No. 22-451

In the Supreme Court of the United States

LOPER BRIGHT ENTERPRISES, ET AL.,

Petitioners,

v.

GINA RAIMONDO, IN HER OFFICIAL CAPACITY AS SECRETARY OF COMMERCE, ET AL.,

Respondents.

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

BRIEF OF ELECTRONIC NICOTINE DELIVERY SYSTEM INDUSTRY STAKEHOLDERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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GLOSSARY

ANPRM	Advanced Notice of Proposed Rulemaking
APPH	Appropriate for the Protection of the Public Health
ENDS	Electronic Nicotine Delivery Systems
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
FDCA	Food, Drug and Cosmetic Act
MDO	Marketing Denial Order
MGO	Marketing Granted Order
NAS	National Academies of Sciences
PMTA	Premarket Tobacco Product Application
TCA	Family Smoking Prevention and Tobacco Control Act
TPL	Technical Project Lead

INTERESTS OF *AMICI CURIAE*

Amici are national and state trade associations, as well as small businesses, who represent manufacturers, distributors, and retailers of Electronic Nicotine Delivery Systems ("ENDS") (commonly known as "e-cigarettes").[1] Millions of addicted smokers in the U.S. have used ENDS to transition away from more dangerous traditional cigarettes. Indeed, many of these companies were started by individuals who themselves relied on ENDS to successfully move on from their own smoking habits. *Amici* therefore share a common mission in advocating for a reasonably regulated marketplace that gives consumers access to less risky tobacco products.

Amici also have a substantial interest in this litigation and, in particular, how *Chevron* deference is applied by lower courts going forward. Over the past several years, they have watched with great alarm as 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. What is worse, the majority of circuit courts considering challenges to FDA's universal denials of premarket applications

[1] This brief was not authored in whole or in part by counsel for any of the parties; no party or party's counsel contributed money for preparing or submitting this brief; and no one other than *amici* and their counsel have contributed money for preparing or submitting this brief. *Amici* are listed in the attached appendix.

for such products have afforded FDA extreme deference in rubber-stamping a regulatory approach not reflected in the TCA itself.

Amici are understandably concerned that courts have abdicated their constitutional oversight role when reviewing how FDA has both interpreted and implemented the TCA's premarket application provisions. In this brief, *Amici* thus reflect on their experiences with *Chevron* deference and how it has adversely impacted this industry and the addicted adult smokers it serves, and recommend some important course corrections aimed at restoring the proper role of federal courts in reviewing agency action.

SUMMARY OF ARGUMENT

In the TCA, Congress granted FDA authority to ensure addicted, adult cigarette smokers in this country have access to lower risk tobacco products to help them move away from more dangerous, combustible cigarettes. ENDS are now firmly recognized by the scientific community as a risk reduction tool for cigarette smokers.

Under the TCA, ENDS manufacturers must submit to FDA premarket tobacco product applications ("PMTAs") to obtain marketing authorization for their products. FDA is required by the statute's plain language to then evaluate all information and data submitted by a manufacturer when determining whether a given product is "appropriate for the protection of the public health" ("APPH"). Significantly, 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 product.

For example, part of the APPH process involves ensuring ENDS do not appeal to minors, and that youth access and marketing are restricted. But any concerns about youth (under 21 years-old) use must be balanced against all other evidence contained in the PMTA warranting a grant of marketing authorization. Before FDA ever received a PMTA, Congress had already made a policy choice, in creating its first ever *population-level* health standard, that only through a complete review of a PMTA would FDA be able to fairly account for all stakeholder interests involved. 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 has swung the pendulum far to one side, in effect banning all non-tobacco flavored (*e.g.*, mint and fruit) ENDS products, and in the process focusing its attention largely on underage use at the expense of adult smokers. FDA implemented this *de facto* ban not by asking Congress to amend the TCA or by promulgating a tobacco product standard via public notice and comment rulemaking, as required by 21 U.S.C. § 387g(c), but rather through a statutory interpretation that is not grounded in the TCA's text, structure, and context.

Specifically, FDA adopted a new strategy following a deluge of PMTAs filed prior to a court-imposed deadline – what FDA described in an internal memo as the "fatal flaw" approach – expressly designed to quickly deny marketing authorization for as many non-tobacco flavored ENDS as possible. Although FDA had told manufacturers it would conduct a full scientific review of each PMTA, agency staff were suddenly ordered to engage in a simple box-checking exercise and issue a marketing denial if the PMTA merely failed to contain a single study comparing the cessation benefits of the manufacturer's tobacco and non-tobacco flavored ENDS. Needless to say, FDA's interpretation – concluding it could base a marketing denial solely on the absence of one piece of evidence – did not accurately reflect Congress's intent.

In a world where *Chevron* deference is routinely doled out by lower courts, it is no surprise FDA has pushed its interpretation of the TCA to one extreme. Indeed, the majority of circuit courts hearing challenges to these marketing denials have upheld the "fatal flaw" approach. *Chevron* signals to agencies they are free to find whatever statutory ambiguity is needed to justify a particular outcome and courts will defer even to those interpretations that land well beyond any common sense reading of a statute. This deference also paves the way for agencies to achieve what they could not accomplish except through constitutional means, such as a statutory amendment or agency rulemaking. And it creates

an environment where agencies can suddenly change their view of a statute, knowing its new interpretation, or even another one after that, does not need to be any better than the prior one, thus leaving regulated entities to constantly wonder where the agency actually stands.

