No. 23-1125

In the Supreme Court of the United States

LOGIC TECHNOLOGY DEVELOPMENT LLC,
PETITIONER,
v.
FOOD AND DRUG ADMINISTRATION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF

FDA created and imposed retroactively an unlawful, heightened standard on all non-tobacco-flavored Electronic Nicotine Delivery Systems ("ENDS") premarket tobacco product applications ("PMTAs"), seeking to eliminate this multi-billion-dollar product category. FDA did this in two steps. The agency first imposed its new standard on pending fruit-, candy-, and dessert-flavored ENDS, requiring applicants to show that these products help consumers switch from combustible cigarettes at some unspecified greater degree than tobacco-flavored ENDS. FDA then extended that same heightened standard to pending menthol-flavored ENDS PMTAs—even though menthol-flavored combustibles remain lawful and popular, and despite FDA's prior statements that menthol-flavored ENDS "may be important to adult smokers seeking to transition away from cigarettes." Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps to Protect Youth (Nov. 15, 2018). The benefits that menthol-flavored ENDS offer for adult menthol smokers remain critical today, including given FDA's recent decision to postpone indefinitely its proposed ban on menthol-flavored combustible cigarettes. *See* Press Release, U.S. Dep't of Health & Human Servs.,

Secretary Becerra Statement on the Proposed Menthol Cigarette Rule (Apr. 26, 2024).

In its Petition, Logic Technology Development LLC ("Logic") asked this Court to review two Questions Presented: (1) whether FDA unlawfully created and retroactively applied a heightened comparative-efficacy standard to fruit-, candy-, and dessert-flavored ENDS PMTAs; and (2) whether FDA unlawfully extended that standard to pending menthol-flavored ENDS PMTAs. In its Brief, FDA concedes that this Court should review Logic's first Question Presented, but urges that this review take place only in *FDA v. Wages & White Lion Investments, LLC*, No.23-1038 (filed Mar. 19, 2024), while holding Logic's Petition in abeyance and not resolving the second Question Presented now.

But as the Petition explained, this Court should grant review now on both Questions, for three reasons. First, there is a circuit split on the second Question Presented between the Third Circuit in this case and the Fifth Circuit in *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182 (5th Cir. 2023), which this Court should resolve. Second, FDA's retroactive imposition of its heightened standard on menthol-flavored ENDS PMTAs violates this Court's caselaw. Third, FDA should have to defend its anti-flavored ENDS policy

in the case where that policy is most impactful and least legally defensible—that is, a case involving a responsible company like Logic, which submitted robust, product-specific evidence that its menthol-flavored products help adults switch from cigarettes—rather than only in a case like *Wages*, where the applicant submitted no such studies for dessert-flavored products with names like "Suicide Bunny Mother's Milk and Cookies."

FDA has no persuasive response to any of these reasons for granting the Petition now on both Questions Presented. As to the circuit split, FDA argues that the Fifth Circuit's published decision in *R.J. Reynolds*—which the Third Circuit explicitly rejected below—does not establish a split because the Fifth Circuit issued that decision in the stay posture. But the Fifth Circuit has repeatedly cited *R.J. Reynolds* as binding circuit precedent in published cases. Indeed, FDA is seeking relief from *R.J. Reynolds*' venue holding in a petition pending before this Court. As to the merits of the Third Circuit's decision, FDA offers no response to several of Logic's arguments, while having no persuasive answer for others. And FDA ignores Logic's argument that the agency should not be permitted to defend its anti-flavored ENDS policy before this Court only in a case

like *Wages*, where the manufacturer did not submit robust evidence in support of its PMTAs.

This Court should grant the Petition.

I. As FDA Concedes, This Court Should Grant Review On The First Question Presented

FDA does not dispute that this Court should grant review on Logic's first Question Presented. Pet.27–30. Instead, FDA argues that Logic's Petition is a less ideal vehicle for resolving that Question than FDA's *Wages* petition because: the Fifth Circuit in *Wages* found numerous flaws in FDA's approach; Logic's Petition involves menthol-flavored ENDS, rather than fruit-, candy-, or dessert-flavored ENDS; and the Third Circuit below did not offer any reasoning on the first Question Presented, given its already binding precedent on that Question. *See* FDA Br.7–10. FDA is wrong on all three of these claims.

