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IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 19-60921

[Filed: June 25, 2020]

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

Plaintiffs–Appellants,

versus

FOOD & DRUG ADMINISTRATION; STEPHEN M. HAHN, Commissioner of Food and Drugs; ALEX M. AZAR, II, Secretary, U.S. Department of Health and Human Services, in his official capacity,

Defendants–Appellees.

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

Before SMITH, HIGGINSON, and ENGELHARDT, Circuit Judges.

JERRY E. SMITH, Circuit Judge:

The Family Smoking Prevention and Tobacco Control Act[1] establishes a thorough framework for regulating tobacco products. Four such products—cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco—are automatically subject to the Act. But in section 901 of the TCA, Congress authorized the Secretary of Health and Human Services ("the Secretary") to determine which other products should be governed by the TCA's regulatory scheme. Big Time Vapes, Incorporated, and the United States Vaping Association sued the Food and Drug Administration ("FDA"), its Commissioner, and the Secretary, asserting that Congress's delegation to the Secretary was unconstitutional. The district court dismissed, and we affirm.

I.

The facts are not disputed. This appeal turns on a purely legal question: Whether section 901's delegation to the Secretary violates the nondelegation doctrine.

A.

In 2009, Congress enacted the TCA, thereby amending the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*. Congress sought to empower the FDA to

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[1] Pub. L. No. 111–31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387, *et seq*.) ("TCA" or "the Act").

regulate tobacco products,[2] whose use Congress found to be "the foremost preventable cause of premature death in America." TCA § 2(13), 123 Stat. at 1777. "Because past efforts to restrict advertising and marketing of tobacco products ha[d] failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products [we]re needed." *Id.* § 2(6). Accordingly, Congress gave the FDA broad authority to address "the public health and societal problems caused by the use of tobacco products." *Id.* § 2(7).

To advance its public-health purpose, Congress established a detailed framework for regulating tobacco. But that statutory scheme did not apply—at least not immediately—to all forms of tobacco. Instead, Congress automatically applied the TCA "to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco."[3] Section 901 provided that the TCA also would apply "to any other tobacco products[4] that

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[2] In so acting, Congress legislatively abrogated the result of the watershed decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000), which held that the FDA lacked the authority to regulate tobacco as a "drug."

[3] TCA § 901, 123 Stat. at 1786 (codified at 21 U.S.C. § 387a(b)). Each of those terms is statutorily defined. *See* 21 U.S.C. § 387(3)–(4), (15), (18).

[4] Congress defined "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 Secretary [of Health and Human Services][5] by regulation deems to be subject to [the Act]." *Id.* § 387a(b).

The TCA imposes several requirements on "tobacco product manufacturers."[6] They must submit to the FDA truthful information about their products, including: (1) "all ingredients, [*i.e.*,] tobacco, substances, compounds, and additives"; (2) "[a] description of the content, delivery, and form of nicotine in each tobacco product"; and (3) certain information, including manufacturer-developed documents, related to the "health, toxicological, behavioral, or physiologic effects of current or future tobacco products" and their component parts. *Id.* § 387d(a). Manufacturers must file annual registration statements listing all tobacco products they make, *id.* § 387e(i)(1), and those lists must be updated biannually to reflect current offerings, *id.* § 387e(i)(3).

The TCA likewise prohibits manufacturers from introducing any "new tobacco product" without premarket authorization. *Id.* § 387j(a). A tobacco product is considered "new" if it "was not commercially marketed in the United States as of February 15,

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[5] The Secretary delegated that power to the FDA Commissioner, who delegated it to several deputy and associate commissioners. *See* FDA Staff Manual Guide 1410.21(1)(G)(1).

[6] That term "means any person, including any repacker or relabeler, who–(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States." 21 U.S.C. § 387(20).

2007."[7] A manufacturer can obtain premarket authorization through two primary channels: (1) by tendering a "premarket tobacco application" ("PMTA") demonstrating that the product "would be appropriate for the protection of the public health," *id*. § 387j(a)(2), (c)(2)(A); or (2) by submitting a "report" showing that the product "is substantially equivalent to a tobacco product commercially marketed" before February 2007, *id*. § 387j(a)(2)(A)(i).[8] The PMTA process is onerous, requiring manufacturers to gather significant amounts of information.[9]

Finally, the FDA can impose additional rules by regulation, such as minimum-age restrictions,

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[7] *Id*. § 387j(a)(1)(A). The definition also encompasses "any modification . . . of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." *Id*. § 387j(a)(1)(B).

