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

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

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INTERESTS OF *AMICI CURIAE*

Amici are national and state trade associations, which represent small businesses manufactures, distributors, and retailer of Electronic Nicotine Delivery Systems (ENDS) products (commonly known as "e-cigarettes").[1] Millions of smokers have used them to transition away from cigarettes and many of these businesses were started by individuals who used ENDS products to quit smoking. *Amici* therefore share a common mission to advocate for a reasonably regulated marketplace that gives consumers access to less harmful tobacco products.

Amici have a substantial interest in this litigation given the manner in which the U.S. Food and Drug Administration (FDA) has reached far beyond any reasonable interpretation of the Family Smoking Prevention and Tobacco Control Act (TCA) and instituted a *de facto* ban on all non-tobacco flavored ENDS. A majority of circuit courts have rubber-stamped FDA's *de facto* ban. Two circuits, however, have reached diametrically opposite conclusions, including a recent *en banc* ruling by the Fifth Circuit in *Wages & White Lion Invs., LLC v. FDA*, 90 F.4th 357 (5th Cir. 2024) which, in strong terms, (describing FDA's process as a "wild goose chase") wholly negated FDA's review process. The result is a robust circuit split which the Court should resolve lest a quandary exist, especially if the Court alters *Chevron* deference.

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[1] Pursuant to Supreme Court Rule 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 Supreme Court Rule 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.

SUMMARY OF THE ARGUMENT

In the TCA, Congress granted FDA authority to ensure this country's addicted, adult smokers have access to lower risk tobacco products which help them move away from cigarettes. The scientific community, and FDA itself, now firmly recognize that ENDS products are an important smoking risk reduction tool.

The TCA requires that ENDS product manufacturers submit to FDA a premarket tobacco product application (PMTAs) to obtain marketing authorization. The TCA's plain language requires FDA to evaluate all PMTA information and data submitted when determining whether a given product is "appropriate for the protection of the public health" (APPH). Significantly, APPH is not a one-size-fits-all process, as the evidence warranting the marketing of one product may not justify it for another product.

The APPH process also involves ensuring ENDS products do not appeal to minors through restricting access and marketing to them. But any concerns about youths (under age 21) using ENDS products must be balanced against all other evidence as to adults contained in the PMTA which warrants a marketing authorization. Congress made a policy choice *vis-à-vis* the APPH process by creating its first ever *population-level* health standard which required a complete review of a PMTA to fairly account for all stakeholder interests. Congress did so by 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).

Unfortunately, FDA has applied a one-size-fits-all approach which swung the pendulum far to one side. The result is a *de facto* ban on all non-tobacco flavored

(*e.g.*, mint and fruit) ENDS products.[2] FDA did so by focusing its attention largely on underage use at the expense of adult smokers. FDA implemented its *de facto* ban not by asking Congress to amend the TCA or by promulgating a tobacco product standard via public notice-and-comment rulemaking required by 21 U.S.C. § 387g(c). Rather, FDA adopted a statutory interpretation that is not grounded in the TCA's plain text, structure, and context.

Specifically, FDA adopted this strategy – what it internally described as the "fatal flaw" approach – following a deluge of approximately 6.5 million PMTAs filed prior to a court-imposed deadline. FDA expressly calculated its "fatal flaw" approach to allow a quick denial of the PMTAs for as many non-tobacco flavored ENDS products as possible. Despite telling manufacturers it would conduct a full scientific review of each PMTA, FDA suddenly decided to engage in a simple box-checking exercise and issue marketing denials without even the benefit of issuing a deficiency letter if a PMTA merely failed to contain a single study comparing the cessation benefits of tobacco and non-tobacco-flavored ENDS products. FDA's interpretation of the APPH process – concluding it could base a marketing denial solely on the absence of one piece of evidence – did not accurately reflect Congress's intent.

Moreover, FDA's review process has been strong-armed by key political leaders, constituting undue political interference which disregarded the scientific reality that ENDS products benefit the protection of public health—a proposition FDA officials themselves have repeatedly acknowledged.

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[2] *See* 90 F.4th at 384, note 5.

ARGUMENT

I. NON-TOBACCO FLAVORED ENDS PRODUCTS PRESENT LESS RISK THAN CIGARETTES AND ARE EFFECTIVE IN HELPING TRANSITION ADULT SMOKERS

It is now well-established that ENDS products pose far less health risks than cigarettes. In 2018, the National Academies of Sciences (NAS) completed a comprehensive review of over 800 research and scientific papers examining ENDS and their health impacts.[3] NAS found "**substantial evidence** that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible cigarettes."[4]

FDA's *de facto* ban of non-tobacco flavored ENDS products directly contradicts the TCA's mandate. A recent study, funded in part by FDA, analyzed five years of cigarette sales data from 7 states and 375 localities that banned flavored ENDS products and found an increased use of 15 cigarettes (3/4 of a pack) for every banned 0.7ml flavored pod.[5] Pertinent to this case, because FDA is so concerned with youth, the study noted increased cigarette sales among brands disproportionately used by them. The study concluded that "any public health benefits of reducing ENDS use

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[3]National Academies of Sciences, *Public Health Consequences of E-Cigarettes*, NAT'L ACADEMIES PRESS, at Preface (2018), https://tinyurl.com/3k2tua82.