FDA offers no sound basis for denying Logic's Petition as to the first Question Presented. Logic's framing of its first Question, as well as its explicit preservation of all issues below in the face of *Liquid Labs LLC v. FDA*, 52 F.4th 533 (3d Cir. 2022), *see* Pet.i, 30, is very similar to FDA's framing of its question presented in *Wages*, *see* Pet. for Writ of Cert.

at i, *Wages*, No.23-1038, and thus encompasses all of the errors that the Fifth Circuit identified in *Wages*. Logic's preservation of all arguments on the first Question Presented renders irrelevant FDA's point that the Third Circuit below did not repeat its holding in *Liquid Labs* here. As to the flavor of the products, FDA concedes by silence Logic's position that "there is no possible argument that FDA acted lawfully in imposing its new standard on menthol-flavored ENDS, if it was unlawful for FDA to impose it as to fruit-, candy-, and dessert-flavored ENDS." Pet.3. Regardless, Logic's Petition put forward the second Question Presented regarding FDA's treatment of menthol-flavored ENDS, providing an independent reason for granting Logic's Petition now on both Questions Presented. Pet.31–45.[1]

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[1] While FDA worries that granting both Logic's Petition and the *Wages* petition would place FDA as the respondent in one case and the petitioner in another, *see* FDA Br.8, that is not unusual. Just this Term, this Court received briefing and heard oral argument in *Moody v. NetChoice, LLC*, No.22-277 (filed Sept. 23, 2022), and *NetChoice, LLC v. Paxton*, No.22-555 (filed Dec. 19, 2022), where NetChoice was the respondent in one case and the petitioner in the other.

II. FDA Offers No Good Reason For Delaying Decision On The Second Question Presented

This Court should also grant review on the second Question Presented, which asks whether FDA acted unlawfully by extending its heightened standard to pending menthol-flavored ENDS PMTAs. In its Petition, Logic gave three reasons why this Court should grant review on this second Question Presented now. First, there is a circuit split between the Third and Fifth Circuits on this Question. *See* Pet.33–35. Second, the Third Circuit's decision is contrary to this Court's caselaw. *See* Pet.35–42. Finally, FDA should have to defend its retroactive application of a heightened standard before this Court in the context of Logic's robust menthol-flavored ENDS PMTAs, where the agency's conduct is most practically significant and legally indefensible. Pet.4–5, 42–45. FDA's response to the first two of these arguments is unconvincing, and the agency ignores the third argument entirely.

A. The Third Circuit explained that it was "part[ing] ways" with the Fifth Circuit's published decision in *R.J. Reynolds* on the second Question Presented, Pet.App.30a, and that circuit split is worthy of this Court's review, Pet.33–35.

While FDA argues that this Court should disregard *R.J. Reynolds* because the Fifth Circuit issued that decision in a stay posture, FDA Br.13–16, both the Fifth Circuit and FDA understand that *R.J. Reynolds* is binding in the Fifth Circuit. The Fifth Circuit has repeatedly cited its published decision in *R.J. Reynolds* as circuit precedent. Pet.34 (citing *Inhance Techs., LLC v. EPA*, 96 F.4th 888, 895 (5th Cir. 2024); *Chamber of Comm. of U.S. v. SEC*, 85 F.4th 760, 777 n.23 (5th Cir. 2023)); *see also Calumet Shreveport Refining, LLC v. EPA*, 86 F.4th 1121, 1135 (5th Cir. 2023). While FDA claims that Fifth Circuit merits panels have only relied upon *R.J. Reynolds* for "general principles of administrative law," FDA Br.15, FDA cites nothing for its premise that the same published decision can be circuit precedent in some respects but not others. FDA further claims that "Petitioner cites no case in which the Fifth Circuit has treated *R.J. Reynolds* as binding precedent on the question presented," FDA Br.16, but that is only because FDA itself has understood that *R.J. Reynolds* is binding circuit precedent on that Question Presented by not opposing a stay in another menthol-flavored ENDS case after the Fifth Circuit issued *R.J. Reynolds* (but prior to its *en banc* decision in *Wages & White Lion Investments, LLC v. FDA*, 90 F.4th 357 (5th Cir. 2024)), *see* Mot. to Stay, *R.J. Reynolds Vapor Co. v. FDA*, No.23-60128 (5th Cir. filed Mar. 29, 2023).

