No. _____

In the Supreme Court of the United States

BIG TIME VAPES, INCORPORATED; UNITED STATES VAPING ASSOCIATION, INCORPORATED,
Petitioners,

v.

FOOD & DRUG ADMINISTRATION; STEPHEN M. HAHN, COMMISSIONER OF FOOD AND DRUGS; ALEX M. AZAR, II, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN HIS OFFICIAL CAPACITY,
Respondents.

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

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Congress enacted the Tobacco Control Act (TCA or "the Act") in 2009, imposing a detailed regulatory framework initially limited to cigarettes and "smokeless tobacco" (essentially, snuff). But TCA § 387a(b) also gave the Secretary of Health and Human Services the unilateral power to extend the TCA's reach to cover any other "tobacco product," a capacious term capturing "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." The TCA does not require the Secretary to make any factual finding, consider any particular factors, or even hew to any broadly worded limiting principle in deciding whether to extend federal regulation over additional "tobacco products."

In 2016, the FDA employed this authority, "deeming" everything meeting the "tobacco product" definition to be subject to the TCA. In one fell swoop, the Agency extended the TCA's requirements to *everything* Congress had declined to regulate in 2009 (like cigars, hookah, and pipe tobacco), as well as to any other existing and future "tobacco products," including the vapor products of particular concern to Petitioners.

The question presented is:

Whether Petitioners have stated a claim that § 387a(b) grants excessive policymaking discretion to the executive branch to determine which tobacco products shall be federally regulated, impermissibly delegating legislative authority in violation of the separation of powers established by the Constitution.

PARTIES TO THE PROCEEDING

Petitioners, who were the plaintiffs below, are Big Time Vapes, Inc., a Mississippi corporation, and the United States Vaping Association, a non-profit trade association that brought this action on behalf of its member businesses, one of whom is Big Time Vapes, Inc. None of the petitioners has a parent corporation, and no publicly held company owns 10% or more of stock of any of the petitioners.

Respondents, who were the defendants below, are the Food & Drug Administration; Stephen M. Hahn, Commissioner of Food and Drugs; and Alex M. Azar, II, Secretary, U.S. Department of Health and Human Services.

STATEMENT OF RELATED PROCEEDINGS

There are no proceedings in state or federal trial or appellate courts, or in this Court, directly related to this case within the meaning of this Court's Rule 14.1(b)(iii).

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PETITION FOR A WRIT OF CERTIORARI

With the enactment of the Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1777 (codified at 21 U.S.C. 387, et seq.) (TCA or "the Act") in 2009, Congress imposed a new regulatory regime on cigarettes and smokeless tobacco. Notably, Congress left other types of tobacco—including such widely-used products as cigars and hookah—*un*regulated. Congress punted to the Secretary of Health and Human Services the authority to "deem" any other "tobacco products" to be subject to the TCA, with no guidance as to the circumstances under which the Secretary should regulate additional products. While the FDA chose to deem everything at once, it was equally free to deem hookah and pipe tobacco but not ENDS or cigars. It could have deemed *any* products, or *no* products, in its unbridled discretion.

This Court has certainly upheld delegations under broadly worded standards, but it has also considered a statute that imposed *no* standard in its operative text. *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). In that case, the Court refused to concoct a standard based on the broad purposes in the Act's preface, and held the law unconstitutional. *Id.* at 418-19. The *Panama Refining* Court noted that, "[a]mong the numerous and diverse objectives broadly stated" in the preface to the National Industrial Recovery Act, "the President *was not required to choose*," 293 U.S. at 418 (emphasis added). Therefore, any "effort by ingenious and diligent construction to supply a criterion still permits such a breadth of authorized action as

essentially to commit to the President the functions of a Legislature." *Id.* at 419.

The TCA is another statute imposing *no* discernible standard. Thus, even the cases frequently cited by this Court as illustrating the outer bounds of permissible delegations (*see Big Time Vapes, Inc. v. Food and Drug Admin.*, 963 F.3d 436, 442 n.18 (5th Cir. 2020) (App. 12 n.18) (citing cases)) do not support the deeming authority, because—broad as they may have been—*every one* of the statutes considered in those cases incorporated some limiting principle beyond the fact that the authority operated within a given field of activity. Petitioners argued that, given that the TCA lacks even a broad operative standard like those found sufficient in *Yakus v. United States*, 321 U.S. 414, 420, 426 (1944), and other cases, *Panama Refining precludes* any judicial attempt to derive an overarching principle from ambiguous statements of purpose that are in actual tension with one another. *See also Gundy v. United States*, 139 S. Ct. 2116, 2146 (2019) (Gorsuch, J., dissenting) (criticizing reliance on "broad and sweeping statements … about a statute's basic purpose," because "the fact remains that the law [Congress] actually adopted for pre-Act offenders leaves everything to the Attorney General.") Yet the panel below did what this Court refused to do in *Panama Refining*: it imagined an overarching limiting principle, stitched together from the broad statements of congressional purpose found in the Act's preface. App. 16-18.

The Fifth Circuit never acknowledged the part of *Panama Refining* refusing to create a standard omitted

by Congress. Instead, it repeatedly adverted to the fact that this Court has not held a delegation to be excessive "in … nearly nine decades." App. 12; *see also* App. 20 ("The Court has found only two delegations to be unconstitutional. Ever. And none in more than eighty years."). Consequently, the Fifth Circuit suggested that the purpose statements sufficed for a standard, despite the fact that the FDA itself had expressly stated, in the final "Deeming Rule,"[1] and later in another federal court,[2] that *no* substantive standard limited its exercise of deeming authority. The Fifth Circuit's opinion, therefore, reflects that the lack of any enforcement of the nondelegation doctrine for eight decades has now eroded even the threadbare limitations that *Panama Refining* and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935), should command.

While the Fifth Circuit apparently felt compelled to uphold this standardless delegation, it may have subtly invited this Court's scrutiny. The panel concluded its opinion by noting that "the Court might well decide—perhaps soon—to reexamine or revive the nondelegation doctrine," "[b]ut we are not supposed to read tea leaves to predict where it might end up." App. 23 (internal punctuation and citation omitted).

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[1] FDA, *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, No. FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule").

[2] See discussion *infra* at 11.

Petitioners Big Time Vapes, Inc., and the United States Vaping Association respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit.

OPINIONS BELOW

The Fifth Circuit's opinion is reported at 963 F.3d 436, and reproduced at App. A. The order of the Fifth Circuit denying rehearing en banc is reproduced at App. D. The District Court's opinion and order granting Defendants' motion to dismiss and denying plaintiffs' motion for preliminary injunction is reported at 427 F.Supp.3d 831 and reproduced at App. B, and the District Court's final judgment is unreported but reproduced at App. C.