[4] *Id.* at 18 (emphasis in original).

[5] Friedman, A., *et al., E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales* (Sept. 26, 2023). *See* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4586701

via flavor restrictions may be offset by public health costs from increased cigarette sales."[6]

The significantly reduced health risks lie in the fact that ENDS products do not even contain tobacco, and there is neither combustion nor smoke. Rather, the heating and vaporization of an e-liquid solution produces an aerosol which the user inhales. Not surprisingly, NAS concluded the "evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk" than cigarettes.[7]

How significant is this harm reduction potential? Well, 2021 and 2022 studies predicted that converting smokers to ENDS products would avoid 1.8 million American deaths and save 38.9 million life years by 2060,[8] and substantially reverse mortality risks.[9] A January 2024 presentation shows ENDS products are achieving such goal: having already saved 1.66 million life years between 2007 and 2019.[10] This dovetails with the conclusions in an October 2023 study that the lower smoking rates linked to ENDS products saved

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[6] *Id*.

[7] NAS at 11. FDA agrees. 81 FED. REG. 28,974, 29,030 (May 10, 2016) (FDA concluding in rule applying the TCA to ENDS products that "completely switching from combusted cigarettes to [e-cigarettes] may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products.").

[8] Levy, *et al.,* Public Health Implications of Vaping in the USA: the Smoking and Vaping Simulation Model, POPUL. HEALTH METRICS, (Apr. 17, 2021).

[9] Thomson, B., *et al*., Association Between Smoking, Smoking Cessation, and Mortality by Race, Ethnicity, and Sex Among US Adults, JAMA NETWORK OPEN, 2022;5(10) (Oct. 24, 2022).

[10] Pesko, *et al., Pharmaceutical Drug Regulation and Mortality: The Peculiar Case of E-cigarettes*, Tobacco Online Policy Seminar (Jan. 5, 2024).

113,000 lives between 2010 and 2022, preserved $137 billion in gross domestic product and saved $39 billion in healthcare costs.[11]

Regrettably, all of this is at grave risk because any ban of flavored ENDS products "is likely to offset mortality reduction gains that e-cigarettes are otherwise providing."[12] This wholly avoidable risk is troubling because most of the nation's adult ENDS products users are either current or former smokers. Many use them to reduce or completely quit their smoking habits.[13]

Recent studies validate these efforts, with a 2022 Cochrane Systematic Review being particularly instructive.[14] A diverse group of global researchers reviewed 78 completed studies, including randomized controlled trials and cross-over trials, which investigated whether ENDS products help adults stop smoking.[15] Their review concluded that "people are more likely to stop smoking for at least six months using nicotine e-cigarettes than using . . . e-cigarettes without nicotine . . . ."[16] In human terms, "this might lead to an additional seven quitters per 100"

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[11] Shapiro*, et al.*, *The Major Benefits and Modest Risks of Nicotine Vaping Products*, Center for Black Equity 5 (Oct. 2023).

[12] *Id.*

[13] Ping Due, MD, Ph.D, *et al.*, *Changes in E-Cigarette Use Behaviors and Dependance in Long-term E-Cigarette Users*, AM. J. PREV. MED. 2019:57(3):374-383, at 375; Yoonseo Mok, MPH, et al., *Associations between e-cigarette use and e-cigarette flavors with cigarette smoking quit attempts and quit success: Evidence from a US large, nationally representative 2018-2019 survey*, NICOTINE AND TOBACCO RESEARCH, at 5 (2022) ("Mok, *et al.*").

[14] J. Hartmann-Boyce, *et al.*, *Electronic cigarettes for smoking cessation (Review)*, Cochrane Database of Systematic Reviews, Abstract (no free access) (2022), https://tinyurl.com/22jbyw52.

