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. D/B/A TRITON DISTRIBUTION, *ET AL.*,

Respondents.

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

BRIEF OF VAPING INDUSTRY STAKEHOLDERS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICI CURIAE*

Amici are businesses and trade associations which represent a diverse cross-section of manufacturers, distributors, and retailer of flavored Electronic Nicotine Delivery Systems (ENDS) products (colloquially "e-cigarettes").[1] Millions of smokers have used them to transition away from cigarettes and many of them started businesses to help promote this novel and beneficial technology. *Amici* thus share a common mission to advocate for a reasonably regulated marketplace that allows consumer access to less harmful products. FDA's regulatory regime has been anything but reasonable.

The ENDS products industry finds itself at a crossroads given FDA's decision to impose a *de facto* ban on flavored e-liquids through its adjudication of Pre-Market Tobacco Product Applications (PMTA). *Amici* have a substantial interest in the outcome of this and the other industry cases now pending before the Court.[2] *Amici* are keenly interested in how the Court decides the circuit split arising from the U.S. Food and Drug Administration's (FDA) decision to reach far beyond any reasonable interpretation of the Family Smoking Prevention and Tobacco Control Act (TCA) by instituting a *de facto* ban on all non-tobacco flavored

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[1] Pursuant to S. CT. R. 37.6, counsel for *amici curiae* state that no counsel for any party authored this brief in whole or in part or made any monetary contribution. Pursuant to S. CT. R. 37.2, notice of intent to file was provided to counsel for all parties more than 10 days in advance of the filing deadline. *Amici* are listed in the attached appendix.

[2] *Magellan Technology, Inc. v. FDA*, No. 23-799; *Lotus Vaping Technologies, LLC v. FDA*, No. 23-871; and *Logic Technology Development LLC v. FDA*, No. 23-1125.

products. The "wild goose chase" described by the *en banc* Fifth Circuit in *Wages & White Lion Invs., LLC v. FDA*, 90 F.4th 357 (5th Cir. 2024) is common to all prior and pending industry appeals. The Court should thus grant review in this case, as well as the *Magellan*, *Lotus* and *Logic* cases, to resolve the existing circuit split to bring certainty to the industry.

SUMMARY OF THE ARGUMENT

The TCA's preamble evidences a clear congressional intent that FDA have authority to ensure addicted, adult smokers have access to lower risk products which help them move away from cigarettes. *See* 21 U.S.C. § 387 *notes*. The scientific community, and FDA itself, now firmly recognize that ENDS products are an important smoking risk reduction tool.

The TCA requires that product manufacturers obtain premarket authorization from FDA through the submission of a PMTA for each product. The TCA's plain language requires FDA to evaluate all information and data included in a PMTA when determining whether a given product is "appropriate for the protection of the public health" (APPH). This is not a one-size-fits-all process as the evidence warranting the marketing of one product may not justify the approval of another.

For example, the APPH standard requires that FDA evaluate whether each ENDS product appeals to minors, and that manufacturers ensure youth access and marketing are restricted. This standard, however, requires that FDA must balance any concerns about youth (under age 21) access against all other evidence contained in the PMTA warranting a grant of marketing authorization. The TCA reflects a congressional policy choice mandating that FDA

consider, *inter alia*, both the benefits and risks of a tobacco product across the population as a whole. 21 U.S.C. § 387j(c)(4). This represented Congress' first ever *population-level* health standard which required that FDA account for all stakeholder interests by conducting a complete review of each PMTA.

Unfortunately, FDA has ignored the TCA's plain language by applying a one-size-fits-all approach which swung the PMTA review pendulum far to one side. The effect has been a *de facto* ban of all non-tobacco flavored (*e.g.*, mint and fruit) ENDS products. FDA's myopic view of the APPH standard caused a disproportionate skewing of its attention by focusing on underage use at the expense of adult smokers. FDA did not either ask Congress to amend the TCA to adopt a tobacco product standard which banned flavored ENDS products or promulgate a tobacco product standard *via* public notice and comment rulemaking, as required by 21 U.S.C. § 387g(c). Rather, FDA chose to initiate this policy initiative through the PMTA adjudication process in a manner not grounded in the TCA's plain text, structure, and context. The *en banc* Fifth Circuit accurately found FDA's review process was fatally flawed.

