No. 23-1038

IN THE

Supreme Court of the United States

UNITED STATES FOOD AND DRUG ADMINISTRATION,
Petitioner,

v.

WAGES AND WHITE LION INVESTMENTS, L.L.C., DBA TRITON DISTRIBUTION, ET AL.,
Respondents.

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

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BRIEF OF THE VAPOR TECHNOLOGY ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

The *Amicus Curiae*[1] Vapor Technology Association (VTA) is a national non-profit industry trade association whose members are dedicated to developing and selling high quality electronic nicotine delivery systems (ENDS), also known as e-cigarettes or vapor products[2], that provide adult consumers with an alternative to smoking combustible cigarettes. Since its founding, VTA has been engaged on critical regulatory issues confronting the vapor industry, advocating for science-based regulations to protect against youth access to and appeal of vapor products.

VTA has engaged with Congress and federal regulators, including the U.S. Food & Drug Administration (FDA), on myriad issues and specifically on the issue of flavored ENDS regulation. In 2018, when the FDA published its Advance Notice of Proposed Rulemaking, Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12294 (Mar. 21, 2018) (hereafter, "Flavor ANPRM"), VTA submitted substantive comments to the FDA detailing all of the scientific studies at that time demonstrating the role that flavors play in smoking cessation amongst other issues.

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[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than amicus, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Petitioners are not and have not been members of VTA.

[2] Herein we refer to ENDS products as e-cigarettes and vapor products as those terms are used interchangeably. *See*, *Wages & White Lion Invs. LLC v. U.S. Food & Drug Administration*, 14 F.4th 1130, 1134 (5th Cir. 2021) (discussing the interchangeability of the terms).

In 2019, when the FDA in the Trump Administration announced a ban all flavored vapor products through a modification of its deferred enforcement policy (which it later elected not to do), VTA shared information with the Administration on the role that flavored vaping products play in assisting adult smokers quit, and presented the economic impact analysis of John Dunham & Associates (JDA), which showed that the proposed national flavor ban would shut down 13,000 small businesses whose adult customers relied on flavored vaping.[3]

The Administration ultimately elected not to ban open-system flavored vaping products (like Respondents' at issue) and, instead, modified its deferred enforcement policy to limit FDA's flavor ban only to pod and cartridge closed system products that the FDA had tied directly to the problem of youth vaping. FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket *Authorization*, January 2020. VTA also championed raising the age to purchase all tobacco products to 21 as a common sense way to address the issue of youth vaping, which the Administration endorsed and Congress passed in December 2019. *See* Further Consolidated Appropriations Act, 2020 Pub. L. No. 116-94, 133 Stat. 2534, 3123.

In 2024, VTA's Executive Director testified before the Senate Judiciary Committee regarding the myriad problems with FDA's regulatory process,

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[3] *The Economic Impact of a Ban on Flavored Vapor Products*, John Dunham & Associates, November 21, 2019, p. 6, available at https://vaportechnology.org/wp-content/uploads/2022/11/Dunham-Economic-Impact-of-Flavor-Ban-11-21-19.pdf (the "JDA 2019 Report").

including its violations of law. With this extensive background and involvement on the issue of vaping product regulation, Amicus Curiae offers this additional context that may assist the Court in assessing the importance of denying the relief sought by the U.S. Food & Drug Administration in its brief (the "Brief").

SUMMARY OF ARGUMENT

After *Loper Bright Enterprises v. Raimondo, et al.* 144 S. Ct. 2244, 603 U.S. ___ (2024) ("*Loper*") the jurisprudence in the United States for reviewing administrative agency actions has changed. No longer is it acceptable for federal agencies to throw up any reasonable justification to support its actions. Now, it is essential that every agency action be evaluated in the context of the best reading of the statute empowering the agency in the first place. In this case, the FDA's denial orders not only in conflict with the best reading Family Smoking Prevention and Tobacco Control Act of 2009, 123 Stat. 1776, 1777, codified at 21 U.S.C. § 387 (hereafter, the "Tobacco Control Act" or "Act"), they undermine the Act altogether.