JURISDICTION

The Fifth Circuit entered its judgment on June 25, 2020. App. 1. It denied a timely petition for rehearing en banc on August 25, 2020. App. D. This Court has jurisdiction under 28 U.S.C. § 1254(1). This petition is timely filed, as it is filed within 150 days from the date of the Fifth Circuit's order denying rehearing en banc. Order, 589 U.S. __ (Mar. 19, 2020).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article I, Section 1 of the Constitution provides: "All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives."

Section 901 of the TCA, 21 U.S.C. § 387a(b), provides that "[t]his chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter."

21 U.S.C. § 321(rr)(1) provides that "[t]he term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."

21 U.S.C. § 387 provides the text of relevant definitions, as follows:

> (4) Cigarette tobacco
>
> The term "cigarette tobacco" means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this subchapter shall also apply to cigarette tobacco.
>
> …
>
> (15) Roll-your-own tobacco
>
> The term "roll-your-own tobacco" means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or

> purchased by, consumers as tobacco for making cigarettes.
>
> …
>
> (18) Smokeless tobacco
>
> The term "smokeless tobacco" means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.
>
> …
>
> (20) Tobacco product manufacturer
>
> The term "tobacco product manufacturer" means any person, including any repacker or relabeler, who--
>
> (A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or
>
> (B) imports a finished tobacco product for sale or distribution in the United States.

STATEMENT OF THE CASE

I. Congress Passes the Tobacco Control Act, But Applies It Narrowly to a Subset of "Tobacco Products".

The TCA provides that "[t]obacco products … shall be regulated by the Secretary under this subchapter[.]" 21 U.S.C. § 387a.

A variety of products fitting the "tobacco product" definition—*i.e.*, "made or derived from tobacco" and

"intended for human consumption"—were in widespread use in 2009. Such products include cigarettes, chewing tobacco, premium and nonpremium cigars, hookah (waterpipe) tobacco, and pipe tobacco. However, Congress only applied the TCA to cigarettes and snuff, and punted the authority to expand the reach of this new regulatory apparatus across Independence Avenue, to the HHS Secretary, stating:

> This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.

21 U.S.C. § 387a(b). Congress provided no guidance as to why or when the Secretary should declare any additional tobacco product to be subject to federal regulation.

With respect to any products subjected to the TCA, the statute imposes several requirements. Any "manufacturer" of a regulated tobacco product must register with the FDA, file full lists of products and ingredients and other information, file annual statements of product offerings (with biannual updates), and be subject to inspection. 21 U.S.C. §§ 387d(a), 387e(b), (g), (i); *see* App. 4-6. Manufacturers are prohibited from introducing any "new tobacco product," defined as a product that "was not commercially marketed in the United States as of February 15, 2007," without premarket authorization. The Act provides three pathways for seeking premarket authorization, but because vapor products (dubbed "electronic nicotine delivery systems" or "ENDS" by

FDA) were not on the market as of February 2007, the only pathway available for them is the most onerous "premarket tobacco application" (PMTA) pathway. *See* App. 8; *see also* FDA, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50566, 50568 n.1 (Sept. 25, 2019) ("Proposed Final PMTA Rule").

Finally, placing a product under the TCA allows the FDA to "impose additional rules by regulation, such as minimum age restrictions, mandatory health warnings, method-of-sale limits, and advertising constraints." App. 5-6; *see* 21 U.S.C. § 387f(d). Failure to comply subjects a manufacturer's products to be designated as "adulterated" or "misbranded," *see* 21 U.S.C. §§ 387b, 387c, which could result in civil penalties and seizure of product, *see id.* §§ 333f(8)-(9), 334, and even criminal penalties, *see id.* §§ 331(a), (b), (c), 333(a)(1).

II. The FDA Deploys Its "Deeming" Authority to Unilaterally Extend Federal Regulation Over All "Tobacco Products," Including Those Congress Itself Left Unregulated in 2009, Correctly Explaining That the Statute Grants FDA Unlimited Discretion.

The Secretary internally delegated the "deeming" authority to the FDA Commissioner, who delegated it to several deputy and associate commissioners. *See* App. 4 n.5 (citing FDA Staff Manual Guide 1410.21(1)(G)(1)).[3] In 2016, the FDA proposed a rule

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[3] Accordingly, the Deeming Rule was issued in May 2016 by Associate Commissioner for Policy Leslie Kux. The Court of Appeals for the District of Columbia recently rejected an

that would extend the TCA's scope under one of two options. "Option 1" proposed deeming everything meeting the "tobacco product" definition; "Option 2" also proposed deeming everything, except for "premium cigars." *See* Deeming Rule, 81 Fed. Reg. at 29,020.

After notice and comment, the FDA chose Option 1. Thus, when it issued the final Deeming Rule, the FDA applied the TCA to any product meeting the "tobacco product" definition—that is, to (i) *everything* Congress itself had declined to regulate in 2009, plus (ii) *any and all* current and future "tobacco products." FDA explained the breadth of the Deeming Rule:

> Products that meet the statutory definition of "tobacco products" include currently marketed products such as dissolvables not already regulated by FDA, gels, waterpipe tobacco, ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes), cigars, and pipe tobacco.
>
> In addition, this final rule deems any additional current and future tobacco products that meet the statutory definition of "tobacco product[.]"

81 Fed. Reg. 28,976.

As discussed further below, Petitioners are active in the ENDS industry. Vapor devices, also known as

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Appointments Clause challenge to the Rule, holding that ratification in 2019 by then-Commissioner Gottlieb cured any Appointments Clause defect. *Moose Jooce v. Food & Drug Admin.*, __ F.3d __, No. 20-5048, 2020 WL 7034417 (D.C. Cir. 2020).

"electronic cigarettes," "e-cigarettes," or "electronic nicotine delivery systems (ENDS)," are handheld electronic devices used to heat and aerosolize a liquid mixture ("e-liquid") that includes flavoring and various levels of liquid nicotine, including zero nicotine. ROA.374.[4] Once the liquid is aerosolized, the user inhales the "vapor" in a manner similar to that of inhaling actual tobacco smoke, but without setting any tobacco on fire. *Id.* ENDS devices come in "closed" or "open" systems. In a "closed system," either the device itself or interchangeable pods or cartridges intended for use with that device come pre-filled with a particular type of e-liquid. *See* ROA.136 (definition of "E-cigarette"). In an "open system," the device will not come pre-filled; rather, the user will separately buy bottled e-liquid(s) and use them to fill the device's e-liquid reservoir, or "tank," with the e-liquid and nicotine level of his or her choice. *Id.*

In the Deeming Rule, the FDA frankly acknowledged that significant distinctions can be made regarding health effects between combustible and non-combustible products. 81 Fed. Reg. at 28,982 ("Researchers recognize that the effects from nicotine exposure by inhalation without combustion are likely not responsible for the high prevalence of tobacco-related death and disease in this country.") But the FDA rejected the notion that the statute imposed any substantive guidance—regarding a public health standard or otherwise—on its deeming discretion.