First, the *en banc* Fifth Circuit correctly found that FDA acted arbitrarily in denying the Respondents' PMTAs by: (1) relying upon *post hoc* justifications to justify its PMTA rejections; (2) failing to provide fair notice when applying its comparative efficacy standard; (3) changing a substantive position without displaying an awareness of the change and explaining it; and (4) ignoring the Respondents' reliance interests. *Amici* discuss each of the *en banc* Fifth Circuit's particular findings in showing that it reached the correct conclusions.

Second, the *amici* argue that FDA's regulatory efforts are unconstitutional because Congress violated the major question doctrine and this Court's holding in *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120 (2000). The Court therein held that the regulation of tobacco products was a major question and FDA lacked regulatory authority absent specific enabling legislation. Congress permissibly identified four product subsets in the TCA for which it granted regulatory authority to FDA. 21 U.S.C. § 387a(b). Congress, however, impermissibly delegated FDA with legislative authority to determine which tobacco products would be regulated under the TCA beyond the four initial product subsets. Review is necessary to consider the underlying constitutionality of Congress' delegated grant of legislative authority to FDA *vis-à-vis* ENDS products.

Finally, any change to the agency deference standard resulting from *Loper*/*Relentless* necessitates the Court consider the future viability of the type of *ad hoc* regulatory adjudications permitted by *SEC v. Chenery Corp.*, 332 U.S. 194 (1947) *(Chenery II*). A continued adherence to *Chenery II* is inconsistent with this Court's recent administrative law jurisprudence. It is appropriate to review this case and the other pending cases to determine whether *Loper*/*Relentless* bring that adherence to an end.

ARGUMENT

I. THE *EN BANC* FIFTH CIRCUIT EXPOSED THE INHERENT LEGAL DEFECTS OF FDA'S PMTA REVIEW PROCESS FOR FLAVORED ENDS PRODUCTS.

The facts here evidence that FDA's PMTA review process is fundamentally flawed for the following reasons: (1) FDA invented *post hoc* justifications to justify its rejection of Respondents' PMTAs; (2) FDA failed to provide fair notice when applying its comparative efficacy standard; (3) FDA changed a substantive position without displaying an awareness of the change and explaining it; and (4) FDA ignored Respondents' reliance interests.

A. FDA'S *POST HOC* RATIONALIZATIONS ARE AN ATTEMPT TO JUSTIFY AND RESCUE ITS FLAWED PMTA PROCESS.

The Respondents fleshed out the significant legal flaws with FDA's after-the-fact, disguised tobacco product standard for flavored ENDS products. FDA responded by resorting to *post hoc* rationalizations to justify its position. The *en banc* Fifth Circuit accurately deduced FDA's *post hoc* rationalizations and adjudged their illegitimacy based on the basic proposition that the:

> "grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."

90 F.4th at 371, citing *SEC v. Chenery Corp. (Chenery I),* 318 U.S. 80, 87 (1943).

The administrative record reflects that FDA had many interactions with ENDS product stakeholders

over several years in which it made affirmative representations that PMTAs would not need the support of long-term studies. FDA certainly never informed stakeholders that they needed studies which compared the efficacy of flavored ENDS products to that of tobacco-flavored products. Instead, FDA focused on the importance of stakeholders' marketing plans, including specific details about the contents of such plans. 90 F.4th at 372. That should have framed the scope of FDA's PMTA review. It did not.

The *en banc* Fifth Circuit noted that FDA predicated Respondents' marketing denial order on a determination that:

> "the *mere existence of flavor* was sufficient to justify denial of a PMTA because flavor standing alone was enough to prove that youth would use the proposed product and that youth use would outweigh any countervailing benefit to adults.

90 F.4th at 372. *See also* Pet. App. at 200a – 201a n. xix. Despite numerous representations about the importance of marketing plans, FDA admitted in its marketing denial order that "it did not even read the marketing plans it previously said were critical." 90 F.4th at 372. *See also* Pet. App. at 201a n. xix (acknowledging FDA's failure to review Respondents' marketing plans). FDA defended this failure by pointing to an evolved mindset based on what claimed to have it "learned" from "review[ing] PMTAs for flavored ENDS."[3] *See* Pet. App. 181a, n. vi.

