No. 19-60921

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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

Plaintiffs-Appellants,

v.

FOOD AND 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,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of Mississippi

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CERTIFICATE OF INTERESTED PERSONS

Big Time Vapes, Inc. v. FDA

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Plaintiffs-appellants:

Big Time Vapes, Inc.
United States Vaping Association, Inc.

Defendants-appellees:

U.S. Food and Drug Administration
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Stephen M. Hahn, M.D., Commissioner of Food and Drugs[1]

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[1] Dr. Stephen M. Hahn was sworn in as Commissioner of Food and Drugs on December 17, 2019. Pursuant to Federal Rule of Appellate Procedure 43(c)(2), Commissioner Hahn is automatically substituted for Acting Commissioner Admiral Brett P. Giroir.

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STATEMENT REGARDING ORAL ARGUMENT

Oral argument is appropriate in this case to ensure the proper resolution of plaintiffs' constitutional challenge to a federal statute and implementing regulations.

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INTRODUCTION

Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) in 2009 to establish a comprehensive scheme for the regulation of tobacco products and to empower the Food and Drug Administration (FDA) to regulate such products. Pub. L. No. 111-31, 123 Stat. 1776 (2009). Congress found that "[t]obacco use is the foremost preventable cause of premature death in America." TCA § 2(13). Noting that "past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents," Congress found that "comprehensive restrictions on the sale, promotion, and distribution of such products are needed." *Id.* § 2(6). Among other purposes, the Act is meant 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." *Id.* § 3(2).

The Act's provisions "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 subchapter." 21 U.S.C. § 387a(b). Congress defined "tobacco product" to include "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." *Id.* § 321(rr)(1).

Consistent with the Act's purpose, FDA promulgated a 2016 rule that deemed all products meeting the statutory definition of "tobacco product" (except accessories)

subject to the Act's provisions, including the requirement that new tobacco products not marketed prior to February 2007 obtain premarket authorization from FDA. 81 Fed. Reg. 28,975 (May 10, 2016). FDA explained that the shared attributes of tobacco products, including the delivery of nicotine to users, create a risk to the public health. *See id.* at 28,981, 28,983. The agency thus concluded that, even if certain new tobacco products could potentially provide a benefit to some individuals—*e.g.*, people already dependent on conventional cigarettes—regulation of these products consistent with the TCA's requirements will benefit the public health. *Id.* at 28,984.

Plaintiffs urge that the TCA provision authorizing FDA to deem items meeting the definition of "tobacco product" subject to the Act's requirements is an unconstitutional delegation of authority. Congress has delegated authority to the executive branch since the Founding, and the Supreme Court has only twice held a statute invalid on non-delegation grounds. One of those provisions gave "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.'" *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 474 (2001) (citing *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935); *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935)).

In urging that this should be the third such case, plaintiffs disregard the limited scope of the authority delegated by Congress and the ample direction provided by the TCA's findings, purpose, and structure. The Act is highly prescriptive and sets forth a

clear purpose, together with detailed requirements for the regulation of tobacco products. Congress made four types of tobacco products immediately subject to those requirements, and it did not violate non-delegation principles in authorizing FDA to deem other products falling within the carefully defined category of "tobacco products" subject to the same requirements.

STATEMENT OF JURISDICTION

Plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. § 1331. ROA.11. The district court denied plaintiffs' motion for a preliminary injunction, granted the government's motion to dismiss, and entered final judgment on December 16, 2019. ROA.715-26. Plaintiffs filed a timely notice of appeal on December 17, 2019. ROA.727; Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Whether Congress permissibly delegated authority to FDA to deem additional products meeting the statutory definition of "tobacco product" subject to the clearly delineated controls and authorities set forth in the Tobacco Control Act.

STATEMENT OF THE CASE

A. The Tobacco Control Act

The Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387 *et seq.*), establishes a comprehensive scheme for the regulation of tobacco products. In support of these requirements, Congress made forty-nine

findings about the dangers posed by such products and set forth ten statements of purpose to guide their regulation. TCA §§ 2, 3. For example, Congress found that "[t]obacco use is the foremost preventable cause of premature death in America," *id.* § 2(13), and that, "[b]ecause past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed," *id.* § 2(6).

