No. 20-850

In the Supreme Court of the United States

BIG TIME VAPES, INCORPORATED, ET AL., PETITIONERS

v.

FOOD AND DRUG ADMINISTRATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether Congress provided an intelligible principle to guide the discretion of the U.S. Food and Drug Administration in determining whether to subject certain tobacco products to regulation under 21 U.S.C. 387a(b).

ADDITIONAL RELATED PROCEEDINGS

United States District Court (S.D. Miss.):

Big Time Vapes, Inc. v. *Food & Drug Admin.*, No. 19-cv-531 (Dec. 16, 2019)

United States Court of Appeals (5th Cir.):

Big Time Vapes, Inc. v. *Food & Drug Admin.*, No. 19-60921 (June 25, 2020)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-23) is reported at 963 F.3d 436. The opinion and order of the district court (Pet. App. 24-36) is reported at 427 F. Supp. 3d 831.

JURISDICTION

The judgment of the court of appeals was entered on June 25, 2020. A petition for rehearing was denied on August 25, 2020 (Pet. App. 39-40). The petition for a writ of certiorari was filed on December 18, 2020. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. The Family Smoking Prevention and Tobacco Control Act (Act or TCA), Pub. L. No. 111-31, Div. A, 123 Stat. 1776 (21 U.S.C. 387 *et seq.*), established a com-

prehensive scheme for the regulation of tobacco products and granted the U.S. Food and Drug Administration (FDA) authority over their regulation. In support of those requirements, Congress made 49 findings about the dangers posed by tobacco products, 21 U.S.C. 387 note (findings), and adopted ten statements laying out the purposes of the Act, 21 U.S.C. 387 note (purpose). All of these findings and statements of purpose were adopted by Congress as part of the enacted text of the TCA.

In its findings, Congress focused primarily on the health risks associated with the use of tobacco products and problems connected to the marketing and promotion of tobacco products, particularly in relation to minors. Congress found that "[a] consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects," and that "[t]obacco use is the foremost preventable cause of premature death in America." 21 U.S.C. 387 note (findings (2) and (13)). And Congress determined that "[v]irtually all new users of tobacco products are" minors; that "[c]hildren are more influenced by tobacco marketing than adults"; and that "[p]ast efforts to oversee [the advertising, marketing, and promotion of tobacco products] have not been successful in adequately preventing such increased use [of tobacco products by minors]." 21 U.S.C. 387 note (findings (4), (15), and (23)). Congress further determined that the "Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products." 21 U.S.C. 387 note (findings (7)).

Congress enacted the TCA for the purpose, *inter alia*, of "impos[ing] appropriate regulatory controls on the tobacco industry." 21 U.S.C. 387 note (purpose (8)). Congress intended the Act "to ensure 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"; "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"; and "to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products." 21 U.S.C. 387 note (purpose (2), (4), and (6)).

To advance those interests, Congress established specific requirements for the regulation of tobacco products. For example, the TCA provides that manufacturers of tobacco products must register with FDA, 21 U.S.C. 387e(b), file a list of the tobacco products they make, 21 U.S.C. 387e(i), and disclose to FDA accurate information about their products and related health risks, including the identity and quantity of the ingredients in such products, 21 U.S.C. 387d(a)(1)-(2); see 21 U.S.C. 387c. The Act also authorizes FDA to impose additional "restrictions on the sale and distribution of * * * tobacco product[s], including restrictions on the access to, and the advertising and promotion of, the tobacco product[s]." 21 U.S.C. 387f(d)(1). The Act provides for FDA premarket review of certain types of tobacco products, including new products not on the market as of February 15, 2007, and products marketed as

presenting a modified health risk. 21 U.S.C. 387j(a)(1)-(2), 387k(a) and (g). A product marketed without necessary premarket approval is adulterated and misbranded in violation of the Act. 21 U.S.C. 387b(6)(A); see 21 U.S.C. 387c(a)(6).