With the *Loper* matter, this Court now has an opportunity to confirm that *Chevron* deference should be applied in only limited circumstances – it should be the exception not the rule. *Amici* request this Court clarify that lower courts under *Chevron*: (i) should prioritize traditional rules of statutory construction, following a statute's plain language, structure, and context; (ii) reserve deference for those instances when a statute is "genuinely ambiguous" and after well-established rules of statutory interpretation fail to discern Congress's intent; and (iii) afford no deference where there are indications Congress never intended to delegate interpretative authority, such as when the question at hand does not implicate agency expertise. While this is not intended to be an exhaustive list of the types of limitations on *Chevron* deference that might be imposed by the Court, they represent a necessary start.

ARGUMENT

I. Non-Tobacco Flavored ENDS Present Less Risk Than Cigarettes And Are Effective In Helping Transition Adult Smokers

It is now well-established ENDS pose far less health risk than traditional cigarettes. For instance, 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.[2] 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."[3] This is because ENDS do not burn tobacco leaf or even contain tobacco, and there is no combustion or smoke. Rather, the aerosol produced by an ENDS is created by heating and vaporizing an e-liquid solution. Not surprisingly, NAS concluded the "evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes."[4]

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

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

[4] *Id.* at 11. FDA agrees. 81 Fed. Reg. 28974, 29030 (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

Most adult ENDS users in this country are also either current or former smokers, with many of these individuals turning to ENDS to reduce or completely quit their smoking habits. [5] Recent studies validate these efforts, with a Cochrane Systematic Review being particularly instructive.[6] A group of university researchers from the United States and around the world reviewed 78 completed studies, including randomized controlled trials and cross-over trials, which investigated whether ENDS help adults stop smoking. [7] They concluded based on relevant studies that "people are more likely to stop smoking for at least six months using nicotine e-cigarettes than using…e-cigarettes without nicotine..."[8] In terms of the number of individuals, "this might lead to an additional seven quitters per 100."[9] As such, based on these studies, there is

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tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products.").

[5] 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.").

[6] 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.

[7] *Id.*

[8] *Id.*

[9] *Id.*

"moderate-certainty evidence that [ENDS with nicotine] increase quit rates compared to [ENDS] without nicotine."[10]

The latest research also places into serious question the wisdom of preventing adult access to non-tobacco flavored ENDS which are increasingly recognized as a key factor in enhancing adult smokers' ability to quit combustible cigarettes for good. For example, the greater efficacy of flavored ENDS in supporting adult smokers quitting combustible cigarettes was explored in depth by Gades, *et al.* Experts at the University of Minnesota conducted an extensive literature review of research, including clinical studies, from 2007 to 2020.[11] Results from 104 of those studies

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[10] *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"); Karin A. 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").

[11] Mari S. Gades BA, et al., *The Role of Nicotine and Flavor in the Abuse Potential and Appeal of Electronic Cigarettes for Adult Current and Former Cigarette and*

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." [12] 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. Evidence-based effects of regulating…flavors must be considered for the population as a whole, including smokers."[13]

Electronic Cigarette Users: A Systematic Review, NICOTINE AND TOBACCO RESEARCH 2022:1332-1343, at 1332.

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

[13] *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%)).

II. FDA Received PMTAs Covering Millions Of Flavored ENDS Products, But Adopted An Across-The-Board Strategy Of Denying Marketing Authority For All Non-Tobacco Flavored ENDS

Congress enacted the TCA in 2009.[14] While the statute initially applied to only four listed tobacco products (*i.e.*, cigarettes, smokeless tobacco, roll-your-own tobacco, and cigarette tobacco), Congress authorized FDA to "deem" additional tobacco products as subject to the TCA via rulemaking.[15] In August 2016, FDA's "Deeming Rule" went into effect, which applied the TCA to ENDS.[16]

At the time, tens of thousands of ENDS products were already on the market.[17] Under the Deeming Rule, these ENDS, and those introduced into the marketplace in the future, were immediately subject to numerous TCA provisions, including a requirement that manufacturers obtain premarket authorization from FDA before continuing to market and sell their products.[18] A

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[14] 21 U.S.C. § 387, *et seq*.

[15] 21 U.S.C. § 387a(b).

[16] 81 Fed. Reg. 28974 (May 10, 2016).

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

[18] 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).

manufacturer must submit a PMTA which 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 before granting or denying market authorization.[19]

To avoid a sudden, mass market exit of ENDS products, FDA adopted an enforcement policy which permitted existing ENDS to remain on the market for up to a year after a timely filed PMTA. Initially, the Deeming Rule set an August 8, 2018 PMTA filing deadline.[20] FDA said this balanced concerns regarding underage use and providing access to products adult smokers may be using to move away from more dangerous cigarettes.[21] Over the ensuing years, FDA extended the PMTA deadline, finally landing on August 8, 2021.[22] But in response to a lawsuit filed by anti-vaping groups, a federal judge in Maryland eventually moved the due date back to September 9, 2020 and allowed products with timely filed applications to remain on the market for an additional year (or

[19] 21 U.S.C. § 387j(b)-(c).