Among other purposes, Congress enacted the Tobacco Control 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," "to vest [FDA] with the authority to regulate the levels of tar, nicotine, and other harmful components of 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." TCA § 3(2), (4)-(6).

To advance these interests, the Tobacco Control Act establishes specific requirements for the regulation of tobacco products. For example, the Act 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, *id.* § 387e(i), and disclose to FDA accurate information about their products and related health risks, including the identity and quantity of all ingredients in such products, *id.* §§ 387c, 387d(a)(1)-(2). The Act also directs that manufacturers cannot market products as providing a reduced or modified health risk without FDA authorization. *Id.* § 387k. FDA may also impose additional requirements on tobacco products, such as minimum age and identification requirements and health warnings. *Id.* § 387f(d)(1)-(2).

In addition, to address the potential for new and harmful tobacco products to enter the market and addict new generations of users before regulators can assess their risks, the Act requires manufacturers to obtain premarket authorization from FDA before introducing into interstate commerce any "new tobacco product," defined as a tobacco product not commercially marketed in the United States as of February 15, 2007. 21 U.S.C. § 387j(a)(1)-(2). A manufacturer may seek premarket authorization through one of three pathways: by submitting a "premarket tobacco application" demonstrating that the sale of the product would be "appropriate for the protection of the public health," *id.* § 387j(b)-(c); by submitting a "report" establishing that the product is "substantially equivalent" to a predicate product marketed prior to February 2007, *id.* §§ 387j(a)(2)(A)(i), 387e(j)(1); or by requesting an exemption from the substantial equivalence requirement, *id.* §§ 387j(a)(2)(A)(ii), 387e(j)(3).

Congress made these requirements immediately applicable to four types of tobacco products, including conventional cigarettes and smokeless tobacco, and it

authorized FDA to bring within the scope of these requirements "any other tobacco products," as that term in is defined in the Act, "that the Secretary [of Health and Human Services] by regulation deems to be subject to this chapter." 21 U.S.C. § 387a(b). In addition, FDA "may by regulation require restrictions on the sale and distribution of tobacco products . . . if the [agency] determines that such regulation would be appropriate for the protection of the public health." *Id.* § 387f(d)(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). Products meeting this definition contain or are related to the use of nicotine and present associated public health risks. "The term 'tobacco product' does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title." *Id.* § 321(rr)(2). The definition likewise excludes any "tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives." *Id.* § 387a(c)(2)(A).

B. FDA's Deeming Rule

a. In a final rule issued in May 2016, FDA exercised its authority under 21 U.S.C. § 387a(b) to deem all products that meet the definition of "tobacco product,"

excluding accessories of such products, to be subject to the Tobacco Control Act's requirements. 81 Fed. Reg. at 28,975. The rule took effect in August 2016, ninety days after its publication, making the TCA's requirements applicable to the newly deemed products as of that date. E-cigarettes are among the tobacco products regulated as a result of this rule. *Id.*[2]

FDA explained that, by bringing all tobacco products within the comprehensive scheme established by Congress, 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. Among other benefits, the rule will enable FDA "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." *Id.* The rule will also "prevent from entering the market new tobacco products that are not appropriate for the protection of public health." *Id.* The deeming rule thus serves an important regulatory function by subjecting newly deemed products to the specific requirements set forth in the Tobacco Control Act, and by subjecting such products to other FDA authorities, thereby enabling the agency to impose minimum age restrictions for the sale of such products, among other measures.

[2] This brief uses "e-cigarettes" to refer to all electronic nicotine delivery systems (ENDS), often referred to as "vaping" devices, including e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. *See* 81 Fed. Reg. at 29,028.

With respect to e-cigarettes, although FDA noted that the full measure of potential 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—and there have not yet been long-term studies conducted to support either claim at this time—*regulation* of [e-cigarettes] will still benefit public health." 81 Fed. Reg. at 28,984 (emphasis added). E-cigarettes typically contain and deliver nicotine—"one of the most addictive substances used by humans," *id.* at 28,988, and a powerful pharmacologic agent that acts in the brain and throughout the body, *id.* at 28,981, 28,986. In some instances, e-cigarettes can deliver more nicotine than conventional cigarettes. *Id.* at 29,031.

