No. _____

In the Supreme Court of the United States

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

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

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

2. Whether FDA's subsequent, retroactive extension of this heightened evidentiary standard to pending PMTAs for menthol-flavored ENDS was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.*

PARTIES TO THE PROCEEDINGS

Petitioner Logic Technology Development LLC was the sole petitioner in the court of appeals.

Respondent United States Food and Drug Administration was the sole respondent in the court of appeals.

CORPORATE DISCLOSURE STATEMENT

Petitioner's parent company is JTI (US) Holding Inc., a Delaware corporation, and no publicly held company owns 10% or more of its stock.

STATEMENT OF RELATED PROCEEDINGS

The following proceedings are directly related to this case within the meaning of Rule 14.1(b)(iii):

- *Logic Technology Development LLC v. FDA*, No.22-3030 (3d Cir. Oct. 19, 2023).

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PETITION FOR WRIT OF CERTIORARI

Electronic nicotine delivery systems ("ENDS"), also known as e-cigarettes, come in different flavors, including tobacco, menthol, candy, fruit, and dessert. Tobacco- and menthol-flavored ENDS are particularly important for adult smokers seeking to switch from combustible cigarettes, as menthol-flavored cigarettes make up roughly 37% of all cigarette sales in the United States, with tobacco-flavored cigarette sales making up the rest. *See* CDC, *Menthol Tobacco Products* (last rev. Aug. 23, 2023).[1] As Former FDA Commissioner Scott Gottlieb explained, menthol-flavored ENDS, in particular, "may be important to adult smokers seeking to transition away from cigarettes," given that "combustible cigarettes are still sold in menthol flavor." *See* Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps to Protect Youth (Nov. 15, 2018) (hereinafter "Statement from Commissioner Gottlieb").[2] On the

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[1] Available at https://www.cdc.gov/tobacco/basic_information/menthol/index.html (all websites last visited on Mar. 14, 2024).

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

other hand, candy-, fruit-, and dessert-flavored ENDS have no analogue in lawfully sold cigarettes.

In the present case, Petitioner Logic Technology Development LLC ("Logic") challenges FDA's effort to effectively ban menthol-flavored ENDS. Without notifying regulated parties, FDA's new political leadership overruled its career experts and imposed retroactively on pending menthol-flavored ENDS premarket tobacco product applications ("PMTAs") the same heightened, amorphous, and vague evidentiary standard under which FDA has not "approved a single PMTA for" any "of the more than 1,000,000 flavored e-cigarette products." *See Wages & White Lion Invs., LLC v. FDA*, 90 F.4th 357, 370 (5th Cir. 2024). This heightened standard forces ENDS companies to prove a purposefully impossible proposition: that their ENDS help consumers switch from smoking cigarettes to some unspecified higher degree than tobacco-flavored ENDS. Since FDA never told menthol-flavored ENDS companies that they would need to carry this burden—and, indeed, indicated that its new standard applied only to fruit-, candy-, and dessert-flavored ENDS—the result is that FDA will deny every menthol-flavored ENDS PMTA, effectively outlawing the country's multibillion-dollar menthol-flavored ENDS market.

This Petition thus raises two related but importantly distinct Questions Presented:

(1) whether FDA acted unlawfully in creating and retroactively applying this heightened comparative-efficacy standard, which FDA first imposed on fruit-, candy-, and dessert-flavored ENDS; and (2) whether FDA acted unlawfully in then imposing that standard on pending menthol-flavored ENDS PMTAs.

Currently before this Court are three other petitions for writs of certiorari raising the first of these Questions Presented. As the ENDS company petitioners in *Lotus Vaping Technologies, LLC v. FDA*, No.23-871 (filed Feb. 9, 2024), and *Magellan Technology, Inc. v. FDA*, No.23-799 (filed Jan. 22, 2024), and the Solicitor General in *FDA v. Wages & White Lion Investments, LLC*, No.23-1038 (filed Mar. 19, 2024), have explained, this Court should resolve the first Question Presented. Petitioner here agrees that this Court should take up this Question Presented, which, if resolved in the ENDS companies' favor, would necessarily lead to relief for Logic here. After all, there is no possible argument that FDA acted lawfully in imposing its new evidentiary standard on menthol-flavored ENDS, if it was unlawful for FDA to impose it as to fruit-, candy-, and dessert-flavored ENDS.

This Petition also raises a second Question Presented, which Logic respectfully submits this Court should also answer now: whether FDA's retroactive extension of its heightened evidentiary

standard for fruit-, candy-, and dessert-flavored ENDS to pending PMTAs for menthol-flavored ENDS was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). As the Fifth Circuit and the dissent at the Third Circuit in this case explained, what FDA has done with menthol-flavored ENDS is plainly unlawful. FDA's career experts in the Office of Science recommended granting marketing authorization to Logic's menthol-flavored ENDS, concluding that Logic did everything required under the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") and FDA's extant guidance. Yet, as revealed in two extraordinary internal memoranda, FDA's new political leadership then changed course, concluding in secret that FDA would now treat menthol-flavored ENDS exactly as it treats fruit-, candy-, and dessert-flavored ENDS. That means that a responsible company like Logic—which has never marketed to youth and instead sells menthol-flavored ENDS to adults who want to reduce or stop smoking menthol cigarettes—now needs to carry the same amorphous, purposefully impossible-to-satisfy burden as to adult switching that FDA has imposed on products like "Iced Pineapple Express" and "Suicide Bunny Mother's Milk and Cookies." *See* Pet. for Writ of Cert. at 6, *FDA v. Wages & White Lion Invs., LLC*, No.23-1038 (filed Mar. 19, 2024).

Logic respectfully submits that granting review on only the first Question Presented in one of the three pending petitions, while holding this Petition for resolution of those cases, would leave this Court with an incomplete picture of the nature of FDA's actions. This would allow FDA to avoid answering before this Court for the most indefensible and practically consequential aspect of its new anti-ENDS approach: its effort to outlaw a multibillion-dollar menthol-flavored ENDS industry that is critical to the millions of menthol smokers who want to quit or reduce smoking cigarettes. "If men must turn square corners when they deal with the government, it cannot be too much to expect the government to turn square corners when it deals with them." *Niz-Chavez v. Garland*, 593 U.S. 155, 172 (2021). And if FDA is going to defend its blanket anti-ENDS policy before this Court, it should be required to do so in a case where that policy made the key difference: that is, where the company submitted such robust evidence of its products' benefits and lack of youth appeal that FDA's career experts unanimously recommended granting marketing authorization, before being overruled by FDA's new political leadership.

This Court should grant the Petition on both Questions Presented.

DECISION BELOW

The Third Circuit's decision denying Logic's petition for review is reported at *Logic Technology Development LLC v. FDA*, 84 F.4th 537 (3d Cir. 2023), and is reproduced at Pet.App.1a–59a. The Third Circuit's order denying Logic's petition for rehearing en banc is unreported but is available at Pet. App.228a–229a.