[20] 81 Fed. Reg. at 28978.

[21] *Id.* at 28977-78.

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

until September 2021) without the threat of enforcement.[23]

Although FDA anticipated it would receive less than 6,800 PMTAs,[24] applications covering *26 million products* were eventually submitted.[25] Mitch Zeller, then-Director of FDA's Center for Tobacco Products, admitted in February 2021 that these unexpectedly large numbers would present review "challenges" for FDA due to the "size, complexity and diversity" of the PMTAs.[26] Since mid-2021, while FDA has made determinations on 99% of these PMTAs,[27] it has issued Marketing Granted Orders ("MGOs") for only 31 products, none of which were for non-tobacco flavored

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

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

[25] FDA, *FDA Makes Determinations On More Than 99% of the 26 Million Tobacco Products For Which Applications Were Submitted* (March 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.*

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

[27] *Supra* note 25.

ENDS.[28] In contrast, FDA has issued Marketing Denial Orders ("MDOs") for over 1.2 million products, almost all of which were for non-tobacco flavored ENDS.[29] Just in its initial release of MDOs in August 2021, FDA denied applications *en masse* for about 55,000 non-tobacco flavored ENDS products.[30] 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 based on the "fatal flaw" approach.[31]

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[28] 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.

[29] *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*.

[30] 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.

[31] 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; FDA Cannot Short-Cut That Process

By its plain language, the TCA requires FDA to conduct a complex, science-based evaluation of each PMTA based on *all* contents in the application 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 application's contents in its entirety.

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.[32] The statute defines APPH in broad terms with respect to "the risks and benefits to the population *as a whole*," including "users and nonusers of the tobacco product."[33] In this context, the statute enumerates numerous forms of evidence that must be in any PMTA, including data on health risks, ingredient and additive information, product design, manufacturing practices, product samples, labeling specimens, and any other information required by FDA.[34] The TCA also obligates FDA to evaluate, among other things, whether an ENDS product will help people quit other tobacco

[32] 21 U.S.C. § 387j(c)(2) (emphasis added).
[33] 21 U.S.C. § 387j(c)(4) (emphasis added).
[34] 21 U.S.C. § 387j(b)(1).

products (*i.e.*, cessation) or compel them to start (*i.e.*, initiation).[35]

More specifically, when the TCA says FDA must consider the *whole* population, this includes not only adult smokers and underage non-smokers, but also any other demographics that might be impacted by a particular ENDS product (*e.g.*, adult non-smokers and underage cigarette smokers, etc.). FDA must also gauge not only the relative cessation benefits to adult smokers, but also all other *risks and benefits* of a given product, including health factors, such as the extent to which a product results in relatively less or more exposure to hazardous constituents.[36] The statute also explicitly envisions that FDA consider the impact that restrictions on the sale or distribution of a product could have on the APPH determination. [37] These include constraints on access to a given product, as well as advertising and marketing limitations, aimed at reducing underage use (*e.g.*, only allowing face-to-face transactions in adult-only facilities).[38]

All of this is consistent with Congress's choice of words in adopting the APPH standard itself. Congress did not employ any words or terms of limitation. Rather, it used the word "appropriate"

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[35] 21 U.S.C. § 387j(c)(4).

[36] *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).

[37] 21 U.S.C. § 387j(c)(1)(B).

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

– "the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors." [39] Further, common definitions of "public health" are broad and refer to protecting the "community" as a whole; they are not otherwise restricted to certain persons or population demographics. [40] Indeed, nowhere in the TCA is there any indication Congress authorized FDA to make an APPH determination on something less than a complete evaluation of each PMTA.[41]

Finally, the PMTA provisions comport with one of the underlying purposes of the statute – to boost harm reduction efforts. To be sure, Congress set out in the TCA, in part, to protect underage consumers.[42] But it also requires FDA 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." [43] FDA

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

[40] Merriam-Webster Dictionary, https://tinyurl.com/55p876pn ("the art and science dealing with the protection and improvement of community health"); American Heritage Dictionary, https://tinyurl.com/ywxdthby ("The science and practice of protecting and improving the health of a community").

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

[42] 21 U.S.C. § 387 note (2) (Sec. 3. Purpose).

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

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."[44] And FDA is to "promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases."[45]

Given the TCA's plain language, structure, and context, FDA has most often interpreted the PMTA provisions as demanding that each application 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."[46] In other words, the APPH standard is a relative concept and thus FDA must "balance" all risks and benefits of a given product.[47] Indeed, FDA has requested that PMTAs include numerous types of information and data considered relevant to an APPH finding, including underage sales restrictions, label warnings, health risk studies, toxicological and pharmacological testing, public literature reviews, pharmacokinetic evaluations, and consumer perception and intention studies. [48] Accordingly, FDA has

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

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

[46] 86 Fed. Reg. 55300, at 55314, 55335 (Oct. 5, 2021) (final PMTA rule); *Bidi* Dkt. 40 at FDA-BIDIVAPOR-004667-68 (transcript from Oct. 2019 public meeting).