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[4] Citations to the record refer to the "Record on Appeal," as it is denominated in the Court of Appeals for the Fifth Circuit.

During the comment period required by the Administrative Procedures Act, a commenter asserted that the FDA is required to "establish that deeming [a product] will benefit public health." Deeming Rule, 81 Fed. Reg. at 28983. The FDA gently corrected the commenter, explaining that this suggestion "*attempted to impose a standard for the application of FDA's deeming authority that is not created by statute or otherwise*." *Id.* (emphasis added). The FDA reiterated this position in defending against an APA challenge in the District Court for the District of Columbia, writing that "Congress authorized the FDA to subject 'any' tobacco product … to the [TCA] as it 'deems' fit, *without articulating any standards to cabin the agency's discretion*." ROA.338-39 (FDA's legal memorandum, filed in *Nicopure Labs, LLC v. Food and Drug Admin.*, 266 F. Supp. 3d 360, 393 (D.D.C. 2017) (emphasis added), *aff'd*, 944 F.3d 267 (D.C. Cir. 2019)); *see also id.* (FDA writing that "Congress's choice of the deferential word 'deems' *and the absence of any standard*—beyond the requirement that the product meet the definition of a 'tobacco product'—demonstrate that Congress committed the exercise of this authority to the agency's broad discretion.") (emphasis added). The *Nicopure* District Court agreed with the FDA, recognizing that "the statute did not provide standards for when and how the agency was to exercise its discretion to deem[.]" *Nicopure Labs, LLC*, 266 F. Supp. 3d at 393.[5]

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[5] The *Nicopure* District Court made this statement in the course of holding that the only substantive limitation on the Secretary's deeming authority, and thus justiciable for purposes of Nicopure's APA challenge, is that deeming extends only to "tobacco products."

Despite recognizing that non-combustible products are "likely" not responsible for the health problems associated with traditional combustible tobacco, *supra* at 10, the FDA also recognized that imposing the TCA would have comparatively harsh consequences on the market for ENDS. ENDS products, particularly e-liquids, are characterized by a high degree of variation, due to the number of possible combinations of flavors, nicotine concentrations, and bottle sizes. As an example, Petitioner Big Time Vapes "manufactures" its own proprietary flavors—350 of them—which can be sold in varying levels of nicotine content (0-24 mls), and in six different bottle sizes. ROA.12. As a result, Big Time Vapes has registered 98,000 stock keeping units (SKUs) with the FDA. The FDA advises that any variation in flavor, nicotine content, or bottle size constitutes a unique "new tobacco product" requiring its own PMTA. Proposed Final PMTA Rule, 84 Fed. Reg. at 50573 (discussing proposed final definition of "new tobacco product").[6] FDA estimated that an initial premarket review application for e-liquids would cost between $181,686 and $2,014,120 *per application*, and applications for delivery devices between $285,656 and $2,622,224 *per application.*[7]

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266 F. Supp. 3d at 393. Nicopure did not assert a violation of the nondelegation doctrine, and, as demonstrated below, merely defining the field of *potential* regulation is insufficient.

[6] The final PMTA rule has still not yet been promulgated.

[7] FDA, 81 Fed. Reg. 28973, Reference 204: Final Regulatory Impact Analysis for the Deeming Rule, at 87 (Table 11a), 90-91 (Table 12a) (May 9, 2016), *available at* https://www.fda.gov/media/97875/download ("Final RIA").

The particularly wide product variability characterizing the ENDS industry, coupled with the prohibitive costs of even a single PMTA, illustrate why the FDA estimated that, based solely on "compliance costs," applying the TCA to ENDS would cause 87.5% of e-liquids to "exit the market." Final RIA at 78-79. By contrast, FDA estimated only 5% of combusted tobacco products (cigars, pipes, and hookah)—which can take advantage of a less burdensome approval pathway—would exit the market. *Id.*[8]

III. The FDA Struggles for Years to Determine Its Priorities Regarding Newly-Regulated Tobacco Products, Prompting Interest Groups to Advance Their Preferences In Federal Court.

For years following promulgation of the Deeming Rule, the FDA repeatedly acknowledged that it was not prepared to implement the TCA with respect to this industry. While the ENDS market was frozen as of the effective date of the Deeming Rule (precluding Petitioners from marketing any new products not already being sold as of the Rule's effective date in August 2016), the FDA withheld enforcement against those products already on the market, pending timely submission of PMTAs. Deeming Rule, 81 Fed. Reg. at 21,977-78. PMTAs were initially due in August 2018, *id.*, but the FDA extended the deadlines (and changed

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[8] Cigarette and cigar manufacturers can seek premarket approval by "submitting a 'report' showing that the product 'is substantially equivalent to a tobacco product commercially marketed' before February 2007." App. 5 (quoting 21 U.S.C. § 387j(a)(2)(A)(i).

its enforcement policy in other ways) in a series of guidance documents.

In June 2017, then-FDA Commissioner Scott Gottlieb, M.D., stated that the "foundational regulatory architecture" was not in place "because the Agency's tobacco program itself is so new," ROA.382, and that "the FDA intends to issue regulations outlining what information the agency expects to be included in [PMTAs]" and "how it intends to review PMTAs for ENDS," ROA.382. The following month, FDA issued its August 2017 Guidance, extending the initial PMTA submission deadline for ENDS products to August 2022. *See* ROA.192-205. Then, for the next two years, Commissioner Gottlieb continued to emphasize that "[t]he foundational regulations for the tobacco program were never put in place and so we're going to take the time to put those in place so we have a firm foundation from which to regulate." ROA.382; *see also* ROA.383-84 (collecting additional statements).

Objecting to the FDA's delayed enforcement schedule, a number of anti-vaping interest groups challenged the FDA's extended deadlines in the District Court for the District of Maryland. *See Am. Acad. of Pediatrics v. Food and Drug Admin.*, 8:18-cv-00883-PWG (D. Md.) (*AAP*). The *AAP* District Court held that the August 2017 extension of the enforcement deadlines violated the APA, and indicated that the court would set a new deadline.