JURISDICTION

FDA entered its Marketing Denial Order ("MDO") on October 26, 2022, Pet.App.60a–70a, and Logic filed a petition for review of that order in the Third Circuit on October 27, 2022. The Third Circuit denied Logic's petition for review on October 19, 2023, Pet.App.1a–59a, and denied Logic's petition for rehearing en banc on December 15, 2023, Pet.App.228a–229a. Justice Alito extended the deadline for petitioning for writ of certiorari to April 15, 2024. This Court has jurisdiction to hear this Petition and review the Third Circuit's decision under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant statutory provisions are reproduced in the Appendix. Pet.App.230a–247a.

STATEMENT OF THE CASE

A. Legal And Regulatory Background

Under the Tobacco Control Act, manufacturers seeking to market "new tobacco product[s]" in interstate commerce must first receive authorization from the Secretary of Health and Human Services, 21 U.S.C. § 387j(a)(2)(A), acting through FDA, 21 U.S.C. § 393(d)(2). Applicants must submit PMTAs showing that their product "would be appropriate for the protection of the public health." *Id.* § 387j(c)(2)(A). FDA, in turn, must assess "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." *Id.* § 387j(c)(4). The agency must further consider "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." *Id.* § 387j(b)(4)(A)–(B). FDA may premise its decision on "well-controlled investigations," including "clinical investigations," and other "valid scientific evidence." *Id.* § 387j(b)(5).

Although FDA has regulated cigarettes and smokeless tobacco since Congress enacted the Tobacco Control Act in 2009, *see* 21 U.S.C. § 387a(b), the agency did not seek to regulate ENDS until several years later. In 2016, FDA finalized the

"Deeming Rule," which concluded that ENDS meet the statutory definition of a "tobacco product" under the Tobacco Control Act. *See* 81 Fed. Reg. 28,974 (May 10, 2016). Because the United States already had by this time a robust ENDS marketplace, FDA issued guidance in 2017 making clear that ENDS manufacturers could continue to sell products already on the market pending FDA's decision on timely submitted PMTAs. *See Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 468 (D. Md. 2019). Any other approach would have been unlawful. *See Dep't of Homeland Security v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020).

The agency initially gave ENDS manufacturers over five years to submit their applications, *see Am. Acad. of Pediatrics*, 379 F. Supp. 3d at 468, 472, but, after litigation with anti-tobacco lobby groups, that deadline was moved up to September 9, 2020, Order, *Am. Acad. of Pediatrics v. FDA*, No.8:18-cv-00883 (D. Md. Apr. 22, 2020), Dkt.182. Logic, the Petitioner here, supported an earlier submission deadline for ENDS manufacturers to submit their PMTAs. *See Vaping in America: E-Cigarette Companies' Impact on Public Health Before the Subcomm. on Oversight and*

Investigations of the H. Comm. on Energy and Com., 116th Cong. 7–8 (2020).[3]

B. Factual And Procedural Background

1. Logic manufactures ENDS products, which serve as a safer alternative to traditional combustible cigarettes. Logic's ENDS feature a rechargeable battery-operated device that delivers nicotine through an aerosolized vapor. *See* JA.1219; JA.1222; JA.1225.[4] Logic has three types of devices: Logic Vapeleaf, Logic Power, and Logic Pro. *See* JA.1298; JA.1315; JA.1332. Logic Power and Logic Pro operate by heating a solution (also known as an "e-liquid") in a disposable cartridge to produce a nicotine-containing aerosol inhaled by the user. JA.1315; JA.1332. Logic Vapeleaf operates by heating an e-liquid in a disposable cartridge to form a vapor that flows through a disposable tobacco capsule containing granulated tobacco. JA.1298. Logic sells the devices

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[3] Available at https://www.congress.gov/116/meeting/house/110462/witnesses/HHRG-116-IF02-Wstate-LoftinJ-20200205.pdf.

[4] Citations of "JA.__" are of the Joint Appendix filed with the court below. 3d Cir. No.22-3030, Dkts.39–45 (Volumes I through VII). Citations of "SA.__" are of the Supplemental Appendix filed with the court below. 3d Cir. No.22-3030, Dkt.65. Citations of "R.__" are of the circuit court's docket. 3d Cir. No.22-3030.

in a matte black finish and in simple packaging designed not to appeal to youth. *See* JA.3026–27.

2. Investing tens of millions of dollars, Logic started preparing PMTAs for its ENDS products in tobacco, menthol, and fruit flavors shortly after FDA finalized the Deeming Rule, and continued this effort until submitting its PMTAs in mid-2019. Throughout this time, FDA never once suggested what would become key to its unlawful anti-menthol ENDS policy: that Logic must submit long-term studies designed to show that menthol-flavored ENDS are more effective, to some unspecified degree, than tobacco-flavored ENDS in helping adults reduce or quit smoking combustibles.

At first, FDA only provided ENDS manufacturers with a May 2016 draft version of FDA's guidance document on PMTAs, *see* FDA, *Premarket Tobacco Product Applications for Electronic Delivery Systems* (May 2016) (hereinafter "2016 Guidance"),[5] which guidance FDA finalized in June 2019, *see* FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems* (June 2019)

[5] Available at https://www.fda.gov/files/tobacco%20products/published/DRAFT-GUIDANCE-Guidance-for-Industry-Premarket-Tobacco-Product-Applications-for-Electronic-Nicotine-Delivery-Systems.pdf.

(hereinafter "2019 Guidance").[6] The 2019 Guidance advised, among other things, that applicants should compare the physiological health risks of their ENDS products as against other ENDS and combustibles. *See id.* This guidance did not suggest that manufacturers should design long-term switching studies to compare the efficacy of their ENDS as against tobacco-flavored ENDS in helping current smokers reduce or quit smoking combustibles.

In 2019, the agency issued a proposed rule on PMTAs for ENDS products, which similarly offered no indication that ENDS manufacturers would need to design long-term studies showing that the submitted ENDS products have some added switching benefit over tobacco-flavored ENDS. *See* 84 Fed. Reg. 50,566 (proposed Sept. 25, 2019). To the contrary, the proposed rule 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. *Id.* at 50,619. The proposed rule further indicated that marketing plans would be "critical to FDA's determination of the likelihood of changes in tobacco product use behavior" and that the agency "will review the marketing plan to evaluate potential youth access to, and youth exposure to, the labeling,

[6] Available at https://www.fda.gov/media/127853/download.

advertising, marketing, or promotion of, a new tobacco product." *Id.* at 50,581.