[47] FDA-BIDIVAPOR-000070; *see* 86 Fed. Reg. at 55384.

[48] *Id. at* FDA-BIDIVAPOR-004504, -4515, -004520-21, -004526-27, 004530-32 (FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems:*

committed to evaluating products based on an "individualized" basis, the "risks and benefits of a *specific* tobacco product," and most importantly "*all* of the contents of the application."[49]

IV. FDA Interpreted The TCA As Allowing It To Forgo Any Full Scientific Reviews And, Instead, Uniformly Denied Marketing Authorization For All Non-Tobacco Flavored ENDS Based On The Mere Absence Of One Type Of Specific Evidence

Unfortunately, FDA did not adhere to the TCA. Despite the statute's clear language, FDA proceeded to issue cookie-cutter MDOs for over one million non-tobacco flavored ENDS products without conducting a full scientific review of each PMTA. Rather, FDA has denied marketing authorization for every non-tobacco flavored ENDS product for the same reason – because the PMTAs did not contain a single, highly-specific study designed to elicit a discrete datapoint in which the cessation benefits of the applicant's non-tobacco flavored ENDS were compared to the applicant's tobacco-flavored products (in what has become known as the "comparative efficacy"

Guidance for Industry (June 2019)); *see* 86 Fed. Reg. at 55414-32 (21 C.F.R. § 1114.7 listing of extensive information and data required for PMTAs).

[49] 86 Fed. Reg. at 55320, 55390 (emphasis added); *see Bidi* Dkt. 40 at FDA-BIDIVAPOR-004504 (FDA "weighs all of the potential benefits and risks from information contained in the PMTA…").

test).[50] Confusingly, FDA required this efficacy showing without ever specifying how effective an ENDS product must be to pass muster.

FDA informed applicants that, without this distinct evidence, the PMTAs could not demonstrate there would be an added benefit to smokers of using non-tobacco flavored ENDS sufficient to outweigh risks of such products to underage users, and thus the products were not APPH.[51] Significantly, the MDOs stated FDA did not proceed to assess any other part of the applications once it noted the absence of a comparative efficacy study.[52]

In fact, FDA's review of the PMTAs consisted of nothing more than a literal box-checking exercise. For each application, FDA staff completed a check-list indicating the PMTA did not include a randomized controlled trial, longitudinal cohort study, or other similarly robust evidence evaluating the impact of the manufacturer's non-tobacco flavored ENDS on adult switching or cigarette reduction over time compared to a tobacco flavored ENDS.[53] As with the MDOs, these checklists indicated FDA would only move to a "full scientific review" if such evidence was present.[54]

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[50] *See*, *e.g.*, *Bidi* Dkt. 40 at FDA-BIDIVAPOR-000031-33 (MDO example).

[51] *Id.*

[52] *Id.* at FDA-BIDIVAPOR-000032.

[53] *See*, *e.g.*, *id.* at FDA-BIDIVAPOR-000057-60 (checklist example).

[54] *Id.* at FDA-BIDIVAPOR-000059.

And that is not all. The MDOs and checklists tracked an approach outlined by FDA in an internal document distributed just a month before the first MDOs were issued. In a July 9, 2021 memo, FDA set forth what it called a "fatal flaw" review in which PMTAs for non-tobacco flavored products that did not contain a comparative efficacy study would likely be denied.[55] This "simple" review would be implemented in lieu of a full scientific review.[56] Tellingly, the stated goal of the fatal flaw memo placed expediency over substance by allowing FDA to "manage" the large number of PMTAs and to "take final action on as many applications as possible by September 10, 2021," when the year-long grace period for timely filed PMTAs ended.[57] FDA kicked this process off by issuing MDOs for 55,000 products in one fell swoop.[58] So much for the APPH standard.

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[55] *Id.* at FDA-BIDIVAPOR-005226-27.

[56] *Id.* at FDA-BIDIVAPOR-005227.

[57] *Id.* at FDA-BIDIVAPOR-005226.

[58] *Supra* note 30. In ensuing litigation over the MDOs, FDA has argued the "fatal flaw" memo was "Superseded." *See*, *e.g.*, *Bidi* Dkt. 16 at 8 (certified administrative record index). Whether true or not, 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

Indeed, at no time before those initial MDOs were issued did FDA warn manufacturers they must conduct a specific study comparing the cessation efficacy of their non-tobacco and tobacco flavored ENDS, let alone indicate its absence would prevent a PMTA from receiving a full substantive, scientific review and, instead, *automatically* result in a marketing denial.