First, the denial orders were all issued based on the absence of a specific study – a long term comparative efficacy study which required Respondents to prove that its *non-tobacco flavored* e-cigarettes were more efficacious at helping adults to quit smoking than its *tobacco-flavored* e-cigarettes (hereafter, the "Comparative Efficacy Test") – which the FDA had never stated was a requirement before Respondents' applications were filed. FDA only announced this Comparative Efficacy Test *after* Respondents' PMTAs had been filed. Retroactively requiring Respondents to have included a specific

piece of information, failing to give Respondents an opportunity to provide such information, and then denying Respondents' application solely based on the absence of that information contradicts any reasonable conception of what a fair application process should look like, much less what Congress required in the Act.

Second, the demand for the Comparative Efficacy Test undermines the central purpose of the Act of ensuring that new tobacco products are comparatively less harmful than cigarettes. What FDA referred to as a "fatal flaw" justifying its denials was in fact the fatal flaw in its post-hoc attempt to justify its actions as lawful. Not only does this misapprehend the Tobacco Control Act's intent for each new tobacco product be evaluated on its own merit, but it also undermines the fundamental purpose of the Tobacco Control Act to provide a pathway to market for products less harmful than combustible cigarettes. See, e.g., Tobacco Control Act §3(4) (stating that a purpose of the Tobacco Control Act is to facilitate the marketing of less harmful tobacco products); see generally Food, Drug & Cosmetic Act, 21 U.S.C. §387j (providing pathways to market for products that are less harmful than combustible cigarettes).

Third, no section of the Tobacco Control Act empowers the FDA to create a *de facto* tobacco product standard through a series of denial orders for e-cigarette flavors without FDA first adopting a tobacco product standard—as laid out expressly in the Tobacco Control Act by Congress—through the required notice and comment process. Here again, FDA flouted the terms of the Tobacco Control Act by retroactively imposing a tobacco product standard against non-tobacco flavors with giving applicants

prior notice of this standard, much less an opportunity to comment on it, before PMTAs were due.

Thus, while *Loper* was decided after the Fifth Circuit's decision below, and as Respondents correctly note does not preclude in any way the Fifth Circuit's finding that they were not given fair notice, it is clear that post-*Loper* jurisprudence aligns with the Fifth Circuit's criticisms and findings regarding the FDA's actions. What is equally clear is that FDA's attempt to wrap itself in *Loper* is folly. The very notion that FDA plucks one word – "appropriate" – out of its context in the Tobacco Control Act to claim that this one word gives it "significant flexibility" is not only the epitome of cherry-picking but demonstrates the highly tenuous ground on which it knows it is standing. See, FDA Brief, p. 16. Accordingly, the decision of the Fifth Circuit should be upheld based on Respondents' arguments but particularly so when viewed through the prism of this Court's *Loper* jurisprudence.

ARGUMENT

I. *LOPER* REQUIRES THAT FDA'S DENIAL ORDERS BE SET ASIDE BECAUSE THEY VIOLATE THE BEST READING OF THE TOBACCO CONTROL ACT.

The Court's decision in *Loper* requires that every agency action derive from the best reading of the statute empowering the agency in the first place. No longer can a court allow an agency to justify its actions simply because they are "based on a permissible construction of the statute." *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842 (1984) ("Chevron"). Instead, "[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its

statutory authority, as the APA requires." *Loper*, 144 S.Ct. at 2273. It is "the will of Congress" that matters, not the will of the agency. *See Id.* at 2263.

This case concerns the question: "Whether the [Fifth Circuit] erred in setting aside FDA's denial orders as arbitrary and capricious." FDA Brief I. These denial orders were made under 21 U.S.C. §387j (c)(2)(A), which provides FDA shall issue a denial order if "[t]here is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health" (the "APPH Test"). See *Id.* The APPH Test is set forth in 21 U.S.C. §387j, which describes what is required for a PMTA approval. Thus, whether FDA acted in an arbitrary and capricious manner when issuing denial orders necessarily requires the Court "to 'interpret … statutory provisions'" in relation to the PMTA process and specifically the APPH Test. See *Loper*, 144 S.Ct. at 2270 (quoting 5 U.S.C. §706 and 5 U.S.C. §706(2)(A)); *see also Id.* at 2269 ("[T]he APA[] demand[s] that courts exercise independent judgment in construing statutes administered by agencies.")