Many e-liquids used in e-cigarettes also contain other chemicals that pose known risks, including formaldehyde, diacetyl and acetyl propionyl, and various aldehydes. 81 Fed. Reg. at 29,029-31; *see* Joseph G. Allen, *The Formaldehyde in Your E-Cigs*, N.Y. Times (Apr. 4, 2018) (noting that "[s]tudy after study . . . has confirmed that e-cigs can deliver formaldehyde to the user," and they have "found diacetyl in over 75 percent of e-cigs tested").[3] E-cigarettes are the tobacco product most commonly used by young people, *see* 83 Fed. Reg. 12,294, 12,296 (Mar. 21, 2018), and youth use of these products has been increasing at an alarming rate, *see* Richard Miech et al., *Trends in Adolescent Vaping, 2017-2019*, 381 New Eng. J. Med. 1490 (2019).

[3] Available at https://www.nytimes.com/2018/04/04/opinion/formaldehyde-diacetyl-e-cigs.html.

b. Exercising its enforcement discretion, FDA explained in the deeming rule that the agency did not plan to bring enforcement actions under the TCA's premarket-review provisions for a period of two-to-three years following the rule's effective date. 81 Fed. Reg. at 29,010-11. FDA noted that, "[a]s with any such policy, the Agency will review and revise this policy as appropriate." *Id.* at 29,008.

Based on the available information regarding the risks presented by various tobacco products, FDA has adjusted these enforcement priorities several times. In August 2017, FDA announced its intent to further defer enforcement of premarket-review requirements for certain products until August 2021 or 2022. FDA, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* 3 (Aug. 2017); *see* 82 Fed. Reg. 37,459 (Aug. 10, 2017). And in March 2019, FDA requested public comment on draft guidance that proposed to take enforcement actions with respect to certain products in advance of the timeline set forth in the 2017 guidance. FDA, *Modifications to Compliance Policy for Certain Deemed Tobacco Products* 5 (Mar. 2019), https://go.usa.gov/xdz4S.

FDA issued new enforcement guidance in January 2020. FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (Jan. 2, 2020), https://go.usa.gov/xpJbT. Citing data showing that e-cigarette use more than doubled among middle- and high-school students from 2017 to 2019, *id.* at 12, FDA stated its intent to prioritize enforcement almost immediately for e-cigarette products that are most widely used by

youth, and beginning May 12, 2020 for all other e-cigarettes, *id.* at 10-11. For other types of tobacco products, FDA explained that, after May 12, 2020, the agency intends to "make enforcement decisions on a case-by-case basis" based on "the likelihood of youth use or initiation." *Id.* at 31. The guidance notes that FDA "retains discretion to pursue enforcement action at any time against any deemed new tobacco product marketed without premarket authorization, regardless of whether it falls within one of these categories of enforcement priorities." *Id.* at 11.

In March 2018, while FDA was reassessing its enforcement priorities, a number of public health groups filed suit in the U.S. District Court for the District of Maryland, arguing that FDA's 2017 guidance was substantively and procedurally deficient. In May 2019, the court granted summary judgment for the plaintiffs and vacated the 2017 guidance, *American Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 498 (D. Md. 2019), and in July 2019 the court entered a remedial order directing FDA to require manufacturers to submit premarket applications for all newly deemed products by May 12, 2020, 399 F. Supp. 3d 479, 487 (D. Md. 2019). That case remains pending on appeal. Nos. 19-2130, 19-2132, 19-2198, and 19-2242 (4th Cir.).

C. Prior Proceedings

Plaintiffs Big Time Vapes and United States Vaping Association are, respectively, a manufacturer and retailer of e-cigarettes and an industry trade association. ROA.12. Plaintiffs filed suit more than ten years after the Tobacco Control Act was enacted, seeking to invalidate under the non-delegation doctrine both

the Act's provision giving FDA authority to deem additional "tobacco products" subject to the requirements established by Congress, and the final rule promulgated pursuant to that authority. ROA.25-29. Almost two months after filing suit, plaintiffs moved for a preliminary injunction, asking the court to enjoin FDA "from exercising any authority over any 'tobacco products' deemed to be subject to the TCA pursuant to [21 U.S.C. § 387a(b)]." ROA.120.

