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.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Respondents make bottled "e-liquids"—a liquid that contains nicotine used in electronic nicotine delivery systems ("ENDS"). Respondents flavor their e-liquids to taste like fruit or sweets; and they began selling their e-liquids years before FDA adopted a rule giving itself regulatory authority over ENDS products. By a court-ordered deadline, Respondents (and hundreds of other companies) filed applications with FDA so they could keep their products on the market. But while those applications were pending, and with no notice to applicants, FDA decided it (1) would not grant marketing authorization for a flavored ENDS product unless the application established via a product-specific longitudinal comparative efficacy study that the product was more effective than tobacco-flavored ENDS products in helping adult smokers quit smoking; and (2) would not bother to review applicants' proposed plans to keep their products out of kids' hands even though FDA had told applicants those plans were "critical" to the applications. Based on those decisions, FDA later denied Respondents' applications. But the en banc Fifth Circuit found FDA's denials arbitrary and capricious because FDA (1) changed its position on the authorization requirements without fair notice to Respondents and without considering Respondents' reliance interests, and (2) committed prejudicial error by refusing to consider Respondents' plans to prevent underage access and use.

The question presented is:

Whether FDA's denial of Respondents' marketing applications was arbitrary and capricious

where FDA changed its position on the authorization requirements without fair notice to Respondents and without considering Respondents' reliance interests and where FDA ignored other aspects of the applications the agency previously described as "critical."

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, the undersigned counsel of record certifies that neither Respondents Wages and White Lion Investments, L.L.C. (d/b/a Triton Distribution) nor Vapetasia, L.L.C. has a parent corporation and no publicly held company owns 10 percent or more of the stock of either Respondent. There is no other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of this case.

PARTIES TO THE PROCEEDINGS

Petitioner (respondent below) is the Food and Drug Administration. Respondents (petitioners below) are Wages and White Lion Investments, L.L.C. (d/b/a Triton Distribution), and Vapetasia, L.L.C.

RELATED PROCEEDINGS

United States Court of Appeals (5th Cir.):

Wages & White Lion Investments, L.L.C. v. FDA, No. 21-60766 (Jan. 3, 2024)

Wages & White Lion Investments, L.L.C. v. FDA, No. 21-60800 (Jan. 3, 2024)

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STATEMENT

A. Statutory Background

The Family Smoking Prevention and Tobacco Control Act of 2009 ("Act") gave FDA regulatory authority over "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b). Congress granted this authority to FDA because those products "cause cancer, heart disease, and other serious adverse health effects." § 2(2), 123 Stat. 1776, 1777.

Indeed, Congress found that the use of such products "is the foremost preventable cause of premature death in America," that it "causes over 400,000 deaths in the United States each year," and that "approximately 8,600,000 Americans have chronic illness relating to smoking." § 2(13), 123 Stat. 1776, 1777. Congress also found that a 50 precent "reduction in youth smoking" would save "over 3,000,000" minors "from premature death due to tobacco-related disease" and "would result in approximately $75,000,000,000 in savings attributable to reduced health care costs." *Ibid.* And Congress found that "[b]ecause the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely." § 2(34), 123 Stat. 1776, 1779.

All that said, the Act prohibits FDA from "banning all cigarettes." 21 U.S.C. § 387g(d)(3)(A). In fact, cigarette manufacturers can market "new" cigarettes—defined as cigarettes that were not commercially marketed in the United States as of February 15, 2007—if the manufacturer can

demonstrate to FDA that the new cigarette is "substantially equivalent to" one marketed in the United States before that date. 21 U.S.C. § 387j(a)(2); 21 U.S.C. § 387e(j). FDA has authorized the marketing of hundreds of new cigarettes through the issuance of "substantially equivalent" orders.[1]

B. Electronic Nicotine Delivery Systems ("ENDS")

The Act also authorizes FDA to issue rules that "deem" other "tobacco products" to "be subject to [the Act]." 21 U.S.C. § 387a(b).[2] In 2016, FDA finalized a rule that deemed electronic nicotine delivery systems ("ENDS")—also referred to as "electronic cigarettes"—to be subject to the Act.[3]

Unlike combustible cigarettes (*i.e.,* traditional cigarettes), ENDS do not contain tobacco leaf that is burned to create smoke that the user inhales. Instead,

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[1] *See* FDA Searchable Products Database, available at https://www.accessdata.fda.gov/scripts/searchtobacco/ (last accessed on May 11, 2024).

[2] The Act defined a "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr)(1) (2010). Nicotine is derived from tobacco. Congress later expanded the definition to include products "containing nicotine derived from any source." 21 U.S.C. § 321(rr)(1) (2022).

[3] *See Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974 (May 10, 2016); *see also* 21 C.F.R. § 1100.1.

ENDS use an "e-liquid" that usually contains nicotine and other ingredients. The liquid is heated to create an aerosol that the user inhales.