[8] Under certain circumstances not relevant here, manufacturers can also request an exemption from the "substantial equivalence" requirements. *See id*. § 387j(a)(2)(A)(ii); *see also id*. § 387e(j) (outlining the parameters for products exempt).

[9] PMTAs must include (1) report(s) "concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products"; (2) a full statement of the product's ingredients, components, and principles of operation; (3) a description of how the product is manufactured and prepared for sale; (4) references to any applicable statutory standards and information showing how those standards are met; (5) product samples; and (6) examples of the proposed labeling for the product. *Id*. § 387j(b)(1). According to the plaintiffs, curating the necessary data to submit a PMTA can cost anywhere from about $180,000 to more than $2 million.

mandatory health warnings, method-of-sale limits, and advertising constraints. *See id.* § 387f(d). Failing to comply with the TCA's or the FDA's regulations has serious consequences. A non-compliant manufacturer's product may be designated as "adulterated" or "misbranded," *see id.* §§ 387b, 387c, which could result in, among other things, civil penalties, *see id.* § 333(f)(8)–(9), or seizure of the offending product, *see id.* § 334.

B.

In May 2016, the FDA promulgated a rule that "deem[ed] all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products, to be subject to FDA's tobacco product authorities under [the TCA]."[10] That swept into the TCA's ambit several popular tobacco products, including Electronic Nicotine Delivery Systems ("ENDS").[11] The FDA maintained that regulating

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[10] Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products ("Deeming Rule"), 81 Fed. Reg. 28,974 28,976 (May 10, 2016).

[11] ENDS include "ecigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes." *Id.* Those devices work by heating and aerosolizing a liquid mixture–called an "e-liquid"–that includes various levels of nicotine and sometimes flavoring. *See Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). After the liquid is aerosolized, it is then inhaled as vapor. *See id.* Not all e-liquids contain nicotine, but "[d]ata suggest that experienced ENDS users are able

ENDS would benefit public health, because (1) those products had the potential to effect public harm, and (2) regulation would permit the FDA to "learn more about that potential." Deeming Rule, 81 Fed. Reg. at 28,983. That was especially true given that long-term studies hadn't yet been conducted to determine whether ENDS products were harmful or beneficial to public health. *Id*. at 28,984.

As a result of the FDA's rule, ENDS and e-liquid producers were "subject to all of the statutory and regulatory requirements applicable to [tobacco] manufacturers," including the TCA's reporting, registration, and premarket authorization mandates. *Id*. at 29,044. The FDA required compliance with some TCA provisions as soon as the Deeming Rule became effective,[12] but the FDA indicated that it would not enforce the premarket-review provisions, for products already on the market, for several years following the rule's effective date.[13] For any new products, however,

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to achieve clinically significant nicotine levels and levels similar to those generated by traditional cigarettes." Deeming Rule 81 Fed. Reg. at 29,031. Some e-liquids can also contain chemicals that are known to pose health risks including diacetyl and acetyl propionyl, formaldehyde, and various other aldehydes. *Id*. at 29,029-31.

[12] For example, the FDA required newly deemed products containing nicotine to display the following statement: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." Deeming Rule, 81 Fed. Reg. at 28,979.

[13] *See id*. at 29,011–12. The length of the compliance period varied by the type of application to be submitted. PMTAs received the longest compliance period (36 months), followed by substantial equivalence petitions (30 months) and exemption requests from the

tobacco manufacturers had to obtain premarket authorization before those products could be sold. *Id*. at 28,978. Because ENDS technology is relatively young—*i.e.*, there were very few (if any) products on the market before February 2007—ENDS products and e-liquids are effectively required to submit PMTAs. *See id*. at 28,978–79.

C.

Big Time Vapes, a small-business manufacturer and retailer of e-liquids, and the United States Vaping Association, an ENDS industry trade association, sued the FDA, contending that the TCA unconstitutionally

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substantial equivalence requirements (24 months). *Id*. at 29,011. Those compliance deadlines have been delayed several times. *See, e.g.*, FDA, EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE (REVISED) 9 tbl.2 (2019) (revising 2017 guidance, which extended the compliance period for certain tobacco products until either August 2021 or August 2022); *see also* 82 Fed. Reg. 37,459 (Aug. 10, 2017) (announcing the 2017 guidance).