In 2020, FDA issued another guidance document detailing its enforcement priorities with respect to ENDS products. JA.1106 (the "2020 Guidance"). The 2020 Guidance explicitly distinguished between so-called "flavored" ENDS products—that is, fruit-, candy-, and dessert-flavored ENDS—on the one hand, and tobacco- and menthol-flavored ENDS products, on the other. JA.1109. As FDA explained, it would prioritize enforcement against "flavored, cartridge-based ENDS products (other than tobacco- or menthol-flavored)." JA.1126. "This approach strikes an appropriate balance between restricting youth access to [fruit-, candy- and other dessert-like flavored 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." *Id.*

After Logic submitted its PMTAs in mid-2019 for several different ENDS products—including the three menthol-flavored products at issue here, as well as three tobacco-flavored ENDS and four fruit-flavored ENDS, *see* JA.1299; JA.1316; JA.1333—on June 26, 2020, FDA sent Logic a deficiency letter outlining additional information that the agency now required to authorize Logic's ENDS products. *See* JA.3010–22.

With respect to Logic's fruit-flavored ENDS, FDA asked Logic for the first time to provide a new category of evidence: "scientific evidence and rationale to demonstrate whether these flavor variants may facilitate adult smokers switching to Logic products at a rate *beyond that of tobacco- or menthol-flavored products, which may have lower youth appeal*." JA.3016 (emphasis added). FDA further indicated that this could include "[d]ata or information from studies demonstrating uptake/switching among adult smokers using *flavored* variants of the products relative to uptake/switching among *tobacco- or menthol-flavored users*," and "[d]ata or information from studies demonstrating *appeal (e.g., preference or intention to use) of flavored variants (fruit and fruit-combination flavored products) compared to tobacco- or menthol-flavored variants* among adult users interested in switching to ENDS." *Id.* (emphases added). Even though this deficiency letter (i) also dealt with Logic's menthol-flavored ENDS PMTAs, *see* JA.3020, and (ii) specifically requested comparative efficacy data for Logic's fruit -flavored ENDS, *see* JA.3016, the letter nowhere suggested that Logic should submit data showing the same comparative switching efficacy as between its menthol- and tobacco-flavored ENDS.

In July 2021, FDA circulated an internal memorandum acknowledging that FDA would now

apply a new "standard for evidence" when evaluating marketing applications for "flavored" ENDS products, a category that FDA then defined to include only fruit-, candy-, and dessert-flavored ENDS, but not menthol- and tobacco-flavored ENDS. *See* Mem. from Anne Radway, Assoc. Dir., Div. of Regul. Project Mgmt., FDA, ENDS Containing Non-Tobacco-Flavored E-Liquid (July 9, 2021).[7] PMTAs with a "fatal flaw"—namely, a lack of long-term studies showing that the applicant's "flavored" ENDS have some undefined added benefit over tobacco-flavored ENDS in helping current smokers reduce or quit smoking combustibles—would "likely" be denied. *Id.* at 2. On August 17, 2021, FDA circulated another internal memorandum reiterating that FDA would deny marketing authorization unless a "flavored" ENDS applicant provided long-term studies showing that the applicant's product was more effective in helping current smokers reduce or quit smoking than an "appropriate comparator" tobacco-flavored ENDS product. *See* Mem. from Benjamin Apelberg, Deputy Dir., Off. of Sci., FDA, PMTA Review: Evidence to Demonstrate Benefit of Flavored ENDS to Adult

[7] Available at https://files.vaporvoice.net/wp-content/uploads/sites/3/2021/11/CTP-OS-Memos-from-Triton-Administrative-Record.pdf.

Smokers (Aug. 17, 2021).[8] FDA purported to rescind this memorandum on August 25, 2021—the day before it issued its first MDOs for flavored ENDS. *See* Mem. from Benjamin Apelberg, Deputy Dir., Off. of Sci., FDA, Rescission of Aug. 17, 2021, Mem. re PMTA Review (Aug. 25, 2021);[9] Press Release, FDA, *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products* (Aug. 26, 2021).[10]

FDA then proceeded to deny *en masse* PMTAs submitted for fruit-, candy-, and dessert-flavored ENDS, including Logic's fruit-flavored ENDS PMTAs (which products are not at issue in this case). *See* FDA, *Tobacco Products Marketing Orders* (Mar. 7, 2024).[11] As the Fifth Circuit has explained, "months after receiving hundreds of thousands of applications

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[8] Available at https://files.vaporvoice.net/wp-content/uploads/sites/3/2021/11/CTP-OS-Memos-from-Triton-Administrative-Record.pdf.

[9] Available at https://files.vaporvoice.net/wp-content/uploads/sites/3/2021/11/CTP-OS-Memos-from-Triton-Administrative-Record.pdf.

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

[11] Available at https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders.

predicated on its instructions, FDA turned around, pretended it never gave anyone any instructions about anything, imposed new testing requirements without any notice, and denied all one million flavored e-cigarette applications for failing to predict the agency's *volte face*." *Wages*, 90 F.4th at 362.

3. The agency then went on to perform the same about-face with respect to menthol-flavored ENDS.

Logic invested tens of millions of dollars to prepare its menthol PMTAs, and submitted thousands of pages of documents and evidence supporting those applications. R.8 at 4; *see* JA.1227–50; JA.1251–72; JA.1273–94. As relevant here, that evidence showed both that Logic's menthol-flavored ENDS are beneficial for adult smokers and that they are not used by youth in any appreciable amounts.

With respect to adult benefit, Logic showed that its ENDS products have substantial benefits for current adult smokers. For example, Logic's 60-day studies demonstrated that 76% of study participants who received the Logic Power menthol flavor reduced their cigarettes per day by 80% by the end of the study. SA.087. Current smokers who switched to Logic's ENDS products also had 50–95% lower concentrations of biomarkers of exposure to harmful constituents than when using combusted cigarettes, JA.1988–90; JA.2176–78; JA.2370–72, and were

exposed to significantly less nicotine, JA.1943; JA.2120; JA.2309. Further, study participants who used Logic's menthol products, in particular, for 60 days consistently reported stronger overall impressions of the product's flavor compared to participants who received the tobacco-flavored products, JA.2537; JA.2630; JA.2725, and reported the strongest desire to use the product to reduce and/or quit smoking, JA.2572; JA.2666; JA.2761. Across all three of Logic's products, the study participants assigned the menthol variants had higher compliance with instructions to use the product instead of smoking cigarettes than the participants assigned a tobacco variant. JA.1958; JA.2130–31; *see* JA.2512. The 60-day studies further showed that current menthol cigarette smokers had more positive experiences and perceptions of Logic's ENDS when they received a menthol-flavored product rather than when they received a tobacco-flavored one. JA.2761–62; JA.2666–67; JA.2572.

Logic's PMTAs also demonstrated that youth do not use its ENDS products in any appreciable amounts. Logic submitted data from the National Youth Tobacco Survey ("NYTS"), which showed that youth do not use its ENDS products to any significant degree. The NYTS survey asked high-school and middle-school students across the United States about their tobacco-product use, including their preferred brands of ENDS products. *See* JA.3033.