The FDA warned against setting an unrealistic deadline that would threaten the viability of ENDS manufacturers. Mitchell Zeller, Director of the FDA's Center for Tobacco Products, stated that "mass market

exit of [ENDS] products would limit the availability of a potentially less harmful alternative for adult smokers seeking to transition or stay away from combustible tobacco products," and that "[d]ramatically and precipitously reducing availability of these products could present a serious risk" to adults. *AAP* (Dkt. No. 120-1 ¶15). In July 2019, the *AAP* District Court entered an order accelerating the deadline for ENDS PMTAs to May 2020 (just ten months from the date of that order). *AAP*, 2019 WL 3067492, at *7 (D. Md. Jul. 12, 2019).[9]

IV. Petitioners Challenge the Deeming Authority in Federal District Court.

The *AAP* District Court's order moved the deadline for ENDS PMTAs up by 27 months. Petitioners filed suit in the Southern District of Mississippi on August 19, 2019, alleging that § 387a(b) was an unconstitutional delegation of legislative authority, and seeking a declaratory judgment and permanent injunction prohibiting the FDA from enforcing the TCA or the Deeming Rule against them. App. 9. Plaintiff Big Time Vapes, Inc., is a Mississippi corporation wholly owned by Belinda Dudziak, who smoked one-and-a-half to three packs of cigarettes every day for 26 years until she was able to quit entirely within days of trying her first e-cigarette. ROA.12. She began vaping

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[9] Shortly before this deadline, on April 22, 2020, the *AAP* District Court granted the FDA's request to extend the deadline to September 9, 2020, due to the effects of the coronavirus and related restrictions on business activity. *Am. Acad. of Pediatrics v. Food and Drug Admin.*, No. 8:18-cv-00883-PWG (D. Md. Apr. 22, 2020).

e-liquids with 18% nicotine content, gradually reduced the nicotine level, and now vapes exclusively without nicotine. *Id.* Big Time Vapes is a single-location retailer and "manufacturer" of vaping products with approximately 4,000 customers, 98% of whom have quit smoking cigarettes entirely. *Id.* Plaintiff United States Vaping Association is a trade association representing small "manufacturers" and retail shops in the industry. ROA.12-13.[10]

Weeks after Petitioners' suit was filed, in a press conference televised live from the White House, the Administration announced its intent to modify its enforcement policy to remove all flavored vapor products from the market (other than tobacco flavors) within a matter of weeks. *See* ROA.387-88.

In light of this threatened ban on a substantial portion of their products, Petitioners moved for a preliminary injunction on October 10, 2019, arguing that the impending PMTA deadline, and the newly-announced ban on nearly all flavored products, each independently threatened irreparable harm. ROA.405-10. The FDA[11] filed a Rule 12(b)(6) motion to dismiss the suit contemporaneously with a response to Petitioners' injunction request, and a combined memorandum arguing both in support of dismissal and

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[10] The USVA had approximately three dozen members in August 2019, ROA.13, which expanded to more than fifty when the motion for preliminary injunction was filed in October 2019, ROA.341. Membership has expanded significantly since then.

[11] Respondents are sometimes referred to herein collectively as "the government" or "FDA."

opposition to the requested injunction. ROA.443-506. The combined memorandum leads off with eighteen pages of "introduction" and "background" material, including references to selected representations of facts from the congressional record in 2009 and decades-old government reports regarding *combustible* tobacco products and *cigarette* manufacturers.

Petitioners argued that dismissal would be unwarranted because they had stated a valid claim, but that, even if that were doubtful, they should be afforded reasonable discovery on discrete issues prior to dismissal, especially in light of the government's reliance in the combined memorandum on selective references to factual material that was not cited in Petitioners' complaint.

On December 16, 2019, the District Court granted the FDA's motion to dismiss and denied the injunction. App. B, D. Petitioners appealed to the Fifth Circuit.

V. Petitioners Appeal to the Fifth Circuit.

a. Contradicting its position in *Nicopure*, the FDA now argues that a general policy can be deduced from the Act's preface.

Petitioners argue that § 387a(b) is an unconstitutional delegation because Congress failed to provide any policy, standard, or even factors for the Secretary's consideration in determining which additional segments of the nationwide "tobacco products" industry shall be federally regulated. Despite its argument to the federal court in *Nicopure*—that Congress had failed to "articulat[e] any

standards to cabin the agency's discretion," *supra* at 11—the FDA recognized it had to change tack here.

The FDA relies heavily on the fact that the TCA limits the scope of the deeming authority to the field of "tobacco products," as defined by statute, and that, *once a product is deemed*, the TCA supplies the framework of substantive regulation applicable to it. FDA Br. at 13-25. While true, as Petitioners explain *infra* at 30-31, these features of the TCA do *not* substitute for the fact that the Secretary has uncabined discretion to determine whether any given product shall be regulated in the first place. On this dispositive question, the FDA struggled to articulate any guiding principle.

Given the lack of any standard or criteria in the Act's operative text, the FDA relied on the principle that "the standards of the statute … must derive meaningful content from the purpose of the statute and its factual background and the statutory context in which the standards appear." FDA Br. at 18 (citing a circuit case, which quotes *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 104-05 (1946)). Referring to the Act's preface (adopted, of course, in 2009), the FDA noted that "Congress made extensive findings regarding the unique dangers posed by tobacco products and the particular risks they present to children, TCA § 2(1) – (49)[12] … [and] concluded that 'comprehensive restrictions on the sale, promotion, and distribution of such products are needed.' *Id.* § 2(6)." FDA Br. at 18. Of the ten broadly-worded statements

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[12] *See* 21 U.S.C. § 387, note.

of purpose in TCA § 3, the FDA dialed in on only four of them. These included the purposes of "ensur[ing] that [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco," and "provid[ing] 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." FDA Br. at 19 (quoting TCA §§ 3(2), (4)).

Respondents then summarized their argument:

> *FDA's* determination that products falling within the statutory definition of "tobacco product" should be subject to the Act's requirements thus comports with the general policies set forth in the statute's findings and statement of purpose. … Congress plainly *contemplated* such inclusive regulation of tobacco products under this "comprehensive" scheme, TCA § 2(6), and that congressional intent properly factors in this analysis.

FDA Br. at 20 (italics added).