Congress made those requirements immediately applicable to four types of tobacco products, including conventional cigarettes and smokeless tobacco. 21 U.S.C. 387a(b). Congress also authorized FDA to bring within the scope of the Act's requirements "any other tobacco products that the [agency] by regulation deems to be subject to this subchapter." *Ibid.* (deeming provision).[1] The Act defines "'tobacco product'" as "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. 321(rr)(1). The Act excludes a number of associated products from the definition of "tobacco product," including drugs and devices, 21 U.S.C. 321(rr)(2), and tobacco leaf that is not in the possession of a manufacturer of tobacco products is excluded from the Act's coverage, 21 U.S.C. 387a(c)(2)(A).

b. In a final rule issued in May 2016, FDA exercised its authority under Section 387a(b) "[t]o deem all products that meet the definition of 'tobacco product' under the law, except accessories of a newly deemed tobacco

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[1] The TCA gives various responsibilities to the Secretary of the Department of Health and Human Services. See, *e.g.*, 21 U.S.C. 387a(b). The Secretary carries out these responsibilities through the FDA Commissioner. See 21 U.S.C. 393(d)(2). This brief refers interchangeably to FDA and the Secretary.

product, and subject them to the [TCA's requirements]." 81 Fed. Reg. 28,974, 28,975 (May 10, 2016) (deeming rule or final rule). The rule took effect on August 8, 2016, 90 days after its publication, and generally made the TCA's requirements applicable to the newly deemed products as of that date. *Id.* at 28,974.

In adopting the deeming rule, FDA brought all products that fall within the statutory definition of tobacco product (other than accessories of such products) under the comprehensive regulatory scheme established by Congress in the TCA—including its premarket review provisions—as well as FDA's requirements, promulgated pursuant to its authority under the Act, involving age-related restrictions on access to tobacco products and health warnings on advertisements and product packaging. FDA explained that it was adopting the deeming rule "to reduce the death and disease from tobacco products" and that the "deeming rule affords FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use." 81 Fed. Reg. at 28,975. FDA highlighted that, among other benefits, the rule will enable it "to obtain critical information regarding the health risks of newly deemed tobacco products, including information derived from ingredient listing submissions and reporting of harmful and potentially harmful constituents." *Ibid.* In addition, the deeming rule "authorizes FDA to take enforcement action against manufacturers who sell and distribute products with unsubstantiated modified risk tobacco product * * * claims, or false or misleading claims on their labeling or advertising," that will "allow[] for better-informed consumers and help[] to prevent the use of misleading campaigns targeted to youth populations." *Ibid.*

E-cigarettes—and related products such as e-hookahs, e-cigars, and vape pens—are among the tobacco products subject to the TCA's coverage following FDA's issuance of the deeming rule. 81 Fed. Reg. at 28,976. Although FDA noted in the deeming rule that the full measure of these products' risks is not yet known, it determined that, "[w]hether [e-cigarettes] generally may eventually be shown to have a net benefit on or harm to public health at the population level[,] * * * regulation of [e-cigarettes] will still benefit public health." *Id.* at 28,984 (emphasis omitted). E-cigarettes typically contain and deliver nicotine—"one of the most addictive substances used by humans," *id.* at 28,988 (citation omitted)—and FDA found that in some instances e-cigarettes can deliver more nicotine than conventional cigarettes, see *id.* at 29,031. FDA emphasized that many e-liquids used in e-cigarettes also contain other chemicals that pose known risks, including formaldehyde, diacetyl and acetyl propionyl, and various aldehydes. *Id.* at 29,029-29,031. E-cigarettes are now the tobacco product that is most commonly used by young people. See Andrea S. Gentzke et al., Centers for Disease Control & Prevention, *Tobacco Product Use Among Middle and High School Students – United States, 2020*, 69 Morbidity & Mortality Weekly Report 1883 (Dec. 18, 2020), https://go.usa.gov/xHWGM.

FDA announced in the deeming rule that it planned to exercise its discretion to defer enforcement of premarket review requirements for new tobacco products that were on the market as of the rule's effective date for a period of one to three years following that date. 81 Fed. Reg. at 29,011-29,012. The agency explained that its decision not to prioritize this enforcement as of the

rule's effective date "strikes an appropriate balance between providing industry time to transition and protecting the public health." *Id.* at 29,014. FDA noted that, "[a]s with any such policy, the Agency will review and revise this policy as appropriate." *Id.* at 29,008. FDA has adjusted its enforcement priorities several times. See, *e.g.*, 82 Fed. Reg. 37,459, 37,460 (Aug. 10, 2017); Center for Tobacco Prods., FDA, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (Revised)* (Aug. 2017), https://go.usa.gov/xHb45. Consistent with those adjustments and the district court's orders in *American Academy of Pediatrics* v. *FDA*, No. 18-883 (D. Md. filed Mar. 27, 2018), which found that FDA's August 2017 enforcement policy violated the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, 701 *et seq.*, by establishing a policy of deferring enforcement for several years beyond the rule's effective date, *American Academy of Pediatrics* v. *FDA*, 379 F. Supp. 3d 461, 494-498 (D. Md. 2019), appeal dismissed, 812 Fed. Appx. 128 (4th Cir. 2020) (per curiam), beginning in 2020 FDA began prioritizing enforcement of premarket review requirements for newly deemed products that were marketed as of the deeming rule's effective date. See, *e.g.*, 85 Fed. Reg. 23,968, 23,968-23,969 (Apr. 30, 2020).[2]