Thus, the "question that matters" is: "Does the statute authorize the challenged agency action?" *Id.* It does not; FDA's denial orders resulted from a decision making process so disconnected from the text of the Tobacco Control Act as to render the denial orders arbitrary and capricious. See *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 42 (1983) ("State Farm") (To survive arbitrary and capricious review an agency action must be "based on consideration of the relevant factors, and within the scope of the authority delegated to the agency by the statute."); 5 U.S.C. §706(2)(A). Accordingly, the Fifth Circuit's decision

to set the denial orders aside as arbitrary and capricious should be upheld because FDA has failed to act in accordance with the best reading of the Tobacco Control Act.

A. The Various Courts Of Appeals That Have Considered This Issue All Failed To Analyze Whether FDA's Denial Orders Conformed With The Best Reading Of The Tobacco Control Act.

While *Chevron* was not directly raised in the case below or any of the parallel circuit court cases, its ghost haunts them all. See *Loper,* 144 S.Ct. at 2275 Concurring (Gorsuch, J.) ("Today, the Court places a tombstone on Chevron no one can miss."). While none of the cases which upheld FDA actions expressly relied on *Chevron,* Chevron still reigned supreme as those courts readily demurred to FDA's broad deference arguments allowing it to change its position from pre-application guidance through post-application decision making, a course of conduct which was presumed to be "permissible." 467 U. S. at 843. However, since this Court declared that "[i]n the business of statutory interpretation, if it is not the best, it is not permissible," decisions deferentially approving FDA actions are now, at best, wholly incomplete. See *Loper*, 144 S.Ct. at 2266.

B. The Fifth Circuit's Decision To Set Aside FDA's Denial Orders Is Consistent With *Loper* Because The FDA's Denial Orders Violate The Best Reading Of The Tobacco Control Act.

Of all of the prior cases on this issue, the Fifth Circuit's decision is the only one that aligns with the post-*Loper* jurisprudence. Essentially, the Fifth Circuit found PMTA applicants could not fairly

deduce the decision making criteria of FDA's denial orders based on the guidance documents and other communications FDA provided before applications were due (collectively, the "Guidance"). Pet. A 2a-4a. As a result, the Fifth Circuit found:

> In sum, FDA's denials of petitioners' PMTAs were arbitrary and capricious. The agency did not give manufacturers fair notice of the rules; the agency did not acknowledge or explain its change in position; the agency ignored reasonable and serious reliance interests that manufacturers had in the pre-MDO guidance; and the agency tried to cover up its mistakes with post hoc justifications at oral argument.

Wages & White Lion Investments, LLC v. Food & Drug Administration, 90 F.4th 357, 388 (*en banc)* (2024).

Analysis of the relevant statutory provisions fortifies the Fifth Circuit's decision. The pre-application Guidance accorded with the best reading of the statute; FDA's later decision making criteria for the denial orders did not. Accordingly, it is not hard to see why thousands of applicants submitted PMTAs for more than a million proposed products that were all denied without the benefit of a full review: applicants could not predict that FDA's decision making would ignore the actual requirements of the Tobacco Control Act.

FDA's shift in position from its Guidance to its extra-statutory decision making criteria is exactly the sort of problem Chevron enabled and which *Loper* now rejects. See *Loper*, 144 S.Ct. at 2272 ("Chevron thus allow[ed] agencies to change course even when Congress has given them no power to do so" […] "Under Chevron, a statutory ambiguity . . . bec[ame] a license authorizing an agency to change positions as

much as it likes" […] "Chevron foster[ed] unwarranted instability in the law, leaving those attempting to plan around agency action in an eternal fog of uncertainty"). Thus, the Fifth Circuit's decision, which directly calls out the FDA for its changing requirements and post-hoc justifications, is in full alignment with post-*Loper* jurisprudence because it invalidates FDA's shift in position away from the best reading of the Tobacco Control Act. See Pet. A. 2a.

The specific details of the FDA's Guidance are described at length in the Fifth Circuit's opinion and need not be fully recounted here. See Pet. A. 6a-14a. What is important to note is the fact that while the Guidance was full of "recommendations" as to what information FDA would like to see in a PMTA, nowhere in this Guidance did the FDA ever state it would unequivocally require any specific study. See J.A. 5.