FDA's position as to the Fifth Circuit's decision in *R.J. Reynolds* is particularly indefensible given that the agency is presently seeking review of that same decision's holding as to venue in *FDA v. R.J. Reynolds Vapor Co.*, No.23-1187 (filed May 2, 2024). There, FDA repeatedly cites *R.J. Reynolds* as a "published" decision establishing the Fifth Circuit's "settled" position on whether the Fifth Circuit is the proper venue for challenges to marketing denial orders brought by retailers located within the Fifth Circuit. Pet. for Writ of Cert. at 5, 7, 15, 16, *R.J. Reynolds Vapor Co.*, No.23-1187. FDA argues here that the admitted conflict between the Third Circuit's decision below and the Fifth Circuit's published decision in *R.J. Reynolds* on whether FDA violated the Administrative Procedure Act ("APA") in assessing menthol-flavored ENDS PMTAs is insufficient to constitute a circuit split in need of this Court's resolution, FDA Br.13–16, while at the same time asking this Court to grant review based upon the published venue holding in *R.J. Reynolds* that no other Court of Appeals has disagreed with. In truth, *R.J. Reynolds* is published, settled precedent of the Fifth Circuit for all of its holdings, as the Fifth Circuit's (and FDA's) actions and words make clear.

B. The Petition further explained that the Fifth Circuit correctly answered the second Question

Presented, while the Third Circuit got it wrong under this Court's binding caselaw. *See* Pet.35–42. To briefly summarize, FDA unfairly surprised Logic, which had acted in "good-faith" reliance on FDA's prior guidance. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156–57 (2012). FDA never suggested that Logic would need to design studies comparing the switching benefits of menthol- and tobacco-flavored ENDS, and, indeed, indicated through its deficiency letter to Logic that such evidence was only necessary for fruit-, candy-, and dessert-flavored ENDS. Pet.10–13. But after FDA's own career experts concluded that Logic did everything the Tobacco Control Act required to obtain authorization, FDA's new leadership retroactively imposed the agency's amorphous comparative-efficacy standard to deny marketing authorization to Logic's menthol-flavored products. Pet.35–37. This change in policy was also substantively arbitrary and capricious in numerous respects, including because FDA cited no record evidence that would support equating menthol-flavored ENDS with fruit-, candy-, and dessert-flavored ENDS in terms of youth appeal. Pet.37–39. And the Third Circuit improperly relied upon FDA's new rationales found nowhere in the administrative record to defend FDA's actions, in clear violation of *SEC v. Chenery Corp.*, 332 U.S. 194

(1947), and *Calcutt v. FDIC*, 598 U.S. 623 (2023) (per curiam).

FDA's efforts to defend the Third Circuit's ruling on the merits fail.

On FDA's unfair surprise of Logic, the agency has nothing to say about the most conclusive evidence of its bait-and-switch: the 2020 deficiency letter, which is the same type of deficiency letter that FDA sent to other ENDS companies, such as R.J. Reynolds. Pet.12–13, 33–34. That deficiency letter "never requested a comparison between menthol and tobacco products . . . despite specifically asking Logic to compare its fruit and fruit-combination flavored ENDS." Pet.App.52a. The 2020 deficiency letter shows that FDA did not believe such comparative-efficacy evidence to be necessary for menthol-flavored ENDS prior to retroactively extending its heightened standard to these products in late 2022. *See* Pet.App.57a. That is, of course, why even FDA's career experts had no inkling that menthol-flavored ENDS companies would need to meet this new standard when they unanimously recommended granting marketing authorization to Logic's menthol-flavored ENDS products in the Summer of 2022,

before being overruled by FDA's new leadership in the Fall, long after Logic had submitted its PMTAs.[2]

FDA's effort to reframe its internal memoranda documenting the agency's secret policy change with respect to menthol-flavored ENDS is similarly unpersuasive. FDA Br.12–13. FDA contends that an agency does not act arbitrarily by overruling its career experts, FDA Br.12 (quoting *Dep't of Comm. v. New York*, 139 S. Ct. 2551, 2569–71 (2019)), but that is an incomplete statement of the law and, in any event, is irrelevant to Logic's unfair surprise argument. While agency heads have "policymaking discretion," they nevertheless must "consider the evidence and give reasons for [their] chosen course of action." *Dep't of Comm.*, 139 S. Ct. at 2571. Regardless, FDA does not dispute that the internal memoranda evidence a *previously undisclosed change* in FDA's policy on menthol-flavored ENDS, one that the agency's own scientific experts were unaware of until FDA's political leadership informed them of it,

[2] Rather than address the deficiency letter, FDA focuses only on FDA's 2020 Guidance, FDA Br.11, but that Guidance made a clear, substantive distinction between menthol and other flavors, explaining that "[m]enthol is unique" as the "only characterizing flavor available in cigarettes," JA.1129.

and that secret change alone establishes a violation of the APA. *See* FDA Br.12–13.