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[2] FDA's current policy prioritizes enforcement of premarket review requirements for flavored, cartridge-based electronic nicotine delivery system (ENDS) products (other than tobacco- or menthol-flavored products). See Center for Tobacco Prods., FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry* 18 (Apr. 2020), https://go.usa.gov/xHWp2. FDA is also prioritizing enforcement with respect to all other ENDS products for which a manufacturer

2. Petitioner Big Time Vapes is a manufacturer and retailer of e-cigarettes, and petitioner United States Vaping Association is an e-cigarette industry trade association. Pet. App. 8. Petitioners filed suit in district court on August 19, 2019—more than ten years after Congress enacted the TCA—seeking a declaration that both the statutory provision giving FDA authority to "deem[]" additional tobacco products subject to the TCA's requirements, 21 U.S.C. 387a(b), and the final deeming rule promulgated pursuant to that authority, are invalid under the nondelegation doctrine. See Compl. 21. They also sought an injunction barring the government from enforcing the TCA against petitioners. Compl. 21-22. Petitioners subsequently moved for a preliminary injunction, asking the court to enjoin FDA "from taking any regulatory or enforcement action against [petitioners] arising under, or by reason of, the [FDA's] purported authority under the [TCA] to 'deem' 'tobacco products' to be subject to the TCA." D. Ct. Doc. 15, at 1 (Oct. 10, 2019).

The district court granted the government's motion to dismiss for failure to state a claim and denied petitioners' motion for a preliminary injunction. Pet. App. 24-36. The court found that "Congress provided sufficient guidance when it delegated authority to the FDA to designate which products should be governed by the

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fails to take adequate measures to prevent minors' access, and ENDS products that are targeted to, or whose marketing is likely to promote use by, minors. *Ibid.* With respect to ENDS products that do not fall within those categories, after September 9, 2020, FDA is prioritizing enforcement for all products offered for sale in the United States for which the manufacturer did not submit a timely premarket application, or for which FDA has taken a negative action on a timely application. *Id.* at 19.

TCA," and therefore determined that the TCA did not violate the nondelegation doctrine. *Id.* at 35.

3. A unanimous panel of the court of appeals affirmed. Pet. App. 1-23.

The court of appeals noted that, although the nondelegation doctrine requires that the legislative power be exercised by Congress, Pet. App. 10; see U.S. Const. Art. I, § 1, grants of authority to the Executive Branch have long been found "constitutional so long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized [to exercise the authority] is directed to conform,'" Pet. App. 11 (quoting *J. W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394, 409 (1928)) (brackets in original). The court explained that "[i]t is 'constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority.'" *Ibid.* (quoting *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946)) (brackets in original). The court further noted that this Court has only twice found a delegation of legislative power unlawful—in *A. L. A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495 (1935), and *Panama Refining Co.* v. *Ryan*, 293 U.S. 388 (1935)—and has not done so in nearly nine decades. Pet. App. 11-12.

The court of appeals rejected petitioners' contention that, in authorizing FDA to deem additional tobacco products subject to the Act's requirements, Congress did not provide "any parameters or guidance whatsoever" to guide the agency's exercise of that discretion. Pet. App. 15. The court began by finding that "Congress undeniably delineated its general policy in the TCA," *id.* at 16, by adopting statements of purpose and findings through bicameralism and presentment, *id.* at

16-18 & n.24. Relying on Congress's statements of purpose, the Court concluded that "the TCA's purpose sounds in (1) protecting public health and (2) preventing young people from accessing (and becoming addicted to) tobacco products." *Id.* at 17. The court further found that the TCA's purpose was "informed by Congress's extensive fact-finding" regarding the addictive nature of nicotine and the use of tobacco products by minors. *Ibid.* And the court noted that "Congress meant for the FDA to attack those problems *comprehensively*, that is, in an 'all-encompassing or sweeping' fashion." *Id.* at 17-18 (quoting *Gundy* v. *United States*, 139 S. Ct. 2116, 2127 (2019) (plurality opinion)) (footnote omitted).

The court of appeals also determined that "Congress plainly limited the authority that it delegated * * * in two important ways." Pet. App. 18. First, the court noted that "Congress enacted a controlling definition of 'tobacco product,' which necessarily restricts the Secretary's power to only products meeting that definition," and "identified four products * * * that were immediately subject to the TCA's mandates." *Ibid.* The court reasoned that "those features have the effect of constricting the Secretary's discretion to a narrow and defined category." *Id.* at 18-19 (brackets and internal quotation marks omitted). Second, the court noted that "Congress restricted the Secretary's discretion by making many of the key regulatory decisions itself," such as requiring premarket authorization and annual registration statements. *Id.* at 19.

