No. 23-1038

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION,
Petitioner,

v.

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

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

BRIEF FOR *AMICUS CURIAE* COALITION OF MANUFACTURERS OF SMOKING ALTERNATIVES IN SUPPORT OF RESPONDENTS AND AFFIRMANCE

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QUESTION PRESENTED

Whether, in addition to being arbitrary and capricious, the Food and Drug Administration's creation of a new, heightened standard for evaluating already-pending premarket tobacco product applications for certain electronic nicotine delivery systems ("ENDS") products was an unlawful attempt to impose a "tobacco product standard" that would prohibit or severely restrict all flavored ENDS products?

INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae the Coalition of Manufacturers of Smoking Alternatives ("CMSA") is a trade coalition that represents a diverse array of members who manufacture and distribute smoking harm reduction products, including but not limited to oral nicotine products and ENDS products, such as vapor products and e-cigarettes. Such products provide a lower-risk alternative for millions of adult smokers seeking to transition and remain away from using combustible cigarettes. CMSA companies have decades of direct experience fostering innovation in support of smoking harm reduction and support reasonable and fair regulation. But they oppose unreasonable or arbitrary requirements imposed without following proper procedures allowing for notice, input, and review of the multifaceted issues surrounding smoking cessation.

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[1] This brief was not authored in whole or in part by counsel for any party, and no person or entity other than *amicus curiae* or its counsel has made a monetary contribution toward the brief's preparation or submission.

CMSA's member companies have invested significant resources to file premarket tobacco product applications ("PMTAs") for ENDS products, and they have experienced the lack of clear guidance and inequitable application of the standards improperly adopted by the Food and Drug Administration ("FDA"). *Amicus* thus has a significant interest in the outcome of this case and urges the Court to uphold the Fifth Circuit's decision.

SUMMARY OF ARGUMENT

CMSA writes to highlight that FDA's actions in denying Respondents' PMTAs are an attempt to circumvent the notice-and-comment rulemaking process required to ban or severely restrict flavored ENDS products. While Congress provided FDA the seemingly legislative authority to impose such restrictions, it expressly conditioned FDA's exercise of this authority on the use of rulemaking to establish a "tobacco product standard." 21 U.S.C. § 387g(c)(1). As a result, if FDA wishes to ban or severely restrict all flavors in ENDS products, it must do so through the Family Smoking Prevention and Tobacco Control Act's notice-and-comment process, not through mechanistic review and rejection of effectively all applications to (continue to) market such products.

Given how detailed and challenging the process for establishing a tobacco product standard is, *id.* § 387g(c)-(d), it is not surprising that FDA avoided going through that process and instead imposed a tobacco product standard through wholesale rejection of PMTAs for flavored ENDS products. But imposing such a *de facto* standard is contrary to the statute's plain text, circumvents the very procedures Congress

imposed to check the arbitrary or unreasonable exercise of such delegated power, and causes real harms as FDA misleads and whipsaws manufacturers seeking to provide a robust set of options for adult consumers seeking to quit smoking. FDA's current approach destroyed numerous existing businesses, delays or forecloses entry to the market of novel products with harm-reduction potential, deters investment, and ignores or downplays competing considerations that could have been analyzed and reviewed under the robust notice-and-comment procedures. Those procedures thus not only would provide proper notice to regulated parties and an orderly approach to compliance but also would mitigate constitutional separation-of-powers concerns always latent in statutes that grant Executive Branch entities the authority both to make and enforce the law.

To avoid these statutory and constitutional failings in FDA's conduct, this Court should affirm the decision below.