According to FDA, "ENDS are generally likely to have fewer and lower concentrations of harmful and potentially harmful constituents (HPHCs) than combustible cigarettes, and biomarker studies demonstrate significantly lower exposure to HPHCs among current exclusive ENDS users than current smokers." Pet. App. 251a-252a. And according to FDA, "the currently available evidence indicates that smokers who switch completely to ENDS will have reduced toxic exposures and this likely leads to less risk of tobacco-related diseases." FDA, *Technical Project Lead (TPL) Review of PMTAs* at 6 (May 12, 2022).[4]

As a general matter, there are three categories of ENDS: (1) cartridge-based ENDS, (2) disposable ENDS, and (3) "open system" ENDS. Cartridge-based and disposable ENDS are referred to as "closed" systems and "tend to be smaller" and easier to use than open system ENDS. *See Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1196 (11th Cir. 2022).

This case deals with Respondents' bottled e-liquids, which are sold for use in open system ENDS. Although this case does not deal with cartridge-based or disposable ENDS, the differences between the three categories of ENDS are important when determining

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[4] FDA cites this document at page 5 of its Petition. The document is available at https://www.fda.gov/media/165236/download?attachment (last accessed May 11, 2024).

whether FDA's denials of Respondents' product applications were arbitrary and capricious.

1. Cartridge-Based ENDS

Cartridge-based ENDS use a replaceable cartridge (also called a "pod") filled with e-liquid. Once all the e-liquid in a cartridge is used, the user can replace the empty cartridge with a new, pre-filled cartridge. JUUL is perhaps the most well-known cartridge-based ENDS.

The photo below, which is taken from the CDC's Visual Dictionary for E-Cigarettes and Vaping Products, shows a cartridge-based ENDS on the left, four cartridges, and a USB charger for the product on the right.[5]

FDA says that cartridge-based products have "design features" that make them "popular with young people," such as "pre-filled cartridges or pods," and "a relatively small size that allows for easy concealability" in "the palm of one's hand or in a pocket." C.A. App. A199. According to FDA, this

[5] The CDC Visual Dictionary is available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf (last accessed May 5, 2024).

concealability "may allow youth to use" cartridge-based ENDS "in circumstances where use of tobacco products is prohibited, such as at school." *Ibid.*[6]

2. Disposable ENDS

Disposable ENDS come pre-filled with e-liquid and are intended to be thrown away once that e-liquid is used up. In other words, the user does not replenish the e-liquid once the disposable ENDS is empty. Disposable ENDS are generally similar in size to cartridge-based ENDS. The photo below, which is taken from FDA's website, shows two examples of disposable ENDS.[7]

3. Open System ENDS

Open system ENDS do not come pre-filled with e-liquid and do not use pre-filled cartridges or pods of

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[6] Starting in or around 2019, several public school districts sued JUUL on the theory that JUUL products created a "youth e-cigarette crisis" in their schools. *See In re JUUL Labs, Inc., Mktg., Sales Practices, & Prods. Liab. Litig.*, 497 F. Supp. 3d 552, 577-78 (N.D. Cal. 2020).

[7] The relevant FDA website page is https://www.fda.gov/tobacco-products/products-ingredients-components/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends (last accessed May 5, 2024).

e-liquid. Instead, the products have an open tank. Users of open system ENDS purchase bottles of e-liquid, typically manufactured by a different company than the one who manufactured the open system ENDS, and then fill the tank with that e-liquid. The photo on the left below, which is taken from the CDC's Visual Dictionary, shows two examples of open system ENDS; the photo on the right shows an example of one of the bottled e-liquids at issue in this case.

Unlike cartridge-based and disposable ENDS—which are sold in convenience stores—open system ENDS and bottled e-liquids are sold primarily in "vape shops." *See* C. Berg, et al., *Vape Shop Owners/Managers' Opinions About FDA Regulation of E-Cigarettes*, 23 Nicotine and Tobacco Research

535, 536 (2021).[8] Vape shops "are tobacco specialty stores that predominately sell vaping devices and nicotine e-liquids but not conventional tobacco products." *Id.* at 536.

A "substantial proportion of vape shops are small businesses or single-store owners." *Id.* at 536-37. And "many people working in the vape shop industry are former smokers who used vaping to quit smoking traditional cigarettes or reduce harm, believe that their products are effective for these purposes and are largely safe, and want to help their consumers." *Id.* at 537.

C. The Shifting Deadline for Submitting ENDS Premarket Applications

When FDA "deemed" ENDS to be tobacco products in 2016, there were already millions of ENDS on the market in the United States (including Respondents' products). Those products immediately became subject to the Act's premarket authorization requirement. *See* 21 U.S.C. § 387j. And because those products did not have premarket authorization, they were immediately "deemed to be adulterated" under the Act. 21 U.S.C. § 387b(6)(A).

Persons who sell adulterated tobacco products in interstate commerce are subject to civil money penalties of up to $20,678 for each violation, not to exceed $1,378,541 for all violations adjudicated in a

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[8] Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7885784/ (last accessed May 5, 2023). The Berg article is based on research conducted in 2018 and funded by, among other organizations, the National Cancer Institute. *See* Berg at 537, 541.

single proceeding (such proceedings are conducted by an ALJ, not an Article III judge).[9] They are also subject to criminal prosecution that can result in up to one year in prison and/or a fine of up to $1,000. *See* 21 U.S.C. §§ 331(a), 333(a)(1).