Petitioners acknowledged that § 387a(b) must be tested in its full context, but explained that the context does not supply an intelligible principle for three reasons. First, there is no *operative standard* to be fleshed out with reference to the general declarations of purpose. In fact, Petitioners argued from the beginning that § 387a(b) is worse than even the most extreme examples of upheld delegations because it lacks *any* operative standard whatsoever. *See*

ROA.403-04. Second, the declarations of purpose are both amorphous and self-contradictory, and in such a situation, *Panama Refining* recognized that article I is violated if the executive is allowed unbridled discretion to select which of several competing priorities to pursue. Third, even if one could discern a guiding principle from the statements of purpose, Congress's narrow initial application of the TCA is–to say the least –an important part of the "context," precluding any easy conclusion that all-encompassing regulation was Congress's aim.

b. The Fifth Circuit detects a standard and affirms dismissal.

The Fifth Circuit panel effectively acknowledged that the TCA lacks an express standard, App. 14-16, but imagined one based on "the TCA's purpose and the relevant factual background." App. 16. As to purpose, the Fifth Circuit quoted from four of Congress's ten statements (though, tellingly, not the same four highlighted in the FDA's brief). App. 16-17. The panel then purports to synthesize the broad purposes of the Act, stating, "[o]bviously, the TCA's purpose *sounds in* (1) protecting the public health and (2) preventing young people from accessing (and becoming addicted to) tobacco products." App. 17 (emphasis added).

As to factual background, the panel wrote that "Congress concluded that, for several reasons, tobacco products posed a significant risk to children." App. 17. Then, of forty-nine legislative findings, the panel placed heavy emphasis on the five in which Congress used the word "comprehensive," but ripping that word from its context in those findings. App. 17, 17 n.25.

The panel effectively read these legislative findings as if they *compelled* the Secretary to extend the TCA to all products through deeming:

> Congress meant for the FDA to attack those problems *comprehensively*, that is, in an "all-encompassing or sweeping' fashion." *Gundy*, 139 S. Ct. at 2127 (plurality). Those findings, when coupled with Congress's stated purposes in legislating, undoubtedly identify a "general policy" for the Secretary to pursue.

App. 17-18 (italics in original; footnote omitted).

The panel expressly likened the TCA to the Sex Offender Registration and Notification Act (SORNA). In *Gundy*, a plurality of this Court read SORNA's disputed language as "*instruct[ing]* the Attorney General to apply SORNA's registration requirements to pre-Act offenders as soon as feasible." 139 S. Ct. at 2129 (emphasis added). Here, the Fifth Circuit wrote that "[t]he TCA's commission to the Secretary mirrors [SORNA's] delegation to the Attorney General." App. 20.

The Fifth Circuit also noted that Congress "enacted a controlling definition of 'tobacco product,'" and "restricted the Secretary's discretion by making many of the key regulatory decisions itself," *i.e.*, by laying out the substantive framework that would become applicable *if* a product were deemed. The panel did not respond to Petitioners' arguments as to why those two features were insufficient.

Accordingly, the panel affirmed dismissal of the case. The panel did not acknowledge *Panama*

Refining's holding that permitting the executive to choose between vague, competing "purpose" statements violated the nondelegation doctrine. Neither did the Fifth Circuit consider—as part of the relevant statutory "context"—the implication of Congress's narrow application of the TCA in 2009. The opinion likewise fails to address the FDA's own disavowal of any substantive standard in the final rule, or the FDA's arguments and the district court's holding in the *Nicopure* litigation.

Petitioners' request for *en banc* rehearing was denied on August 25, 2020.

REASONS FOR GRANTING THE PETITION

I. The Fifth Circuit's Failure to Validate Petitioners' Claim Conflicts With This Court's Precedent and Vitiates Any Remaining Limits on Delegation.

a. TCA § 387a(b) impermissibly delegates quintessential legislative power.

The authority to decide the circumstances under which a given activity or product shall be subjected to federal regulation is quintessentially one of legislative policy. *Field v. Clark*, 143 U.S. 649, 693 (1892) ("Legislative power was exercised when *congress* declared that the suspension should take effect *upon a named contingency*.") (emphasis added); *Opp Cotton Mills v. Admin. of Wage and Hour Division of Dep't of Labor*, 312 U.S. 126, 144 (1941) ("The adoption of the declared policy by Congress *and its definition of the circumstances in which its command is to be effective*, constitute the performance, in the constitutional sense,

of the legislation function") (emphasis added); *Yakus*, 321 U.S. at 424 ("The essentials of the legislative function … are preserved when Congress has specified the basic conditions of fact upon whose existence or occurrence, ascertained from relevant data by a designated administrative agency, it directs that its statutory command shall be effective").

In accordance with this established principle, the plurality in *Gundy* recognized that, if SORNA conferred authority on the Attorney General to determine *whether* SORNA applied to pre-Act offenders at all, it would have presented a serious constitutional question. 139 S. Ct. at 2123 ("If that were so, we would face a nondelegation question."). The plurality avoided that question, because it held that the "Court has already interpreted § 20913(d) to say something different—to require the Attorney General to apply SORNA to all pre-Act offenders as soon as feasible." *Id.* (citing *Reynolds v. United States*, 565 U.S. 432, 442-43 (2012)).

b. The Fifth Circuit's decision ignores and contradicts *Panama Refining*.

1. In *Panama Refining*, the Court likewise recognized that "the question whether … transportation [of hot oil] shall be prohibited" "is obviously one of legislative policy," 293 U.S. at 415, and held the delegation unconstitutional. The Court wrote:

> Section 9(c) [of the Recovery Act] does not state whether or in what circumstances or under what conditions the President is to prohibit the transportation of the amount of petroleum or

> petroleum products produced in excess of the state's permission. It establishes no creterion to govern the President's course. It does not require any finding by the President as a condition of his action. The Congress in section 9(c) thus declares no policy as to the transportation of the excess production. So far as this section is concerned, it gives to the President an unlimited authority to determine the policy and to lay down the prohibition, or not to lay it down, as he may see fit.

Id. at 415.

The Court held this delegation unconstitutional despite expressly acknowledging that the scope of authority was narrowly circumscribed to the particular subject matter ("hot oil") and despite the binary nature of the President's authority. *Id.* at 414-15.

In a portion of *Panama Refining* that the Fifth Circuit never acknowledges, much less distinguishes, the Court examined the Recovery Act's surrounding provisions and statements of purpose, but found they did not establish a discernible standard. *Id.* at 417-18. This aspect of the decision warrants discussion in some detail, because it announces perhaps the last enforceable limit on the delegation of legislative power under the Court's current approach, but has been dispatched by the decision below.