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[3] FDA employed this same explanation in its marketing decisions for all other flavored open-system ENDS products adjudicated to date.

It was reasonable for FDA to adopt a changed mindset as its experiences evolved. The law, however, required that FDA both acknowledge such evolution and articulate a "detailed justification" *before* the PMTA deadline if it desired to abandon its stated and existing expectations. *Encino Motorcars, LLC v. Navarro,* 579 U.S. ___, 136 S. Ct. 2117, 2125 (2016) (quotation omitted).

What likely happened is that FDA realized it could not comply with an artificial court-imposed[4] review deadline.[5] It was thus incumbent upon FDA to seek judicial relief from such constraint instead of making up a new evidentiary rule as a matter of expediency. FDA's hasty change of position was indeed the "surprise switcheroo" initially found by the Fifth Circuit stay panel. *Wages and White Lion Invs. v. FDA*, 16 F.4th 1130, 1138 (5th Cir. 2021). The *en banc* Fifth Circuit did not err in refusing to give deference to FDA on the merits because it arbitrarily sprung a new and unexpected evidentiary requirement on Respondents after it was too late to comply.

A legitimate regulatory adjudication process should be able to stand the crucible of scrutiny without the need for *post hoc* rationalizations. FDA's marketing denial order to Respondents was rife with *post hoc* rationalizations which speak for themselves. FDA, as the *en banc* Fifth Circuit recognized, doubled down by advancing even more *post hoc* rationalizations

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[4] The Maryland District Court in *Amer. Acad. of Pediatrics v. FDA*, 399 F. Supp.3d 479, 487 (D. Md. 2019) set a new May 9, 2020 PMTA deadline, later extended to September 9, 2020.

[5] *See* Reagan-Udall Foundation, *Operational Evaluation of Certain Components of FDA's Tobacco Programs*, 11 (Dec. 19, 2022).

in the proceedings on the merits. *See* 90 F.4th at 373, 388.

B. FDA'S ACTIONS VIOLATE THE FAIR NOTICE STANDARD.

This Court's administrative law jurisprudence premises that agency regulatory processes must be fair, open and transparent. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) (agencies must "provide regulated parties fair warning" of what it "prohibits or requires" before punishing noncompliance) and *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (agencies cannot "depart from a prior policy *sub silentio* or simply disregard[ ] rules that are still on the books"). Thus, an agency cannot announce a particular position, create an "unfair surprise" by pivoting to a new position, and then penalize the reliance on such prior position. *Christopher* at 156-57 (quotation omitted). This principle applies to agency regulatory actions based upon informal guidance. *See e.g.*, *Morton v. Ruiz*, 415 U.S. 199, 235 (1974).

The *en banc* Fifth Circuit's opinion laid bare that the FDA PMTA review process was anything but fair, open, and transparent *vis-à-vis* flavored ENDS products. The opinion discussed in detail the timeline of numerous FDA interactions with ENDS product stakeholders. FDA's actions commenced with its August 2017 extension of the PMTA deadline so it could clarify the mechanics of the APPH standard provided by 21 U.S.C. § 387j(c) and allow itself time to "promulgate application instructions." 90 F.4th at 363.

FDA then provided "instructions on five relevant occasions," namely FDA's October 2018 stakeholder presentation; a lengthy June 2019 guidance document; an October 2019 public stakeholder meeting; a

September 2019 proposed PMTA rule; and a January 2020 guidance document in which FDA prioritized its enforcement against non-tobacco and non-menthol "flavored, cartridge-based ENDS products." 90 F.4th at 363 – 366. The crux of the *en banc* Fifth Circuit's "dizzying detail" in its analysis was that:

> "[n]ever in this long, winding, and byzantine regulatory process of meetings, PowerPoint decks, proposed rules, comment periods, guidance documents, and enforcement priorities did FDA *ever* say that it was contemplating an across-the-board ban on flavored products."

Id. at 368. The *en banc* Fifth Circuit thus found FDA never gave "fair notice that *flavored* product manufacturers had to submit robust scientific studies on *flavored*" open-system products.[6] *Id*. at 368-9.