This data showed that, in 2019, only 0.8% of high school students used Logic products—the lowest reported value in the NYTS at that time—and Logic products were not identified as the usual brand by *any* middle school students. *Id.* Further, in the 2022 NYTS results, 9.4% of youth-survey-respondents identified as ENDS users, and only 0.4% of all youth reported using any Logic products (not just menthol) in the past 30 days. JA.1159. *The 2022 NYTS study, later relied upon by FDA, did not identify any youth who reported Logic as their regular brand*. *Id.* Logic also provided FDA with a marketing plan designed to eliminate youth appeal and access: for example, Logic's products eschew trendy colors, flavors, and vivid imagery, opting instead for a plain, matte black finish and product features designed to avoid concealment during use. *See* JA.3026–28. Logic also terminated its social media accounts in September 2020, JA.3028, and ceased all online sales in early 2021, *see* JA.3168.

3. After Logic's PMTAs were fully submitted and pending, FDA retroactively and in secret imposed upon menthol-flavored PMTAs the same amorphous comparative-efficacy requirement that it had used to deny all fruit-, candy-, and dessert-flavored ENDS PMTAs. The imposition of this secret policy change played out between FDA's career experts and its new political leadership, and did so in the context of Logic's menthol-flavored ENDS PMTAs.

As would later be revealed in two extraordinary internal agency memoranda disclosed for the first time in this litigation, the FDA's Center for Tobacco Products' Office of Science, after reviewing all of Logic's comparative health risk data, unanimously recommended granting Logic's PMTAs for its menthol-flavored ENDS. *See* JA.908. Applying the Tobacco Control Act's risk-benefit analysis, *see* 21 U.S.C. 387j, the Office of Science's non-partisan 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." JA.908. Menthol smokers' "documented preference" for menthol-flavored ENDS, coupled with Logic's "product-specific evidence," outweighed any risk to youth of the menthol products and thus met the "legal standard for authorization." *Id.*

But then the Center's political leadership changed and, in July 2022, that new leadership overruled the Office of Science's evidence-based recommendation. New leadership instead decided to extend the agency's heightened requirements for fruit-, candy-, and dessert-flavored ENDS, now requiring applicants to show that menthol-flavored ENDS are more effective, to some unspecified degree, than tobacco-flavored ENDS in helping current

smokers reduce or quit smoking. JA.904; JA.909; *see* JA.907–08. New leadership stated that, "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." JA.909. Put another way, every menthol-flavored ENDS application would be denied unless the applicant provided "robust, product-specific evidence showing that their menthol-flavored products facilitate complete switching or significant reduction in smoking . . . among adults greater than that facilitated by tobacco-flavored ENDS." *Id.* Although new leadership stated that it considered the prospect that its new approach to menthol-flavored ENDS would eliminate all non-tobacco-flavored ENDS products, it offered no answer for this concern. JA.904 & n.3. In internal meetings, Office of Science staff criticized the agency's conduct, including for its lack of "transparency." JA.905.

c. On October 26, 2022, FDA issued the marketing denial order ("MDO") for Logic's three menthol-flavored ENDS, rejecting Logic's PMTAs for these products and ordering Logic to remove them from the market immediately. Pet.App.60a–70a; *see* Pet.App.71a–227a (Technical Project Lead review). Consistent with the new approach to menthol-flavored ENDS articulated in the then-secret memoranda, FDA said that it was unable to ascertain

from Logic's studies or from the peer-reviewed literature "whether or to what extent [Logic's] menthol flavored new products facilitate complete switching [of cigarette smokers to Logic products] or significant cigarette reduction as compared to tobacco flavored ENDS products." Pet.App.64a.

FDA provided no record evidence that would support its decision to extend the same unlawful approach that the agency had previously taken with respect to fruit-, candy-, and dessert-flavored ENDS to menthol-flavored ENDS. Indeed, the agency continued to acknowledge, as it had in the past, that menthol-flavored ENDS are less popular among youth than other ENDS products. *See* Pet.App.158a.

The nature of FDA's reasoning and the evidence before the agency demonstrate that FDA designed its new anti-menthol ENDS policy to be so vague as to allow the agency to deny all menthol-flavored ENDS. Recall that in the PMTAs at issue, Logic submitted the data on its menthol-flavored ENDS and tobacco-flavored ENDS together, so if FDA was actually interested in the comparative efficacy of Logic's products, it could have reviewed that data. *See, e.g.*, JA.1299; JA.1316; JA.1333. For example, that data showed that 76% of study participants who received the Logic Power menthol flavor reduced their cigarettes per day by 80% or more by the end of the 60-day study, whereas 63% of participants who

received the Logic Power tobacco flavor reduced their cigarettes per day by 80% or more by the end of that study. SA.087. FDA did not attempt to explain why this difference did not satisfy its new comparative efficacy standard as to menthol-flavored ENDS, simply declaring that Logic's data was not "acceptably strong" enough to demonstrate "an added benefit relative to that of tobacco-flavored ENDS in facilitating smokers completely switching away from or significantly reducing their smoking." Pet.App.204a–205a. FDA declined to state what degree of added benefit would, in fact, be sufficient to meet the agency's new, retroactively imposed standard for evaluating menthol-flavored ENDS, instead setting an illusory target for ENDS companies applying for marketing authorization. *See id.*

Thereafter, FDA issued MDOs for several more menthol-flavored ENDS PMTAs submitted by other manufacturers. *See* FDA, *Tobacco Products Marketing Orders*, *supra*. To date, and consistent with its new, effective-ban standard for evaluating menthol products, FDA has not granted marketing authorization to any menthol-flavored ENDS. *See id.* The agency has, moreover, denied these menthol applications in nearly identical fashion, concluding that the applicant's purported failure to provide evidence showing, to some unspecified degree, that their menthol products have an added benefit over

tobacco-flavored ENDS in helping adults reduce or quit smoking was fatal to their application. *See R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 188 (5th Cir. 2023); Pet.'s Br. at 17–18, *SWT Global, Inc. v. FDA*, No.23-2403 (8th Cir. filed Sept. 14, 2023); *see also* FDA, *FDA Denies Marketing Applications for Flavored blu E-Cigarette Products* (Feb. 5, 2024);[12] FDA, *FDA Denies Marketing of myblu Menthol E-Cigarette Product* (July 10, 2023).[13]

6. On October 27, 2022, Logic filed a petition for review, challenging the MDOs for Logic's menthol-flavored ENDS. R.1. The Third Circuit granted Logic an emergency partial administrative stay as to Logic Pro Menthol e-Liquid Package and Logic Power Menthol e-Liquid Package, the two Logic menthol products currently on the market. R.6. Following briefing, the Third Circuit also granted Logic's motion for a full stay pending its petition for review. R.35.

Logic thereafter submitted its merits briefing. As to the Questions Presented in this case, Third Circuit

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[12] Available at https://www.fda.gov/tobacco-products/ctp-newsroom/fda-denies-marketing-applications-flavored-blu-e-cigarette-products.