V. *Chevron* Deference Enabled FDA To Ignore The TCA, Achieve What It Could Not In Congress Or Through The Rulemaking Process, And Base MDOs On A Statutory Interpretation Without Any Fair Notice

Chevron deference has been criticized on many grounds, at least three of which are implicated here. **First**, it creates a perverse incentive to jam a square peg into a round hole – *i.e.*, it "encourages the Executive Branch…to be extremely aggressive in seeking to squeeze its policy goals into ill-fitting

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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 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).

statutory authorizations and restraints."[59] And this is of particular concern where courts largely abdicate their responsibility to interpret the law. "[W]hen unchecked by independent courts exercising the job of declaring the law's meaning, executives throughout history have sought to exploit ambiguous laws as license for their own prerogative."[60] Knowing courts will likely defer to a broad range of interpretations undoubtedly sends a message to agencies that they need not focus on a statute's plain language and meaning but rather what policy they think should win the day. As one commenter put it, "*Chevron* deference may inspire agencies to adopt adventurous interpretations, far from any good faith reading of Congress's intent."[61] This, in turn, violates any

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[59] Brett M. Kavanaugh, *Fixing Statutory Interpretation*, 129 HARV. L. REV. 2118, 2150 (2014) (book review).

[60] *Gutierrez-Brizuela v. Lynch*, 834 F.3d 1142, 1152 (10th Cir. 2016) (Gorsuch, J., concurring); *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803) ("It is emphatically the province and duty of the judicial department to say what the law is."); 5 U.S.C. § 706 (the "reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action").

[61] Jack M. Beerman, *End The Failed Chevron Experiment Now: How Chevron Has Failed And Why It Can And Should Be Overlooked*, 42 CONN. L. REV. 779, 837 (2010) (citation omitted); David S. Tatel, *The Administrative Process and the Rule of Environmental Law*, 34 HARV. ENVTL. L. REV. 1, 1-2 (2010) (questioning agency adherence to the principles of administrative law and stating "[i]t looks for all the world like agencies choose their policy first and then later seek to defend its legality").

notion of separation of powers as it opens the door to agencies, not Congress, to define the extent of their own power.[62]

This is no mere academic exercise. In the context of rulemaking, one survey of agency personnel at seven federal agencies responsible for drafting regulations, including the U.S. Department of Health and Human Services (which houses FDA), illustrates just how much *Chevron* drives agency decision-making.[63] Specifically, 90% of the drafters reported they take into account *Chevron* deference, more than any other rule of statutory interpretation. [64] Perhaps even more telling, 80% of those surveyed agreed on some level with the statement that "a federal agency is more aggressive in its interpretive efforts if it is confident that *Chevron* deference…applies." [65] There is no reason to think agency staff and leadership, when taking other forms of agency

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[62] *Buffington v. McDonough*, 143 S. Ct. 14, 19 (2022) (Gorsuch, J., dissenting from denial of certiorari); *Pereira v. Sessions*, 138 S. Ct. 2105, 2120 (2018) (Kennedy, J., concurring) (ruing some circuit courts' cursory application of *Chevron* Step 1 and stating "when [*Chevron*] deference is applied to other questions of statutory interpretation, such as…the scope of [an agency's] own authority…" such "reflexive deference…" is "more troubling still.").

[63] Christopher J. Walker, *Inside Agency Statutory Interpretation*, 67 STAN. L. REV. 999 (2015).

[64] *Id.* at 1062.

[65] *Id.* at 1063.

action, would approach statutory interpretation any differently.[66]

Indeed, all indications point to *Chevron* playing a key role leading up to FDA's decision-making which resulted in the MDOs. With *Chevron* lurking in the background, FDA could confidently push far beyond the TCA's APPH concept, knowing courts would likely defer to its alternative "fatal flaw" approach. FDA interpreted the TCA as allowing it to deny marketing authorization to millions of non-tobacco flavored products based on the lack of a single comparative efficacy study.

And FDA's bet paid off. A majority of circuit courts have, at the stay or merits stage, upheld an MDO for non-tobacco flavored ENDS products without seriously considering what the TCA actually says. [67] Yet when one "carefully

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[66] *See*, *e.g.*, *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 632-33 (D.C. Cir. 2021) (vacating FDA designation of company's diagnostic contrast agents as drugs and not devices under the FDCA as contrary to the unambiguous plain language of the statute).

[67] *Magellan Tech., Inc. v. FDA*, 70 F.4th 622 (2d Cir. 2023); *Liquid Labs LLC v. FDA*, 52 F.4th 533 (3d Cir. 2022); *Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022); *Breeze Smoke, LLC v. FDA*, 18 F.4th 499 (6th Cir. 2021); *Gripum, LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022); *Lotus Vaping Techs., LLC v. FDA*, No. 21-71328 (9th Cir. July 7, 2023); *Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022). In contrast, the Eleventh Circuit found FDA's actions to be arbitrary and capricious. *Bidi Vapor LLC v. FDA*, 47 F.4th 1191 (11th Cir. 2022). The Fifth Circuit entered a stay of an MDO as likely unlawful, *Wages and White Lion Invs., LLC v. FDA*, 16 F.4th 1130 (5th Cir. 2021),

consider[s] the text, structure, history, and purpose" of the statute,[68] it is clear Congress envisioned the APPH standard as encompassing a holistic, multi-factored analysis that demands a full substantive, scientific review of each PMTA.[69]

Second, *Chevron* deference gives the executive branch license to attain through agency action what it could not in Congress or through rulemaking. "Presidents run for office on policy

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and after a different panel denied the petition for review on the merits, 41 F.4th 427 (5th Cir. 2022), the Fifth Circuit vacated and granted a hearing *en banc*, 58 F.4th 233 (5th Cir. 2023). That matter is still pending. The Fifth Circuit also stayed an MDO as violating the TCA in a separate proceeding involving menthol flavored products, *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182 (5th Cir. 2023).