Yet, FDA issued denial orders for PMTAs of non-tobacco flavored e-cigarette products if they did not include "robust and reliable evidence," newly defined after the fact as a "randomized controlled trial" or a "longitudinal cohort study," comparing use of non-tobacco flavored products with that of tobacco flavored products "over time" in order to show that the non-tobacco flavored products have an "added benefit relative to that of tobacco flavored [e-cigarettes] in facilitating smokers completely switching away from or significantly reducing their smoking" – the Comparative Efficacy Test. See Pet. A. 180a-82a.

The oddity of such a contrived post-hoc requirement cannot be overlooked. Because neither non-tobacco flavored e-cigarettes nor tobacco flavored e-cigarettes were authorized at the time applications

were due, the Comparative Efficacy Test only involved a comparison between one type of not-yet-authorized e-cigarette product with another type of not-yet-authorized e-cigarette product, but utterly failed to compare the proposed e-cigarette products to the existing authorized combustible cigarettes on the market. This failing strikes at the core of the Tobacco Control Act, which Congress intended to facilitate the introduction of new, novel and less harmful tobacco products into the market as alternatives to cigarettes. See, e.g., Tobacco Control Act §3(4) (Congress stating that a purpose of the Act is "to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products" such as e-cigarettes).

Instead of reviewing the full applications which Respondents submitted, FDA chose instead to only perform a cursory review of non-tobacco flavored product PMTAs in search of the Comparative Efficacy Test which were never previously required. See J.A. 615-638. Pet. A. 182a. If a PMTA did not include the Comparative Efficacy Test – which FDA knew was likely given FDA's failure to previously make such studies a requirement – then the PMTA was summarily denied without the benefit of a full review. J.A. 243; Pet. A. 182a. As described in more detail below, FDA had no statutory basis to establish what the FDA called a "Fatal Flaw" Comparative Efficacy Test prerequisite *after* applications were due, and then use that retroactive prerequisite to justify its refusal to conduct a full PMTA review. Accordingly, the Fifth Circuit's holding that FDA must re-do its evaluations of applicants' PMTAs in a comprehensive manner should be upheld—with the added caveat that these reevaluations must fully comply with the

best reading of the Tobacco Control Act. See Pet. A. 4a; *Loper*, 144 S.Ct. at 2266.

II. THE BEST READING OF THE TOBACCO CONTROL ACT DOES NOT ALLOW FDA TO ISSUE DENIAL ORDERS BASED ON THE POST-HOC COMPARATIVE EFFICACY TEST.

A. The Tobacco Control Act Requires FDA To Consider The Population As A Whole, But FDA Used The Comparative Efficacy Test To Only Consider Two Segments Of The Population.

FDA claims it denied Respondents' PMTAs because it found they did not meet the APPH Test. See Pet. A. 182a, 236a, 290a. However, FDA's imposition of the Comparative Efficacy Test prerequisite improperly ignored the statutory requirement that it assess the "risks and benefits to the population as a whole," choosing instead to only consider two discrete sub-segments of the population in isolation.

The APPH Test reads in full:

> For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account--
>
> A. the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

> B. 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). Here, the primary directive of Congress is that FDA assess the "risks and benefits to the population as a whole." *Id.* Then, using conjunctive "and, taking into account" language, the Tobacco Control Act requires that two subgroups be considered: existing users and new users. *Id.* at (c)(4)(A)-(B). Accordingly, the new tobacco product's net public health benefit must be assessed as it pertains to the whole population and "taking into account" both new and existing tobacco product users. See *Id.* § 387j(c)(4).