ARGUMENT

I. FDA's Authority to Issue Tobacco Product Standards Is Subject to Important Substantive and Procedural Constraints.

As the Fifth Circuit and Respondents correctly note, the practical effect of FDA's wholesale approach to evaluating and rejecting marketing applications for flavored ENDS products goes beyond mere individualized adjudications and amounts to a sweeping and restrictive "standard" for such products. As the Fifth Circuit found, the severe burden of proof FDA imposed *post hoc* on companies seeking to

continue marketing flavored ENDS products effectively created a "categorical ban" on such products. Pet. App. 47a n.5 ("FDA unquestionably failed to follow § 387g's notice-and-comment obligations before imposing its de facto ban on flavored e-cigarettes.").

Under the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"), Congress gave FDA the authority to develop standards regarding the composition, design, labeling, or marketing of tobacco products if FDA determines that such standards are "appropriate for the protection of the public health." 21 U.S.C. § 387g(a)(2)-(3). These are referred to as "tobacco product standards."

Although the TCA does not generally define the term "tobacco product standard," it gives a number of examples of standards that FDA might consider. *Id.* § 387g(a)(4). The ability to issue tobacco product standards related to flavors derives from the statute's authorizing promulgation of "provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product." *Id.* § 387g(a)(4)(B)(i). The flavor of a tobacco product is a "property" of that tobacco product. Additionally, Congress specifically called a ban on certain flavors in certain tobacco products a "tobacco product standard,"[2] and FDA has regularly understood its

[2] See *id.* § 387g(a)(1)(A) (prohibiting cigarettes and their component parts from containing a flavor (other than tobacco or menthol) that is a "characterizing flavor," "including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut,

rulemaking obligations to apply to restrictions on flavored products, having proposed rules to restrict them through its "tobacco product standards" authority.[3] In light of such examples, FDA's wholesale, differential, and restrictive treatment of flavored ENDS products amounts to a tobacco product standard both conceptually, pursuant to the internal context of the TCA, and in FDA's own understanding reflected in its previous conduct.

FDA's June 21, 2024, authorizations of NJOY LLC's menthol-flavored ENDS products do not negate the existence of a tobacco product standard.[4] Rather, it is the dubious exception that proves the rule. FDA applied an undisclosed, wholesale, and mechanistic test during review of Respondents' PMTAs (and in its denials of thousands of other PMTAs). That it seems to have briefly bent the rules in a gambit to deny the

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licorice, cocoa, chocolate, cherry, or coffee"); see also *id.* § 387g(a)(2) (cross-referencing notice-and-comment obligation to revise statutory flavor standard for cigarettes and their component parts)

[3] See *Tobacco Product Standard for Menthol in Cigarettes*, 87 Fed. Reg. 26454 (proposed May 4, 2022); *Tobacco Product Standard for Characterizing Flavors in Cigars*, 87 Fed. Reg. 26396 (proposed May 4, 2022); see also FDA, *TAB A 2014-850 Deeming Draft RIA as Submitted to OMB* 4-5, Regulations.gov (Oct. 2015), https://tinyurl.com/ytm847yx (addressing the need for a rule to cover "all additional tobacco products," "including e-cigarettes" that covered, among other things, "flavored products") [hereinafter "*Deeming Draft RIA*"].

[4] FDA, *FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products after Extensive Scientific Review* (June 21, 2024), https://tinyurl.com/3n984p3r.

existence of such rules means nothing (or at least nothing good).[5]

The TCA imposes significant guardrails on FDA's authority to create a tobacco product standard. 21 U.S.C. § 387g(c)-(d). Though like the Administrative Procedure Act's ("APA") familiar notice-and-comment rulemaking requirements, the TCA goes further.