[68] *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (citation omitted) (noting rule applies under *Chevron*); *see Buffington*, 143 S. Ct. at 19 (Gorsuch, J., dissenting from denial of certiorari) ("When reading statutes, we insist that courts pay careful attention to text, context, and traditional tools of interpretation. We demand interpretations that comport with how a reasonable reader would have understood the law at the time of its adoption.").

[69] Kavanaugh, *supra* note 59, at 2121 ("[C]ourts should seek the *best reading* of the statute by interpreting the words of the statute, taking account of the context of the whole statute, and applying the agreed-upon semantic canons.") (italics in original); *see Wages and White Lion Invs. v. FDA*, 41 F.4th 427, 447 (5th Cir. 2022) (dissenting judge in now vacated merits decision noting FDA had "acknowledged its duty to consider each PMTA individually and holistically"); *Breeze Smoke*, 18 F.4th at 508-09 (Kethledge, J., dissenting) (stating FDA wrongfully "decided these applications *en masse* rather than individually").

agendas and it is often difficult to get those agendas through Congress. So it is no surprise that Presidents and agencies often will do whatever they can within existing statutes."[70] As an example, this Court need look no further than FDA's previous attempt to regulate the tobacco industry before the TCA was adopted. Over the course of decades, Congress had considered and rejected a number of bills that would have given FDA authority to regulate tobacco products. [71] Despite the lack of any explicit legislative imprimatur, FDA in 1996 promulgated a final rule that regulated cigarettes and smokeless tobacco under the Food, Drug and Cosmetic Act's ("FDCA") then-existing authorities.[72] This Court ultimately held in *FDA v. Brown & Williamson* that the regulation of tobacco products is a "major question" and FDA's rule was inconsistent with Congress's "clear intent" as "expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation it has enacted…"[73]

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[70] Kavanaugh, *supra* note 59, at 2151.

[71] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 147-48, 155 (2000).

[72] *Id.* at 126.

[73] *Id.* at 126, 159; *see also* E. Donald Elliott, *Chevron Matters: How the Chevron Doctrine Redefined the Roles of Congress, Courts and Agencies in Environmental Law*, 16 VILL. ENVTL. L.J. 1, 3 (2005) (giving another example of the U.S. Environmental Protection Agency ("EPA") proposing a cap and trade rule under the existing Clear Air Act to reduce air pollution after several failed attempts by Congress to amend the statute to do the same) ("Before *Chevron*, EPA would not even imagine that it possessed the

Now, FDA is at it again. In the two years leading up to the September 2020 PMTA deadline, Congress saw bills introduced in both chambers that, with a limited exception, would have banned outright non-tobacco flavored ENDS.[74] These efforts all failed. By subsequently denying every PMTA for a non-tobacco flavored ENDS product based on virtually identical, across-the-board MDOs, we now know FDA has been able to effectively achieve a ban, and with circuit courts' approval no less, without ever having to go through the hard work of the legislative process or even the notice and comment rulemaking which the TCA commands.[75] As the Fifth Circuit noted in bucking the majority of circuit court decisions and granting a stay of an MDO for a menthol ENDS product, FDA likely "created a *de facto* rule banning all non-tobacco-flavored e-cigarettes without following…notice and comment requirements."[76]

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authority to work such fundamental reforms into a major statutory scheme without the benefit of statutory amendment.").

[74] *See*, *e.g.*, S. 3319, 115th Cong. § 2 (2018); H.R. 293, 116th Cong. § 301 (2019); H.R. 1498, 116th Cong. § 3 (2019); S. 655, 116th Cong. § 3 (2019); H.R. 2339, 116th Cong. § 103 (2019); H.R. 4425, 116th Cong. § 3 (2019); S. 2519, 116th Cong. § 3 (2019); S. 3174, 116th Cong. § 103 (2020).

[75] 21 U.S.C. § 387g(c) (requiring rulemaking for tobacco product standards). FDA published an Advanced Notice of Proposed Rulemaking ("ANPRM"), 83 Fed. Reg. 12294 (March 21, 2018), seeking comment on the role of flavored ENDS products in cessation and initiation. No further action has been taken on the ANPRM.

[76] *R.J. Reynolds*, 65 F.4th at 189.

Third, without any judicial check, *Chevron* deference inspires "avowedly politicized administrative [agencies] seeking to pursue whatever policy whim may rule the day" to modify or completely reverse their prior statutory interpretations knowing full-well any reasonable interpretation of an arguably ambiguous provision will likely be upheld.[77] The resulting regulatory whiplash places individuals and businesses subject to the regulatory scheme in an untenable position. As Justice Gorsuch recently observed, if a court is not able to render a final judgment on what a statute actually says, then the regulated community will be forever left guessing at what standards in fact apply.[78] Indeed, when courts are obligated to simply defer to an agency's latest interpretation, this raises serious due process and fair notice concerns, particularly where violative conduct may otherwise give rise to civil penalties, or worse, criminal liability.[79]

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[77] *Gutierrez-Brizuela*, 834 F.3d at 1152 (Gorsuch, J., concurring) (noting regulated entities "must always remain alert to the possibility that the agency will reverse its current view 180 degrees anytime based merely on the shift of political winds and *still* prevail.") (emphasis in original).