[15] *Id.*

[16] *Id.*

smokers.[17] The Cochrane Review concluded there is "moderate-certainty evidence that [ENDS products with nicotine] increase quit rates compared to [ENDS products] without nicotine."[18]

The latest research also places into serious question the wisdom of FDA preventing adult access to non-tobacco flavored ENDS products, which are increasingly recognized as a key factor in enhancing adult smokers' ability to permanently quit cigarettes. For example, the greater efficacy of flavored ENDS products in supporting adult smoking cessation was explored in depth by a 2022 study funded in part by the National Institutes of Health[19]

Experts at the University of Minnesota conducted an extensive literature review of research from 2007 to 2020, including clinical studies.[20] Results from 104 of

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[17] *Id.*

[18] *Id.*; *see also*, *e.g.*, NAS, *supra* note 2, at 19 (finding "moderate evidence from randomized controlled trials that e-cigarettes with nicotine are more effective than e-cigarettes without nicotine for smoking cessation"); Mok, *et al.*, *supra* note 5, at 14 (data from nationally representative survey "clearly indicat[ing] that those who use e-cigarettes more intensely (at least 20 of the past 30-days) . . . have . . . a higher odds of making a quit attempt and of succeeding in quitting cigarette smoking"); Kasza, *et al.*, *Associations between nicotine vaping uptake and cigarette smoking cessation vary by smokers' plans to quit: longitudinal findings from the International Tobacco Control Four Country Smoking and Vaping Surveys*, ADDICTION 2022;1-13, at 1-2, 7 (finding smokers "not planning to quit in the next 6 months who started vaping daily experienced a 32% cigarette quit rate compared with a 7% quit rate among their counterparts who did not take up vaping").

[19] Gades, *et al.*, *The Role of Nicotine and Flavor in the Abuse Potential and Appeal of Electronic Cigarettes for Adult Current and Former Cigarette and Electronic Cigarette Users: A Systematic Review*, NICOTINE AND TOBACCO RESEARCH 2022:1332-1343.

[20] *Id.* at 1332.

those studies suggested that access to a variety of non-tobacco flavors is likely to be associated with higher use levels and appeal for cigarette smokers, and that flavor variety "might facilitate complete substitution for cigarettes."[21] Accordingly, the researchers warned:

> [r]egulation of . . . flavors aimed at decreasing naïve uptake may inadvertently decrease uptake and complete switching among smokers, reducing the harm reduction potential of e-cigarettes. FDA must consider the evidence-based effects of regulating flavors as to the population as a whole, including smokers.[22]

FDA knows all of this, but these scientific facts do not conform to its agenda.

II. FDA ADOPTED A UNIFORM STRATEGY OF DENYING MARKETING AUTHORITY FOR MILLIONS OF NON-TOBACCO FLAVORED ENDS PRODUCTS.

Congress initially applied the TCA solely to cigarettes, smokeless tobacco, roll-your-own tobacco,

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[21] *Id.* at 1332, 1339.

[22] *Id.* at 1332; *see also*, *e.g.*, Robyn L. Landry, *et al.*, *The role of flavors in vaping initiation and satisfaction among U.S. adults*, ADDICT. BEHAV. 2019 Dec;99:106077, at 14, https://tinyurl.com/24j47x8c (survey of over 1,000 adult vapors showing "[t]hose who used flavors, particularly mint/menthol and flavors other than tobacco flavor, had higher odds of reporting high satisfaction with vaping . . . than respondents who did not use flavored e-cigarettes."); Lin Li, Ph.D., *et al.*, *How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys*, NICOTINE AND TOBACCO RESEARCH 2021:1490-1497, at 1490-91, 1494 (survey of concurrent (or dual) users of cigarettes and ENDS finding that the greatest success in quitting occurred among adult smokers using sweet-flavored ENDS (13.8%) relative to tobacco-flavored ENDS (9.6%)).

and cigarette tobacco and authorized FDA to "deem" additional tobacco products via rulemaking.[23] FDA's "Deeming Rule" went into effect in August 2016, and applied the TCA to ENDS products.[24]

Tens of thousands of ENDS products were already on the market at the time.[25] The Deeming Rule subjected them to numerous TCA provisions, including a requirement of obtaining premarket authorization before continuing to market their products.[26] Each PMTA entails a time-consuming and costly process (often totaling millions of dollars per product) of compiling extensive scientific, technical, and marketing data that FDA must review when considering market authorization.[27]

To avoid a sudden, mass market exodus, FDA adopted an enforcement policy which permitted existing ENDS products to remain on the market upon a timely-filed PMTA while it was under FDA review. Initially, the Deeming Rule set an August 8, 2018

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[23] 21 U.S.C. § 387a(b). *Amici* question the constitutionality of this delegation of deeming authority given the Court's holding in *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120 (2000) that the regulation of tobacco products was a "major question" which only Congress could answer. If regulating tobacco products was a major question, so too was the identification of the products to be regulated. *Brown & Williamson* constrained Congress from delegating authority to identify which tobacco products would be subject to the TCA.

[24] 81 FED. REG. 28,974 (May 10, 2016).