The court of appeals concluded that "[t]he relevant caselaw dr[ove] [its] conclusions home." Pet. App. 20. The court reasoned that while the provisions at issue in *Panama Refining* and *Schechter Poultry Corp.* "placed

almost no limits on how the President—and in *Schechter*'s case, private groups—could wield their delegated authority * * * , the TCA's delegation to [FDA] is circumscribed, and Congress provided far more signposts to direct the exercise of the authority it delegated." *Id.* at 21. The court also found that "the TCA's deputizing of [FDA] mirrors" the "delegation to the Attorney General" in the Sex Offender Registration and Notification Act (SORNA), 34 U.S.C. 20901 *et seq.*, Pet. App. 21, which permitted the Attorney General to determine whether sex offenders convicted prior to the enactment of SORNA were required to comply with its registration requirements and which this Court upheld in *Gundy*, 139 S. Ct. at 2130 (plurality opinion); *id.* at 2131 (Alito, J., concurring in the judgment). The court of appeals reasoned that "[b]oth SORNA and the TCA established detailed regulatory frameworks that automatically applied to certain classes of persons or products," and that "[i]n both statutes, Congress delegated to an executive branch official the power to determine whether those requirements applied to other non-covered classes." Pet. App. 22-23.

ARGUMENT

Petitioners contend (Pet. 22-39) that the court of appeals erred in holding that the deeming provision and deeming rule do not violate the nondelegation doctrine. The court's decision is correct and does not conflict with any decision of this Court. In the definitions, findings, and statements of purpose that it included in the TCA, Congress laid out intelligible principles with appropriate boundaries for FDA to apply: that FDA should comprehensively regulate the tobacco industry to protect the public from nicotine dependence, tobacco-related health risks, and false and misleading advertising—

with a particular emphasis on protecting children from such dangers. That is more than Congress was required to do to satisfy the nondelegation doctrine. This Court has only twice found a delegation excessive—in each case because "Congress had failed to articulate any policy or standard" to confine discretion. *Mistretta* v. *United States*, 488 U.S. 361, 373 n.7 (1989). That plainly is not the case here. Petitioners' expansive view of the nondelegation doctrine has no basis in this Court's decisions and would impose an unprecedented and unrealistic constraint on Congress.

The court of appeals' decision likewise does not conflict with any decision of another court of appeals. Indeed, in the 12 years since Congress adopted the TCA, the court of appeals and district court below are the only courts to even consider whether FDA's deeming authority violates the nondelegation doctrine—despite multiple challenges to the deeming rule brought on other grounds. Further review is not warranted.

1. The court of appeals correctly held that Congress provided ample guidance to FDA in specifying four tobacco products to which the TCA's requirements immediately applied and granting the agency authority to subject other products that meet the statutory definition of "tobacco product" to those requirements.

a. The Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. Art. I, § 1. While "[t]his text permits no delegation of those powers," *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 472 (2001), this Court has long recognized "that the separation-of-powers principle, and the nondelegation doctrine in particular, do not prevent Congress from obtaining the assistance of its coordinate Branches," *Mistretta*, 488 U.S.

at 372, and do not "deny to the Congress the necessary resources of flexibility and practicality that enable it to perform its functions," *Gundy* v. *United States*, 139 S. Ct. 2116, 2123 (2019) (plurality opinion) (quoting *Yakus* v. *United States*, 321 U.S. 414, 425 (1944)) (brackets omitted). The Court has accordingly recognized that the nondelegation doctrine is satisfied where a statutory grant of authority from Congress to the Executive sets forth an "intelligible principle" that "clearly delineates" (1) "the general policy" to be pursued, (2) "the public agency which is to apply it," and (3) "the boundaries of this delegated authority." *Mistretta*, 488 U.S. at 372-373 (citation omitted).