[78] *Buffington*, 143 S. Ct. at 20 (Gorsuch, J., dissenting from denial of certiorari); *see also BNSF Railway Co. v. Loos*, 139 S. Ct. 893, 908 (Gorsuch, J., dissenting) (noting "executive agencies' penchant for changing their views about the law's meaning almost as often as they change administrations").

[79] *Buffington*, 143 S. Ct. at 19 (Gorsuch, J., dissenting from denial of certiorari); *Guedes v. Bureau of Alcohol, Tobacco, Firearms and Explosives*, 140 S. Ct. 789, 790 (Gorsuch, J., statement on denial of certiorari) (concluding

In FDA's case, it has actually flip-flopped twice. Before it began issuing MDOs in August 2021, FDA demanded in a 2019 PMTA guidance document that manufacturers submit extensive information and data covering numerous scientific disciplines with no mention of the highly specific comparative efficacy test, and stating it would weigh "all" of the product risks and benefits contained in an application.[80] Then FDA abruptly did an about-face and, without warning, denied marketing authorization to 55,000 non-tobacco flavored ENDS products in one day based on the singularly focused "fatal flaw" approach. But even then, FDA was not done. It further muddied the waters only a few months later in October 2021 when it seemingly reversed course again and promulgated a final PMTA rule in which it committed to evaluating each PMTA on an "individualized" basis and in light of "all" of the contents of an application.[81]

What is a manufacturer to do with all of these mixed signals? How is it supposed to spend millions of dollars and plan for a multi-year application process when FDA cannot get its own messaging straight? And most importantly, how can it help meet the TCA's goal of harm reduction by innovating novel, less risky tobacco products when there is no discernable pathway to market authorization?

"whatever else one thinks about *Chevron*, it has no role to play when liberty is at stake").

[80] *Supra* note 48.

[81] *Supra* note 49.

These are not idle questions. FDA recently commissioned the Reagan-Udall Foundation ("RUF"), an independent organization created by Congress to advance the agency's mission, to evaluate its Center for Tobacco Product's implementation of the TCA and the PMTA process.[82] The resulting report repeatedly noted FDA's lack of transparency and stakeholder frustrations involving "policy shifts with broad impact on the industry occur[ing] without notice."[83] These comments held particularly true "regarding important public policy decisions associated with applying the Appropriate for the Protection of the Public Health (APPH) standard in the TCA," with the report observing that FDA "did not specifically announce" its shift from a strategy of harm reduction to rejecting marketing authorization for all non-tobacco-flavored ENDS products.[84] RUF concluded FDA needs to better "explain how [it] is interpreting the APPH standard" and recommended it "provide clarity, predictability, and transparency concerning scientific standards for application review."[85]

Nevertheless, in the meantime, hundreds of manufacturers, mostly small businesses and mom-and-pop shops, now face what could be overwhelming civil penalties, criminal liability,

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[82] Reagan-Udall Foundation, *Operational Evaluation Of Certain Components Of FDA's Tobacco Program* (Dec. 2022), https://tinyurl.com/33xytzeu.

[83] *See*, *e.g.*, *id.* at Executive Summary, 11, 13-15.

[84] *Id.* at 11.

[85] *Id.* at 15, 18.

and injunctive relief because they could not readily predict how FDA was interpreting the TCA.[86]

VI. This Court Should Provide Guidance To Lower Courts Clearly Defining Those Circumstances When *Chevron* Deference Applies

FDA's handling of the PMTA process provides just one example of how the *Chevron* doctrine invites agency mischief or worse. When courts abdicate their duty to interpret the law in the first instance, and instead impulsively defer to increasingly far-flung agency positions, any notion of Constitutional separation of powers is lost.[87] Agencies, not the judiciary, will continue to have the final say. *Amici* therefore request that this Court, at minimum, cabin *Chevron's* scope and applicability to ensure lower courts properly discern Congressional intent and enforce statutory provisions as written.

Based on the ENDS industry's experiences alone, here are just three clarifications that would have otherwise helped avert FDA's wholesale bungling of the PMTA reviews. **First**, this Court should reassert the primacy of *Chevron's* Step 1. Courts must employ well-established rules of

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[86] *Supra* note 79; 21 U.S.C. §§ 331-333; *see also R.J. Reynolds Tobacco Co. v. County of Los Angeles*, No. 22-338, *Brief of The Vapor Technology Association as Amicus Curiae In Support of Petitioners*, at 8 (Nov. 14, 2022) (citing economic analysis showing majority of vape companies are small businesses).

[87] U.S. CONST., art. I, § 1 (vests "[a]ll legislative Powers herein granted…in a Congress of the United States.").

statutory interpretation, abiding by a statute's plain language, structure, and context. As *Chevron* stated itself, if a "court employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect." [88] Indeed, absent explicit statutory language indicating Congressional intent leaving room for an agency to fill-in an interpretive gap, courts should almost always finish their analysis at Step 1.[89] Simply put, Step 1 must have bite. As to the PMTA process, the TCA is clear on its face when it comes to what information and data must be evaluated, thus foreclosing anything resembling the cookie-cutter MDOs issued to date based solely upon on a "fatal flaw" approach.