[25] *Vapor Tech. Ass'n v. FDA*, 977 F.3d 496, 498 (6th Cir. 2020).

[26] 21 U.S.C. § 387j. Under the TCA, ENDS are subject to the PMTA requirement because they are "new" tobacco products – *i.e.*, they were introduced into the marketplace after February 15, 2007, and therefore were not grandfathered from the PMTA process, as were more dangerous cigarettes that had been commercialized prior to that date. 21 U.S.C. § 387j(a).

[27] 21 U.S.C. § 387j(b)-(c).

PMTA filing deadline.[28] In August 2017, FDA extended the PMTA deadline to August 8, 2022.[29] A Maryland federal court eventually set the deadline as September 9, 2020, in response to a lawsuit by anti-vaping groups but allowed products with timely PMTAs to remain on the market for an additional year pending review without the threat of enforcement.[30]

FDA initially anticipated receiving less than 3,000 PMTAs.[31] Although FDA upwardly increased that expectation,[32] ENDS product manufacturers eventually submitted PMTAs covering some *26 million products*.[33] Mitch Zeller, then-Director of FDA's Center for Tobacco Products (CTP), admitted in February

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[28] 81 FED. REG. at 28,978. This date was logically tied to the number of PMTAs (no more than 2,500) that FDA expected to receive.

[29] FDA News Release, *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death* (Jul. 27, 2017), https://tinyurl.com/vrubw8tz; FDA, *Modifications to Compliance Policy for Certain Deemed Tobacco Products* (Mar. 2019), https://tinyurl.com/vr6ph8.

[30] *Am. Academy of Pediatrics v. FDA* (*AAP*), 8:18-cv-00883-PWG (D. Md.) (Dkt. 127 & 182).

[31] FDA, *Final Regulatory Impact Analysis Final Regulatory Flexibility Analysis Unfunded Mandates Reform Act Analysis*, p. 48 (May 2016).
https://www.fda.gov/media/97875/download

[32] *AAP*, Dkt. 120-1 at 15 (Declaration of Mitch Zeller, Director, FDA Center for Tobacco Products).

[33] FDA, *FDA Makes Determinations On More Than 99% of the 26 Million Tobacco Products For Which Applications Were Submitted* (Mar. 15, 2023), https://tinyurl.com/3spczmy5. This figure includes PMTAs for 6.7 million products filed by September 9, 2020, applications for more than 18 million products received after that deadline, and PMTAs for another 1 million products covering e-liquids made with non-tobacco derived nicotine (or synthetic nicotine) that were filed by a May 14, 2022 PMTA deadline established by a new federal law (Consolidated Appropriations Act of 2022) passed in April 2022, which added such products to coverage under the TCA. *Id.*

2021 these unexpectedly large numbers would present review "challenges" due to the "size, complexity and diversity" of the PMTAs.[34] Since mid-2021, while FDA has made determinations on 99% of these PMTAs,[35] it has issued Marketing Granted Orders (MGOs) for only 31 products, but none for non-tobacco flavored ENDS products.[36] In contrast, FDA has issued Marketing Denial Orders (MDOs) for over 1.2 million products, almost all of which were for non-tobacco flavored products.[37] Just in its initial release of MDOs in August 2021, FDA denied applications *en masse* for about 55,000 non-tobacco flavored ENDS products.[38] And a few weeks later, FDA announced it had resolved applications for 6.5 million products subject to timely filed PMTAs, including MDOs issued for 946,000 non-tobacco flavored ENDS products based on its aforementioned "fatal flaw" approach.[39]

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[34] *Bidi Vapor LLC v. FDA*, 21-13340 (11th Cir.) (Public Statement of Mitch Zeller) (Dkt. 40 at FDA-BIDIVAPOR-005261-62).

[35] *Supra* note 25.

[36] Brian King, Ph.D, MPH, Director, FDA Center for Tobacco Products, *Director's Update: Center For Tobacco Products* (FDLI Presentation) (May 18, 2023), at 15.

[37] *Id*. The remaining 25 million determinations constituted refusals to accept or file incomplete or otherwise non-compliant PMTAs based on an initial screening process. *Id*.

[38] FDA, News Release: *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health* (Aug. 26, 2021), https://tinyurl.com/n9c9rwu8.

[39] FDA, News 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), https://tinyurl.com/24kmkdnb.

III. THE TCA'S CLEAR TEXT, CONTEXT, AND STRUCTURE REQUIRE FDA TO CONDUCT A FULL SCIENTIFIC REVIEW OF EACH PMTA: A PROCESS IT CANNOT SHORT-CUT

The TCA's plain text requires that FDA conduct a complex, science-based evaluation of each PMTA based on *all* its contents to determine whether a product satisfies the APPH standard. Once FDA receives a complete PMTA, it must do more than a cursory evaluation; it must review and assess the entirety of the PMTA's contents.