When FDA finalized its "deeming" rule in 2016, it also announced a "compliance policy" under which the agency would not initiate enforcement actions against ENDS products that were on the market as of August 8, 2016, so long as the manufacturer submitted a premarket tobacco product application ("PMTA") by August 8, 2018. *See* 81 Fed. Reg. 28,974, 29,011. The compliance policy also provided that if a manufacturer submitted a timely PMTA for an ENDS, the agency would not initiate an enforcement action against the product for one year after the PMTA was submitted. *Ibid.* In short, under FDA's compliance policy, manufacturers marketing an ENDS product by August 2016 could expect to be able to keep that ENDS on the market without FDA authorization for up to three years (up until August 2019) so long as they submitted a timely PMTA.

A lengthy compliance policy period made sense. After all, even though Congress established a statutory standard for premarket authorization of tobacco products, *see* 21 U.S.C. § 387j(c)(2)(A) (the "appropriate for the protection of the public health" standard),[10] FDA had not even proposed, let alone

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[9] *See* 21 U.S.C. § 333(f)(9)(A); 21 C.F.R. § 17.2; 45 C.F.R. § 102.3.

[10] The statutory standard requires a PMTA applicant to show, among other things, "that permitting such tobacco product to be marketed would be appropriate for the protection of the public health" ("APPH"). 21 U.S.C. § 387j(c)(2)(A). The APPH

finalized, regulations for tobacco product applications.[11]

Rather than immediately issue proposed regulations for PMTAs for ENDS, FDA issued a draft guidance document. *See* FDA Draft Guidance, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems* (May 2016). But even finalized FDA guidance documents do not have the force of law. *See* 21 C.F.R. § 10.115(d)(1) ("Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA."). And in any event, the draft guidance nowhere suggested that PMTAs for flavored ENDS products would have to include evidence that the product is better than a comparator tobacco-flavored ENDS product in helping smokers reduce or quit smoking, much less that such evidence would have to take the form of a product-specific longitudinal study.

In January 2017, a new presidential administration took over. A few months later, FDA

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determination is based on "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." 21 U.S.C. § 387j(c)(4). When making APPH determinations, FDA must 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." 21 U.S.C. § 387j(c)(4)(A)-(B).

[11] FDA always adopts corresponding product application regulations when Congress sets forth a statutory standard for a product approval. *See, e.g.*, 21 U.S.C. § 355(d) (approval standard for new drugs); 21 C.F.R. Ch. I, Subch. D., Pt. 314 (regulations regarding applications to market new drugs).

extended the compliance policy deadline for submission of PMTAs for ENDS until August 2022, and stated that ENDS with timely filed PMTAs could remain on the market unless and until FDA took a negative action on the PMTA. *See* FDA Guidance, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* (August 2017).

In June 2019, FDA finalized its guidance document on PMTAs for ENDS (the "2019 PMTA Guidance"). C.A. App. A284.[12] Like the 2016 draft version, the 2019 PMTA Guidance did not suggest that PMTAs for flavored ENDS would have to include evidence that the product is better than a comparator tobacco-flavored ENDS in helping smokers reduce or quit smoking over time. But the 2019 PMTA Guidance did say "FDA does not expect that applicants will need to conduct long-term studies to support an application." C.A. App. A317.

One month after FDA issued the 2019 PMTA Guidance, a district court ordered FDA to accelerate the PMTA deadline from August 2022 to May 2020, and the court ordered that products with timely-filed PMTAs could remain on the market without being subject to an FDA enforcement action for a period not to exceed one year after the PMTA deadline while the agency considered the applications. *See American Academy of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019). The court later extended the PMTA

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[12] FDA Guidance, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems* (June 2019).

deadline to September 2020 due to the Covid-19 pandemic.[13]

D. FDA's 2019 Proposed PMTA Rule

In September 2019, FDA proposed a rule for PMTAs. *See Premarket Tobacco Product Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50,566 (Sept. 25, 2019). The proposed rule gave no hint that applicants for flavored ENDS would have to establish that their products have an added benefit relative to tobacco-flavored ENDS in helping smokers completely switch away from or significantly reduce their smoking. But the proposed rule said that the agency did "not expect that long-term clinical studies (i.e., those lasting approximately 6 months or longer) [would] need to be conducted for each PMTA." *Id.* at 50,619. And the proposed rule said that applicants' 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

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[13] The district court did not explain what it would have done had FDA not enforced the court's PMTA deadline or had FDA extended its enforcement discretion policy beyond one year after the deadline. It is doubtful that the district court could have done anything if either of those situations occurred. FDA does not have the authority to unilaterally bring an enforcement action against someone who is violating the Federal Food, Drug, and Cosmetic Act (by, for example, selling an unauthorized tobacco product). Like most federal agencies, FDA can only request that the Attorney General initiate an enforcement action. *See Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 599 (1950). And this Court has never held that the Judicial Branch can order the Executive Branch to bring an enforcement action. *See Heckler v. Chaney*, 470 U.S. 821 (1985).

to, and youth exposure to, the labeling, advertising, marketing, or promotion of, a new product." *Id.* at 50,581.