[13] Available at https://www.fda.gov/tobacco-products/ctp-newsroom/fda-denies-marketing-myblu-menthol-e-cigarette-product.

precedent foreclosed Logic's ability to argue that FDA's retroactive adoption of its heightened comparative-efficacy standard for fruit-, candy-, and dessert-flavored ENDS was unlawful, *see Liquid Labs LLC v. FDA*, 52 F.4th 533 (3d Cir. 2022), so Logic preserved that argument for further review, including before this Court, R.46 at 41 n.9; R.63 at 16 n.3; R.118 at 11 n.2. After all, if FDA's adoption of that new standard was unlawful as to fruit-, candy-, and dessert-flavored ENDS, it would necessarily be unlawful for FDA to then impose that same standard on menthol-flavored ENDS. As to the second Question Presented, Logic explained how FDA had upset industry reliance interests by retroactively imposing an evidentiary standard designed for fruit-, candy-, and dessert-flavored ENDS on already-pending menthol-flavored ENDS PMTAs without fair notice. *See* R.46 at 34–45. Logic further argued, *inter alia*, that even putting the unlawful retroactivity of imposing this new standard on pending PMTAs aside, there was no evidence that would permit FDA to impose the same burden on all menthol-flavored ENDS as it had imposed on "flavored" ENDS, including such youth-attractive products as, for instance, "OG Island Fusion." *See* R.46 at 46–56.

On October 19, 2023, the Third Circuit, in a divided opinion, denied Logic's petition for review. Pet.App.1a–59a. The panel majority reasoned that FDA did not "change[ ] 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." Pet.App.30a. The panel majority remarkably blessed as "good government" FDA's 2022 internal memoranda purporting to justify the agency's extension to menthol-flavored ENDS of its heightened, effective-ban approach to fruit-, candy-, and dessert-flavored ENDS. Pet.App.26a–29a. The majority then accepted a similarly implausible interpretation of the 2020 deficiency letter, holding that FDA's failure to request comparative switching evidence as between Logic's menthol- and tobacco-flavored ENDS—despite specifically requesting such evidence for Logic's fruit-flavored ENDS—did not show that the agency later changed its position as to what evidence would be required to support a menthol application. *See* Pet.App.32a–33a. The panel majority further concluded that Logic should have intuited FDA's new comparative-efficacy requirement from the agency's prior guidance, despite the fact that the Office of Science itself was unaware of this new standard when it initially recommended granting marketing authorization for Logic's menthol-flavored ENDS. Pet.App.30a–33a. Finally, the majority accepted FDA's *post hoc* rationale—first articulated by FDA's counsel at oral argument, R.106 at 31:4–7—that Logic's evidence showing that current menthol smokers are more likely to use menthol-flavored

ENDS to reduce or quit smoking was not "statistically significant." *See* Pet.App.32a.

In his dissent, Judge Porter explained that FDA's undisclosed decision to "lump[ ] menthol together with fruit, candy, and dessert flavors" reflected the agency's new, undisclosed policy requiring ENDS manufacturers to include a comparison between menthol- and tobacco-flavored products in PMTAs, which policy upset Logic's substantial reliance interests. Pet.App.41a (Porter, J., dissenting). "No one at the FDA informed Logic of the policy change," or gave "Logic an opportunity to amend the menthol-product PMTAs in response to the new policy." Pet.App.45a. "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." Pet.App.52a. Given all of the agency's public guidance to date, "Logic had no reason to compare menthol products to tobacco products." Pet.App.57a. FDA's change of position required FDA to provide Logic "notice of and a reasoned explanation for its policy departure," as well as assess alternatives to denial. Pet.App.59a (citation omitted).

Logic filed a petition for rehearing en banc, which the Third Circuit denied on December 15, 2023. Pet.App.228a–229a. On January 4, 2024, the Third

Circuit granted Logic's motion to stay the mandate pending this Court's decision on the instant Petition. R.126.

REASONS FOR GRANTING THE PETITION

I. This Court Should Grant Review On The First Question Presented Regarding FDA's Creation Of A New, Heightened Evidentiary Standard For Evaluating Pending PMTAs

This Court should grant review on the first Question Presented: whether FDA's retroactive adoption of a heightened evidentiary standard for "flavored" PMTAs—a standard under which FDA has denied every fruit-, candy-, and dessert-flavored ENDS PMTA it has considered—is unlawful. There is a clear circuit split on this Question, detailed in three other petitions for certiorari currently pending before this Court. *See supra* pp.3; Sup. Ct. R. 10(a).

As the Fifth Circuit sitting en banc correctly held in *Wages*, FDA acted arbitrarily and capriciously, *see* 5 U.S.C. § 706(2)(A), when it unfairly surprised ENDS companies by retroactively adopting and applying its heightened evidentiary standard after these companies had already submitted their PMTAs in "good faith reliance" on the agency's prior positions. *Wages*, 90 F.4th at 384–85 (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156–57

(2012); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009)). In public guidance, FDA told regulated parties that it would consider a variety of evidence as to whether ENDS products are "appropriate for the protection of the public health." *See Wages*, 90 F.4th at 377–81. But FDA then created a heightened evidentiary standard for "flavored" ENDS (a category that FDA then understood to include only fruit-, candy-, and dessert-flavored ENDS), now requiring that already-submitted PMTAs include long-term studies showing that a "flavored" product has some unspecified degree of added benefit over tobacco-flavored ENDS in helping current adult smokers reduce or quit smoking combustibles. *Supra* pp.14–16; *see Wages*, 90 F.4th at 380–81. FDA "received over one million PMTAs for flavored e-cigarette products" and, of course, "not a single one of them contained the scientific studies that FDA now require[d]." *Wages*, 90 F.4th at 386. FDA provided no "fair notice" for its new evidentiary standard and, indeed, sprung it as an unfair surprise on ENDS manufacturers, which acted in good-faith reliance on FDA's prior guidance. *Id.* at 376–81.

Relatedly, the Fifth Circuit and the Eleventh Circuit have faulted FDA for failing to consider applicants' marketing plans in "flavored" ENDS PMTAs, which the agency had previously identified as "critical" to a successful PMTA. *Id.* at 372–73; *Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1203 (11th Cir.

2022). "FDA's refusal even to read the once-'critical' marketing plans constitute[s] an arbitrary and capricious failure to consider 'an important aspect of the problem.'" *Wages*, 90 F.4th at 373 (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *Bidi Vapor*, 47 F.4th at 1203. For that reason, too, FDA's treatment of "flavored" ENDS products was unlawful.