First, FDA's notice of proposed rulemaking must "set forth a finding *with supporting justification* that the [proposed] tobacco product standard is appropriate for the protection of the public health" ("APPH"). *Id.* § 387g(c)(2)(A) (emphasis added). Thus, FDA bears the initial burden of justification under the APPH standard, not the manufacturers. The notice of proposed rulemaking must also "invite interested persons" to "submit a draft or proposed tobacco product standard" or "to submit comments on structuring the standard." *Id.* § 387g(c)(2)(B)-(C). And it imposes a duty of cross-agency consideration by requiring any notice to invite the Secretary of *Agriculture* to "provide any information or analysis

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[5] Based on a review of the publicly available documents related to FDA's review of the NJOY LLC PMTAs, it appears that the applicant was able to provide amendments to its PMTAs after FDA began issuing denials in the summer of 2021 for all flavored ENDS products. FDA, *Technical Project Lead (TPL) Review of PMTAs: PM0000616.PD1, PM0000617.PD1* (June 21, 2024), https://tinyurl.com/2tw9db43; FDA, *Technical Project Lead (TPL) Review of PMTAs: PM0000628.PD1 and PM0000629.PD1* (June 21, 2024), https://tinyurl.com/35rsbbz5. It similarly appears that, during its review of the PMTAs for those few products, FDA applied a more-lenient evidentiary standard, including by acknowledging youth-risk mitigation measures offered in the applicant's marketing plan, even as it refused to do the same for all other PMTAs for ENDS products.

which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard." *Id.* § 387g(c)(2)(D).

Further, as part of a finding that the proposed tobacco product standard is "appropriate for the protection of public health," FDA must consider scientific evidence establishing: the standard's "risks and benefits to the population as a whole"; any increase or decrease in the "likelihood that existing users" will stop using the tobacco product(s) involved; and any increase or decrease in the likelihood that non-users "will start using" the tobacco product(s) involved. *Id.* § 387g(a)(3)(B)(i). In addition to determining the appropriateness of a proposed standard in terms of public health, FDA must also consider whether compliance with the standard is technically achievable, whether the standard might have any countervailing (or negative) effects on the health of young users, adult users, and non-users, and whether it will create "a significant demand for contraband or other tobacco products that do not meet the requirements of this subchapter," *i.e.*, a black market. *Id.* § 387g(b)(1)-(2). Unlike in the mass denials of PMTAs, FDA thus must have support for both sides of its analysis, not merely casual assumptions or non-rigorous analysis about the harm to youth on one side weighed against and protected by unrealistic and unequal demands for proof of product benefit on the other. Such a heightened standard is an entirely appropriate requirement for Congress to impose on FDA's ability to adopt legislative "tobacco product standards" that go beyond the substantive

standards Congress itself imposed through the checks and balances of legislative action.

But this standard is not the only procedural burden that Congress required of FDA before it could impose an industry-wide "tobacco product standard." After a comment period of at least 60 days, if FDA determines that the tobacco product standard is APPH, FDA must then publish in the Federal Register a final rule, which must include FDA's findings on its determination that the tobacco product standard is APPH. *Id.* § 387g(d)(1). In determining the effective date for the regulation, FDA must take into consideration a number of factors such as the technical feasibility of complying, the existence of patents that might make compliance impossible, and potentially required alterations in the methods used to grow domestically produced tobacco used in the tobacco product(s) at issue. *Id.* § 387g(d)(2). And, of course, all of FDA's reasoning and findings would be subject to judicial review.

These substantive and procedural hurdles are important checks on agency discretion, ensure that FDA respects legislative choices, and guard against error, overzealousness, or manipulation of the facts and law to achieve Executive Branch political ends that may not comport with legislative goals and limitations on such authority. Indeed, judicial review of agency notice-and-comment rulemaking regularly results in rejection of agency rules or eventual modification of such rules to better comport with statutory requirements. See, *e.g.*, *Ohio* v. *EPA*, 144 S. Ct. 2040, 2054 (2024) (staying enforcement of EPA rule as arbitrary and capricious because, among other

things, EPA failed to offer a "reasoned response" to comments given during notice-and-comment period); *Mock* v. *Garland*, 75 F.4th 563, 578, 586 (5th Cir. 2023) (holding that a "Final Rule fails the logical-outgrowth test and violates the APA" and "therefore must be set aside as unlawful").