E. FDA's 2020 Enforcement Guidance

In January 2020, less than 10 months before the September 2020 deadline for Respondents and others to submit their PMTAs for bottled e-liquids, FDA published a guidance document describing how the agency "intend[ed] to prioritize [its] enforcement resources with regard to the marketing of certain [ENDS] that do not have premarket authorization." *See* FDA Guidance, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* at 2 (Jan. 2020) ("2020 Enforcement Guidance").[14] According to the 2020 Enforcement Guidance, FDA's top enforcement priority was "[f]lavored, cartridge-based ENDS products (other than tobacco- or menthol-flavored ENDS products)." C.A. App. A193.

FDA's decision to prioritize enforcement against flavored, cartridge-based ENDS was likely driven by the popularity of JUUL products among underage consumers. A paper published two months before the 2020 Enforcement Guidance was released, co-authored by officials from FDA and CDC, and cited in the 2020 Enforcement Guidance, noted:

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[14] *See* C.A. App. A183, A185. The document at C.A. App. 183 is the April 2020 revised version of the guidance document issued in January 2020. The April 2020 revisions are not relevant to this case. *See* C.A. App. A214 (explaining differences between the January 2020 and April 2020 versions of the guidance document).

> Most youth who were current e-cigarette users reported JUUL as their usual e-cigarette brand in 2019; the next most frequent response was "no usual brand." This mirrors trends in retail sales data showing that JUUL has held the majority of the market share of U.S. e-cigarette sales since December 2017.[15]

The 2020 Enforcement Guidance further explained that FDA was prioritizing enforcement against flavored, cartridge-based ENDS because such products had "design features" that make the "products so popular with young people" (*e.g.*, small size, easy concealability, ability to use immediately after purchase, and "prefilled cartridges, which are convenient because they do not require filling prior to use and are easy to dispose of"). C.A. App. A199. The 2020 Enforcement Guidance also noted that "particularly easy-to-use products, such as cartridge-based products, may have lower barriers to entry." C.A. App. A200.

The 2020 Enforcement Guidance stated that FDA's other enforcement priorities were all "other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access," and any "ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors." C.A. App. A201.

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[15] K. Cullen, et al., *E-Cigarette Use Among Youth in the United States, 2019*, 322 JAMA 2095 (2019) (cited in 2020 Enforcement Guidance at 12, n.31, C.A. App. A195); *see also id.* at 16, C.A. App. A199 (stating "the leading brand is a cartridge-based product that commands approximately 70 percent of the market").

Importantly, the 2020 Enforcement Guidance stated that these enforcement priorities "should have minimal impact on small manufacturers (*e.g.*, vape shops) that primarily sell non-cartridge-based ENDS products, unless they market to youth or fail to take adequate measures to prevent youth access." *Ibid.*; *see also* C.A. App. A207 (stating FDA's enforcement priorities "should have minimal impact on those vape shops that primarily sell non-cartridge-based ENDS products and that ensure purchasers are of requisite age and not purchasing for resale (*e.g.*, are not purchasing in large quantities)").

The 2020 Enforcement Guidance also recommended a number of marketing and sales access restrictions that manufacturers of open system ENDS and bottled e-liquids could adopt to prevent minors' access to and interest in their products. *See* C.A. App. A209-210 (marketing restrictions); C.A. App. A205 (sales access restrictions).

F. FDA's Receipt of Applications for Millions of Flavored ENDS

By September 9, 2020—the court-ordered deadline for PMTAs—FDA received 6.5 million applications for newly "deemed" tobacco products, the majority of which were for ENDS products, including e-cigarettes and e-liquids.[16] FDA later described the task of reviewing these applications by September 10, 2021—the court-ordered end of the enforcement

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[16] *See* FDA Press Release, *FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million "Deemed" New Tobacco Products Submitted* (Sept. 9, 2021).

discretion period for unauthorized ENDS—as "unprecedented."[17]

Among the 6.5 million applications were those for Respondents' bottled e-liquids.[18] Due to the court-ordered accelerated deadline for submitting PMTAs, Respondents joined with other similarly situated applicants to jointly fund development of non-product-specific data, including a comprehensive review of the scientific literature on ENDS. *See, e.g.*, C.A. App. A369, A374. Respondents also submitted product-specific data, such as assessments of the levels of harmful or potentially harmful constituents ("HPHCs") in their e-liquids. C.A. App. A382, A452. Respondents also submitted proposed plans for marketing and sales access restrictions that tracked the recommendations in the 2020 Enforcement Guidance. *Compare* C.A. App. A377-378, A392-400, A430-433, A445-452 *with* C.A. App. A205, A209-210.