Seven other circuits have reached a contrary conclusion to the Fifth and Eleventh Circuits. *See Liquid Labs*, 52 F.4th 533; *Magellan Tech., Inc. v. FDA*, 70 F.4th 622 (2d Cir. 2023); *Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022); *Gripum, LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022); *Lotus Vaping Techs., LLC v. FDA*, 73 F.4th 657 (9th Cir. 2023); *Electric Clouds, Inc. v. FDA*, 94 F.4th 950 (10th Cir. 2024); *Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022). These courts have held that FDA's prior guidance on PMTAs sufficiently put the ENDS industry on notice that FDA would require long-term studies showing that "flavored" ENDS are more effective than tobacco-flavored ENDS in helping adult smokers reduce or quit smoking. *See, e.g.*, *Liquid Labs*, 52 F.4th at 542–43; *Magellan*, 70 F.4th at 629–32; *Avail*, 55 F.4th at 422–25. Further, these courts have determined that FDA's failure to review the applicants' marketing plans was harmless. *See, e.g.*, *Liquid Labs*, 52 F.4th at 543–44; *Magellan*, 70 F.4th at 630–31; *Avail*, 55 F.4th at 425–27. In seeking

certiorari from the Fifth Circuit's decision in *Wages*, the Solicitor General acknowledged the need for this Court to provide uniformity in this area of law. *See* Pet. for Writ of Cert. at 13–14, *Wages*, No.23-1038.

This Petition squarely presents this Question, which Logic has preserved below, given binding Third Circuit precedent foreclosing it. *See* R.46 at 41 n.9; R.63 at 16 n.3; R.118 at 11 n.2; *see also Liquid Labs*, 52 F.4th at 543–44. As explained in Part II, the agency's only justification for imposing its new comparative-efficacy requirement on menthol-flavored ENDS is its claim that menthol-flavored ENDS have substantially the same youth appeal as fruit-, candy-, and dessert-flavored ENDS, and thus need to be supported by the same evidence of adult benefit. *See infra* pp.37–38. While there is no record basis for this equivalence, *see infra* pp.37–38, if FDA's policy with respect to fruit-, candy-, and dessert-flavored ENDS is unlawful, then it follows that imposing that policy on menthol-flavored ENDS on the basis that the menthol flavor is similar to fruit, candy, and dessert flavors in terms of youth appeal is necessarily also unlawful.

II. This Court Should Grant Review On The Second Question Presented Regarding FDA's Retroactive Imposition Of This Heightened Evidentiary Standard On Menthol-Flavored ENDS

This Petition also raises a second Question Presented: whether FDA acted unlawfully when it extended retroactively its heightened evidentiary standard for fruit-, candy-, and dessert-flavored ENDS to pending PMTAs for menthol-flavored ENDS. It is critical that this Court decide this second Question Presented alongside the first so that the Court may consider the most practically significant and legally indefensible aspect of FDA's anti-ENDS campaign, in the context of PMTAs that included such robust evidence that FDA's career experts recommended granting marketing authorization before FDA's political leadership intervened.

A. The Third Circuit's Erroneous Decision Approving FDA's Retroactive Imposition Of A Heightened Evidentiary Burden On Menthol-Flavored ENDS Creates A Split With The Fifth Circuit

Following its retroactive imposition of a heightened evidentiary burden on fruit-, candy-, and dessert-flavored ENDS PMTAs, FDA extended this same unlawful standard to menthol-flavored ENDS.

Prior to issuing the MDO here, FDA told ENDS manufacturers that it distinguished between menthol and tobacco flavors, on the one hand, and fruit, candy, and dessert flavors, on the other. *See, e.g.*, JA.1109, 1126. In its 2020 Guidance, the agency noted that "[m]enthol is unique compared to other available ENDS product flavors as it is the only characterizing flavor available in cigarettes, and it may reduce the irritation and harshness of smoking." JA.1129. "Menthol cigarettes are also used by a substantial portion of the U.S. population, who are addicted to nicotine and may be looking for an alternative product to seek to transition completely away from combusted products." *Id.* FDA's 2020 deficiency letter to Logic reflected that same policy: while the agency was (unlawfully) asking for comparative-efficacy evidence as between Logic's fruit- versus tobacco- and menthol-flavored ENDS, JA.3016, FDA never requested such evidence with respect to Logic's menthol-flavored ENDS, *see* JA.3010–22; Pet.App.57a–58a (Porter, J., dissenting). FDA's Office of Science then examined Logic's menthol applications under the agency's then-controlling policy, and recommended granting marketing authorization. *See* JA.908. Only later did FDA's new leadership impose, in secret, a new policy "lump[ing] menthol together with fruit, candy, and dessert flavors." Pet.App.41a (Porter, J., dissenting). This policy, in turn, operates as a de facto ban on menthol-flavored ENDS. *See R.J. Reynolds*, 65 F.4th at 192–94. That is confirmed by the internal

memoranda that the agency prepared in connection with Logic PMTAs, which offered no response to FDA staff's fear that the new heightened standard would result in an effective ban on the menthol ENDS category. *See* JA.904 n.3.

There is a circuit split as to whether FDA's conduct with respect to menthol-flavored ENDS, in particular, was arbitrary and capricious. Sup. Ct. R. 10(a). The panel majority's decision below was also contrary to this Court's caselaw. *Id.*

1. There is a circuit split as to whether FDA acted unlawfully by imposing a heightened evidentiary burden on pending menthol-flavored ENDS PMTAs.

The Fifth Circuit, on one side of the divide, has held that FDA's retroactive extension of its amorphous, heightened evidentiary standard for fruit-, candy-, and dessert-flavored ENDS to menthol-flavored ENDS was unlawful. In *R.J. Reynolds*, the Fifth Circuit granted a stay of an MDO for the petitioner's menthol-flavored ENDS, holding that FDA violated the principles of fair notice in evaluating menthol-flavored ENDS applications. 65 F.4th at 189–91, 195. The facts of *R.J. Reynolds* mirror those here: prior to issuing the MDO, FDA told the petitioner in a deficiency letter to provide comparative switching evidence as between its fruit- and tobacco-flavored products, but did not request

such evidence with respect to the petitioner's menthol products. *Id.* at 188, 190. Pointing to the 2022 internal memoranda that FDA prepared in connection with Logic's PMTAs, the Fifth Circuit explained that the agency's "inexplicabl[e] switch[of] position on menthol-flavored e-cigarettes" evidenced a "disregard for the principles of fair notice and consideration of reliance interests," and so violated the APA. *Id.* at 190–91 (citing *Regents*, 140 S. Ct. at 1913). The Fifth Circuit further held that FDA's change of course lacked adequate justification. *Id.* at 191 (citing *Regents*, 140 S. Ct. at 1913). While the Fifth Circuit issued *R.J. Reynolds* in a stay posture, that court has since cited to *R.J. Reynolds* repeatedly as circuit precedent in APA cases. *See, e.g.*, *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).