Applying that standard, this Court "ha[s] 'almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law.'" *American Trucking*, 531 U.S. at 474-475 (quoting *Mistretta*, 488 U.S. at 416 (Scalia, J., dissenting)). As the Court has repeatedly observed, it has found only two statutory provisions that lacked the necessary "intelligible principle"—and it has not found any in the last 85 years. See, *e.g.*, *Gundy*, 139 S. Ct. at 2123 (plurality opinion) (referring to *A. L. A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495 (1935), and *Panama Refining Co.* v. *Ryan*, 293 U.S. 388 (1935)); *American Trucking*, 531 U.S. at 474 (same); *Loving* v. *United States*, 517 U.S. 748, 771 (1996) (same). One of those statutory provisions "provided literally no guidance for the exercise of discretion, and the other * * * conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *American Trucking*, 531 U.S. at 474.

b. The court of appeals properly applied the framework laid out by this Court and correctly concluded that the limited vesting of authority in FDA to deem "tobacco products" subject to the requirements of the TCA falls well within the bounds of acceptable measures. Congress clearly determined that FDA is the "public agency which is to apply" the TCA's deeming provision, *Mistretta*, 488 U.S. at 373 (citation omitted); see 21 U.S.C. 387a(b), so we address only whether Congress has laid out an "intelligible principle" that "clearly delineates" (1) "the general policy" that FDA must pursue in implementing the TCA, and (2) "the boundaries of this delegated authority." *Mistretta*, 488 U.S. at 372-373 (citation omitted).

i. The text of the TCA—including its definitions, findings, and statements of purpose—lays out intelligible principles that "clearly delineate[]" "the general policy" that FDA must pursue in implementing the TCA. *Mistretta*, 488 U.S. at 372-373 (citation omitted).

By defining "tobacco product" in detail, 21 U.S.C. 321(rr); see p. 4, *supra*, and limiting FDA's deeming authority to products that fit within that definition (and that Congress did not already determine should be covered by the Act), 21 U.S.C. 387a(b), Congress made clear that it was adopting a general policy of permitting FDA to regulate statutorily defined tobacco products. The common feature of the four tobacco products that Congress enumerated in Section 387a and the other products meeting the statutory definition of "'tobacco product'" is that they are "made or derived from tobacco" and "intended for human consumption," or are components, parts, or accessories of such products, 21 U.S.C. 321(rr)(1). Products meeting that definition con-

tain or are related to the use of nicotine and present associated public health risks. While the health concerns associated with the use of tobacco products may vary somewhat by product, all products meeting the statutory definition of tobacco product implicate serious public health concerns, according to Congress's findings and statements of purpose.

Congress's findings and statements of purpose provide that: "[n]icotine is an addictive drug"; "[a]n overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18"; and "[t]obacco dependence is a chronic disease, one that typically requires repeated interventions to achieve long-term or permanent abstinence." 21 U.S.C. 387 note (findings (3), (31), and (33)). Congress likewise adopted findings and statements of purpose focused on health risks associated with the use of tobacco products and problems related to the marketing and promotion of tobacco products, particularly in relation to minors. See pp. 2-3, *supra*. And Congress observed that "[l]ess restrictive and less comprehensive approaches have not * * * and will not be effective in reducing the problems" associated with tobacco use and dependence. 21 U.S.C. 387 note (findings (31)); see 21 U.S.C. 387 note (purpose (2)) (stating that a purpose of the TCA is "to ensure 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"). This Court has rejected nondelegation challenges to statutory provisions based on their inclusion of similar findings. See *Mistretta*, 488 U.S. at 374 (upholding Congress's grant of authority to promulgate sentencing guidelines to the

Sentencing Commission based in part on the fact that "Congress charged the Commission with three goals" and "specified four 'purposes' of sentencing that the Commission must pursue in carrying out its mandate"); *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946) (relying in part on "the general policy declarations of Congress" in a statute that conferred authority on the Securities and Exchange Commission when rejecting a nondelegation challenge).

Taken together, the Act's provisions confirm Congress's intent to regulate the tobacco industry to protect the public from nicotine dependence, the myriad health risks associated with the use of tobacco products, and false and misleading advertising regarding tobacco products—with a particular emphasis on protecting minors. The Court has approved many broad grants of authority, even where the statutory policy was considerably more general than that laid out by the TCA. See *American Trucking*, 531 U.S. at 474-475 (collecting cases); see also *id.* at 472 (upholding a grant of authority to the Environmental Protection Agency to set nationwide air-quality standards limiting pollution to the level required "to protect the public health") (citation omitted); *Federal Power Comm'n* v. *Hope Natural Gas Co.*, 320 U.S. 591, 600 (1944) (upholding a grant of authority to the Federal Power Commission to determine "just and reasonable" rates for wholesale sales of natural gas) (citation omitted); *National Broad. Co.* v. *United States*, 319 U.S. 190, 220 (1943) (upholding a grant of authority to the Federal Communications Commission to regulate broadcast licensing "as public convenience, interest, or necessity requires") (citation omitted). Congress has thus "undoubtedly identif[ied] a 'general

policy' for the Secretary to pursue" in exercising his deeming authority. Pet. App. 18.