The FDA's current guidance, which was issued in January 2020 and revised in April 2020, prioritizes enforcement against (1) "[a]ny flavored, cartridge-based ENDS product," (2) "[a]ll other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access," (3) "[a]ny ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors," and (4) "any ENDS product that is offered for sale after September 9, 2020, and for which the manufacturer has not submitted a premarket application . . . ." FDA, ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION (REVISED) 3 (2020); *see also* 85 Fed. Reg. 23,973 (April 30, 2020) (announcing the guidance).

delegated to the Secretary the power to deem tobacco products subject to the Act's mandates. The plaintiffs requested, *inter alia*, (1) a declaration that section 901 violates the nondelegation doctrine and (2) an injunction preventing the FDA from enforcing the TCA against them.

Shortly after filing suit—and in response to a forthcoming change in federal enforcement strategy—the plaintiffs moved for a preliminary injunction enjoining the FDA "from exercising any authority over any 'tobacco products' deemed to be subject to the TCA . . . ." The FDA opposed the plaintiffs' motion and separately moved to dismiss under Rule 12(b)(6). The plaintiffs countered the FDA's motion by asserting that they were entitled to reasonable discovery.

The district court found no nondelegation violation and dismissed the suit. The court determined that Congress had articulated a sufficiently intelligible principle—specifically, "a desire to protect the public health and to prevent, to the extent possible, underaged persons from having access to tobacco products"—for the delegation to pass constitutional muster. Moreover, the court concluded that the FDA's power was adequately constrained, because (1) "Congress . . . restricted the FDA's discretion with a controlling definition of 'tobacco product,'" and (2) "Congress, itself, designated certain tobacco products as governed by the TCA and presented detailed policies behind its enactment of the TCA." The court naturally denied a preliminary injunction. The plaintiffs appeal.

II.

We review Rule 12(b)(6) dismissals *de novo*. *In re IntraMTA Switched Access Charges Litig.*, No. 18-10768, 2020 U.S. App. LEXIS 16844, at *58 (5th Cir. May 27, 2020). Whether a statute violates the nondelegation doctrine is a legal question we review *de novo*. *See United States v. Johnson*, 632 F.3d 912, 917 (5th Cir. 2011).

A.

"All legislative Powers herein granted shall be vested in a Congress of the United States." U.S. CONST. art. I, § 1. "Accompanying that assignment of power to Congress is a bar on its further delegation." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality). "Th[at] nondelegation doctrine is rooted in the principle of separation of powers that underlies our tripartite system of Government." *Mistretta v. United States*, 488 U.S. 361, 371 (1989). "[T]he lawmaking function belongs to Congress," *Loving v. United States*, 517 U.S. 748, 758 (1996), and Congress "may not constitutionally delegate [that] power to another" constitutional principal, *Touby v. United States*, 500 U.S. 160, 165 (1991).

But that seemingly inflexible constitutional text has long been recognized to be somewhat pliable.[14] "The

[14] *See Loving*, 517 U.S. at 758 ("Th[e] [nondelegation] principle does not mean, however, that only Congress can make a rule of prospective force. To burden Congress with all federal rulemaking would divert that branch from more pressing issues, and defeat the Framers' design of a workable National Government."); *Mistretta*, 488 U.S. at 372 ("[O]ur jurisprudence has been driven by a

Constitution has never been regarded as denying to the Congress the necessary resources of flexibility and practicality to perform its function." *Yakus v. United States*, 321 U.S. 414, 425 (1944) (ellipsis omitted). Delegations are 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." *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928). It 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." *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946).

"Those standards . . . are not demanding."[15] Even

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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.").

[15] *Gundy*, 139 S. Ct. at 2129 (plurality). Some have suggested that the Court's intelligible-principle standard is really no hurdle at all. *See, e.g., id.* at 2140 (Gorsuch, J., dissenting) ("[The intelligible-principle standard] has been abused to permit delegations of legislative power that on any other conceivable account should be held unconstitutional. Indeed, where some have claimed to see 'intelligible principles' many less discerning readers have been able to only find gibberish." (cleaned up)); Gary Lawson, *Delegation and Orginial Meaning*, 88 VA. L. REV. 327, 329 (2002) ("[I]n *Mistretta* . . . the Court aptly summarized more than half a century of case law by unanimously declaring the nondelegation doctrine to be effectively a dead letter."); David Schoenbrod, *The Delegation Doctrine: Could the Court Give It Substance?*, 83 MICH. L. REV. 1223, 1231 (1985) ("The [intelligible-principle] test has become so ephemeral and elastic as to lose its meaning.").