Instead, the *en banc* Fifth Circuit noted that FDA focused its regulatory sights on flavored closed-system pods and cartridges[7] based upon specific characteristics which enhanced their youth appeal. 90 F.4th at 367-69, citing FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*: Guidance for Industry (Apr. 2020) at 5, 16, 17. The Court noted FDA's contrast of open-system products which

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[6] Open system devices are typically larger in size than closed system devices, are operating using interchangeable and refillable e-liquid tanks (referred to as atomizers).

[7] Closed-system products refer to a distinct market segment of ENDS products which are fully disposable or operate using a disposable pre-filled cartridge or pod which offer e-liquid in a limited variety of flavor choices.

characteristics that lessened their youth appeal. 90 F.4th at 367, citing FDA Guidance at 17.

FDA's Guidance, as evidenced by its numerous pre-PMTA dealings with ENDS product stakeholders, signaled a plan to treat flavored open-system products like those made by the Respondents *less strictly* than flavored closed-system products. FDA, however, did an about face after the PMTA deadline without notice or an opportunity for stakeholders to amend their PMTAs. The *en banc* Fifth Circuit's characterizations of a "surprise switcheroo" and a "wild goose chase" were not wrong.

The *en banc* Fifth Circuit's discussion evidences that FDA made a mockery of the fair notice principles. FDA took its mockery a step further by imposing a threshold evidentiary standard which required specific proof that flavored ENDS products were more effective at causing smoking cessation than a tobacco-flavored product without either identifying a comparator tobacco-flavored product or defining how many smokers must quit smoking for a flavored ENDS product to be deemed "effective." It begs the question that stakeholders could never conduct a comparative efficacy comparison without knowing this critical information. This is a textbook example of arbitrary regulatory regime which lacks basic elements of fairness, openness, and transparency. This issue makes the case worthy of review.

C. FDA Failed to Explain its Policy Switch Regarding Flavored E-Liquids.

This Court prohibits agencies from "depart[ing] from a prior policy *sub silentio*" or simply disregarding existing rules. *Fox Television*, 556 U.S. at 515. An agency must "display awareness" of a position change

and support it with a "detailed justification" if the new policy rests upon facts different than those underlying the prior policy if that prior policy has "engendered serious reliance interests." *Id*.

The Court should put itself in the shoes of ENDS product stakeholders when considering the reasonableness of FDA's post-PMTA departure from its pre-PMTA guidance and assurances. For example, FDA announced plans in 2017 to issue "regulations outlining what information" it expected in PMTAs.[8] This was part of a larger policy shift which included a 4-year extension of the PMTA deadline.[9] FDA acknowledged in early 2018 that it had yet to "delineate key requirements" of the PMTA process.[10] By early 2019, FDA still had not determined the PMTA "rules of the road."[11] FDA ostensibly saw no urgency since it had extended the PMTA deadline, and believed very few manufacturers would file a PMTA.[12] The *en*

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[8] *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death* (Jul. 27, 2017), https://tinyurl.com/4e4xutd5.

[9] 82 FED. REG. 37,459, *et seq*. (Aug. 10, 2017).

[10] FDA, *Statement from FDA Comm'r Scott Gottlieb* (Mar. 14, 2018), https://tinyurl.com/22zuh3b4.

[11] *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2020: Hearings Before a Subcomm. of the H. Comm. on Appropriations*, 116th CONG. 35 (2019) (statement of FDA Comm'r Gottlieb).

[12] FDA, *Final Regulatory Impact Analysis Final Regulatory Flexibility Analysis Unfunded Mandates Reform Act Analysis*, Table 9 (May 2016). https://www.fda.gov/media/97875/download

banc Fifth Circuit noted that FDA's numerous pre-PMTA representations disclaimed the need for specific studies or long-term studies. 90 F.4th at 363. FDA not only radically changed its position after the PMTA deadline, it attempted to justify such change by arguing its pre-PMTA guidance were merely "non-binding recommendations" and it "never promised or committed itself to doing any particular thing." 90 F.4th at 383.

The *en banc* Fifth Circuit's comparison of such regulatory tact to a wild good chase, Act 2, Scene 4 of Romeo and Juliet,[13] was appropriate. A more modern analogy is the hotel scene in *The Pink Panther Strikes Again*. In this scene, Peter Sellers, playing Inspector Clouseau, sees a dog in the hotel lobby and, assuming it belongs to the innkeeper, asks him if his dog bites to which the innkeeper responds in the negative. The dog bites Clouseau when he tries to pet it. Clouseau then indignantly queries the innkeeper "I thought you said your dog did not bite" to which the innkeeper responds, "that is not my dog."[14] FDA responds similarly when asked to stand behind its pre-PMTA guidance and representations.