The TCA explicitly provides that a PMTA shall only be denied if "*upon the basis of the information submitted* to [FDA] . . . and any other information before [FDA]" the product is not APPH.[40] The TCA broadly defines APPH with respect to "the risks and benefits to the population *as a whole*," including "users and nonusers of the tobacco product."[41] In this context, the TCA enumerates numerous forms of evidence that a PMTA must contain, including data on health risks, ingredient and additive information, product design, manufacturing practices, product samples, labeling specimens, and any other information required by FDA.[42] The TCA also obligates FDA to evaluate, *inter alia*, whether ENDS products will help people quit other tobacco products (cessation) or compel them to start (initiation).[43]

More specifically, the TCA says FDA must consider the *whole* population, including adult smokers and underage non-smokers, but also adult non-smokers and underage smokers. FDA must also

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[40] 21 U.S.C. § 387j(c)(2) (emphasis added).

[41] 21 U.S.C. § 387j(c)(4) (emphasis added).

[42] 21 U.S.C. § 387j(b)(1).

[43] 21 U.S.C. § 387j(c)(4).

gauge not only the relative cessation benefits to adult smokers, but all other *risks and benefits* of a given product. This includes health factors, such as the extent to which a product results in relatively less or more exposure to hazardous constituents.[44] The TCA also explicitly envisions that FDA consider the impact that restrictions on a product's sale or distribution could have on the APPH determination,[45] including constraints on product access, and advertising and marketing aimed at reducing underage use (*e.g.*, only allowing face-to-face transactions in adult-only facilities).[46]

All of this is consistent with Congress's choice to not employ any limiting words or terms in the plain text of the APPH standard. Rather, it used the word "appropriate" – "the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors."[47] Indeed, nowhere in the TCA did Congress authorize FDA to make an APPH determination on something less than a complete evaluation of each PMTA.[48]

Finally, the PMTA provisions comport with one of the TCA's underlying purposes – to boost harm reduction efforts. Congress sought to protect underage

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[44] *See*, *e.g.*, 21 U.S.C. § 387g(a)(4) (defining APPH in context of tobacco control standards as including reduction or elimination of harmful constituents).

[45] 21 U.S.C. § 387j(c)(1)(B).

[46] *Id.* (referencing examples of restrictions identified in 21 U.S.C. § 387f(d)).

[47] *Michigan v. EPA*, 576 U.S. 743, 752 (2015) (citation omitted).

[48] *City of Arlington v. FCC*, 569 U.S. 290, 321-22 (2013) (Roberts, C.J., dissenting) ("An agency interpretation warrants deference only if Congress has delegated authority to definitively interpret a particular ambiguity in a particular manner.").

consumers,[49] but also required FDA to "provide new and flexible enforcement authority to ensure effective oversight of the development, introduction, and promotion of less harmful tobacco products."[50] FDA also must "continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers,"[51] and must "promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases."[52]

Given the TCA's plain text, structure, and context, FDA has traditionally demanded that each PMTA go through a full scientific review. For example, FDA has described the APPH standard as a "complex determination" that "considers many factors," as "multi-disciplinary," and one that is not based on a "determination [of] one static set of requirements."[53] In other words, the APPH standard is a relative concept which requires that FDA must "balance" all risks and benefits of a given product.[54] Indeed, FDA has requested that PMTAs include numerous types of information considered relevant to an APPH finding, including underage sales restrictions, label warnings, health risk studies, pharmacological and toxicological testing, public literature reviews, pharmacokinetic

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[49] 21 U.S.C. § 387 note (2) (Sec. 3. Purpose).

[50] *Id.* at note (4).

[51] *Id.* at note (7).

[52] *Id.* at note (9).

[53] 86 FED. REG. 55,300, at 55,314, 55,335 (Oct. 5, 2021) (final PMTA rule); *Lotus* Dkt. 12 at LOTUS-FDA 2 4585-86 (transcript from Oct. 2019 public meeting).

[54] LOTUS-FDA 2-000075; *see* 86 FED. REG. at 55,384.

evaluations, and consumer perception and intention studies.[55]

Accordingly, FDA has committed to evaluating PMTAs on an "individualized" basis: the "risks and benefits of a *specific* tobacco product," and most importantly "*all* of the contents of the application."[56] Yet, the Reagan-Udall Foundation's landmark 2022 report noted a "lack of clarity, transparency, and communication" regarding FDA's application of APPH, "extend[ing] to questions about how [FDA] intends to balance individual risk/benefit against population risk/benefit" as it pertains to how FDA "will weigh concerns about youth uptake of nicotine products against the harm-reduction potential of noncombustible tobacco products."[57] FDA has not resolved these questions.