In its review process and in its Brief, FDA completely skips over the primary objective Congress laid out and inaccurately states that the APPH Test only "requires FDA to weigh (1) the likelihood that the new product will help existing smokers (generally adults) completely switch to less dangerous alternatives, or significantly reduce the amount they smoke, against (2) the risk that the new product will entice new users (generally youth) to begin using tobacco products." Pet. Brief 3; see also Pet. A. 182a, 236a, 290a. In framing its argument in this way, FDA entirely discounts the main body of 21 U.S.C. § 387j(c)(4) in favor of its (A) and (B) subparts. Only by ignoring the plain language of the Act can FDA assert that the APPH analysis is limited to adults on the one hand (i.e., use cessation) and youth on the other hand (i.e., use initiation). "FDA's proposed analysis above oversimplifies the APPH analysis into an X-Y equation (combustible cessation – youth uptake), which is not how the statute constructs the APPH framework." Yagi, Dr. Brian, et al., *Appropriate for the Protection of Public Health: Why We Need*

Electronic Nicotine Delivery System Product Standards, Food and Drug Law Journal, vol. 78 (2023), p. 59.

Perhaps FDA's truncated interpretation was "permissible" under *Chevron*, but it is no longer. See 467 U. S. at 843. The "best" – and therefore only permissible – interpretation of 21 U.S.C. § 387j (c)(4) puts the focus of the APPH Test squarely on "the risks and benefits to the population as a whole" with existing adult smokers and potential youth users being mere factors FDA must "tak[e] into account" as part of this whole population analysis. See *Loper*, 144 S.Ct. at 2266.

To be sure, FDA's "X-Y equation" is wrong from the start because it: (1) ignores new adult users; (2) ignores existing youth cigarette users who quit smoking using e-cigarettes; (3) ignores nonusers who benefit from reduced secondhand smoke; and (4) never considers the impact of new users (adult or youth) choosing to initiate tobacco use with e-cigarettes instead of cigarettes. See, e.g., J.A. 361 (Respondents' evidence that: "In the underage nonsmoking group, 57% of frequent vapers had previously smoked."); J.A. 465-66 (Respondents' evidence that: "Universally, any study that compared combustible cigarettes and e-cigarettes found greatly increased effects on the indoor air quality and bystander concentrations from combustible cigarettes."); *Yagi, et al,* at 60 ("ENDS [e-cigarette] product authorizations can still be considered future harm-reducing when considering that any new initiator would be better served by selecting an ENDS product over a combustible product in the first instance. Indeed, while youth use of ENDS products was rising over the past two decades, it was accompanied by a concomitant decline in exclusive

combustible use.") U.S. Public Health Service, U.S. Dep't of Health and Human Services, E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General 49 (2016) at iii (stating that youth e-cigarette use has increased "[a]s cigarette smoking among those under 18 has fallen") and at 49 (finding that between 2011 and 2015 last 30-day high school e-cigarette only use rose from 0% to 7% while last 30-day high school combustible cigarette only use fell from 16% to 7%).

Failing to even consider entire segments of the population in the manner FDA did when it adopted a two-factor test only relating to two subgroups of the population is plainly inconsistent with the holistic, whole population analysis Congress required FDA to conduct when it adopted the APPH Test. See *Loper*, 144 S.Ct. at 2263 ("[T]he role of the reviewing court … is … to … effectuate the will of Congress."). Therefore, because the FDA's actions "entirely failed to consider … important aspect[s]" of the Act in accordance with its congressionally delegated authority, FDA's denial orders must be found to be arbitrary and capricious. See *Id.*; *Motor Vehicle Mfgs. Assn.*, 463 U.S. 43.

B. The Tobacco Control Act Requires FDA To Evaluate New Tobacco Products On An Individual Basis, But FDA Failed to Do So.

Not only did FDA improperly truncate whole population analysis to only involve a two-factor test of risks and benefits, but FDA also never actually evaluated the risks and benefits of Respondents' specific products. Instead, relying only on generalized data FDA made sweeping declarations that *all* flavored ENDS products (not Respondents' specific

products) are attractive to youth to satisfy its review of one prong of the APPH test (i.e., use initiation) and then used that generalized conclusion as the agency's justification to impose never-before announced requirements of a heightened standard of *product-specific* evidence on another prong of the APPH balancing test (i.e., use discontinuation).