The Third Circuit panel majority expressly admitted that it was "part[ing] ways" with the Fifth Circuit's *R.J. Reynolds* decision, holding that FDA did not "change[ ] course" as to the "types of evidence that would be required for a premarket application to win approval" for menthol-flavored ENDS, or the "appropriate comparator for menthol-flavored ENDS." Pet.App.30a. According to the panel majority, FDA's secret 2022 internal memoranda evidencing the agency's change of policy with respect to menthol-flavored ENDS were merely "good

government." Pet.App.26a–29a. The panel majority further concluded that the agency's 2020 deficiency letter did not evidence any prior agency policy of treating menthol-flavored ENDS differently than fruit-, candy-, and dessert-flavored ENDS. Pet.App.32a–33a. The panel majority similarly blessed FDA's extension of its heightened evidentiary standard for fruit-, candy, and dessert-flavored ENDS to menthol-flavored ENDS, seeing no legal problem with FDA's complete discounting of Logic's product-specific evidence demonstrating that its products do not appeal to youth. *See* Pet.App.34a–38a.

2. The Fifth Circuit's resolution of this Question Presented was correct, and the Third Circuit's decision below was contrary to this Court's caselaw.

a. FDA's retroactive imposition of a heightened evidentiary burden on menthol-flavored ENDS PMTAs violates the APA, under this Court's caselaw. An agency cannot upset a regulated party's good-faith reliance interests without fair notice when the party has reasonably relied on the agency's prior guidance. *SmithKline Beecham Corp.*, 567 U.S. at 156; *Fox Television*, 556 U.S. at 515. Here, FDA impermissibly upset the reasonable expectations of Logic and other menthol-flavored ENDS manufacturers, which have wasted hundreds of millions of dollars aiming for FDA's illusory target. *See* Pet.App.46a–50a (Porter, J., dissenting). First, the agency publicized its policy

of treating menthol differently from other "flavored" ENDS given the agency's desire not to "foreclose[ ] one potential means by which some adult smokers might seek to transition completely away from combusted tobacco products," JA.1125, and issued deficiency letters to Logic and other menthol-flavored ENDS manufacturers indicating that their menthol applications would be reviewed in accordance with this policy, *see supra* pp.12–13; *R.J. Reynolds*, 65 F.4th at 188. Then, the agency pulled the rug out from under these regulated parties, retroactively imposing upon their PMTAs a requirement that the applicant demonstrate that its menthol-flavored ENDS are more effective, by some unspecified degree, than tobacco-flavored ENDS in helping adults reduce or quit smoking. *See* JA.908; *R.J. Reynolds*, 65 F.4th at 189–91. Without "fair warning," FDA then penalized Logic for purportedly failing to satisfy this retroactive standard. *See SmithKline Beecham*, 567 U.S. at 156, 158–159; *R.J. Reynolds*, 65 F.4th at 189–91.

That the agency performed a bait-and-switch with respect to Logic's menthol-flavored ENDS is beyond serious dispute, given that FDA's own Office of Science—applying FDA's prior policy with respect to the menthol flavor—recommended granting marketing authorization for Logic's menthol products, changing course only after FDA's new leadership changed the policy. *See* JA.908–09. As

Judge Porter pointed out below, there was no change in the data before the agency between when the Office of Science recommended granting marketing authorization and when the FDA issued the MDO. *See* Pet.App.51a–54a (Porter, J., dissenting).

FDA's imposition of the same heightened evidentiary standard on all menthol-flavored ENDS that it had previously imposed on fruit-, candy-, and dessert-flavored ENDS is also *substantively* unlawful in multiple respects, even had FDA not imposed it retroactively on already pending PMTAs.

As a threshold matter, FDA pointed to no record support for equating menthol-flavored ENDS with fruit-, candy-, and dessert-flavored ENDS, and it was thus arbitrary and capricious for FDA to place the same evidentiary burden on menthol-flavored ENDS as it had previously imposed on these other flavored products. *See State Farm*, 463 U.S. at 43. The evidence before the agency clearly showed that the menthol flavor is less popular among youth than candy, fruit, and dessert flavors. *See* Pet.App.158a. Specifically, menthol-flavored ENDS were used by 26.6% of middle- and high-school ENDS users, which figure was lower than the use rates for fruit (69.1%) and candy/desserts/other sweets (38.3%). JA.1158–59. This obviously does not support importing the "same," JA.909, approach to menthol-flavored ENDS

as that applicable to fruit-, candy-, and dessert-flavored ENDS.

Further, FDA's lumping of Logic together with all other ENDS companies, without giving any heed to Logic's particularly successful marketing and other strategies to mitigate potential youth usage, violates the Tobacco Control Act. That Act requires the agency to determine whether the marketing of the *particular products* at issue would be "appropriate for the protection of the public health," 21 U.S.C. § 387j(c)(2)(A), in light of "the risks and benefits to the population as a whole," *id.* § 387j(c)(4). In reviewing the evidence before it, FDA must consider "the increased or decreased likelihood that existing users of tobacco products will stop using such products," as well as "the increased or decreased likelihood that those who do not use tobacco products will start using such products." *Id.* § 387j(c)(4)(A)–(B). Logic here submitted overwhelming evidence showing that its products meet this standard. Logic's data demonstrated that youth do not use its products in any appreciable amounts. *Supra* pp.17–18. Further, data from the 2022 NYTS study demonstrated that no youth reported Logic as their regular brand. *Supra* pp.18. Logic's 60-day studies also showed that smokers who were randomly assigned to use the menthol product for 60 days achieved an 80% reduction in their cigarette consumption at substantial rates, complied with the study's directive

to only use the assigned Logic product at higher rates than those assigned other products, and smoked fewer cigarettes per day than those assigned other products. *Supra* pp.16–17. But FDA disregarded or ignored this product-specific evidence, instead denying Logic's PMTAs under its anti-menthol ENDS policy, after lumping Logic's products with all other companies' ENDS.

b. The Third Circuit's contrary decision is wrong.

First, the Third Circuit violated this Court's caselaw when it treated the 2022 internal memoranda as evidence of "good government" and required Logic and other menthol-flavored ENDS manufacturers to somehow intuit FDA's previously undisclosed evidentiary requirements for PMTAs. *See* Pet.App.26a–29a. As explained, the internal memoranda clearly lay out the agency's decision to apply, retroactively and without prior notice, the same unlawful approach to menthol-flavored ENDS that the agency had previously adopted with respect to fruit-, candy-, and dessert-flavored ENDS. *Supra* pp.19–20. The panel majority's effort to deny the import of the 2020 deficiency letter fails: the panel concluded that the deficiency letter's failure to ask for comparative efficacy evidence with respect to Logic's menthol products while, at the same time, asking for such evidence with respect to Logic's fruit products was of no moment, because the agency had already

told ENDS companies to design studies comparing the efficacy of menthol- and tobacco-flavored ENDS in terms of complete switching. Pet.App.32a–33a. But that latter premise is incorrect, for all the reasons explained above and in the Fifth Circuit's *R.J. Reynolds* decision. *See supra* pp.34–38; *R.J. Reynolds*, 65 F.4th at 189–94. Remarkably and most tellingly, the Third Circuit claimed that Logic should have somehow intuited FDA's new standard before submitting its PMTAs, even though FDA's own Office of Science did not know about this new standard when assessing those PMTAs. *See* Pet.App.30a–32a.