IV. FDA INTERPRETS THE TCA AS NOT REQUIRING A FULL SCIENTIFIC REVIEW BUT ALLOWING IT TO MAKE MARKETING DECISIONS BASED ON THE MERE ABSENCE OF ONE TYPE OF SPECIFIC EVIDENCE

Unfortunately, FDA has not adhered to the TCA. Despite clear statutory language, FDA proceeded to issue cookie-cutter MDOs for millions of non-tobacco flavored ENDS products, including those of Lotus, without conducting a full scientific review. Rather,

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[55] *Id. at* 1-004422, -4433, -004438-39, -004444-45, 004448-50 (FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry* (Jun. 2019)); *see* 86 FED. REG. at 55,414-32 (21 C.F.R. § 1114.7 listing of extensive information and data requested for PMTAs).

[56] 86 FED. REG. at 55,320, 55,390 (emphasis added); *see* LOTUS-FDA 2-004504 (FDA "weighs all of the potential benefits and risks from information contained in the PMTA . . . .").

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

FDA denied marketing authorization for every non-tobacco flavored ENDS product for the same reason – their failure to include a single, highly-specific study designed to elicit a discrete datapoint in which the cessation benefits of the applicant's non-tobacco flavored ENDS products were compared to its tobacco-flavored products (colloquially its "comparative efficacy" test).[58] Confusingly, FDA required this showing after the fact and without ever articulating how effective a flavored ENDS product must be to pass muster. This violates the ascertainable standards requirement set forth in *Screws v. U.S.*, 325 U.S. 91 (1945), and means any efficacy determination is *per se* arbitrary.

FDA informed applicants like Lotus their products were not APPH because the absence of this distinct evidence meant their PMTAs could not demonstrate a necessary added benefit to smokers of using non-tobacco flavored ENDS products sufficient to outweigh their risks to underage users.[59] Significantly, the MDOs stated that FDA did not proceed to assess any other part of the applications once it noted the absence of a comparative efficacy study that FDA had never previously requested.[60]

In fact, FDA's review consisted of nothing more than a literal box-checking exercise: FDA staff merely completed a check-list indicating whether Lotus's PMTA included a randomized controlled trial, longitudinal cohort study, or other similarly robust evidence evaluating the impact of non-tobacco flavored ENDS products on adult switching or cigarette reduction over time compared to its tobacco flavored

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[58] *See*, *e.g.*, *Lotus* Dkt. 12 at LOTUS-FDA 1-000022-324 (MDO example).

[59] *Id.*

[60] *Id.* at 1-000023.

products.[61] FDA did not move to a "full scientific review" because such evidence was absent.[62]

Further, the Lotus MDO and accompanying checklist tracked an approach outlined by FDA's July 9, 2021 internal document which articulated its aforementioned "fatal flaw" review: PMTAs for non-tobacco flavored products not containing a comparative efficacy study would be denied.[63] FDA implemented this "simple" review in lieu of the TCA's required full scientific review.[64] Tellingly, the stated goal of the fatal flaw memo placed expediency over substance by allowing FDA to "manage" the large number of PMTAs and "take final action on as many as possible" by the end of the grace period.[65] FDA initiated this process by issuing MDOs for 55,000 products in one day.[66] This turned the APPH standard on its ear.

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[61] *See*, *e.g.*, *id.* at 1-000061-64 (checklist example).

[62] *Id.* at 1-000063.

[63] *Id.* at 2-005144-45.

[64] *Id.* at 2-005145.

[65] *Id.* at 2-005144.

[66] *Supra* note 30. In ensuing litigation over the MDOs, FDA has argued the "fatal flaw" memo was "Superseded." *See*, *e.g.*, *Lotus* Dkt. 12 at LOTUS-FDA 2-005144 - 005155. Regardless, FDA clearly implemented an across-the-board, fatal flaw approach for non-tobacco flavored products in which an MDO would issue if a PMTA did not contain any study or other evidence going to a comparative efficacy test. *See R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 193 n.9 (5th Cir. 2023) (noting the checklists followed the fatal flaw memorandum). Along with each MDO, FDA also issued a document titled "Technical Project Lead (TPL) Review of PMTAs" that sought to justify the fatal flaw and comparative efficacy approach. *See* FDA, Tobacco Products Marketing Orders: FDA Sample Decision Summary Document, https://tinyurl.com/npn2x4ec. The TPLs, however, at no point reviewed all the evidence contained in a given PMTA aside from confirming whether a comparative efficacy analysis was conducted. *Id.* at 11. For example, despite conceding that the efficacy of a manufacturer's access and marketing restrictions

Indeed, at no time before FDA issued those initial MDOs did it warn manufacturers they must conduct a comparative efficacy study, let alone indicate its absence would prevent a PMTA from receiving a full substantive, scientific review and, instead, *automatically* result in a marketing denial. Such failure was an integral element of the Fifth Circuit's *en banc* ruling in *Wages* that fully rejected the manner in which FDA imposed its comparative efficacy requirement and held the agency acted arbitrarily and capriciously when utilizing a "fatal flaw" approach in lieu of a full review. 90 F.4th at 388.