Indeed, FDA's pre-PMTA assurances lulled thousands of flavored open-system ENDS product manufacturers to spend millions of dollars each to prepare and timely file a PMTA. These stakeholders did everything FDA said needed to be done in its pre-PMTA guidance. They also did so in the face of both an arbitrarily court-imposed PMTA deadline change which significantly shortened the filing period and the

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[13] William Shakespeare, Romeo and Juliet, act 2, sc. 4.

[14] *The Pink Panther Strikes Again*, United Artists (1976).

many business restrictions resulting from the Covid pandemic. FDA attempts to justify its radical position change by shrugging its shoulders and saying it was not bound by anything contained in the pre-PMTA dealings with the ENDS product industry. This tact is wholly inconsistent with *Fox Television*.

D. FDA FAILED TO GIVE ACCORD TO RESPONDENTS' RELIANCE INTERESTS.

Finally, review is appropriate to consider whether FDA sufficiently give accord to the reliance interests of Respondents and other manufacturers of flavored open-system ENDS products. FDA's regulatory flip-flop after the PMTA deadline was wholly inconsistent with this Court's jurisprudence.

The final point of the *en banc* Fifth Circuit's analysis focused on FDA's failure to give accord to the reliance interests resulting from its pre-PMTA assurances. 90 F4th at 384. This Court held in *Christopher, supra.* at 156-57, that agencies cannot penalize a regulated party for a "good faith reliance" upon a prior regulatory position and in *Fox Television*, *supra.*, at 515, that agencies must take "serious reliance interests" into account. An agency must even take reliance interests into account when the regulatory policy it seeks to reverse was not enacted according to law. *Department of Homeland Security v. Regents of the University of California*, 591 U.S. ___, 140 S. Ct. 1891 (2020).

The *en banc* Fifth Circuit recognized that FDA's pre-PMTA guidance could be interpreted to say that flavored ENDS product manufacturers were on notice of the need to perform long-term scientific studies. 90 F.4th at 385. The court recognized such guidance could also be reasonably interpreted to say that a manufacturer's PMTA did not need "specific studies",

"[y]outh behavioral data", or "long-term studies." *Id*. citing FDA's October 2018 Guidance at 18, 26. The former interpretation is weakened by the fact that:

> "not a single sentence anywhere in the voluminous record" said that "manufacturers should submit long-term scientific studies on the differences between their new flavored e-cigarette products and other nonflavored e-cigarette products."

90 F.4th at 385. Implicit in the *en banc* Fifth Circuit's ruling is the proposition that ambiguities in the FDA guidance documents were to be interpreted against it in finding the agency could not send ambiguous instructions and then penalize Respondents for obeying the wrong one. *Id*. This is a sound proposition which further supports review.

Respondents find themselves in the same shoes as thousands of other open-system flavored ENDS product manufacturers. These stakeholders relied upon a reasonable interpretation of the substance and scope of FDA's many pre-PMTA assurances and representations. It would be one thing if Respondents' interpretation and claimed reasonable reliance occurred in isolation. It is a completely different thing when flavored ENDS manufacturers from all corners of the nation reached the same interpretation. The Court should grant review if it reaches the same interpretation as the Respondents and other flavored ENDS product manufacturers.

II. THE COURT SHOULD ADDRESS THE CONSTITUTIONALITY OF THE TCA'S DEEMING PROVISION UNDER THE MAJOR QUESTIONS DOCTRINE.

This Court's recent administrative law jurisprudence has signaled a significant reliance upon the separation of powers subset principle embodied in the "major questions doctrine." Such doctrine is implicated when an agency adopts a policy which has a broad national effect in the absence of specific congressional authorization. *See e.g.*, *West Virginia v. EPA*, 597 U.S. ____, 142 S.Ct. 2587 (2022) (holding that EPA's regulation of emissions from existing plants based on generation shifting mechanisms was a major question for which Congress had not granted authority) and *Biden v. Nebraska*, 600 U.S. 477, 143 S.Ct. 2355 (2023) (holding the scale of the Department of Education's student loan debt cancellation plan was a major question for which Congress had not granted authority).