That these principles guide the Secretary in determining whether to subject certain "tobacco products" to the TCA and its attendant requirements does not change the analysis. In *Touby* v. *United States*, 500 U.S. 160 (1991), this Court upheld the grant of authority in the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, to the Attorney General to designate controlled substances on a temporary basis—even though such a designation had the result of including new substances within the Controlled Substances Act and triggering criminal consequences. 500 U.S. at 164-167. Because Congress had delineated an intelligible principle to guide the Attorney General's designation, the Court found no nondelegation problems. See *ibid.* What was true in *Touby* must be true here as well. Indeed, Congress provided even more constraints in the TCA than it did in the Controlled Substances Act because the TCA includes a statutory definition for "tobacco products" and only permits the Secretary to deem products that fit within that definition as subject to the Act's coverage.

Petitioners err in contending (Pet. 27-29) that the outcome of the nondelegation inquiry in this case should be different because the TCA's deeming provision does not create a requirement directly analogous to the SORNA provision at issue in *Gundy*.[3] In *Gundy*, this Court viewed SORNA as "requir[ing] the Attorney

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[3] Petitioners' assertion (Pet. 27) that "the Fifth Circuit * * * read[] the TCA as if it mandated [FDA] to regulate *all* tobacco products" is incorrect. The court of appeals never found that, in adopting the TCA, Congress required FDA to bring all tobacco products within the Act's regulatory framework.

General to apply SORNA to all pre-Act offenders as soon as feasible." 139 S. Ct. at 2123 (plurality opinion). The TCA's deeming provision does not require FDA to subject all products meeting the statutory definition of tobacco products to the TCA's requirements. But that difference does not suggest that Congress failed to lay out an intelligible principle that delineates the TCA's general policy. Rather, Congress's definitions, findings, and statements of purpose—along with its stated intent to regulate the tobacco industry to protect the public health—provide ample standards to guide FDA's discretion. See *id.* at 2126-2130 (examining SORNA's statutory definitions, declaration of purpose, and comprehensive nature when determining the statute's meaning and whether it provided an intelligible principle to guide the Executive Branch's discretion).

ii. Congress likewise "clearly delineate[d] * * * the boundaries of [its] delegated authority," in adopting the TCA. *Mistretta*, 488 U.S. at 372-373 (citation omitted). FDA *only* has authority to determine which products that fall into the statutory definition of "tobacco products" are to be covered by the Act's requirements. And, as the court of appeals observed, Congress "restricted the Secretary's discretion by making many of the key regulatory decisions itself," Pet. App. 19, including by establishing disclosure, registration, and premarket-review requirements, all of which automatically apply when FDA deems a tobacco product as covered by the Act. See pp. 3-4, *supra*. This is a "distinctly small-bore" vesting of authority that falls "well within constitutional bounds." *Gundy*, 139 S. Ct. at 2130 (plurality opinion).

2. a. Petitioners suggest (Pet. 23-32) that the decision below is inconsistent with this Court's decision in

Panama Refining. That contention is incorrect. *Panama Refining* involved a provision of the National Industrial Recovery Act (Recovery Act), ch. 90, 48 Stat. 195, a comprehensive law "to regulate the entire economy" enacted at the beginning of the Franklin D. Roosevelt Administration in the depths of the Great Depression. *American Trucking*, 531 U.S. at 474. Section 9(c) of the Recovery Act was at issue in *Panama Refining*; that provision authorized the President "to prohibit the transportation in interstate and foreign commerce of petroleum * * * withdrawn from storage in excess" of state-set quotas and also specified a penalty for violating any such potential prohibition. 293 U.S. at 406 (citation omitted). The Court held the law invalid because it "establishe[d] no criterion to govern the President's course." *Id.* at 415; see *Mistretta*, 488 U.S. at 373 n.7 ("In * * * *Panama Refining* the Court concluded that Congress had failed to articulate any policy or standard that would serve to confine the discretion of the authorities to whom Congress had delegated power."). The Recovery Act's goals also did little to inform the President's decisionmaking. Rather, the Recovery Act's "general outline of policy * * * favor[ed] the fullest possible utilization of the present productive capacity of industries" to mobilize the economy and speed economic recovery. *Panama Ref.*, 293 U.S. at 417-418. But Section 9(c) provided for the President to determine instances in which such "fullest possible utilization"—*i.e.*, marketing oil above State-imposed quotas—should be a crime. *Id.* at 417. Virtually any invocation of the President's power therefore would have been in substantial tension with the Recovery Act's central goal, and the Court concluded that the

statute gave no indication of the countervailing "circumstances or conditions in which" departing from that central goal would be warranted. *Id.* at 430.