V. FDA'S MARKETING DECISIONS HAVE BEEN THE RESULT OF UNDUE POLITICAL INFLUENCE.

The Fifth Circuit's *en banc* opinion in *Wages* was a scathing indictment of FDA's flawed PMTA review process. That opinion explained what happened but did not explain why it happened. Understanding the latter requires the Court to consider the unabashed political meddling which tainted the legitimacy of FDA's PMTA process. This undue political influence explains why FDA wholly ignored both the settled science, including studies which it funded, and the repeated public affirmations of FDA's key leadership.

This Court held in *Dep't of Com. v. New York,* 588 U.S. ____, 139 S. Ct. 2551, 2573 (2019) that:

> a court may not set aside an *agency*'s policymaking decision solely because it might have been *influenced* by *political*

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aimed at reducing underage use could be "critical" to an APPH determination, FDA admitted that "for the sake of efficiency" it had "not evaluated any marketing plans submitted with these applications." *Id.* at 11 n.xix. *See Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1195 (11th Cir. 2022) (holding failure to consider marketing plans was arbitrary and capricious) and *Wages*, 90 F.4th at 388 (same).

> considerations or prompted by an Administration's priorities.

Political pressure, however, invalidates an agency action "when it shapes, in whole or in part, the judgment of the ultimate agency decisionmaker." *Aera Energy LLC v. Salazar*, 642 F.3d 212, 220 (D.C. Cir. 2011).

The test of undue influence is whether "extraneous pressure intruded into the [agency's] calculus of consideration." *D.C. Federation of Civic Ass'ns v. Volpe*, 459 F.2d 1231, 1246 (D.C. Cir. 1971) (House subcommittee chair threatened to withhold funding for one project unless the agency proceeded with another.). This inquiry looks for a "nexus between the pressure and the actual decision maker." *Aera Energy* at 219, citing *ATX, Inc. v. U.S. Department of Transportation*, 41 F.3d 1522, 1528 (D.C. Cir. 1994).

The nexus between the undue political pressure of congressional leaders and FDA's review process requires consideration of how the marketing decisions of the agency's leadership have contradicted their public affirmations about the public health benefits of ENDS products. For instance, FDA's former CTP Director opined in 2014 that it "would be good for public health" if adult smokers "completely switch all of their cigarettes" to an ENDS.[67] FDA's then-Commissioner concurred in 2018[68] and current CTP Director still concurs.[69]

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[67] FDA, Statement of Mitchell Zeller, "*Progress and Challenges: The State of Tobacco Use and Regulation in the U.S.*" at 1:59:00, (May 14, 2014).

[68] C-SPAN, FDA Commissioner on E-Cigarettes and Public Health Concerns, at 10:25, (Sept. 25, 2018).

[69] Perrone, M., *Insider Q&A: FDA official on vaping's "promise or peril,"* The Associated Press, (Sept. 26, 2022).

Painted against these public proclamations, the nexus of undue political influence is evidenced by how the timing of pressure by key congressional leaders aligns precisely with FDA's issuance of key ENDS marketing decisions. By June 2021, FDA had yet to adjudicate any of the more than 6.5 million PMTAs then pending. On June 23, 2021, a House oversight subcommittee grilled FDA's then-Acting Commissioner about the failure to adjudicate these PMTAs.[70] FDA responded by creating its fatal flaw review process, discussed *supra*., which allowed the immediate disqualification of several million PMTAs simply for lacking the newly required comparative efficacy studies.

Moving forward to mid-2022, FDA had yet to adjudicate the marketing applications submitted by Juul Labs, Inc., the industry's largest market share manufacturer. On June 22, 2022, Senator Richard Durbin issued a public statement demanding that FDA's Commissioner either resign or the agency deny market authorization for all remaining ENDS products.[71] Representative Raja Krishnamoorthi, the House subcommittee chair, also had contemporaneous back-channel discussions with FDA's Commissioner on the subject:

> [s]o I am so heartened that the FDA, after I and my office, actually had a long conversation with the FDA

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[70] *An Epidemic Continues: Youth Vaping in America:* Hearing before Subcomm. of H. Comm. on Oversight and Reform, 117th Cong., Jun. 23, 2021.