This Court has rooted its recent major question doctrine jurisprudence in *Brown & Williamson*, another case of FDA overreach. *Brown & Williamson* concerned FDA's adoption of a regulation which classified tobacco products as a drug under the Federal Food Drug and Cosmetic Act (FFDCA). *See* 61 FED. REG. 44,619, *et. seq*. (Aug. 28, 1996).

Brown & Williamson considered Congress' various efforts to regulate tobacco products after the 1964 Surgeon General's report; all of which Congress constrained to labeling and advertising restrictions. 529 U.S. at 137-38. In fact, Congress considered 75 bills between 1965 and 1978 regarding problems

associated with smoking.[15] Among such bills was one to amend the FFDCA to grant FDA regulatory authority.[16] Ultimately, however, Congress took a lesser step: enacting the first federal cigarette labeling act.[17]

This Court noted in *Brown & Williamson* that Congress made the policy choice embodied in 15 U.S.C. § 1331 that the "commerce and the national economy may be . . . protected to the maximum extent consistent with" the principle of consumers "being adequately informed about any adverse health effects." *Id.* at 138-39. Based upon these observations, the Court held that FDA lacked regulatory authority in the absence of enabling legislation because the regulation of tobacco products was a major question which required Congressional imprimatur because tobacco products concerned a "significant portion of the American economy," which had a "unique place in American history and society." *Id*. at 159-60.

Congress and FDA were bound by this Court's major question finding *vis-à-vis* any future regulation of tobacco products. Congress, however, did not take this to heart when enacting the TCA. Congress predicated the TCA's operative provisions upon the extant definition of "tobacco product" which in relevant part includes:

> "any product made or derived from tobacco that is intended for human consumption,

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[15] Klebe, E.R., *Actions of the Congress and the Federal Government on Smoking and Health*, Congressional Research Serv., Report No. 79-219 (Sept. 26, 1979).

[16] See H.R. 2248, 89th Congress (1966).

[17] Klebe, *supra*.

> including any component, part, or accessory...."

21 U.S.C. § 321(rr)(1). Congress, however, chose to not immediately subject all tobacco products to the TCA's requirements. Instead, Congress only subjected only four specific subsets of tobacco products (cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco) to immediate regulation by FDA under the TCA. *See* 21 U.S.C. § 387a(b).

Congress then delegated plenary authority to the Health and Human Services Secretary to subject all other tobacco products to the TCA through a regulatory deeming process. 21 U.S.C. § 387a(b). Congress, however, "did not provide standards for when and how the agency [FDA] was to exercise its discretion to deem[.]" *Nicopure Labs, LLC v. FDA*, 266 F. Supp.3d 360, 392 (D. D.C. 2017). FDA acknowledged the lack of standards governing any deeming in *Nicopure* ("Congress's choice of the deferential word 'deems' and the absence of any standard—beyond the requirement that the product meet the definition of a 'tobacco product'—demonstrate that Congress committed the exercise of this authority to the agency's broad discretion").[18] *Id.*

FDA exercised its deeming authority in May 2016 as to all other products which satisfied the "tobacco products" definition, including ENDS products, by way

[18] Such lack of guiding standards arguably also presents a non-delgation doctrine question. *See Panama Refining Co. v. Ryan*, 293 U.S. 388, 430 (1935); *J.W. Hampton, Jr. & Co. v. U.S.*, 276 U.S. 394, 409 (1928).

of its "Deeming Rule."[19] *See* 81 FED. REG. 28,974 (May 10, 2016). FDA's claim of broad regulatory discretion under the Deeming Rule wholly begged the question because the TCA's deeming provision was itself constitutionally defective.

Brown & Williamson required that Congress, and only Congress, construct any regulatory framework for tobacco products. The letter and spirit of *Brown & Williamson* stands for the proposition that the specific identification of any tobacco products to be regulated was part and parcel of Congress constructing any regulatory framework. Thus, *Brown & Williamson* prohibited Congress from delegating the authority to FDA to determine which specific tobacco products would be subjected to its regulation under the TCA. The Court should accordingly accept review of this case to consider whether the TCA's deeming provision set forth in 21 U.S.C. § 387(a)(b) is an *ultra vires* action which violates the separation of powers doctrine as to ENDS products.