G. FDA's August 17, 2021 Internal Decision Regarding Requirements for PMTAs for Flavored ENDS

In January 2021, another new presidential administration took over. In July 2021, the new administration's Acting FDA Commissioner directed the agency to "develop a new plan" to "take final action on as many applications as possible by September 10, 2021," the day on which the district court said FDA's enforcement discretion for unauthorized products must end. C.A. App. A155.

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[17] *Ibid.*

[18] C.A. App. A3, A109.

A few weeks later, FDA made the internal decision that applicants for flavored ENDS would have to meet "a high burden" to show that the marketing of their products would be appropriate for the protection of the public health. C.A. App. A167. Specifically, applicants would have to provide evidence that their "flavored products have an added benefit relative to tobacco-flavored ENDS in facilitating smokers completely switching away from or significantly reducing their smoking." C.A. App. A168. Based on its "completion of numerous scientific reviews over the last 10 months," C.A. App. A175, FDA concluded that such evidence would "most likely" need to be in the form of a "randomized controlled trial" or a "longitudinal cohort study," C.A. App. A168. Such studies would need to track participants over time and provide product-specific evidence enabling a comparison between the applicant's new flavored ENDS product and an "appropriate comparator" tobacco-flavored ENDS product in terms of their impact on tobacco use behavior among adult smokers. C.A. App. A175-176.

FDA set forth its rationale for this internal decision in an 11-page, single spaced "Memorandum to File," dated August 17, 2021. *See* C.A. App. A167-181. FDA did not release the Memorandum to the public. At bottom, FDA reasoned that because underage users of ENDS preferred flavored ENDS over tobacco-flavored ENDS, an applicant for a flavored product would have to show that the benefit of the flavored product to adults outweighs the risk that youth will be attracted to and use the product. *See* C.A. App. A177.

FDA stated that assessing the risk that youth will be attracted to and use a specific ENDS product "includes evaluating the appropriateness of the proposed marketing plan." C.A. App. A175. But in a footnote, FDA said that "for the sake of efficiency, the evaluation of the marketing plans in applications will not take place at this time." C.A. App. A175 n.xxii. According to FDA, none of the marketing plans included in the PMTAs that it had already reviewed "would decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns" about "youth use," and that the agency was "not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use ENDS." *Ibid.* However, FDA did not identify the marketing plans that it had already reviewed or the products for which access restrictions had been unsuccessful. Nor did it say whether the plans it had reviewed were for open system ENDS or bottled e-liquids, or that it had found access restrictions for open system ENDS or bottled e-liquids to be unsuccessful.

Although the August 17, 2021 Memorandum made a few brief references to the 2019 PMTA Guidance,[19] the Memorandum did not focus on that Guidance. To the contrary, the Memorandum cited 65 publications other than the 2019 PMTA Guidance. *See* C.A. App. A178-181 (listing the Memorandum's "References").

On August 25, 2021—the day before FDA began rolling out its *en masse* denials of applications for

[19] *See* C.A. App. A174, A175, A176.

flavored ENDS products[20]—FDA "rescinded" the August 17 Memorandum in a three-sentence "Memorandum to File." C.A. App. A182. FDA said it had "reconsidered the process for [its] PMTA ENDS reviews and [had] determined that it will not consider or rely on the August 17, 2021, memo as a supporting document in that process," and therefore, "the August 17, 2021, memo is no longer needed." *Ibid.*

FDA did not say what, if any, "process" replaced the one set forth in the August 17, 2021 Memorandum. Nor did FDA say (at least in writing, anyway) that the Memorandum was problematic in that it meets the Administrative Procedure Act's definition of a "rule." *See* 5 U.S.C. § 551(4) (defining "rule" as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy").

H. FDA's Denial of Respondents' PMTAs

In September 2021, FDA denied Respondents' PMTAs for their bottled flavored e-liquids because Respondents had not presented evidence sufficient to show that their products "will provide a benefit to adult users that would be adequate to outweigh the risks to youth." *See, e.g.*, Pet. App. 167a. FDA explained that this "evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored ends [sic] over an appropriate

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[20] *See* FDA Press Release, *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health* (August 26, 2021).

comparator tobacco-flavored ends [sic]," or "other evidence" that "reliably and robustly evaluated the impact of the new flavored vs. Tobacco-flavored [sic] products on adult smokers' switching or cigarette reduction over time." Pet. App. 167a-168a. FDA also explained that because this "key evidence" was "absent," the agency did not review other aspects of the PMTAs (*e.g.*, the proposed marketing and sales access restriction plans). Pet. App. 168a.

