No. 23-871

In the
Supreme Court of the United States

LOTUS VAPING TECHNOLOGIES, LLC,
Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
Respondent.

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

REPLY BRIEF FOR PETITIONER

ERIC N. HEYER
Counsel of Record
JOSEPH A. SMITH
JAMES C. FRASER
THOMPSON HINE LLP
1919 M Street, NW, Suite 700
Washington, DC 20036
Phone: 202.331.8800
Eric.Heyer@ThompsonHine.com

May 7, 2024 *Counsel for Petitioner*

Becker Gallagher · Cincinnati, OH · Washington, D.C. · 800.890.5001

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Other Authorities

REPLY BRIEF FOR PETITIONER

Respondent FDA says that the petition for writ of certiorari in this case does not raise the issue of whether the agency improperly failed to distinguish among different types of electronic nicotine delivery systems ("ENDS") when it denied Petitioner's premarket tobacco product applications for its bottled e-liquids. (Opp. 5-6). FDA is wrong. That issue is subsumed in Petitioner's argument that FDA violated the Administrative Procedure Act when it ignored Petitioner's proposed marketing and sales access restriction plans designed to limit youth interest in and access to its products. (*See* Pet. 19, 26.)[1] Therefore, contrary to FDA's assertion (Opp. 5-6), this case is a proper vehicle for the Court to resolve the circuit conflict that was deepened by the recent Fifth Circuit en banc opinion in *Wages & White Lion*.[2]

As it did when it ignored proposed marketing and sales access restriction plans in countless other applications for bottled e-liquids, FDA said it ignored Petitioner's proposed plans "for the sake of efficiency" because none of the proposed plans it had reviewed in other applications was sufficient to reduce youth access. But as Chief Judge Pryor recognized when writing for the Eleventh Circuit in *Bidi*, there is no evidence that FDA ever reviewed any proposed

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[1] Petitioner raised this issue at the court below, *see, e.g.*, Pet. Br., ECF No. 16 at 42, and the court below briefly addressed the issue, *see* App. 31 n.14.

[2] *Wages & White Lion Investments, LLC v. FDA*, 90 F.4th 357 (5th Cir. 2024) (en banc), petition for cert. pending, No. 23-1038 (filed Mar. 19, 2024).

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 LLC v. FDA*, 47 F.4th 1191, 1203 (11th Cir. 2022) (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]").[3]

Instead of reviewing proposed marketing and sales access restriction plans for bottled e-liquids, including those of Petitioner, 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 were ineffective. *Bidi*, 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 lack of reason."). In short, FDA's decision to ignore Petitioner's marketing and sales access restriction plans was arbitrary and capricious because, among other reasons, in deciding to ignore those plans FDA failed to distinguish among different types of ENDS.

For the Court's benefit, Petitioner provides the following additional information relevant to FDA's arbitrary and capricious decision to ignore Petitioner's proposed marketing and sales access restriction plans.

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[3] *Bidi* involved applications for, among other products, bottled e-liquids. *See Bidi*, 47 F.4th at 1200.

1. Categories of ENDS.

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*, 47 F.4th at 1196.

a. 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 up, the user can replace the empty cartridge with a new 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.[4]

[4] 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).

b. 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. The photo below, which is taken from FDA's website, shows two examples of disposable ENDS.[5]

c. Open System ENDS.

Open system ENDS do not come pre-filled with e-liquid and do not use pre-filled cartridges or pods of 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 below, which is taken from the CDC's Visual Dictionary, shows two examples of open system ENDS.

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[5] 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).

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

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[6] 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.

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.

2. FDA's 2020 Enforcement Guidance.

In January 2020, less than 10 months before the deadline for Petitioner to submit its applications for its bottled e-liquids to FDA, the agency published a sub-regulatory guidance document (the "2020 Enforcement Guidance") describing how FDA "intend[ed] to prioritize [its] enforcement resources with regard to the marketing of certain [ENDS] that do not have premarket authorization." CA.ER-73.[7] According to the 2020 Enforcement Guidance, FDA's top enforcement priority was "flavored, cartridge-based ENDS product[s] (other than tobacco- or menthol-flavored ENDS product[s])." CA.ER-91.