though Congress has delegated power to the President "[f]rom the beginning of the government,"[16] the Court did not find a delegation of legislative power to be unlawful until 1935, when the Court declared two to be unconstitutional. *See Pan. Ref. Co. v. Ryan*, 293 U.S. 388, 433 (1935); *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 542 (1935). But the Court has not done so in the nearly nine decades since[17] and, instead, has long defended "Congress'[s] ability to delegate power under broad standards."[18] In fact, the

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[16] *United States v. Grimaud*, 220 U.S. 506, 517 (1911); *see also Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 41–47 (1825) (upholding a provision of the Process and Compensation Act of 1792 that permitted federal courts to make rules altering the "forms and modes of proceeding" that Congress had adopted); *Cargo of the Brig Aurora v. United States*, 11 U.S. (7 Cranch) 382, 383 (1813) (observing that the Non-Intercourse Act of 1809 authorized the president, by proclamation, to revoke or modify portions of the Act if he found certain facts).

[17] We also have uniformly upheld Congress's delegations. *See, e.g.*, *United States v. Jones*, 132 F.3d 232, 239 (5th Cir. 1998) (upholding delegation of authority to the DOJ to "define nonstatutory aggravating factors" to determine which offenders were "death-eligible" under the Federal Death Penalty Act); *United States v. Mirza*, 454 F. App'x 249 256 (5th Cir. 2011) (per curiam) (upholding International Emergency Economic Powers Act's delegation, which authorizes the President to declare a national emergency and limit certain types of economic activity related to that threat).

[18] *Mistretta*, 488 U.S. at 373. For example, the Court has blessed delegations that authorize regulation in the "public interest" or to "protect the public health." *See, e.g.*, *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 472 (2001) (upholding delegation to EPA to regulate "ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator . . . are

Court has "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." *Am. Trucking*, 531 U.S. at 474–75.

That does not mean, however, that we must rubber-stamp all delegations of legislative power. Indeed, "[w]e ought not to shy away from our judicial duty to invalidate unconstitutional delegations"; "[i]f we are ever to reshoulder the burden of ensuring that Congress itself make the critical policy decisions, these are surely the cases in which to do it."[19] In that spirit,

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requisite to protect the public health"); *Nat'l Broad. Co. v. United States*, 319 U.S. 190, 225-26 (1943) (upholding delegation to FCC to regulate broadcast licensing in the "public interest"); *N.Y. Cent. Sec. Corp. v. United States*, 287 U.S. 12, 24-25 (1932) (upholding delegation of authority to Interstate Commerce Commission to approve railroad consolidations that are in the "public interest"). Moreover, the Court has also approved of delegations that spoke in terms of fairness and equity. *See, e.g., Am. Power*, 329 U.S. at 104 (upholding delegation to SEC to ensure that holding companies didn't "unduly or unnecessarily complicate" corporate structures or "unfairly or inequitably distribute voting power among security holders"); *Yakus*, 321 U.S. at 426-27 (upholding delegation to agency to set commodity prices that are "fair and equitable" and that "tend to promote the purposes of the Act"); *cf. Lichter v. United States,* 334 U.S. 742, 785-86 (1948) (upholding delegation of to Secretary of War to recover "excessive profits" from private businesses in times of crisis).

[19] *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 686-87 (1980) (Rehnquist, J., concurring in the judgment).

several Justices recently expressed interest in reexamining the nondelegation doctrine.[20]

B.

"[A] nondelegation inquiry always begins (and often almost ends) with statutory interpretation," because we need "to figure out what task [the statute] delegates and what instructions it provides." *Gundy*, 139 S. Ct. at 2123 (plurality). Our task should not be limited to the text alone—when evaluating whether Congress laid down a sufficiently intelligible principle, we're meant also to consider "the purpose of the [TCA], its factual background[,] and the statutory context."[21] "That non-blinkered brand of interpretation" generally bodes well for delegations. *Id.* at 2126.