Some purposes of the Recovery Act would seemingly have been furthered if the President chose to prohibit transportation of "hot oil," such as the conservation of natural resources, or eliminating "unfair competitive

practices." *See id.* However, other purposes listed in the Act would have been *undermined* by prohibiting transportation, such as "removing obstructions to the free flow of interstate and foreign commerce." *See id.* In light of these competing goals, the Court refused to read the general statements of purpose to impose a discernible standard, explaining:

> *Among the numerous and diverse objectives broadly stated, the President was not required to choose.* The President was not required to ascertain and proclaim the conditions prevailing in the industry which made the prohibition necessary. The Congress left the matter to the President without standard or rule, to be dealt with as he pleased.

Panama Refining, 293 U.S. at 418–19 (emphasis added). Then, in a critique that seems tailor-made for the Fifth Circuit's decision here, the Court warned that "[t]he effort by ingenious and diligent construction to supply a criterion *still permits such a breadth of authorized action as essentially to commit to the President the functions of a Legislature rather than those of an executive or administrative officer executing a declared legislative policy*." *Id.* at 419 (emphasis added).

The TCA presents the Secretary with the same kind of binary authority as § 9(c) of the Recovery Act, with even vaguer statements of purpose, some of which are in actual tension.

While one of the TCA's purposes is to "address the use of tobacco by young people and dependence on

tobacco," TCA § 3(2), another is "to continue to permit the sale of tobacco products to adults" and "promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases," *id.* §§ 3(7), (9). Former FDA Commissioner Scott Gottlieb recognized that "what primarily causes death and disease from tobacco use isn't the nicotine" but "the act of lighting tobacco on fire to free that drug for inhalation," and "E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products." ROA.183. In light of the important distinctions between combustible and non-combustible products, and the fact that so many adult smokers have used ENDS to quit smoking entirely, it is certainly not a given that the Congress that passed the TCA—grandfathering cigarettes and leaving other products entirely unregulated—would support "deeming" vapor products, where the practical effect would be to extinguish nearly 90% of these products. *Supra* at 13; Moreover, federal law still contains a provision expressly recognizing Congress's interest in protecting "commerce and the national economy … to the maximum extent," 15 U.S.C. § 1331 (regarding cigarette labeling and advertising), which the Supreme Court observed in 2000 "reveal[s] [Congress's] intent that tobacco products remain on the market." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 139 (2000). That statute remains on the books. Far from evidencing a new tack, Congress's narrow application of the TCA in 2009 reflects similar legislative tradeoffs.

Ignoring all this, the Fifth Circuit did what the Supreme Court in *Panama Refining* refused to do. The

panel evades all distinctions and internal tension by mashing the entire "purpose" list into a still more generalized "general policy," claiming that, "[o]bviously, the TCA's purpose sounds in (1) protecting public health and (2) preventing young people from accessing (and becoming addicted to) tobacco products." App. 17. Notably, the Fifth Circuit chose different statements of purpose to emphasize than the statements highlighted by the FDA in its brief, although both the court and the Agency cited only a few of the ten listed purposes.

The Fifth Circuit's abstraction—from Congress's already abstract and competing goals—necessarily required the Fifth Circuit to choose which principles to prioritize. So, it erases from consideration Congress's other stated goals of continuing the sale of products to adults, and even of "promoting cessation," an important goal the FDA itself acknowledges ENDS may further. And in the end, the Fifth Circuit's re-formulated overall standard does nothing to cabin the FDA's discretion, as "public health" may arguably be protected either by terminating the market for ENDS or by facilitating and expanding it to promote cessation. The FDA could defend either with reference to public health, and therefore is left with the discretion to prioritize which particular aims are more important. *Cf. Panama Refining*, 293 U.S. at 418-19; *Gundy*, 139 S. Ct. at 2146 (GORSUCH, J., dissenting).

But the Fifth Circuit went a step further, reading the TCA as if it mandated the Secretary to regulate *all* tobacco products. Perhaps the Fifth Circuit felt obliged to adopt this reading in light of the fact that the FDA already *had* deemed everything. To justify this

interpretation, the court referred to the appearance of the word "comprehensive" in a handful of legislative findings. App. 17 n.25. But these references cannot bear the weight the court has imposed upon them. The handful of references (such as that to "comprehensive restrictions on the sale, promotion, and distribution of such products") are references to the breadth of the *topics* covered by the TCA (marketing, distribution, etc.), and not to the scope of *products* to which the TCA applied. Moreover, Congress's narrow application in 2009 belies any easy conclusion that Congress wanted the broadest coverage possible. Instead, the limited initial scope reflects the principle that "[n]o law pursues just one purpose at all costs, and no statutory scheme encompasses just one element." *King v. Burwell*, 576 U.S. 473, 512 (2015) (Scalia, J., dissenting). *See also Gundy*, 139 S. Ct. at 2146 (Gorsuch, J., dissenting); ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 218 (2012) (explaining that "an expansive purpose in the preamble cannot add to the specific dispositions of the operative text").

If Congress wanted the TCA to apply to all tobacco products, it would have been easy enough to say so itself in the statute rather than severely limiting its initial application. The plain text of § 387a(b) instead clearly and unequivocally vests the Agency with the discretion to apply, or not apply, the TCA to additional tobacco products. The Fifth Circuit's analysis ignores the clear import of this text. The Fifth Circuit's strained reimagination of the statue as if it *compels* all-encompassing regulation is also flatly belied by the fact that the FDA initially considered leaving premium

cigars unregulated, Deeming Rule, 81 Fed. Reg. at 29,020, and stated expressly in the final rule that "FDA agrees that the Agency is not obligated to deem all tobacco products," *id.* at 29,025.

2. Not only does the Fifth Circuit's imagined standard contravene competing principles reflected in the TCA, but the fact that the court attempted to discern a standard in these circumstances marks a novel departure from *Panama Refining*. The panel makes no attempt to distinguish *Panama Refining*, and cites no case fabricating a standard in the absence of some kind of operative statutory standard. The panel's authority for this point, *Am. Power & Light Co.*, 329 U.S. at 104 (*see* App. 15-16, 16 n.23), featured *both* (i) a primary statutory standard and (ii) what the Court called "*a veritable code of rules* … for the Commission to follow in giving effect *to the standards of s 11(b)(2).*" *Id.* at 104-05 (emphasis added). The TCA has neither.[13] Even more puzzling is the fact that the panel imagines a (meaningless) standard "sounding in" public health, despite the fact that the FDA itself eschewed any public health standard *in the final rule*. Oddly, then, in the supposed service of facilitating necessary discretion in executive agencies, a panel of three judges overruled the agency's own contemporaneous view of the statute it administers.

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[13] The panel also cites *Thomas v. Union Carbide Agric. Prod. Co.*, 473 U.S. 568, 593 (1985), App. 16 n.23, which provides even less support to Respondents' position, as the Court expressly refused to opine on the nondelegation claim, noting that it was not litigated before the district court or this Court.