In its denial orders, FDA did not find Respondents' non-tobacco flavored e-cigarettes provided no benefit; it simply generally determined—without reference to Respondents' specific products—that "the literature does not establish that [non-tobacco] flavors differentially promote switching" from combustible cigarettes better than tobacco flavor does. J.A. 266; Pet. A. 202(a), 256(a), 310(a). FDA then issued denial orders for applicants' products solely because it believed all "tobacco-flavored [e-cigarettes] may offer the same type of public health the same type of public health benefit as flavored [e-cigarettes] … but do not pose the same degree of risk of youth uptake." J.A. 248; Pet. A. 181a, 235a, 289a (emphasis added). Importantly, FDA did not determine that Respondents' specific flavored products posed any unique risks or concerns regarding youth initiation, and it did not evaluate any of the information contained in the PMTAs when it conducted its analysis. Thus, FDA did not issue denial orders for non-tobacco flavored products because FDA found such non-tobacco flavored products failed a risk/benefit analysis on the products' own merit, but solely because it thought another product may perform better on a risk/benefit assessment. See Pet. A. 182a, 236a, 290a.

This type of comparative product analysis is not consistent with the best reading of the Act. See *Loper*, 144 S.Ct. at 2266 ("[S]tatutes … have a single, best

meaning."). Instead, the APPH Test sets forth an evaluation of the "risks and benefits" of "the tobacco product" "for which an application has been submitted." 21 U.S.C. § 387j(c)(4). Investigations and scientific evidence about "the tobacco product" that is the subject of an application is used to evaluate an application. 21 U.S.C. § 387j(c)(5). A denial order can only be issued based on information "with respect to such tobacco product" that is the subject of an application. 21 U.S.C. § 387j(c)(2). Thus, the text of the Tobacco Control Act provides that the analysis of, required evidence for, and decision on an application concern the product that is actually the subject of the application.

Accordingly, the best reading of the APPH Test is that FDA must individually analyze each product for which an application has been submitted to determine if such a product can demonstrate a net public health benefit (i.e., whole population health benefits outweigh whole population health risks). See 21 U.S.C. § 387j (c)(4).

The FDA's belief that tobacco flavored e-cigarettes may provide greater net public health benefits does not necessarily mean that non-tobacco flavored e-cigarettes do not provide net public health benefits. Non-tobacco flavored e-cigarettes could still provide a net public health benefit, albeit maybe a smaller one. However, FDA never even attempted to individually analyze the benefits of Respondents' products; it just demanded that Respondents needed to show more benefits than other products.

As for the risk side (i.e., youth) of FDA's "X-Y equation", FDA failed to individually assess the risks associated with Respondents' specific products.

C. FDA Improperly Used Its Application Review Process to Implement a De Facto Tobacco Product Standard While Unlawfully Evading Notice and Comment Rulemaking Requirements.

By requiring that PMTAs for non-tobacco flavored e-cigarettes include the Comparative Efficacy Test, FDA has imposed a de facto tobacco product standard prohibiting non-tobacco flavored e-cigarettes—without following the notice and comment process Congress required in the Tobacco Control Act. Accordingly, FDA's denial orders conflict with the best reading of the Tobacco Control Act for another reason and, therefore, must be set aside.

FDA's authority to establish tobacco product standards is set forth in the Tobacco Control Act. 21 U.S.C. §387g. The section of the Tobacco Control Act that concerns tobacco product standards specifically references flavors. 21 U.S.C. §387g(a)(1)(A), 21 U.S.C. §387g(e)(1). This section also provides for tobacco product standards in relation to "ingredients" and "additives." 21 U.S.C. §387g(a)(4)(B)(i). Since e-cigarettes are naturally unflavored, a flavoring additive is necessary to impart tobacco or non-tobacco flavor. Thus, these provisions make clear that e-cigarette flavors are subject to tobacco product standard regulations. Critically, the Tobacco Control Act expressly provides that all tobacco product standards be subject to notice and comment rulemaking over and above the requirements of the APA. 21 U.S.C. §387g(c)-(d).

FDA is well aware of the fact that the proper way to regulate e-cigarette flavors is through adopting a tobacco product standard subject to a notice and comment requirement. In 2018, FDA published an

Advance Notice of Proposed Rulemaking ("ANPRM") regarding e-cigarette flavors. In the ANPRM, the FDA expressly referenced 21 U.S.C. §387g as its statutory authority for regulating flavors in tobacco products. 83 Fed. Reg. 12,294, 12,295 (March 21, 2018). Since then, FDA has moved forward with two tobacco product standards related to flavors. On May 4, 2022, FDA published its Proposed Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26454 (May 4, 2022). And, FDA published its Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396 (May 4, 2022).