II. FDA's Surprise and Improperly Adopted "Tobacco Product Standard" Significantly Undermines the Reasoned Decision Making Required by Congress and Blinks Important Considerations that Would Have Been Addressed in Rulemaking.

Using the application review process rather than notice-and-comment rulemaking had severe consequences that should have and would have been considered in the ordinary course of rulemaking. By not telling manufacturers about the requirements that would govern their applications until after the applications were due, FDA effectively ensured the denial of all or virtually all applications for non-tobacco-flavored products submitted by September 9, 2020. Furthermore, the standard imposed was so strict that, even when announced, it was functionally impossible to satisfy and far beyond what is commercially and practically reasonable for manufacturers.[6]

[6] And indeed it had proven impossible to satisfy until FDA, while its petition for certiorari was pending, authorized the marketing of a handful of menthol-flavored e-cigarettes to undermine the Fifth Circuit's conclusion that, by imposing a categorical ban, it had created a tobacco product standard without following the necessary notice-and-comment rulemaking process.

For example, FDA's heightened and differential proof requirement, undisclosed at the time the applications were required to be submitted, was impossible to meet in a timely fashion given the time necessary to gather or generate the types of evidence FDA now requires. And even apart from the timing, the expense of generating the evidence FDA demanded, on a product-by-product and flavor-by-flavor basis, would have been extremely costly and, as a practical matter, rendered many products economically non-viable.[7] Furthermore, the long delays in FDA's review of the many PMTAs it has received,[8] coupled with the moving goal posts imposed via the review process, creates a level of uncertainty that severely deters investment and innovation in new products with harm-reduction potential.[9] FDA's unlawful acts and delays deprived millions of adult

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[7] Cardno ChemRisk, *Consortium PMTA Efforts and Costs* 2 (July 2, 2019), https://tinyurl.com/mphsf7mz (estimating a flat PMTA cost of between $8.7 million to $11.2 million, including $597,000 *per flavor*).

[8] As Respondents note (at 31), the review process for their products had languished for ten months before FDA moved the goalposts.

[9] For example, recognizing the onerous standards FDA imposed on it, Reynolds "initiated a 24-month study" to "evaluate its products and the role they can play in tobacco-harm reduction." Reynolds, *Interim Results of Vuse Longitudinal Study* 1, https://tinyurl.com/nxm3yavr. Although the study showed that "[n]early 45% of participants who use[d]" Reynolds' product "switched away from cigarettes," *ibid.*, FDA denied its applications, FDA, *FDA Denies Marketing of Six Flavored Vuse Alto E-Cigarette Products Following Determination They Do Not Meet Public Health Standard* (Oct. 12, 2023), https://tinyurl.com/4ceats75.

smokers access to products that even the agency concedes could benefit them.[10]

Any number of additional factors relating to public health and the practical consequences of a proposed tobacco standard could have been fleshed out and analyzed in an orderly fashion via rulemaking. Indeed, the consideration of broader effects, such as creating demand for and increasing the use of unregulated black-market products, should have given FDA considerable pause in its assumption that youth would be better off if the market for adults lacked legal and regulated products as well as in rejecting use of less-burdensome marketing restrictions for otherwise lawful products. Instead, these and many other factors were ignored, assumed, or distorted behind closed doors and without the substantive and procedural accountability imposed by the TCA's notice-and-comment requirements.

FDA's end run around the TCA's notice-and-comment obligations, however, is perhaps not surprising given that FDA has been floundering in its attempts to establish tobacco product standards for flavored tobacco products for years. For example, in 2016, FDA submitted to the White House a draft rule that would have prohibited the continued marketing of any non-tobacco-flavored e-cigarette, including menthol ones.[11] But the White House removed that

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[10] See, *e.g.*, FDA, *The Relative Risks of Tobacco Products* (Aug. 21, 2024), https://tinyurl.com/3sk4dj8y (recognizing that "e-cigarettes can generally be a lower-risk alternative for adults who smoke cigarettes").