[71] U.S. Senate, Statement of Sen. Dick Durbin, *Durbin Investigation Finds More Than 750,000 Kids Have Picked Up Vaping Since FDA's Missed Deadline to Regulate E-Cigarettes*, Jun. 22, 2022. https://www.durbin.senate.gov/newsroom/press-releases/durbin-investigation-finds-more-than-750000-kids-have-picked-up-vaping-since-fdas-missed-deadline-to-regulate-e-cigarettes

> commissioner about this, finally decided to stop Juul from issuing these.[72]

On cue, FDA issued a marketing denial order with respect to the Juul products the next day.[73]

In fact, key political leaders have not been bashful about their influence. The day after the Juul marketing denial, Representative Krishnamoorthi and Senator Durbin's senior aide participated in a virtual victory lap with members of the anti-vaping group *Parents Against Vaping E-Cigarettes*[74] during which the former cavalierly boasted about his close alliance with FDA.[75] Senator Durbin's assault on ENDS products did not stop there. In September 2022, he again pressured both FDA's Commissioner and CTP's Director.[76] The latter intervened thereafter to overrule the FDA Office of Science's conclusion that scientific review showed Logic Technology's menthol ENDS products were appropriate for marketing.[77]

This political assault has not subsided. On January 10, 2024, Senator Durbin admitted on the Senate floor that FDA's Commissioner, Dr. Robert Califf, promised in advance of his confirmation vote

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[72] Parents Against Vaping E-Cigarettes, *An Update from Congressional Champions on FDA's Decision to Order JUUL Off the Market*, June 24, 2022, at 7:10. https://www.dropbox.com/s/k2j1x97ha3yd1ao/pavepmp4.mp4?dl=0

[73] *See Juul Labs, Inc. v. FDA*, Document #1951837, D.C. Cir. No. 22-1123 (Jun. 23, 2022).

[74] Parents Against Vaping E-Cigarettes, at 7:10.

[75] *Id*., at 7:46.

[76] Office of Senator Dick Durbin, *Durbin Meets with New Director of FDA's Center for Tobacco Products*, (Sept. 29, 2022).

[77] *See Logic Technology Development LLC v. FDA*, No. 22-3030 (3rd Cir) at ECF #34-2, p. 2-3 and ECF #34-3, at 3, filed Dec. 12, 2022.

that he would take on the "vaping interests," and concluded the Commissioner should be replaced if FDA does not regulate the way the Senator desires.[78] As if again on cue, FDA issued an MDO on January 16, 2024, to Shenzhen IVPS Technology Co., Ltd. for its SMOK-branded ENDS devices.[79]

Aera Energy holds that:

> [c]ourts reviewing agency decisions involving political interference must be attuned to the heightened possibility that political influence will have caused agencies to cut corners.

642 F.3d at 219. *Wages* cited this Court's ruling in *Niz-Chavez v. Garland,* 593 U.S. 155, 172 (2021), for the proposition that agencies must turn square corners when dealing with regulated parties and held that FDA's multiple "regulatory switcheroos" bore "no resemblance to square corners." 90 F.4th at 362-63. FDA's corner cutting discussed in *Wages* was the result of the same undue political influence which motivated the corner cutting here.

Representative Krishnamoorthi's declaration that FDA's Commissioner is an ally to the anti-vaping cause and the continued haranguing by Senator Durbin establish a clear nexus to FDA's marketing decisions. Congress should legislate more and delegate less. It should not delegate regulatory authority and then attempt to micromanage how agencies regulate.

FDA is not a congressional tinker toy and any lack of detachment and neutrality must ultimately impact the extent of discretion which any Court affords FDA's

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[78] 170 CONG. REC. No. 5 at S53-54 (Jan. 10, 2024) (statement of Sen. Durbin).

[79] FDA, *FDA Denies Marketing of SMOK E-Cigarette Products* (Jan. 16, 2024).

marketing decisions. In this respect, the Fifth Circuit got it right in *Wages* and the Ninth Circuit got it wrong in this case. This Court should grant review and concur with the Fifth Circuit's analysis.

CONCLUSION

Based on the foregoing, *amici* ask that this Court grant the Petitioner's Petition for Writ of Certiorari.

March 14, 2024

Respectfully submitted,

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APPENDIX

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LIST OF *AMICI CURIAE*

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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.

LOUISIANA VAPING ASSOCIATION, INC.

MARYLAND VAPOR ALLIANCE

MICHIGAN VAPE SHOP OWNERS, INC.

MIDWEST VAPE COALITION, INC.

MINNESOTA SMOKE FREE ALLIANCE

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.

SMOKE FREE ALTERNATIVES COALITION OF ILLINOIS, INC.

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.