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[20] *See Gundy*, 139 S. Ct. at 2131 (Alito, J., concurring in the judgment) ("If a majority of this Court were willing to reconsider the approach we have taken for the past 84 years, I would support that effort."); *id.* (Gorsuch, J., dissenting) (indicating that the court shouldn't wait to reconsider the nondelegation doctrine, whose abandonment is premised on "an understanding of the Constitution at war with its text and history"); *Paul v. United States*, 140 S. Ct. 342 (2019) (Kavanaugh, J., respecting the denial of certiorari) ("Justice GORSUCH's scholarly analysis of the Constitution's nondelegation doctrine in his *Gundy* dissent may warrant further consideration in future cases.").

[21] *Am. Power*, 329 U.S. at 104; *accord United States v. Womack*, 654 F.2d 1034, 1037 (5th Cir. Unit B Aug. 1981) ("The standards of the statute are not to 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.").

In the TCA, Congress delegated to the Secretary the power to "deem" which tobacco products should be subject to the Act's mandates. *See* 21 U.S.C. § 387a(b). But the plaintiffs assert that Congress didn't provide "any parameters or guidance whatsoever" to guide the Secretary's exercise of that discretion. That unbounded delegation of "deeming" authority violates the non-delegation doctrine, the plaintiffs maintain, as did the limitless delegation in *Panama Refining*. And because the TCA laid down *no* principle— notwithstanding the Secretary's authority's being limited to "tobacco products" or the statutory framework established for enumerated tobacco products—the broad delegations that the Court has approved in the past are inapposite.

We disagree. Recall that it is"constitutionally sufficient if Congress [(1)] clearly delineates [its] general policy, [(2)] the public agency which is to apply it, and [(3)] the boundaries of th[at] delegated authority." *Mistretta*, 488 U.S. at 372–73 (quoting *Am. Power*, 329 U.S. at 105). The second factor isn't at issue; the TCA's text facially designates the Secretary. And on the other two, the TCA's delegation, despite the plaintiffs' suggestions to the contrary, falls comfortably within the outer boundaries demarcated by the Supreme Court.[22]

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[22] The plaintiffs raise two additional contentions: The district court erred (1) by dismissing their complaint before reasonable discovery and (2) by denying them a preliminary injunction. Neither is meritorious. The plaintiffs identify no authority that even suggests, much less requires, that the district court had to afford them discovery, especially when additional *facts* wouldn't have helped them overcome a distinctly *legal* barrier. And, because the plaintiffs haven't stated a claim, they cannot show that the district

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Congress undeniably delineated its general policy in the TCA. The plaintiffs improperly discount other materials that we must consider, namely the TCA's purpose and the relevant factual background.[23] Both factors support upholding section 901's delegation.

Start with statutory purpose. The plaintiffs suggest that the TCA's purposes are "various and diverse," so much so that they "are in actual tension with one another." To come to that conclusion, the plaintiffs essentially ignore Section 3 of the TCA, which is aptly labeled "PURPOSE."[24]

In that section, Congress stated that the TCA was meant "to ensure that the [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." TCA, § 3(2), 123 Stat. at 1781. Another purpose was "to provide new and flexible

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court abused its discretion in denying them a preliminary injunction. *See Winter v. NRDC*, 555 U.S. 7, 20 (2008) (requiring the plaintiffs to establish, among other things, they are they're "likely to succeed on the merits").

[23] *See, e.g., Thomas v. Union Carbide Agric. Prod. Co.*, 473 U.S. 568, 593 (1985); *Am. Power*, 329 U.S. at 104; *Womack*, 654 F.2d at 1037.

[24] Section 3 is part of the positive law that ran the gauntlet of bicameralism and presentment. *See* TCA, § 3, 123 Stat. at 1781–82. That's a far cry from "the sort of unenacted legislative history that often is neither truly legislative . . . nor truly historical . . . ." *BNSF Ry. v. Loos*, 139 S. Ct. 893, 906 (2019) (Gorsuch, J., dissenting).

enforcement authority to ensure that there is effective over-sight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." *Id*. § 3(4), 123 Stat. at 1782. And still two more purposes were "to impose appropriate regulatory controls on the tobacco industry" and "to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases." *Id*. § 3(8)–(9). Obviously, the TCA's purpose sounds in (1) protecting public health and (2) preventing young people from accessing (and becoming addicted to) tobacco products.