III. FDA'S REGULATORY TACT CANNOT EXIST IN A POST-LOPER/RELENTLESS WORLD.

This case and the three other pending ENDS product cases come before the Court as its administrative law jurisprudence is at a critical crossroads. This Court's recent administrative law jurisprudence has significantly evolved during recent terms, including frequent invocation of the "major questions" doctrine. This evolution is ongoing with the

[19] The validity of FDA's Deeming Rule fiscal analysis is presently being challenged under the Regulatory Flexibility Act, 5 U.S.C. §§ 601, *et seq*. *See Kealani Distrib, LLC v. FDA*, No. 22-cv-856 (E.D. Tx.).

cases like *Loper/Relentless*[20] which will impact the deference to be afforded agencies such as FDA. A grant of *certiorari* in this case and the other pending ENDS products industry cases is crucial for the Court to address whether FDA's on-the-fly regulatory tact concerning the adjudications of flavored open-system e-liquids places it on the wrong side of the jurisprudential crossroads.

The *en banc* Fifth Circuit addressed how FDA repeatedly articulated clear and unambiguous expectations in its written guidance to ENDS product manufacturers. At no time during FDA's many pre-PMTA dealings with the industry did it mention any intention to apply a comparative efficacy standard when reviewing flavored ENDS product PMTAs. To the contrary, FDA specifically disclaimed the need for any specific type of study, including long-term studies. 90 F.4th at 363, citing FDA's October 2018 presentation. FDA then flipped the script when adjudicating these ENDS product PMTAs—adopting an *ad hoc* policy of requiring a showing that a flavored ENDS product has a "magnitude of the potential benefit to adult smokers" which is "adequate to outweigh the risks to youth." Pet. App. at 167a. This was what the Fifth Circuit's stay panel characterized as a "surprise switcheroo" in *Wages & White Lion*, 16 F.4th at 1138, and its *en banc* panel later characterized as a "wild goose chase." 90 F.4th at 362.

FDA believes the Court should countenance this type of regulatory practice. The Court has seen this before as what FDA wants looks like the Securities and Exchange Commission's regulatory tact countenanced

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[20] *See Loper Bright Enterprises, Inc. v. Raimondo*, No. 22-451 and *Relentless, Inc. v. Dept. of Commerce*, No. 22-1219.

in *Chenery II*. *Chenery* concerned the propriety of the SEC creating a substantive legal standard during the process of adjudicating a regulated party's reorganization plan. The Court countenanced the SEC's authority to regulate informally on an *ad hoc* basis by rationalizing that promulgating rules through a quasi-legislative process is preferred to the extent possible but:

> "any rigid requirement to that effect would make the administrative process inflexible and incapable of dealing with many of the specialized problems which arise."

332 U.S. at 202. The Court felt that agencies should be able to adjust the rulemaking process on-the-fly "to meet particular, unforeseeable situations" and thus "must be equipped to act either by general rule or by individual order." *Id*.

Chenery II, however, is inconsistent with basic notions of due process because it has:

> "empowered agencies to issue retroactive regulations through adjudication, a doctrine that has empowered agencies . . . to announce new rules during enforcement actions without any fair notice to the parties being regulated."[21]

Empowering agencies in this manner is inconsistent with the basic concept of fair notice. As the late Justice Scalia observed, "[r]udimentary justice requires that those subject to the law must have the means of

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[21] Donald F. McGahn, Federalist Society National Lawyers Convention, Barbara K. Olson Memorial Lecture (Nov. 17, 2017) at 29:20 – 29:31. https://fedsoc.org/conferences/2017-national-lawyers-convention#agenda-item-barbara-k-olson-memorial-lecture

knowing what it prescribes."[22] FDA's serial application of its post-PMTA comparative efficacy standard to all flavored open-system ENDS products is an illegitimate "subregulatory action."[23]

Chenery II is inconsistent with this Court's opinion in *Brown & Williamson* which held that "[r]egardless of how serious the problem an administrative agency seeks to address" it cannot "exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" 529 U.S. at 125, citing *ETSI Pipeline Project v. Missouri,* 484 U.S. 495, 517 (1988). In this instance, FDA's marketing denial pointed to the "known risks to youth of marketing flavored [ENDS]," Pet. App at 167a, as the justification for its actions.