On December 16, 2019, the district court granted the government's motion to dismiss for failure to state a claim and denied plaintiffs' motion for preliminary injunction. In rejecting plaintiffs' claims, the court observed that Congress may generally delegate authority to administrative agencies as long as it "lay[s] down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power." ROA.722 (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)). "The standards of the statute are not to be tested in isolation but must derive meaningful content from the purpose of the statute and its factual background and the statutory context in which the standards appear." ROA.723 (quoting *United States v. Womack*, 654 F.2d 1034, 1037 (5th Cir. 1981)).

The district court upheld the delegation at issue because Congress "designated certain tobacco products as governed by the TCA and presented detailed policies behind its enactment." ROA.723. "For example, Congress clearly expressed a desire to protect the public health and to prevent, to the extent possible, underaged persons

from having access to tobacco products." ROA.723-24. Congress also "restricted the FDA's discretion with a controlling definition of 'tobacco product.'" ROA.723. The district court thus held that plaintiffs failed to state a plausible claim for relief and were not entitled to a preliminary injunction. ROA.724. The court also rejected plaintiffs' discovery request on the grounds that it was not necessary to consider documents outside the pleadings in order to evaluate the plausibility of plaintiffs' claim. ROA.721 n.4.

SUMMARY OF ARGUMENT

Under longstanding precedent, Congress may delegate authority to executive agencies so long as it "lay[s] down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform." *Mistretta v. United States*, 488 U.S. 361, 372 (1989). The Supreme Court has "found the requisite 'intelligible principle' lacking in only two statutes, one of which provided literally no guidance for the exercise of discretion, and the other of which conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 474 (2001) (citing *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935); *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935)). In the more than eighty years since the Court issued those decisions, it has approved many delegations of authority far broader than the one presented here. *See id.* at 474-75 (collecting cases).

The limited delegation of authority in the Tobacco Control Act falls well within the bounds of established non-delegation principles. The statute defines "tobacco product" and prescribes detailed standards for their regulation. *See, e.g.*, 21 U.S.C. §§ 321(rr)(1), 387c, 387d, 387e, 387j. Congress made these standards immediately applicable to four types of tobacco products enumerated by statute, and it provided that the Act shall also apply "to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." *Id.* § 387a(b).

It is commonplace for Congress to provide definitions and standards and task agencies with determining their application. Congress was not required to identify all possible products for which regulation would be consistent with the TCA's terms and purpose. Nor did Congress have to leave FDA powerless to regulate dangerous new products until Congress is able to address them in legislation. Whether the rule is reasonable and consistent with the statute may be issues for litigation. *See Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019) (rejecting e-cigarette manufacturers' challenge to the deeming rule on the merits). But plaintiffs' non-delegation argument is foreclosed by binding precedent.

STANDARD OF REVIEW

This Court reviews a district court's ruling on a motion to dismiss de novo, *Wampler v. Southwestern Bell Tel. Co.*, 597 F.3d 741, 744 (5th Cir. 2010), and it reviews the district court's denial of a motion for preliminary injunction and its denial of a discovery request for abuse of discretion, *Moore v. Brown*, 868 F.3d 398, 402 (5th Cir.

2017) (preliminary injunction); *JP Morgan Chase Bank, N.A. v. DataTreasury Corp.*, 936 F.3d 251, 255 (5th Cir. 2019) (discovery request). Legal questions underlying the grant or denial of a preliminary injunction are reviewed de novo. *Pendergest-Holt v. Certain Underwriters at Lloyd's of London,* 600 F.3d 562, 569 (5th Cir. 2010).

ARGUMENT

Congress's Grant of Authority to FDA To Deem "Tobacco Products" Subject to the Tobacco Control Act Does Not Violate Established Non-Delegation Principles.

1. Since the Founding era, the Supreme Court has held that "Congress may certainly delegate to others[] powers which the legislature may rightfully exercise itself." *Wayman v. Southard*, 23 U.S. (10 Wheat) 1, 43 (1825) (Marshall, C.J.). Because "no statute can be entirely precise," *Mistretta v. United States*, 488 U.S. 361, 415 (1989) (Scalia, J., dissenting), the courts have "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," *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 474-75 (2001). The Supreme Court has thus held, time and again, that as long as Congress "lay[s] down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power." *Mistretta*, 488 U.S. at 372.