In contrast, in the TCA Congress adopted clear policy goals: that FDA regulate the tobacco industry to protect the public (and particularly children) from nicotine dependence, the numerous health risks associated with nicotine use, and false and misleading advertising regarding tobacco products. See pp. 2-3, *supra*. And, contrary to petitioners' suggestion (Pet. 24-27), the fact that the TCA includes a number of related objectives does not bring it within *Panama Refining*'s narrow ambit. While essentially any action taken by the President under Section 9(c) would have been out of line with the Recovery Act's main goal, that is not true of actions that may be taken under FDA's authority, which only permits FDA to subject certain, statutorily defined "tobacco products"—which Congress has found create various health risks—to the TCA. See pp. 4, 14-15, *supra*.

b. Petitioners assert (Pet. 25-27) that the TCA lacks an intelligible principle that clearly delineates its general policy because the Act's statements of purpose "are in actual tension" with each other. Pet. 25. Petitioners observe that "[w]hile one of the TCA's purposes is to address the use of tobacco by young people and dependence on tobacco, 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." Pet. 25-26 (citations and internal quotation marks omitted).

These objectives are not at odds with each other. As explained previously, the overarching purpose of the TCA is to protect the public health by reducing use of and dependence on tobacco products, preventing tobacco-

related disease, and barring false and misleading advertising—with a particular focus on preventing the use of tobacco by children. See pp. 14-18, *supra*. All of the objectives cited by petitioners are consistent with that purpose. For example, the goal of preventing children and adolescents from initiating tobacco use is not at odds with the goal of helping adults who are addicted to nicotine to access tobacco products that present a less extreme risk to their health. And none of the Act's findings or purposes contradict the purpose of continuing the sale of tobacco products to adults; indeed, the Act's entire regulatory scheme is premised on the assumption that tobacco products will not be removed from the market entirely. That the agency may need to consider how to prioritize different interests at any given point in time does not suggest the lack of an intelligible principle guiding its discretion. Cf. *Yakus*, 321 U.S. at 425 ("It is no objection that the determination of facts and the inferences to be drawn from them in the light of the statutory standards and declaration of policy call for the exercise of judgment.").

There also is no question that FDA found that the final rule would further the TCA's public health purposes. Petitioners assert that "FDA itself eschewed any public health standard in the final rule." Pet. 29 (emphasis omitted); see Pet. 11. But in the portion of the final rule to which petitioners point, FDA discussed comments arguing that it should not provide for regulation when it is "unable to quantify the health risks of certain products (namely, e-cigarettes) without multiple long-term studies, and that currently such studies do not exist." 81 Fed. Reg. at 28,983 (footnote omitted). In response, FDA explained that the requirements of the deeming provision differ

from the requirements of Section 387f(d)(1), which expressly provides for a more detailed public-health analysis before FDA may impose regulatory requirements in addition to those laid out by Congress in the TCA. *Id.* at 28,983. The agency further explained that, "[a]lthough FDA is not required to meet a *particular* public health standard to deem tobacco products, regulation of the newly deemed products will be beneficial to public health." *Ibid.* (emphasis added). FDA elaborated that it "ha[d] concluded, based on scientific data, that the newly deemed products should be regulated due to their potential for public harm and regulation is necessary to learn more about that potential." *Ibid.* (citation omitted).

c. Petitioners' reliance (Pet. 11, 22) on the agency's litigation position in *Nicopure Labs, LLC* v. *Food & Drug Administration*, 266 F. Supp. 3d 360 (D.D.C. 2017), aff'd, 944 F.3d 267 (D.C. Cir. 2019), and the district court's decision in that case is misplaced. The plaintiffs in *Nicopure* asserted that the deeming rule was arbitrary and capricious under the APA. In defending against that challenge, the agency argued "that its decision to deem is so committed to agency discretion that it is unreviewable," *id.* at 392; see 5 U.S.C. 701(a)(2), but the district court rejected that argument and found that the deeming decision was reviewable under the APA, *Nicopure*, 266 F. Supp. 3d at 392-393. The court then found that FDA's "decision to deem e-cigarettes to be tobacco products is not arbitrary and capricious for a number of reasons," including because "nicotine is indisputably harmful" and because of FDA's concerns about adolescents. *Id.* at 393-394. In reaching that conclusion, the court relied on the TCA's findings. *Id.* at 395.