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,

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[7] "CA.ER" refers to Petitioner's Excerpts of Record filed with the court below. The document at CA.ER-73 is the April 2020 revised version of the guidance document issued in January 2020. The April 2020 revisions are not relevant to this Petition. *See* CA.ER-104-05 (explaining differences between the January 2020 and April 2020 versions of the guidance document).

co-authored by officials from FDA and CDC, and cited in the 2020 Enforcement Guidance, noted:

> 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.[8]

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." CA.ER-89. Such design features included "a relatively small size that allows for easy concealability" and the ability to use the product "immediately after purchase." CA.ER-89.[9]

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[8] K. Cullen, et al., *e-Cigarette Use Among Youth in the United States, 2019*, 322 JAMA 2095 (2019), cited in 2020 Guidance at 12, n.31, CA.ER-85; *see also* 2020 Guidance at 16, CA.ER-89 (stating "the leading brand is a cartridge-based product that commands approximately 70 percent of the market").

[9] *See also* CA.ER-90 ("Thus, particularly easy-to-use products, such as cartridge-based products, may have lower barriers to [youth] initiation."). The 2020 Guidance did not address whether disposable ENDS products (the other type of "closed" ENDS products) had design features, like those of cartridge-based ENDS, that made the products attractive to youth.

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." CA.ER-91. 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." CA.ER-91; *see also* CA.ER-97 (similar statement about vape shops).

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.ER-99-100 (marketing restrictions); CA.ER-94-95 (sales access restrictions). Less than 10 months later, in September 2020, many bottled e-liquid manufacturers, including Petitioner, submitted their product applications with proposed plans for marketing and sales access restrictions that tracked the recommendations in the 2020 Enforcement Guidance. *Compare* CA.-ER-94-95 *and* CA.-ER-99-100 *with* CA.ER-219-222.

FDA will say that youth users moved to flavored disposable ENDS after the 2020 Enforcement Guidance resulted in flavored cartridge-based products coming off the market. But that still does not

excuse the agency's failure to review Petitioner's plans for bottled e-liquids. Moreover, FDA never told Petitioner (or the public) that the agency no longer considered the recommendations for marketing and sales access restrictions for bottled e-liquids in the 2020 Enforcement Guidance to be inoperative. And as Judge Jones noted in her dissenting opinion in the now vacated panel opinion in *Wages*, "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." *Wages & White Lion Investments, LLC v. FDA*, 41 F.4th 427, 447 n.6 (2022) (Jones, J., dissenting).

3. FDA's August 2021 Decision to Ignore Marketing and Sales Access Restriction Plans for all Non-Tobacco Flavored ENDS Applications.

An August 17, 2021 FDA memorandum to file outlined the agency's new position with respect to the type of evidence required for flavored ENDS products to be considered for marketing authorization. CA.ER-46. The memorandum noted that marketing and sales access restriction plans were one factor relevant to whether a product satisfies the statutory standard. CA.ER-54. But a footnote in the memorandum stated that, "for the sake of efficiency," FDA would not evaluate the marketing and sales access restriction plans in the initial review of applications for flavored ENDS because none of the applications FDA had reviewed to date included plans that sufficiently reduced youth usage. CA.ER-54 n.xxii.

On August 25, 2021, FDA rescinded the August 17 memorandum. CA.ER-45. But when FDA began rolling out its *en masse* denials of applications for flavored ENDS products the following day, each denial was based on a written Technical Project Lead ("TPL") report that retained the above-mentioned footnote. *See Bidi*, 47 F.4th at 1201 (noting the TPL reports "included the same footnote from the August 17 memorandum" explaining that FDA was not evaluating marketing and sales access restriction plans). The TPL report for Petitioner's applications included that footnote. CA.ER-23 n.xix.

CONCLUSION

For the forgoing reasons and the reasons discussed in the petition for writ of certiorari, the Court should grant the petition.

Respectfully submitted,

ERIC N. HEYER
Counsel of Record
JOSEPH A. SMITH
JAMES C. FRASER
THOMPSON HINE LLP
1919 M Street, NW, Suite 700
Washington, DC 20036
202.331.8800
Eric.Heyer@ThompsonHine.com

Counsel for Petitioner