Turning to the substantive unlawfulness of FDA's approach to menthol-flavored ENDS, FDA argues that its data showed that more youth had tried menthol-flavored ENDS by 2022 than had tried them in 2019. FDA Br.11–12. But what the 2022 data actually shows is that of youth that had tried any ENDS, 26.6% tried menthol-flavored ENDS, whereas 69.1% tried fruit-flavored ends and 38.3% tried "candy, desserts, or other sweet[ ]" flavored ENDS. JA.1158–59. It was thus facially arbitrary and capricious for FDA to treat menthol-flavored ENDS identically to fruit-, candy-, and dessert-flavored ENDS, and especially so when menthol cigarettes are lawfully sold and popular, whereas there are no legal fruit-, candy-, and dessert-flavored cigarettes.

FDA offers no response to Logic's argument that the Third Circuit violated this Court's holdings in *Chenery* and *Calumet* by upholding FDA's dismissal of Logic's evidence based on reasoning found nowhere in the administrative record. To repeat, Logic's evidence showed that 76% of study participants who received the Logic Power menthol flavor reduced their cigarettes per day by 80% or more in a 60-day study, whereas 63% of participants who received the tobacco

flavor achieved that metric. Pet.21–22. The Third Circuit justified FDA's disregard of this evidence by claiming that the submitted evidence was not "statistically significant," Pet.App.32a, a rationale found nowhere in the record and which FDA's counsel raised for the first time at oral argument before the Third Circuit. That FDA *sub silentio* concluded that Logic's evidence was for some unstated reason insufficient to satisfy the agency's new standard shows that the standard is purposefully so amorphous that FDA can simply deny every menthol-flavored ENDS PMTA, destroying the entire product category. Pet.42. FDA offers no response to these points.

3. Finally, Logic explained that this Court should grant this Petition alongside the *Wages* petition and require FDA to defend its retroactive application of a heightened, amorphous evidentiary standard before this Court in the context where it is most practically significant and legally indefensible. Pet.42–45. That is, this Court should also consider FDA's heightened standard in a case where the manufacturer did everything that the Tobacco Control Act and FDA's extant guidance required, spending tens of millions of dollars on its PMTAs, submitting results of multiple studies showing substantial benefits to adults, and taking numerous steps to avoid any appeal to

youth.[3] As a result of these extensive efforts, FDA's career experts recommended granting marketing authorization to Logic's menthol products before FDA's new leadership imposed its heightened standard. FDA should not have the luxury of coming before this Court only in a case like *Wages*, where the manufacturer did not submit such robust evidence, while marketing products with names like "Suicide Bunny Mother's Milk and Cookies." Pet.4–5, 42–45.

FDA offers no response to any of these points, and the reason for the agency's silence is no mystery. It would, of course, be most convenient for FDA to defend its policy toward non-tobacco-flavored ENDS before this Court only in a case like *Wages*, where the manufacturer did not submit evidence that satisfies the Tobacco Control Act's standards, without regard to FDA's new, retroactive policy. *See* Pet. for Writ of

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[3] FDA repeats its baseless assertion that the Logic brand "was one of the ten most popular e-cigarette brands for middle- and high-school students in the United States," FDA Br.3 (citing JA.1159), but FDA never made this claim in the marketing denial order, and it misinterprets the data in any event. The survey that FDA cites did not obtain data on every ENDS brand, let alone rank every ENDS brand. *See* JA.1159. Logic simply ranked tenth among the few brands that the survey specifically identified. *Id.*

Cert. at 16, *Wages*, No.23-1038. Indeed, in its brief in opposition, the *Wages* manufacturer admitted that it opted to "join[ ] with other similarly situated applicants to jointly fund development of non-product-specific data," Br. in Opp. at 15, *Wages*, No.23-1038 (filed May 17, 2024), while decrying the "time and expense" of litigating before this Court, *id.* at 30. But allowing FDA to defend its approach before this Court only in *Wages*—where, given the nature of the manufacturer's evidence and products, the PMTAs could well have been denied regardless of the heightened burden—would allow the agency to evade grappling with just how arbitrary and capricious its new standard truly is. When FDA creates and retroactively imposes a new policy designed to destroy a multi-billion-dollar industry that many Americans rely upon to switch away from smoking cigarettes, the agency should have to defend that policy in the Nation's highest court in a case where the policy made the critical difference in the regulatory outcome.

CONCLUSION

This Court should grant the Petition.

Respectfully submitted,

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