible ENDS companies

that spent substantial time and money to comply with the law and FDA's guidance.

CONCLUSION

Amicus respectfully requests that this Court affirm the Fifth Circuit's judgment below.

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