A delegation is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Mistretta*, 488 U.S. at 372-73 (quoting *American Power & Light Co.*

v. SEC, 329 U.S. 90, 105 (1946)). This is a practical inquiry, *id.* at 372, and "the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred," *American Trucking*, 531 U.S. at 475. In assessing these questions, courts look not only to the text of the provision delegating authority, *see id.* at 473, but also to the structure, history, and purpose of the broader statutory scheme, *see American Power & Light*, 329 U.S. at 104-05.

Although Congress has delegated authority to the executive branch "[f]rom the beginning of the Government," *United States v. Grimaud*, 220 U.S. 506, 517 (1911), the Supreme Court has "found the requisite 'intelligible principle' lacking in only two statutes, one of which provided literally no guidance for the exercise of discretion, and the other of which 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 (citing *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935); *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935)).

By contrast, in the more than eighty years since those decisions issued, the Court has upheld a wide variety of challenges to congressional grants of power, including "statutes authorizing the War Department to recover 'excessive profits' earned on military contracts, authorizing the Price Administrator to fix 'fair and equitable' commodities prices, and authorizing the Federal Communications Commission to regulate broadcast licensing in the 'public interest.'" *Touby v. United States*, 500 U.S. 160, 165 (1991) (citing *Lichter v. United States*, 334 U.S. 742, 778-86

(1948); *Yakus v. United States*, 321 U.S. 414, 426-27 (1944); and *National Broad. Co. v. United States*, 319 U.S. 190, 225-26 (1943)); *see also American Trucking*, 531 U.S. at 475 (confirming that Congress may authorize an agency decide "how 'imminent' [i]s too imminent, or how 'necessary' [i]s necessary enough, or even . . . how 'hazardous' [i]s too hazardous").

2. The statute at issue falls well within the range of delegations approved by the Supreme Court. Congress provided that the Tobacco Control Act "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 subchapter." 21 U.S.C. § 387a(b). 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." *Id.* § 321(rr)(1). And Congress set forth in detail the requirements applicable to such products. The grant of authority to FDA to deem products within a defined category subject to the Act is entirely consistent with established limits on Congress's power to delegate.

Congress clearly delineated "the boundaries of this delegated authority," *American Power & Light*, 329 U.S. at 105, by making "virtually every legislative determination" in the TCA. *United States v. Whaley*, 577 F.3d 254, 264 (5th Cir. 2009) (quoting in a parenthetical *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009)). Congress itself prescribed the substantive requirements and regulatory framework applicable to "tobacco products" subject to the Act, and it identified four

products falling within the statutory definition of "tobacco product" that are automatically subject to these requirements. The challenged provision authorizes FDA only to identify additional products falling within the statutory definition that the agency determines should also be subject to the Act's requirements. 21 U.S.C. § 387a(b). Those statutory features "ha[ve] the effect of constricting" the agency's remaining "discretion to a narrow and defined category." *Whaley*, 577 F.3d at 264.

Among other provisions in the TCA, Congress specified the requirements for ingredient disclosures, 21 U.S.C. § 387d(a)(1)-(2), product labels, *id.* § 387c, health warnings, *id.* § 387f(d)(1)-(2); 15 U.S.C. § 4402(a)(1), and "modified risk" claims, 21 U.S.C. § 387k. It required manufacturers to register with FDA, *id.* § 387e(b), and to list their products, *id.* § 387e(i), and it placed specific restrictions on industry marketing practices, *id.* § 387a-1(a). Congress also mandated premarket authorization for new tobacco products and detailed three separate procedural pathways for obtaining authorization. *Id.* § 387j. These substantive requirements, together with Congress's definition of "tobacco product" to include a limited category of products that raise shared public health concerns, *id.* § 321(rr)(1), establish clear boundaries for the exercise of FDA's authority to deem other tobacco products subject to the Tobacco Control Act. *American Power & Light*, 329 U.S. at 105.