Second, the panel majority improperly sanctioned FDA's equation of the menthol flavor with fruit, candy, and dessert flavors in terms of youth appeal without record evidence for this equivalence. As explained, no data before the agency supported such an equivalence. *Supra* pp.37–38. Indeed, even the dissenting judges in the Fifth Circuit's en banc decision in *Wages* recognized that FDA grouped menthol- and tobacco-flavored ENDS together as having less youth appeal than fruit-, candy-, or dessert-flavored ENDS. *See* 90 F.4th at 398–99 (Haynes, J., dissenting).

The panel majority similarly erred in allowing the agency to discount entirely Logic's product-specific evidence showing that its products, in particular, do not appeal to youth, in favor of rank speculation that

youth's use of Logic's products might substantially change in the future as other ENDS products are removed from the market. *See* Pet.App.37a–38a. The agency did not offer any evidence supporting this claim. *See* JA.157a; *State Farm*, 463 U.S. at 43. Nor did the panel majority explain why it was proper for the agency to "prognosticat[e] what will happen to children's menthol use as other flavored ENDS exit the market," while ignoring what will happen to current menthol smokers when they no longer have access to menthol-flavored ENDS. *See* Pet.App.38a.

Finally, the panel majority erred in blessing FDA's hide-the-ball approach to menthol-flavored ENDS PMTAs, which included designing its new evidentiary standard to be so vague as to permit the agency to deny all menthol-flavored ENDS PMTAs, without regard to the weight of the evidence supporting those PMTAs. As explained, while Logic did not design studies to compare its menthol and tobacco products in terms of switching efficacy, data in Logic's PMTAs happened to illustrate just such a comparison, given that Logic submitted its menthol- and tobacco-flavored PMTAs at the same time: 76% of study participants using the Logic Power menthol flavor reduced their cigarettes per day by 80% or more by the end of the 60-day study, whereas only 63% of participants who used the Logic Power tobacco flavor reduced their cigarettes per day by 80% or more by the end of that time period. SA.087. This data

provides clear evidence that Logic Power menthol-flavored ENDS have an added benefit over tobacco-flavored ENDS in helping adults reduce or quit smoking, assuming that is relevant at all. And yet, the Third Circuit accepted FDA's *post hoc* contention that this data was not "statistically significant." Pet.App.32a. That was error, first because FDA advanced this contention for the first time at oral argument, and did not make this point in the administrative record. R.106 at 31:4–7; *see Calcutt v. FDIC*, 598 U.S. 623, 629 (2023) (per curiam) (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)). Additionally, the agency has to date failed to offer any indication to regulated parties of what comparative-efficacy evidence could be "statistically significant" enough to merit marketing authorization, thus enabling FDA to rely on its heightened, vague evidentiary standard to deny marketing authorization in all cases, in violation of the APA.

B. This Court Should Grant This Question Presented Now, Rather Than Holding This Case For *Wages*

Logic anticipates that the Solicitor General will resist a grant on this second Question Presented and, instead, urge this Court to hold the present Petition pending disposition of the *Wages* petition on the merits, which petition raises only the first Question Presented at issue in this case. *See, e.g.*, Pet. for Writ

of Cert. at 27, *Wages*, No.23-1038 (asking this Court to hold the *Magellan* and *Lotus* petitions pending the *Wages* petition). Logic respectfully submits that this Court should not take that approach for several important reasons.

FDA leadership's campaign to impose retroactively a heightened evidentiary standard for already-pending PMTAs is most practically important and legally indefensible in the context of menthol-flavored ENDS. As FDA's prior leadership aptly explained, menthol-flavored ENDS "may be important to adult smokers looking to transition away from cigarettes" given that "combustible cigarettes are still sold in menthol flavor." Statement from Commissioner Gottlieb, *supra*. Menthol-flavored cigarettes account for roughly 37% of all cigarette sales in this country, and are—in contrast to fruit, candy, and other dessert flavors—lawful. *See Menthol Tobacco Products*, *supra*; JA.1129 ("[m]enthol cigarettes are . . . used by a substantial portion of the U.S. population"). Menthol-flavored ENDS are helpful to adults seeking to transition away from combustibles, as FDA's own scientific career experts recognized when they recommended granting Logic's PMTAs before FDA's political leadership forced them to change course. *See* JA.908. FDA leadership's present anti-menthol ENDS policy threatens the very situation that FDA' prior leadership sought to avoid when regulating in this

context, namely, "a situation where . . . combustible products have features that make them more attractive than . . . non-combustible products." *See* Statement from Commissioner Gottlieb, *supra*.

This Court's immediate review is also necessary to provide uniformity to the multibillion-dollar menthol-flavored ENDS industry. *See* Pet. for Writ of Cert. at 25–26, *Wages*, No.23-1038; *see also* R.121 at 5. The Fifth Circuit's *R.J. Reynolds* decision allows certain menthol-flavored ENDS companies—namely, those who have challenged MDOs in the Fifth Circuit—to continue selling their menthol products, while other manufacturers must pull theirs from the market. Further, when FDA eventually denies other companies' menthol PMTAs (as it surely will continue to do, *see supra* pp.28–29), those companies that are powerful enough to get their retail partners in the Fifth Circuit to join with them in a petition for review will be able to obtain relief from their MDOs in that forum, just as R.J. Reynolds did. *See R.J. Reynolds*, 65 F.4th at 188. The Solicitor General in *Wages* highlighted the harmful, nationwide effects of the current division of authority on FDA's treatment of ENDS products, explaining that "out-of-circuit entities have begun flocking to the Fifth Circuit, thus evading unfavorable precedent in the D.C. Circuit or their own circuits." Pet. for Writ of Cert. at 25, *Wages*, No.23-1038. This Petition will allow the Court to address the current division in authority on menthol-

flavored ENDS, and thus is a critical companion case should this Court decide to grant certiorari in one of the pending fruit-, candy-, and dessert-flavored cases.

More generally, FDA should not have the luxury of defending its comparative-efficacy gambit before this Court only in a case like *Wages*, where the applicants—unlike Logic—did not submit robust evidence supporting marketing authorization. *See* Pet. for Writ of Cert. at 6–7, *Wages*, No.23-1038. Rather, FDA should have to defend its actions in the context of the MDO here, where the menthol flavor at issue is unquestionably more important to the goal of reducing use of combustible cigarettes, given the widespread availability of menthol combustible cigarettes, and Logic's evidence of adult benefit and lack of youth appeal was so robust that the Office of Science recommended granting authorization before FDA's political leadership changed course with respect to menthol-flavored ENDS. This Court should, accordingly, hear this case alongside *Wages* or one of the other pending petitions addressing FDA's unlawful treatment of flavored ENDS products, granting review on both Questions Presented.

CONCLUSION

This Court should grant the Petition.

Respectfully submitted,

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