However, FDA abandoned the rulemaking process for e-cigarette flavors. Instead of proceeding through the required notice and comment process, FDA imposed a *de facto* tobacco product standard for non-tobacco e-cigarette flavors during adjudication of PMTAs. See Pet. Brief 27. This is why the Fifth Circuit properly noted that "FDA unquestionably failed to follow § 387g's notice-and-comment obligations before imposing its *de facto* ban on flavored e-cigarettes." *Wages & White Lion,* 90 F. 4th at 384, n. 5.

There is simply no difference whatsoever between the FDA's adjudication process and the implementation of a tobacco product standard prohibiting non-tobacco flavors. Under 21 U.S.C. §387j(b)(1)(D), a PMTA must identify any relevant tobacco product standard and provide "either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard." The Comparative Efficacy Test FDA imposed on non-tobacco flavored e-cigarettes is the functional equivalent of a tobacco product standard prohibiting non-tobacco flavors and

providing that the Comparative Efficacy Test can serve as the "adequate information to justify any deviation from such standard."

Indeed, FDA's PMTA adjudication process used the Comparative Efficacy Test in the exact same manner as a tobacco product standard prohibiting non-tobacco flavors would be used. If a PMTA doesn't meet a tobacco product standard and doesn't include the required "information to justify any deviation from such standard," the application can be summarily denied on that basis alone. See 21 U.S.C. §387j(b)(1)(D). This is precisely how FDA used the Comparative Efficacy Test for non-tobacco flavored products despite the fact FDA claimed it was using the Comparative Efficacy Test to conduct whole population analysis under the APPH Test.

FDA's decision to implement a *de facto* tobacco product standard prohibiting non-tobacco flavored e-cigarettes in the manner it did is illegal because it was done without the required notice and comment procedures laid out in the Tobacco Control Act. See 21 U.S.C. §387g(c)-(d). An agency cannot evade notice and comment requirements simply by labeling its decisions as adjudication, particularly when Congress has expressly directed an issue be subject to notice and comment requirements. See *Azar v. Allina Health Servs.*, 587 U.S. 566, 575 (2019) ("Agencies have never been able to avoid notice and comment simply by mislabeling their substantive pronouncements. On the contrary, courts have long looked to the contents of the agency's action, not the agency's self-serving label, when deciding whether statutory notice-and-comment demands apply."); *NLRB v. Wyman–Gordan Co.,* 394 U.S. 759, 764 (1969) (plurality opinion) (agency cannot avoid rulemaking requirements by making rule in course of

adjudication); *Safari Club Int'l v. Zinke,* 878 F.3d 316, 331-333 (D.C. Cir. 2017) (finding enhancement determinations under Endangered Species Tobacco Control Act to be a rule, not an adjudication); *Yesler Terrace Cmty. Council v. Cisneros,* 37 F.3d 442, 449 (9th Cir. 1994) ("An agency cannot avoid the requirement of notice-and-comment rulemaking simply by characterizing its decision as an adjudication."); *General Motors Corp. v. Ruckelshaus,* 742 F. 2d 1561, 1565 (D.C. Cir. 1984) (en banc) ("[T]he agency's own label, while relevant, is not dispositive.").

Despite Congress providing FDA with clear requirements and authority to implement a tobacco product standard, FDA ignored them in the case of flavored e-cigarettes. FDA's decision to regulate such flavoring additives through adjudication is particularly unwarranted given the fact Congress deliberately wrote additional notice and comment requirements for tobacco product standards into the Act—above and beyond the notice and comment requirements of the APA. See *Loper,* 144 S.Ct. at 2263 ("[T]he role of the reviewing court … is … to … effectuate the will of Congress."). Therefore, because FDA acted outside the boundaries of its congressionally delegated authority by imposing a *de facto* tobacco product standard without notice and comment, FDA's denial orders must be set aside as arbitrary and capricious. See *Id.* at 14 (The APA "requires courts to 'hold unlawful and set aside agency action. . . not in accordance with law.'") (quoting 5 U.S.C. §706(2)(A)); *Motor Veh. Mfgs. Assn.*, 463 U.S. 42-43.