Yet, Congress specifically told FDA how to address this risk: adopting a formal tobacco product standard through notice-and-comment rulemaking, 21 U.S.C. § 387g(c), if it desired to regulate a tobacco product's "components, ingredients [or] additives," 21 U.S.C. § 387g(a)(4)(B)(i). FDA essentially applied *Chenery II* in making an end run around the requirements of 21 U.S.C. § 387g as to flavored ENDS products. FDA's worldview, however, is wholly inconsistent with this Court's jurisprudence which has sought to restrain administrative regulatory authority.

FDA significantly premises its arguments here upon the proposition that it should be able to adjust its PMTA review standards in real time as its experiences and understanding evolves. FDA blithely assumes its world view must be correct because other circuits have

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[22] Antonin Scalia, *The Rule of Law as a Law of Rules*, The Univ. of Chicago L. Rev. 56:4 1175, 1179 (Fall 1989).

[23] McGahn at 24:14 - 24:22.

countenanced its *ad hoc* review process. FDA implicitly argues for a continued adherence of *Chenery II* without directly saying so. That view, however, is contrary to this Court's jurisprudence in *ETSI Pipeline*, *Christopher* and *Fox Television*.

Time has proven the accuracy of Justice Jackson's prediction in his *Chenery II* dissent—the position countenanced therein "would in practice, put most administrative orders above the law" by making judicial review "a hopeless formality for the litigant, even where granted to him by Congress" thus reducing "the judicial process in such cases to a mere feint." 332 U.S. at 210 (Jackson, J, dissenting). One reason for the Court to accept review here is to address whether *Chenery II* still applies in a post-*Loper/Relentless* world.

CONCLUSION

Based on the foregoing, *amici* ask that this Court grant FDA's Petition for Writ of Certiorari and those also pending in Nos. 23-799, 23-871 and 23-1125.

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Respectfully submitted,

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APPENDIX

APPENDIX
LIST OF *AMICI CURIAE*

723VAPE, INC. (KY)

BREATHE EASY ALLIANCE OF ALABAMA

DERBECIGS LLC (KY)

DERBECIGS INDIANA LLC (IN)

FLORIDA SMOKE FREE ASSOCIATION, INC.

GEORGIA SMOKE FREE ASSOCIATION, INC.

KANSAS SMOKE FREE ASSOCIATION

KENTUCKY VAPING RETAILERS ASSOCIATION, INC. D/B/A KENTUCKY SMOKE FREE ASSOCIATION

IOWANS FOR ALTERNATIVES TO SMOKE AND TOBACCO, INC.

IOWA VAPE ASSOCIATION, INC.

J-VAPOR LLC, D/B/A NORTH SHORE VAPOR (MA)

LOUISIANA VAPING ASSOCIATION, INC.

MARYLAND VAPOR ALLIANCE

MICHIGAN VAPE SHOP OWNERS, INC.

MIDWEST VAPE COALITION, INC.

MINNESOTA SMOKE FREE ALLIANCE

MISSISSIPPI VAPING ADVOCACY ASSOCIATION, INC.

MISSOURI SMOKE FREE, INC.

MONTANA SMOKE FREE ASSOCIATION, INC.

NEBRASKA VAPE VENDORS ASSOCIATION, INC.

NEVADA VAPING ASSOCIATION, INC.

NEW MEXICO SMOKE FREE ALLIANCE, INC.

NEW YORK STATE VAPOR ASSOCIATION, INC.

NORTH CAROLINA VAPING COUNCIL, INC.

OHIO VAPOR TRADE ASSOCIATION, INC.

OP MURSE HOLDINGS, LLC, D/B/A OPMH PROJECT (KY)

SOUTH CAROLINA VAPOR ASSOCIATION, INC.
VIRGINIA SMOKE FREE ASSOCIATION, INC.
WASHINGTON SMOKE FREE ASSOCIATION, INC.
WEST VIRGINIA SMOKE FREE ASSOCIATION, INC.
UNITED VAPERS ALLIANCE, INC.
VAPOR STOCKROOM, L.L.C. (KY)
VAPOR UNLIMITED, LLC (FL)