In considering whether Congress provided a general policy for the agency to apply, this Court has admonished that "[t]he standards of the statute are not to be tested in isolation but must derive meaningful content from the purpose of the statute

and its factual background and the statutory context in which the standards appear." *United States v. Womack*, 654 F.2d 1034, 1037 (5th Cir. 1981); *see Gundy v. United States*, 139 S. Ct. 2116, 2126 (2019) (plurality op.). This comports with the rule that regulations implementing a statute "must be consistent with Congressional intent and the substantive provisions of the whole statute." *National Confectioners Ass'n v. Califano*, 569 F.2d 690, 695 (D.C. Cir. 1978) (construing 21 U.S.C. § 371(a), a provision cited in the deeming rule that gives FDA "authority to promulgate regulations for the efficient enforcement of" the Federal Food, Drug, and Cosmetic Act). Here, the TCA's deeming provision "derive[s] much meaningful content from the purpose of the Act, its factual background and the statutory context in which [it] appear[s]." *American Power & Light*, 329 U.S. at 104-05.

Contrary to plaintiffs' contention that Congress gave FDA no guidance for determining whether a tobacco product should be governed by the TCA, Br. 45, Congress clearly identified the "general policy" for the agency to pursue. *American Power & Light*, 329 U.S. at 105. Congress made extensive findings regarding the unique dangers posed by tobacco products and the particular risks they present to children, TCA § 2(1)-(49), noting that "[t]obacco use is the foremost preventable cause of premature death in America," *id.* § 2(13). "Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents," Congress concluded that "comprehensive restrictions on the sale, promotion, and distribution of such products are needed." *Id.* § 2(6).

The Act's purpose is to reduce the risks presented by tobacco products, and the risks presented to children and adolescents in particular. Specifically, Congress sought "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," "to vest [FDA] with the authority to regulate the levels of tar, nicotine, and other harmful components of 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." TCA § 3(2), (4)-(6).

These statements of purpose inform FDA's exercise of the authority delegated by 21 U.S.C. § 387a(b) and amply support FDA's decision to bring e-cigarettes within the ambit of the TCA. The statements also make clear that Congress intended to create a scheme of "comprehensive restrictions," TCA § 2(6), in order to protect the public health from the harms caused by products that deliver nicotine and therefore present a high risk of addiction. As a plurality of the Supreme Court recently observed, "[t]he term 'comprehensive' has a clear meaning—something that is all-encompassing or sweeping," *Gundy*, 139 S. Ct. at 2126-27 (plurality op.)—a point that further supports FDA's decision to include within the statutory scheme all tobacco

products meeting the statutory definition (except for accessories). All such products contain or are related to the use of nicotine and thus raise many of the same public health concerns as the products enumerated by Congress. While the extent of these risks, and any arguable benefits, vary by product, FDA reasonably concluded that regulation of tobacco products is appropriate and will benefit the public health. 81 Fed. Reg. at 28, 983-84.

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. Plaintiffs provide no support for their contention that FDA's decision to "deem[] all 'tobacco products' in one fell swoop" somehow reveals a problem with the scope of the delegation. Br. 67. 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.

Courts have similarly relied on Congress's statement of purpose in considering non-delegation challenges to the Sex Offender Registration and Notification Act (SORNA), which gave the Attorney General authority to "specify the applicability" of SORNA's requirements to pre-Act offenders. 34 U.S.C. § 20913(d). In *Gundy*, a plurality of the Supreme Court looked to SORNA's statement of purpose to determine the scope of the delegation. 139 S. Ct. at 2126-27. And this Court held in *Whaley* that "SORNA's statement of purpose, to 'establish[ ] a comprehensive national

system' of sex offender registration to 'protect the public from sex offenders and offenders against children,' is an intelligible principle that guides the Attorney General in exercising his discretion." 577 F.3d at 264 (quoting 42 U.S.C. § 16901).

The TCA's statements of purpose likewise supply an intelligible principle. FDA's exercise of its discretion is guided by Congress's stated intent to impose "comprehensive restrictions on the sale, promotion, and distribution" of tobacco products, TCA § 2(6), and "to ensure that [FDA] has the authority to address . . . the use of tobacco by young people," *id.* § 3(2), among the Act's other purposes. Plaintiffs' attempt to distinguish *Gundy* (Br. 52-53, 66-67) ignores these legislative guideposts.

The sufficiency of Congress's guidance to FDA is even clearer when considered "in light of the complexity of the area at which the legislation is directed and the susceptibility to change of the area in question." *United States v. Gordon*, 580 F.2d 827, 839-40 (5th Cir. 1978). As the district court noted, non-delegation "jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives." ROA.722 (quoting *Mistretta*, 488 U.S. at 372). E-cigarettes had only a *de minimis* presence in domestic markets until years after the TCA's enactment, underscoring the need for "flexible enforcement authority to ensure that there is

effective oversight of the tobacco industry's efforts to develop, introduce, and promote" new tobacco products, TCA § 3(4).