III. FDA PROCESS FOR REVIEWING PMTAS WAS HEAVILY CRITICIZED BY AN INDEPENDENT TOBACCO EXPERT PANEL WHICH CALLED OUT

THE FDA'S FAILURE TO CONSISTENTLY APPLY THE APPH TEST.

The very concerns raised by Respondents have been echoed by an independent review of FDA's tobacco regulatory process. On December 19, 2022, just two weeks before the Fifth Circuit issued its order, an Independent Tobacco Expert Panel – convened at the request of FDA Commissioner Robert Califf under the auspices of the Congressionally-created Reagan-Udall Foundation to advise the FDA – released its report which laid bare the FDA's mishandling of, among other things, PMTAs.[4] Not only do the Independent Tobacco Expert Panel's findings buttress Respondents' claim that FDA's requirements for establishing what products are "appropriate for the protection of public health" are unclear, the Panel also concurred that FDA was not transparent in explaining how it was evaluating what products are appropriate for the protection of public health and that FDA didn't even have a clearly articulated basis for making its determinations.

The Independent Tobacco Expert Panel called out the FDA for its lack of clarity in what Respondents, and every other applicant, should submit to FDA to satisfy an APPH determination:

> "**Applicants, however, will struggle to address the issues necessary to meet the APPH standard unless FDA clearly articulates its expectations**. A lack of clarity results in extraneous work on both sides--for

[4] Operational Evaluation of Certain Components of FDA's Tobacco Program: A Report of the Tobacco Independent Expert Panel, Silvis, et. al; 2022 available at https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf

> applicants and for the Agency. **CTP has a responsibility to clearly identify application requirements,** if for no other reason than to reduce the burden on the Agency itself and improve efficiency."

Id. at 20. (emphasis supplied). The Independent Tobacco Expert Panel also concurred with Respondents' argument regarding the lack of clear rules, finding that, "While CTP has issued some foundational regulations and guidances, many gaps remain." *Id.* As a result, the Independent Tobacco Expert Panel expressed the urgent need for FDA to create a strategic plan "now" and demanded that "the plan must … explain how FDA is interpreting the APPH standard." *Id.* at 15. FDA's recalcitrance, even when confronted by criticism levied by an independent review it asked for itself, was best evidenced by FDA ignoring the admonitions of the Independent Tobacco Expert Panel by issuing a strategic plan one year later that failed to even address its concerns about the opacity of the PMTA process and FDA's approach to APPH. *See generally, Id*.

Respondents rightly raise the concern that FDA implemented a policy of banning all flavored vaping products under the guise of its scientific review of Respondents' application. This concern was also supported by the Independent Tobacco Expert Panel which cited FDA's inability to separate policy decisions, at the core of Respondents' denials, and scientific decisions:

> "One such question that scientific analysis alone will not resolve is how to weigh the public health benefits of the percentage of adults who use ENDS that will completely quit smoking combustible tobacco products against the potential public

> health harms that youth who use ENDS will acquire a lifelong addiction to nicotine or proceed to use combustible tobacco products. At times, a lack of clarity about the distinction between, and the intersection between, policy and science has created controversy within CTP and may lead to a perception that the Center's scientific integrity is being challenged when, in fact, policy decisions that transcended the science are being made."

Id.

Finally, the Independent Tobacco Expert Panel also offered its support for Respondents' complaint that FDA inappropriately failed to consider all aspects of its application (i.e., its plan to restrict youth access and appeal) in making its APPH determination:

> "To the extent that CTP intends to review certain critical sections of an application first, and if deficient, not proceed to other sections, such a policy should be reflected in a public guidance that explains to applicants how CTP will triage its substantive reviews."

Id. at 20.

Thus, every element of FDA's failures to honestly and lawfully administer its regulatory duties as argued by Respondents and as found by the Fifth Circuit, has been buttressed by the FDA's own independent review of its process; processes which, to date, FDA has declined to fix.

CONCLUSION

For the foregoing reasons, the decision below should be upheld and FDA should be required to conduct a "full and fair regulatory proceeding"

consistent with the best reading and purposes of the Tobacco Control Act.

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Respectfully submitted,

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