Further, given that the FDA has already deemed everything that has been, is now, or ever will be a "tobacco product" to be subject to the TCA, the panel's limitation cannot constrain the exercise of the delegated power.

3. The fact that the deeming provision confers discretion only with respect to the field of "tobacco products" does not save the TCA any more than the fact that § 9(c) of the Recovery Act was strictly circumscribed to a subset of petroleum products withdrawn in violation of state law. *Panama Refining* expressly recognized that "[t]he subject to which [the President's] authority relates *is defined*" as the narrow field of oil produced in violation of the limits allowable under state law, 293 U.S. at 414 (emphasis added), but proceeded to hold it unconstitutional. This was done over Justice Cardozo's dissent, in which he argued that the president's discretion was sufficiently limited by the fact that he had only a binary choice (to prohibit the transportation, or not), regarding a "particular commodity," further limited to when such commodity was withdrawn in violation of another legal standard (state law). 293 U.S. at 434-35 (Cardozo, J., dissenting); *see also A.L.A. Schechter Poultry Corp*, 295 U.S. at 552 (Cardozo, J., concurring).

Every delegation case involves a delegated task that operates within a certain field of activity. If limiting potential regulation to a certain field of activity were sufficient for an intelligible principle, then *Gundy*, and all other nondelegation cases, would have been much easier for this Court to dispatch by simply noting that the authority only operates within the field at issue.

For example, in *Gundy*, while the challenged authority was circumscribed within the narrow field of "sex offenders" as defined in SORNA, 139 S. Ct. at 2122 (acknowledging SORNA's "sex offender" definition), the separation of powers required the Court to analyze whether Congress had sufficiently limited the Attorney General's discretion to determine SORNA's applicability to pre-Act offenders, *id.* at 2123.

4. Likewise, the fact that the TCA supplies the requirements applicable to *regulated* products does not remedy the lack of any standards to guide the Secretary's decision whether a given tobacco product *shall be* so regulated. For example, in *Touby v. United States*, the Court examined whether Congress had provided sufficient guidance to "meaningfully constrain" the Attorney General's discretion to temporarily schedule a purported controlled substance, *despite* the fact that the Controlled Substances Act supplied a detailed regulatory framework to any drugs subjected to it. 500 U.S. 160, 160-65 (1991).[14]

Panama Refining and *Touby* thus foreclose the panel's claim that vesting a cabinet official with the unilateral authority to decide whether a given segment of the economy is regulated or not is merely a "finishing touch" under the TCA. *Cf.* App. 20. Deciding whether

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[14] The statute in *Touby* was upheld because it required the Attorney General to "find that [temporarily scheduling a substance] is 'necessary to avoid an imminent hazard to the public safety,'" he was "required to consider three [identified] factors," *and* "must satisfy the requirements of § 202(b)," which "identifies the criteria for adding a substance to each of the five schedules." *Id.* at 166-67.

cigars (or any other product) shall be regulated, after Congress left them unregulated, is not a "finishing touch."

5. The unbridled discretion feared and avoided even by the plurality in *Gundy* is the precise discretion vested in the Secretary here. And unlike with SORNA, there is no way to read the TCA as if it *required* that the Secretary deem any particular product to be subject to the requirements of the TCA, at any time or for any reason. Congress limited the regime to cigarettes and snuff and left any other products unregulated, except at the Secretary's whim.

c. Section 387a(b) is particularly troubling because it delegates authority to decide major policy questions.

Forty years ago, then-Justice Rehnquist urged the Court to enforce the nondelegation doctrine, especially where Congress has delegated "important choices of social policy to politically unresponsive administrators." *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 686-87 (1980) (Rehnquist, J., concurring in judgment). So far, this call has not been heeded, and the boundless delegation in the TCA illustrates the increasing Congressional lassitude inevitably resulting from the decades-long failure of the judicial branch to enforce the structural limits on delegation imposed by article I. At least five justices of the current Court have expressed a willingness to examine this unwarranted dilution of the nondelegation doctrine, especially where a question of major policy or economic significance is involved. *Gundy*, 139 S. Ct. at 2141-42 (Gorsuch, J.,

dissenting); *id.* at 2130-31 (Alito, J., concurring); *Paul v. United States*, 589 U.S. __, __ (2019) (Kavanaugh, J., statement respecting the denial of certiorari). This is just such a case.

Determining whether entire segments of "tobacco products" in this country shall be federally regulated is clearly a major policy question. This Court has already recognized that the tobacco industry is rife with historical economic and political import, *see Brown & Williamson*, 529 U.S. at 160, yet § 387a(b) gives an executive agency unilateral discretion to decide which products shall be regulated. Thus it was that the FDA was able to unilaterally extend federal regulation over products like cigars, hookah, and pipe tobacco, which Congress declined to regulate. It also asserted federal power over the entirely new ENDS industry, which is materially distinct from the combustible tobacco products Congress examined in 2009, both in the function and variability of the products and in their health effects. In fact, material distinctions exist within the ENDS industry (*e.g.*, open systems versus closed, cartridge-based systems, as noted *infra* at 35 n.16), and material distinctions abound among the different combustible products as well. *See, e.g.*, Deeming Rule, 81 Fed. Reg. at 29,020 (acknowledging that "compared with persons who smoke cigarettes, those who use cigars exclusively have a lower risk for many smoking-related diseases," as "cigar smokers generally smoke at a lower frequency and tend not to inhale the smoke"). Extending federal regulation over new segments of this industry involves policy judgments, and prioritization of interests, of deep significance.

The significant policy choices involved in, and following from, the deeming authority are further illustrated by the very public manner in which the Administration has seen fit to wield this authority, along with its frequently shifting priorities and haphazard solicitation of stakeholder input.

When the Administration announced yet another intended modification to its enforcement policy in September 2019 (the intent to "finalize a guidance document" that would "remove[] from the market" all flavored e-cigarettes other than tobacco flavor), it did so in a press conference from the White House, attended by the President, the Secretary, and the FDA Commissioner, and televised live on national news. *See* ROA.387-88.

In a Senate committee hearing two months later, senators expressed diverse views on the proposed action. Joyce Frieden, *Senators Slam FDA for Inaction on Youth Vaping Epidemic*, MEDPAGE TODAY (Nov. 13, 2019), https://www.medpagetoday.com/primarycare/smoking/83324. Several Senators expressed impatience and urged FDA officials to act without further delay. *Id.* Senator Mitt Romney lamented that legislation proposed in the Senate eight months earlier to restrict ENDS flavors lacked support to advance. *Id.*[15] Amidst the roiling debate, the President hosted a hastily arranged meeting at the White House on November 22, 2019, with various invited stakeholders jockeying for the President's attention. Sarah Owermohle, *Trump hosts vaping shoutfest at the White*

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[15] *See* Safe Kids Act, S. 655, 116th Cong. (2019).