Second, as this Court stated in *Kisor v. Wilkie* when placing limitations on the analogous *Auer* doctrine, a regulation (or, in this case, a statute) must be "genuinely ambiguous, even after a court has resorted to all the standard tools of

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[88] *Chevron v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n.9 (1984).

[89] *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 707 (1991) (Scalia, J., dissenting) ("Deference is appropriate where the relevant language, carefully considered, can yield more than one reasonable interpretation, not where discerning the only possible interpretation requires a taxing inquiry."); *Biden v. Nebraska*, No. 22-506, 2023 WL 4277210, at *9-11 (June 30, 2023) (relying on examination of plain language of student loan statute to hold federal government did not have authority to implement loan forgiveness program).

interpretation." [90] *Chevron* deference does not "require[] [courts] to accept [a] strained and implausible construction advanced" by an agency. [91] In the MDOs, FDA completely abandoned its statutory duty to balance all risks and benefits of an ENDS product across the population as a whole.[92]

FDA, when considering PMTAs, refused to consider all relevant evidence across the broad spectrum of our population in lieu of a single data point of one subset of the population. For instance, what if there is no evidence minors are using a manufacturer's product and the circumstances indicate that any future underage use is unlikely (*e.g.*, a PMTA submitted by a single vape shop located in a sparsely populated area that employs strict marketing and access restrictions, and only makes e-liquids "to order" for known, adult customers)? Surely, under those circumstances, the scales would tip heavily in favor of granting market authorization, provided other evidence showed those e-liquids are being used by the adult customers to reduce or quit their smoking habits and such products are less risky than combustible cigarettes. But under the FDA's interpretation of the TCA, those factors would never be considered and, in fact, are rendered totally irrelevant.[93]

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[90] *Kisor*, 139 S. Ct. at 2414.

[91] *Pauley*, 501 U.S. at 707 (Scalia, J., dissenting).

[92] 86 Fed. Reg. at 55384.

[93] *Bidi Vapor*, 47 F.4th at 1195 (holding failure to consider marketing plans was arbitrary and capricious).

Third, courts must ask whether an "agency's interpretation…in some way implicate[s] its substantive expertise."[94] If not, it is unlikely Congress intended for the agency to fill-in any alleged interpretive gaps.[95] Whether Congress has delegated such authority, however, is a question for courts to resolve and should be addressed before *Chevron* deference is ever applied.[96] In FDA's case, whether it had authority to completely forego full scientific review for an entire class of ENDS products hardly implicates FDA's expertise. One only needs to read the TCA's plain language itself to realize that Congress intended for FDA to evaluate and balance a wide-range of information and data in a PMTA before making an APPH determination. As such, circuit courts should not have reflexively deferred to FDA's comparative efficacy approach. Indeed, *amici* believe that the decisions in the MDO challenges would have played out differently under the standards proposed above.

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[94] *Kisor*, 139 S. Ct. at 2417.

[95] *City of Arlington*, 589 U.S. 310-11 (Breyer, J., concurring).

[96] *Id.* at 317 (Roberts, C.J., dissenting) ("But before a court may grant such deference, it must on its own decide whether Congress – the branch vested with lawmaking authority under the Constitution – has in fact delegated to the agency lawmaking power over the ambiguity at issue.").

CONCLUSION

Based on the foregoing, *amici* ask that this Court at least clarify and limit how the *Chevron* doctrine is to be applied by lower courts so agencies, like FDA, do not continuously venture outside clear Congressional intent.

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Respectfully submitted,

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ECIG CHARLESTON LLC (SC)

FLAVOUR ART NORTH AMERICA (Canada)

FLORIDA SMOKE FREE ASSOCIATION, INC. (FL)

FLV USA, d/b/a Flavorah (WA)

INDIANA SMOKE FREE ALLIANCE, INC. (IN)

KENTUCKY VAPING RETAILERS ASSOCIATION, INC., d/b/a KENTUCKY SMOKE FREE ASSOCIATION (KY)

MATRIX MINDS, LLC (TX)

MICHIGAN VAPE SHOP OWNERS, INC. (MI)

MONTANA SMOKE FREE ASSOCIATION, INC. (MT)

NICQUID, LLC (OH)

OHIO VAPOR TRADE ASSOCIATION, INC. (OH)

PASTEL CARTEL, LLC (TX)

SOUTH CAROLINA VAPOR ASSOCIATION (SC)

SS VAPE BRANDS (FL)

STREAMLINE GROUP/MH GLOBAL (CA)

SV3, LLC (CA)

TENNESSEE SMOKE FREE ASSOCIATION, INC. (TN)

VAPE ELEMENT LLC,
d/b/a BLVK E-Liquid (CA)

WAGES AND WHITE LION INVESTMENTS, LLC,
d/b/a Triton Distribution (TX)

WHITE HORSE VAPOR (RI)

YLSN DISTRIBUTION LLC,
d/b/a Happy Distro (AZ)