Each of the PMTA denial orders was based on a document titled "Technical Project Lead ("TPL") Review." *See, e.g.*, Pet. App. 177a. Although the TPLs were not word-for-word copies of FDA's August 17, 2021 Memorandum, the TPLs were substantively the same as the Memorandum. For example, The TPLs included a footnote that repeated the footnote in the August 17, 2021 Memorandum about declining to review the applicants' proposed marketing and sales access restriction plans "for the sake of efficiency." *Compare, e.g.*, Pet. App. 200a-201a n.xix *with* C.A. App. A175 n.xxii. As another example, with one exception, the 66 publications listed in the "References" section of the TPLs were the same 66 publications listed in the "References" section of the

Memorandum. *Compare, e.g.*, Pet. App. 216a-225a *with* C.A. App. A178-181.[21, 22]

Respondents were not the only applicants to have their PMTAs denied. "FDA admits that it 'has yet to grant' a single application to market non-tobacco-flavored [ENDS]. This means it has denied over 355,000 such applications, which amount to 99% of all timely-filed PMTAs." *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 192 (5th Cir. 2023) (quoting FDA press release).

I. Proceedings Below

Respondents timely filed separate petitions for review of FDA's denial orders at the Fifth Circuit. A unanimous motions panel granted Respondent Triton Distribution's motion to stay pending disposition of its petition. Pet. App. 144a. The motions panel found, among other things, that Triton was likely to succeed on the merits because FDA changed the requirements for authorization of flavored ENDS after Triton

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[21] Reference number 20 in the TPLs was a 2019 article by A.M. Leventhal in the journal Pediatrics; reference number 20 in the August 17 Memorandum was a 2019 article by A.M. Leventhal in the Journal of the American Medical Association. Both articles address youth usage of flavored ENDS. *See* Pet. App. 219a; C.A. App. A179.

[22] Neither the denial orders nor the TPLs said FDA's decisions were based on the names of Respondents' bottled e-liquids. FDA's reference to some of those names in its Petition (Pet. at 6) is a distraction from the relevant issues in this case. If FDA believes that a name change is necessary, it can require such a change in a marketing granted order, so long as the required change complies with the First Amendment. *See* 21 U.S.C. § 387j(c)(1)(B); 21 C.F.R. § 1114.31.

submitted its PMTAs but without giving Triton notice of the changed requirements and because FDA ignored Triton's proposed marketing and sales access restriction plans. *Id.* at 148a-161a.

The circuit court subsequently consolidated the Triton and Vapetasia petitions. In a 2-1 decision, the merits panel denied the petitions. In her dissenting opinion, Judge Jones observed that "FDA (1) changed the rules for private entities in the middle of their marketing application process, (2) failed to notify the public of the changes in time for compliance, and (3) then rubber-stamped the denial of their applications *because* of the hitherto unknown requirements." Pet App. 126a.

The full Fifth Circuit vacated the merits panel decision and reheard the case en banc. The court granted the petitions for review because FDA (1) changed its position on the authorization requirements without fair notice to Respondents and without considering Respondents' reliance interests, and (2) committed prejudicial error by refusing to consider Respondents' plans to prevent underage access and use. Pet. App. 1a et seq.

FDA timely filed a Petition for Writ of Certiorari.

REASONS FOR DENYING THE PETITION

A. The Decision Below is Correct

1. FDA changed its position on the authorization requirements for ENDS without giving Respondents fair notice and without considering Respondents' reliance interests.

A federal agency must give regulated parties fair notice when it changes the requirements the agency places on those parties. *See, e.g.*, *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012). And an agency must take parties' reliance interests into account when changing those requirements. *See, e.g.*, *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2000). For example, when an agency intends to adopt those new requirements through a rule, the agency must, at a minimum, publish the proposed rule and the bases for the rule in the Federal Register and give interested persons the opportunity to submit comments on the rule. 5 U.S.C. § 553.

Here, FDA adopted certain requirements for PMTAs for flavored ENDS in August 2021—nearly a year after Respondents had submitted their PMTAs pursuant to the court-imposed deadline. As reflected in FDA's internal August 17, 2021 Memorandum, FDA decided that manufacturers seeking authorization for flavored ENDS would have to meet the "high burden" of establishing that their "flavored products have an added benefit relative to tobacco-flavored ENDS in facilitating smokers completely switching away from or significantly reducing their

smoking." C.A. App. A167-168. Applicants would need to show this added benefit through a product-specific longitudinal comparative efficacy study that compared their product to a tobacco-flavored ENDS product in terms of smoking reduction or cessation over time. C.A. App. A175-176.

The requirement adopted in the August 17, 2021 Memorandum was a "rule" because it was "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). Indeed, the Memorandum had many of the features of a preamble in a notice of proposed rulemaking. *See* 1 C.F.R. § 18.12 (stating proposed rules "shall" include "a preamble which will inform the reader . . . of the basis and purpose for the rule"). Specifically, the Memorandum included nearly 11 single-spaced pages of analysis in support of FDA's new requirement, and it included 24 footnotes and 66 endnotes in a "References" section listing 66 publications, nearly all of which were articles from medical or scientific journals. C.A. App. A180-181.