Delegations of the type at issue are commonplace and have never been held to raise constitutional concerns. For example, Congress in the Clean Water Act defined "pollution" and provided a non-exhaustive list of "pollutant[s]," 33 U.S.C. § 1362(6), (19), thereby delegating to the Environmental Protection Agency authority to determine which other materials should be included in the list and thus subject to the Act's restrictions, *id.* § 1314(a)(4). *See National Wildlife Fed'n v. Gorsuch*, 693 F.2d 156, 174 n.56 (D.C. Cir. 1982). Similarly, the Federal Mine Safety and Health Act defines "accident" by providing an enumerated list of terms, 30 U.S.C. § 802(k), and gives the Mine Safety and Health Administration authority to determine what other actions should be included in that list and thus subject to the Act's requirements. *See Pattison Sand Co. v. Federal Mine Safety & Health Review Comm'n*, 688 F.3d 507, 513 (8th Cir. 2012). Although these provisions give the agencies considerable authority to determine the range of conduct to which the statutes' substantive requirements apply, the constitutionality of that implicitly delegated authority has not been called into doubt.

Notably, the scope of the authority that the TCA's deeming provision grants FDA is no different under Supreme Court precedent than if Congress had granted FDA discretion to exempt otherwise-covered tobacco products from the TCA's requirements. Many statutes authorize the Executive to grant exemptions from

otherwise-applicable requirements.[4] Congress could have adopted that approach in the TCA without altering the scope of FDA's authority. Although such a statute would have established a different default rule for most tobacco products, the scope of FDA's decisionmaking authority—and thus the degree of specificity with which Congress had to articulate the statute's general policy—would be the same. Given the limited scope of that authority, the general policy Congress conveyed in the TCA to guide the exercise of FDA's authority is sufficient under Supreme Court precedent. *See, e.g.*, *American Trucking*, 531 U.S. at 475 (noting that "the degree of agency discretion that is acceptable varies according to the scope of the power" delegated).

The TCA resembles in all relevant respects the statute at issue in *United States v. Womack*, 654 F.2d 1034 (5th Cir. 1981), in which this Court rejected a non-delegation challenge to a statute that defined, and provided a nonexhaustive list of, "explosives" and directed the Secretary of the Treasury to publish "a list of these and any additional explosives which he determines to be within the coverage of this chapter." 18 U.S.C. § 841 (1976). Based on that definition and directive, and after considering

[4] *See, e.g.*, 7 U.S.C. § 1637b(b)(2)(D) (reporting requirements for small dairy producers); 15 U.S.C. § 78u-5(g) (various securities-law requirements); *id.* § 78j-1(m)(3)(C) (audit-committee independence requirements); *id.* § 5711(a)(5) (requirements on pay-per-call services); 16 U.S.C. § 823a(b) (requirements for hydroelectric facilities); 29 U.S.C. § 1112(e) (bonding requirements for employee-benefit plans); 46 U.S.C. § 4305 (recreational-vessel requirements); 49 U.S.C. §§ 20306, 47528(b) (railroad-equipment and aircraft-noise-control requirements).

Congress's purpose, the *Womack* Court held that the statute gave the Secretary adequate standards to guide his authority. 654 F.2d at 1038.

The TCA's command that its requirements shall apply to the enumerated tobacco products and any others that FDA "deems to be subject to this subchapter," 21 U.S.C. § 387a(b), is indistinguishable from the directive on which the Court relied in *Womack* providing that the Treasury Secretary shall publish a list of the enumerated explosives and any others that the Secretary "determines to be within the coverage of this chapter," 18 U.S.C. § 841(d) (1976). Plaintiffs do not explain how the authority to "deem[] [tobacco products] to be subject" to the TCA's requirements is constitutionally distinguishable from the authority approved in *Womack* to "determine[] [explosives] to be within the coverage" of the relevant provisions.