House, POLITICO (Nov. 22, 2019), https://www.politico.com/news/2019/11/22/trump-white-house-vaping-meeting-072937. Some advocated a comprehensive ban on flavored ENDS products to avoid appealing to adolescents, while others argued that distinctions must be made between the sleek, cartridge-based products popular with young persons and the open-tank systems popular with adults, and that banning flavors across the board would destroy thousands of small businesses and make it more difficult for smokers to quit or stay off of cigarettes. *Id.* Senator Romney—reduced to lobbying the Administration in light of the failure of Congressional action—"told the president that most adults are not using flavors, prompting vaping industry leaders in the room to shout, 'Yes they do!' and to offer sales statistics[.]" *Id.* While no conclusions were announced that day, in January 2020, the FDA announced its decision to prioritize enforcement against *cartridge*-based (closed system) flavored ENDS.[16]

The November 22 White House roundtable featured spirited advocates from several sides of a policy debate, all attempting to influence the Administration's

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[16] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization: Guidance for Industry* (Jan. 2020) at 11, 15 (concluding that "youth overwhelmingly prefer cartridge-based ENDS products"); *see also id.* at 19, 21 ("cartridge-based products … [are the] primary driver in youth experimentation with, and continued use of, ENDS products"); *id.* at 15-16, 19, 21 (recognizing distinctions in cartridge-based versus open-tank systems that make cartridge-based products attractive to youth, such as ease of use and concealability)

enforcement policy regarding ENDS. This is a reflection of the importance of this issue to several different constituencies in this country. But under the TCA, the Administration did not even have to take the step of extending its regulatory jurisdiction over ENDS in the first place. It applied the TCA to ENDS—along with several other entire "tobacco product" industries—in its unilateral discretion

These are precisely the types of legislative decisions dedicated to the Congress alone under the Constitution. "The framers went to great lengths to make lawmaking difficult," "insist[ing] that any proposed law must win the approval of two Houses of Congress—elected at different times, by different constituencies, and for different terms in office[.]" *Gundy*, 139 S. Ct. at 2134 (Gorsuch, J., dissenting). Yet there in November 2019 were the vaping restrictionists, on the one side, pleading with the president to destroy the market for flavored products by executive fiat, while others pleaded for the rights of small business owners and former smokers who quit through vaping. *Cf. Gundy*, 139 S. Ct. at 2135 (Gorsuch, J., dissenting) ("Without the involvement of representatives from across the country or the demands of bicameralism and presentment, legislation would risk becoming nothing more than the will of the current President."). Congressional representatives were lobbying the President rather than enacting legislation.[17]

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[17] In addition to Senator Romney, who was present at the meeting, other Senators lobbied the President through letters. Press Release, Sen. Dick Durbin, *Durbin Sends Bipartisan & Bicameral*

II. This Case Presents an Especially Compelling Need For Enforcement of The Nondelegation Principle Because of the Particularly Broad and Standardless Delegation of Power to Decide Major Policy Questions In An Area Devoid of Any Inherent Presidential Authority.

In many decisions before and after then-Justice Rehnquist's plea in *Industrial Union*, this Court has dutifully nodded to the viability of the nondelegation doctrine in theory, while facilitating its demise in practice. This case illustrates the result of this progression. Despite the fact that the deeming authority is literally standardless, just like the statute in *Panama Refining*, the Fifth Circuit felt obliged to give Congress a pass, and did what the Court in *Panama Refining* refused to do. The Fifth Circuit abstracted from vague and competing aspirational statements, ignoring their internal contradictions, in order to imagine a still-more-meaningless purported standard. The FDA could meet that purported standard regardless of any decision it made. Moreover, in imagining a standard, the Fifth Circuit ignored the fact that the *FDA itself* stated flatly in the Deeming

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Letter to President Trump Urging For Final E-Cigarette Flavor Ban (Dec. 3, 2019), https://www.durbin.senate.gov/newsroom/press-releases/durbin-sends-bipartisan-and-bicameral-letter-to-president-trump-urging-for-final-e-cigarette-flavor-ban (touting signatures of 25 Members of Congress); Press Release, Sen. Patty Murray, *Senators Murray, Cantwell Slam FDA E-Cigarette Policy Riddled With Loopholes for Kid-Appealing Flavors* (Jan. 14, 2020), https://www.murray.senate.gov/public/index.cfm/newsreleases?ContentRecord_id=7F5D8E7C-539B-486F-AE63-D8809D18D6AC.

Rule that no substantive standard guided its discretion, and later defended this position in federal court. Thus, in the supposed service of the notion that broad delegations must be permitted so expert agencies can administer the statutes entrusted to their care, the Fifth Circuit ignores the contemporaneous, official position of the Agency here. Present nondelegation jurisprudence thus apparently requires federal courts to invent standards that Congress refused to write and the agency expressly rejected—resulting not merely in permissive delegations to the executive, but, effectively, legislative delegations *to the judiciary*. This, indeed, is delegation run amok.

If the vesting Clause of Article I is to retain any force whatsoever, it is no longer sufficient for this Court to nod to the nondelegation principle in theory. The Court must "call foul when the constitutional lines are crossed." *Gundy*, 139 S. Ct. at 2135 (Gorsuch, J., dissenting). This is an especially broad delegation of authority to make major policy decisions, in an area of domestic social and economic policy entirely outside of any independent executive authority. *Cf. id.* at 2140 (observing that some broad delegations may be explained because they "implicated the president's inherent Article II authority" over military affairs or long-established executive fact-finding functions); *Indust. Union Dep't, AFL-CIO*, 448 U.S. at 684 (Rehnquist, J., concurring) (contrasting presidential authority over foreign affairs with regulation of domestic affairs).

Accordingly, this case presents a particularly compelling illustration of the need for enforcement of

article I's vesting clause, and the Court should not hesitate to grant review. The Court should correct the "mutated version of the 'intelligible principle' remark," which was indeed "plucked" from its original context, as explained in Justice Gorsuch's dissent in *Gundy*, 139 S. Ct. at 2139-40, and apply a more robust test. Nonetheless, the deeming authority violates the Constitution because it lacks an "intelligible principle" even under current caselaw, under the authority of *Panama Refining*.

CONCLUSION

For the foregoing reasons, the petition should be granted.

Respectfully submitted,

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