FDA did not make the August 17, 2021 Memorandum public, let alone publish a notice of proposed rulemaking for its new longitudinal comparative efficacy study requirement for flavored ENDS. Although FDA purportedly "rescinded" the August 17, 2021 Memorandum on August 25, 2021— the day before it released its first massive wave of denial orders for flavored ENDS— the TPLs for each

denial were substantively the same as the Memorandum.[23]

As for the timing of the purported rescission, "FDA's very able [agency] counsel presumably recognized that [the August 17, 2021 Memorandum] spelled trouble for the agency," Pet. App. 24-a, in that the requirement adopted in the Memorandum was arguably a "rule," but that the agency could hopefully alleviate that trouble if the requirement were adopted in an "adjudication," such as a TPL. However, an agency "may not escape [the notice-and-comment] requirements of § 553 by labeling its rule an 'adjudication.'" *Safari Club Int'l v. Zinke*, 878 F.3d 316, 332 (D.C. Cir. 2017); *see also Nat'l Ass'n of Home Builders v. U.S. Army Corp of Eng'rs*, 417 F.3d 1272, 1285 (D.C. Cir. 2005) ("It is of course the [agency's] decision whether to proceed by rule or adjudication, but 'rules is rules,' no matter their gloss.") (cleaned up).

In its Petition for Certiorari, FDA argues that its 2019 PMTA Guidance, when read in conjunction with the text of the TCA itself, put applicants for flavored ENDS on notice that they would need to establish that their products have an added benefit relative to tobacco-flavored ENDS in facilitating smokers completely switching away from or

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[23] The Administrative Procedure Act does not require notice and comment for "interpretive rules." 5 U.S.C. § 553(b)(4)(A). But even if the requirement FDA adopted in the August 17, 2021 Memorandum could be called an "interpretative rule," the Federal Food, Drug, and Cosmetic Act and FDA regulations required FDA to give the public advance notice of such a rule. *See* 21 U.S.C. § 371(h)(1)(C); 21 C.F.R. §§ 10.115, *et seq*.

significantly reducing their smoking. Pet. at 15-17. But that begs the question: If the 2019 Guidance and the text of the TCA put applicants on notice of that requirement, why did FDA feel the need to write an 11-page, single-spaced memorandum, complete with 24 footnotes and 66 endnotes, setting forth the requirement and the bases for that requirement?

Moreover, FDA does not cite to any language in the 2019 Guidance, or any other public statement from the agency prior to the first wave of its *en masse* denials of PMTAs, in which FDA said something along the lines of: "applicants will have to demonstrate that their flavored products have an added benefit relative to tobacco-flavored ENDS in facilitating smokers completely switching away from or significantly reducing their smoking through a product-specific comparative cessation study conducted over time." FDA cherry-picks a handful of snippets from the 2019 Guidance, but FDA takes those snippets out of context, and none of them show the agency put the public on notice of the requirement FDA adopted in August 2021.

For example, FDA says: "The 2019 Guidance stated that applications 'should include' an assessment of 'the trends by which users consume the product over time.'" Pet. at 17 (quoting C.A. App. A310). But that language is in the section of the Guidance where FDA recommends that applications include a summary of all published and unpublished research on the product. C.A. App. A309-301. In that section of the Guidance, FDA says the summary is "not required," but that the summary can address published and unpublished research on various issues,

including "user topography (how individual users consume the product, e.g., the number of puffs, puff duration, puff intensity, duration of use), and *the trends by which users consume the product over time*." C.A. App. A310 (emphasis added); *see also* C.A. App. A324-325 (similar). That language cannot be read as putting applicants for flavored ENDS on notice that they should submit evidence of "the impact of the new flavored vs. Tobacco-flavored [sic] products on adult smokers' switching or cigarette reduction over time." C.A. App. A167a-168a.

As another example, FDA says that the 2019 Guidance says applicants should submit "scientific reviews of flavors." Pet. at 17 (quoting C.A. App. A327). But the full passage does not say that such scientific reviews must include a review of "the impact of the new flavored vs. Tobacco-flavored [sic] products on adult smokers' switching or cigarette reduction over time." The full passage does not even say that such reviews must be in the form of randomized controlled trials, longitudinal cohort studies, or other studies conducted "over time." It says, "scientific reviews" could include "toxicological analyses of flavor additives, chemistry analysis, clinical studies, [and] literature reviews." C.A. App. A327.

2. FDA committed prejudicial error when it ignored Respondents' marketing and sales access restriction plans.

FDA concedes that it erred in ignoring Respondents' marketing and sales access restriction plans. Pet. at 17-18. That concession makes sense. Instead of reviewing proposed marketing and sales

access restriction plans for bottled e-liquids, including those of Respondents, FDA just assumed that such plans would be ineffective because FDA had concluded that certain marketing and sales access restriction practices for another category of ENDS products (cartridge-based products) were ineffective. *Bidi Vapor*, 47 F.4th at 1205. But that is not reasoned decision making. *See St. Vincent Randolph Hosp., Inc. v. Price*, 869 F.3d 510, 513 (7th Cir. 2017) (Easterbrook, J.) ("When the agency just asserts an *ipse dixit*, then the decision falls for the lack of reason.").