[11] *Deeming Draft RIA*, *supra* note 3, at 76-77.

provision, thwarting FDA's plan.[12] FDA has also issued proposed rules that would establish product standards that would ban menthol in cigarettes and ban all non-tobacco flavors in cigars.[13] These proposed rules are still pending, suggesting that the rulemaking process is doing its job in providing necessary procedural and substantive checks against hasty agency decisions on matters that might reasonably be viewed as legislative in nature.

Seemingly impatient with the required rulemaking process, FDA's current approach of wholesale denial of PMTAs lowers the substantive and procedural bar for FDA's desired outcome. But that gambit undermines the very reason why the TCA and the APA require notice-and-comment rulemaking in the first place. Rulemaking provides regulated entities with both "notice and predictability" about the legality of their conduct. *Talk Am., Inc.* v. *Michigan Bell Tel. Co.*, 564 U.S. 50, 69 (2011) (Scalia, J., concurring). The need for both notice and predictability, in turn, stems from a "fundamental principle in our legal system * * * that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC* v. *Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). The consequences of shirking the rulemaking responsibility are enormous. After all, although

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[12] FDA, *TAB B 2014-850 Deeming Final Rule Redline Changes* 22-23, Regulations.gov (May 2016), https://tinyurl.com/46c9754a.

[13] See FDA, *Tobacco Product Standard for Menthol in Cigarettes*, 87 Fed. Reg. 26454, 26455-26456 (proposed May 4, 2022); FDA, *Tobacco Product Standard for Characterizing Flavors in Cigars*, 87 Fed. Reg. 26396, 26397-26398 (proposed May 4, 2022).

rulemaking is an "exercise[] of * * * the executive Power," *City of Arlington* v. *FCC*, 569 U.S. 290, 304 n.4 (2013) (citation omitted), "[w]hen an agency engages in *rulemaking*, it does something that looks very much like a legislature passing a law."[14]

Allowing the agency to duck the checks on its power, and to do so by pretending to engage in individualized or holistic review, cf. *Students for Fair Admissions, Inc.* v. *President & Fellows of Harvard Coll.*, 600 U.S. 181, 298 (2023) (Gorsuch, J., concurring) (recognizing argument that holistic approach "disguise[s] * * * [unlawful] efforts" to achieve predetermined result), undermines the checks and balances of constitutional and administrative law. And to deny the existence of a tobacco product standard merely because FDA, in a cynical post-loss move, has granted a bare handful of PMTAs through unequal application of its standards, is too cute by half and would render the TCA's rulemaking requirements a nullity. Rather, such anomalies are the exceptions that prove the rule and show why a more comprehensive review of the evidence and competing concerns should properly be performed via rulemaking.

Given the breadth of the seeming delegation of legislative authority to FDA to impose rules based on what it determines to be "appropriate for the protection of public health," the least this Court should do is strictly and rigorously apply what few guardrails Congress has seen fit to impose. Here, that means that

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[14] Gary Lawson, *Federal Administrative Law* 48 (6th ed. 2013) (emphasis in original).

broad determinations that effectively ban whole product categories should at least clear the procedural hurdles imposed by the TCA. Principles of constitutional avoidance would seem to require no less. *Reno* v. *Flores*, 507 U.S. 292, 314 n.9 (1993) ("Statutes should be interpreted to avoid *serious* constitutional doubts."); cf. *Snyder* v. *United States*, 144 S. Ct. 1947, 1960 (2024) (Gorsuch, J., concurring) ("Lenity may sometimes * * * go unnamed. * * * 'Fair notice' or 'fair warning'"—such as that provided by notice-and-comment rulemaking—"are especially familiar masks.").

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals that FDA's denial of Respondents' marketing applications was arbitrary and capricious should be affirmed.

Respectfully submitted,

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