Plaintiffs instead urge (Br. 56) that *Womack* is distinguishable because, they contend, the statute at issue *required* the Treasury Secretary to list all explosives meeting the statutory definition. But *Womack* did not adopt that interpretation, much less rely on that construction of the statute in its non-delegation analysis. Instead, the Court considered the statutory definition and the grant of authority to list other explosives that the Secretary "determines to be within the coverage" of the statute and held that these standards were "sufficiently definite given the complexity and nature of the area to which the legislation [wa]s directed." *Womack*, 654 F.2d at 1038. Consideration of the TCA's comparable statutory features confirms the validity of the delegation at issue. *See* 21 U.S.C. §§ 321(rr)(1), 387a(b).

3. Plaintiffs' reliance on *Panama Refining* further illustrates the error of their analysis. The Supreme Court has described the statute at issue in that case, which permitted the President to prohibit the shipment of oil for any reason, as "provid[ing] literally no guidance for the exercise of discretion.'" *American Trucking*, 531 U.S. at 474. There, "Congress left the matter to the President without standard or rule, to be dealt with as he pleased." *Panama Refining*, 293 U.S. at 419. Plaintiffs' reliance on *Panama Refining* is premised on their contention that "the TCA provides *no* standard to guide the Secretary's deeming decisions." Br. 66. For the reasons stated above, that is plainly not the case.

By setting forth clear statements of purpose, defining "tobacco product" and providing enumerated examples, and establishing the specific requirements that apply to such products, the TCA substantially cabins FDA's authority. Contrary to plaintiffs' suggestion (Br. 66), Congress's acknowledgment of public health objectives that may sometimes be in tension with each other—*e.g.*, preventing youth use and addiction and preserving potentially less harmful alternatives for adult users of conventional cigarettes—only underscores the complexity of the regulated area and does not call into doubt the sufficiency of Congress's policies. *See Womack*, 654 F.2d at 1038; *Gordon*, 580 F.2d at 839.

There is likewise no merit to plaintiffs' contention (Br. 47) that FDA's position that its exercise of the deeming authority is committed to agency discretion by law and therefore not subject to review under the Administrative Procedure Act suggests a

non-delegation problem. *See* ROA.338-39. It plainly is not the case that decisions committed to agency discretion necessarily run afoul of non-delegation principles. To the contrary, courts have held that agency action is unreviewable because it is committed to the agency's discretion without raising any concerns about the constitutionality of the delegated authority. *See, e.g.*, *National Fed'n of Fed. Emps. v. United States*, 905 F.2d 400, 404-05 (D.C. Cir. 1990) (holding both that Congress supplied an "intelligible principle" to govern process of military base closures, and 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) of the Administrative Procedure Act).

Finally, plaintiffs assert that "affected businesses have no avenue for challenging the application of the TCA to their industry or business, precisely because the TCA lacks any substantive standard." Br. 55 (emphasis omitted). That assertion is mistaken. After FDA chose to deem all tobacco products subject to the Act's requirements, affected businesses filed suit on a variety of legal theories. The only court to consider the question rejected the contention that FDA's exercise of its deeming authority was committed to agency discretion by law and therefore unreviewable. *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 393 (D.D.C. 2017). And the D.C. Circuit considered and rejected the manufacturers' deeming-rule challenges on the merits. *Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019).

The regulated industry thus had ample opportunity to challenge FDA's exercise of its deeming authority.

4. After determining that plaintiffs failed to state a plausible claim for relief, the district court did not abuse its discretion in holding that plaintiffs' motion for preliminary injunction should be denied, or in rejecting plaintiffs' discovery request. The court reasonably concluded that it was not necessary to consider documents outside the pleadings to determine the deficiency of plaintiffs' claim. ROA.721 n.4. Plaintiffs' non-delegation claim presents a legal question for which discovery is unnecessary. To the extent that any facts could conceivably inform this inquiry, the relevant records are those compiled by Congress and FDA in enacting the TCA and issuing the deeming rule, respectively. The information plaintiffs seek—*e.g.*, regarding "the size of the ENDS industry and other newly-deemed industries (cigars, etc.), the jobs at stake, the number of smokers transitioning, etc.," Br. 72—does not bear on the question presented and is in any event not of a type that is properly sought from the government through discovery.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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March 2020

CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2020, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,743 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Garamond 14-point font, a proportionally spaced typeface.

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