Rather than defend its decision to ignore those plans, FDA says any error was harmless because Respondents "have failed to show the measures they proposed differ from those *the agency* has already deemed inadequate. Pet. at 18 (emphasis in original). But as Chief Judge Pryor recognized when writing for the Eleventh Circuit in *Bidi Vapor*, there is no evidence that FDA ever reviewed any proposed marketing and sales access restriction plans for bottled e-liquids, let alone evidence that FDA found proposed plans for bottled e-liquids to be ineffective. *See Bidi Vapor*, 47 F.4th at 1203 (stating it is "unclear from the record before this Court what marketing plans or sales access restrictions [FDA] considered before making the decision to ignore the plans proposed by these six [applicants]"). (*Bidi Vapor* involved applications for, among other products, bottled e-liquids. *See id.* at 1200).

FDA notes that when it "prioritized enforcement against cartridge-based flavored e-cigarettes that were popular with youth in 2020, youth

migrated to disposable flavored e-cigarettes." Pet. at 9. But FDA omits the fact that its enforcement against cartridge-based products resulted in "a meaningful reduction in" overall "youth use prevalence." C.A. App. A169.[24] In any event, the fact that taking cartridge-based ENDS off the market resulted in some youth moving to disposable ENDS—another "closed" system ENDS with many of the same features as cartridge-based products—does not excuse the agency's failure to review Respondents' plans for bottled e-liquids—products used in "open" systems, which are much less user-friendly than "closed" systems. *See* photos *supra* at 4-6.

Moreover, FDA never told Respondents (or the public) that the agency now considered the recommendations for marketing and sales access restrictions for bottled e-liquids in the 2020 Enforcement Guidance[25] to be inoperative. And as

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[24] In the Department of Health and Human Services' Annual National Youth Tobacco Survey ("NYTS") conducted from January 16 – March 16, 2020, 13.1% of middle and high school students reported using an ENDS during the previous 30 days. *See* A. Gentzke et al., *Tobacco Product Use Among Middle and High School Students – United States, 2020*, 69 Morbidity and Mortality Weekly Report 1881, 1884 (Dec. 18, 2020). When that same survey was conducted from January 18 to May 21, 2021, only 7.6% of middle and high school students reported using an ENDS during the previous 30-days. Park-Lee, et al., *E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021*, 70 Morbidity and Mortality Weekly Report 1387, 1388 (Oct. 1, 2021).

[25] *See* C.A. App. A209-210 (FDA recommended marketing restrictions); C.A. App. A205 (FDA recommended sales access restrictions).

Judge Jones noted in her dissenting opinion in the now vacated merits panel decision in this case: "To the extent FDA means to say that youth will migrate to any flavored ENDS products if other avenues are closed off, it provided no evidence of that migration toward petitioners' [bottled e-liquid] products during the periods in question." Pet. App. 137a n.6.

FDA says *Bidi Vapor* is distinguishable because in that case the court's finding of prejudicial error hinged on the fact that the applicants proposed "novel" sales-access-restriction plans. Pet. at 19. FDA is wrong. Only two of the six applicants in *Bidi Vapor* proposed plans described as "novel," and the court found prejudicial error in FDA's refusal to review all six plans, including e-liquid manufacturers' plans that were not "novel." *Bidi Vapor*, 47 F.4th at 1205; *see also id.* at 1216 (Rosenbaum, J., dissenting) (noting that "only two" of the applicants submitted "novel access-restriction plans").

B. This Court Has Other Vehicles to Resolve the Circuit Splits on These Issues

As FDA highlights in its Petition, circuits other than the Fifth and Eleventh Circuits have denied petitions for review of FDA denials of PMTAs for flavored ENDS. Respondents will not attempt to point out the flaws in those circuits' opinions here. But Respondents will note it's no secret that "reflexive deference" to agency decisions is common in the lower courts, *Pereira v. Sessions*, 585 U.S. 198, 221 (2018) (Kennedy, J., concurring), especially when another lower court has already ruled for the agency on the same issue. So, it is unsurprising that the (now

vacated) merits panel decision in this case started a domino effect in some other circuits that benefited FDA.[26]

In any event, Respondents respectfully submit that this Court has other appropriate cases through which it can resolve the circuit splits on the issues raised in petitions for review of FDA marketing denial orders for flavored ENDS products. *See Lotus Vaping Techs., LLC v. FDA*, petition for cert. pending, No. 23-871 (filed Feb. 9, 2024); *Magellan Tech, Inc. v. FDA*, petition for cert. pending, No. 23-799 (filed Jan. 22, 2024). And unlike the present case, those cases do not involve small business applicants who have had to undertake the time and expense of both a merits panel hearing and an en banc rehearing.

CONCLUSION

For the reasons discussed above, Respondents request that the Court deny the Petition for Certiorari.

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[26] About one week after the merits panel released its decision in this case, the D.C. Circuit released its decision in *Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022). And about one month after that, the Seventh Circuit released its decision in *Gripum, LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022). And two months after that, the Third Circuit released its opinion in *Liquid Labs LLC v. FDA*, 52 F.4th 533 (3d Cir. 2002). Perhaps this deference train would have never left the station had the Fifth Circuit merits panel reached the decision that the full Fifth Circuit eventually reached.

Respectfully submitted,

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