The district court in *Nicopure* thus did not consider—let alone hold—whether, for purposes of the nondelegation doctrine, the TCA includes an intelligible principle to guide the agency's judgment. And, although the *Nicopure* court rejected the agency's argument that the deeming decision is unreviewable because it is committed to agency discretion by law, it plainly is not the case that decisions committed to agency discretion within the meaning of Section 701(a)(2) necessarily run afoul of nondelegation principles. Whether Congress adequately cabined the agency's discretion for purposes of the nondelegation doctrine and whether Congress provided judicially manageable standards for review of agency decisions are discrete inquiries, and courts have found that there is no constitutional defect resulting from the granting of authority to an agency while simultaneously finding that the agency's action is unreviewable because it is committed to the agency's discretion. See, *e.g.*, *National Fed'n of Fed. Emps.* v. *United States*, 905 F.2d 400, 404-405 (D.C. Cir. 1990) (rejecting a nondelegation challenge and holding that Congress supplied an "'intelligible principle'" to govern the determination of which military bases should be subjected to closure, but also holding that the decision to close a military base was not subject to any "'judicially manageable standards'" and was thus "committed to agency discretion by law" under Section 701(a)(2)) (citation and emphases omitted).

d. Petitioners finally take issue with the deeming provision because, in their view, it "delegates authority to decide major policy questions." Pet. 32 (emphasis omitted). But, as this Court has confirmed, its "cases do not at all suggest that delegations of this type may not carry with them the need to exercise judgment on

matters of policy." *Mistretta*, 488 U.S. at 378. The Court has frequently upheld such measures that permit the making of policy judgments more significant than those at issue here. See, *e.g.*, *id.* at 377 (noting that "the [Sentencing] Commission enjoys significant discretion in formulating [sentencing] guidelines," including "to determine the relative severity of federal crimes and to assess the relative weight of the offender characteristics," but finding that there was no nondelegation problem); *Yakus*, 321 U.S. at 420 (upholding a statute authorizing the Price Administrator to fix commodity prices that "in his judgment will be generally fair and equitable and will effectuate the purposes of this Act" to stabilize prices); cf. pp. 15-16, *supra* (discussing broad grants of authority, many of which had significant policy implications).[4]

This Court has repeatedly determined that the nondelegation doctrine "do[es] not prevent Congress from obtaining the assistance of its coordinate Branches," *Mistretta*, 488 U.S. at 372, and does not "deny[] to the Congress the necessary resources of flexibility and practicality . . . to perform its function," *Yakus*, 321 U.S. at 425 (citation omitted). The need for flexibility is particularly evident in the context of the regulation of tobacco products, because manufacturers develop new products that fit within Congress's definition at a rapid rate, and the government needs to be able to adapt to the

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[4] To the extent petitioners question FDA's implementation of Congress's purpose, asserting that "it is certainly not a given that the Congress that passed the TCA * * * would support 'deeming'" e-cigarettes as covered by the Act, Pet. 26, that argument goes to the reasonableness of FDA's deeming decision—which petitioners have not challenged in this litigation—and does not suggest that the statute itself poses a nondelegation problem.

ever-changing market for tobacco products. Congress's granting of authority to FDA to deem additional tobacco products subject to the Act helps to ensure that Congress's purposes in adopting the Act are not thwarted by the government's inability to keep pace with industry innovation. See 21 U.S.C. 387 note (purpose (4)) (identifying as one of the Act's purposes the "provi[sion] [of] 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"). As in other contexts, "Congress simply [could not] do its job" of adequately regulating tobacco products "absent an ability to delegate power under broad general directives." *Mistretta*, 488 U.S. at 372.

And, contrary to petitioners' view, the deeming provision does not provide FDA with authority over major policy questions. The decision whether to regulate products that are already within Congress's definition of tobacco product does not involve the determination of a "major policy question"; rather, such a choice is a "less-major or fill-up-the-details decision[]." *Paul* v. *United States*, 140 S. Ct. 342, 342 (2019) (statement of Kavanaugh, J., respecting the denial of certiorari); see *Gundy*, 139 S. Ct. at 2145 (Gorsuch, J., dissenting) ("[Congress] may always authorize executive branch officials to fill in even a large number of details, [and] to find facts that trigger the generally applicable rule of conduct specified in a statute."). Put differently, the extent of the discretion that the deeming provision confers is the same as a statute that automatically applied the TCA to *all* products that meet the definition of tobacco product but authorized the Secretary to grant waivers to some tobacco products or otherwise

make exceptions. Although such a statute would have established a different baseline rule, the scope of the agency's authority would be the same, and such a statute surely would not be viewed as authorizing FDA to make major policy decisions.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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