That purpose was informed by Congress's extensive fact-finding. *See id*. § 2, 123 Stat. at 1776–81. Congress concluded that, for several reasons, tobacco products posed a significant risk to children: (1) "[T]obacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects"; (2) "[n]icotine is an addictive drug"; (3) "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products"; and (4) "[t]obacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents." *Id*. § 2(1)–(5), 123 Stat. at 1777. And Congress meant for the FDA to attack those problems *comprehensively*,[25] that is, in an "all-encompassing or

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[25] *See, eg.*, TCA, § 2(6), 123 Stat. at 1777 ("Because 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." (emphasis added)); *id*. § 2(7) ("Federal and State governments have lacked the legal and regulatory authority and resources they need to address *comprehensively* the public

sweeping" fashion. *Gundy*, 139 S. Ct. at 2127 (plurality). Those findings when coupled with Congress's stated purposes in legislating, undoubtedly identify a "general policy" for the Secretary to pursue.

2.

Likewise, Congress plainly limited the authority that it delegated. Far from giving the Secretary carte blanche, the TCA cabined its delegation in two important ways.

First, and critically, Congress enacted a controlling definition of "tobacco product," which necessarily restricts the Secretary's power to only products meeting that definition. *See* 21 U.S.C. § 321(rr)(1). Congress also identified four products—"cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"—that were immediately subject to the TCA's mandates. *Id.* § 387a(b). Together, those features

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health and societal problems caused by the use of tobacco products." (emphasis added)); *id.* § 2(25), 123 Stat. at 1778 ("*Comprehensive* advertising restrictions will have a positive effect on the smoking rates of young people." (emphasis added)); *id.* § 2(27) ("International experience shows that advertising regulations that are stringent and *comprehensive* have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones." (emphasis added)); *id.* § 2(31), 123 Stat. at 1779 ("An 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. Tobacco advertising and promotion play a crucial role in the decision of these minors to being using tobacco products. Less restrictive and less *comprehensive* approaches have not and will not be effective in reducing the problems addressed by such regulations." (emphasis added)).

"ha[ve] the effect of constricting the [Secretary's] discretion to a narrow and defined category." *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009) (cited favorably by *United States v. Whaley*, 577 F.3d 254, 264 (5th Cir. 2009)). We recognized as much in the context of a federal statute criminalizing the production of "explosives."[26]

And second, Congress restricted the Secretary's discretion by making many of the key regulatory decisions itself. *See Ambert*, 561 F.3d at 1214. Among myriad other things, the TCA requires tobacco manufacturers to submit comprehensive data about their products' ingredients (including nicotine) and health effects. *See* 21 U.S.C. § 387d(a). The Act also requires manufacturers to file annual registration statements listing their products and to update those lists biannually. *See id.* § 387e(i)(1); *id.* § 387e(i)(3). And finally, the TCA prohibits manufacturers from introducing new tobacco products without premarket authorization, and it details the steps manufacturers must take to obtain approval. *See id.* § 387j(a). As those

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[26] *See Womack*, 654 F.2d at 1038 (rejecting assertion that federal statute regulating explosives lacked "adequate standards," given that the statute "carefully define[d] the term 'explosives' . . . and an illustrative list of subject explosives [wa]s provided"). The plaintiffs spill a lot of ink to distinguish *Womack*'s facts, likely because the district court found *Womack* to be analogous to this case. The plaintiffs assert that the statute in *Womack* essentially conferred no discretion; it required the Treasury Secretary to list all "explosives" that met the statutory definition. We needn't determine whether those factual differences are of any moment. Even assuming that *Womack* is factually distinct and therefore does not *control*, it doesn't follow that the delegation at issue here must be unconstitutional.

substantive provisions show, Congress painted much of the regulatory canvas, leaving the finishing touches to the FDA. The Court has held, time after time, that that's enough to clear the Constitution's low hurdles. *See, e.g., Mistretta*, 488 U.S. at 372–74 (collecting cases).

3.

The relevant caselaw drives those conclusions home. It bears repeating: The Court has found only two delegations to be unconstitutional. Ever. And none in more than eighty years. *See Pan. Ref.*, 293 U.S. at 433; *Schechter*, 295 U.S. at 542. Considering those decisions, it's evident that we confront nothing similar here. Instead, the TCA's commission to the Secretary mirrors the delegation to the Attorney General of the Sex Offender Registration and Notification Act ("SORNA"), which the Court approved just last year. *See Gundy*, 139 S. Ct. at 2121 (plurality). In *Panama Refining* and *Schechter*, the Court invalidated two of the National Industrial Recovery Act's delegations to the President.

In *Panama Refining*, 293 U.S. at 406, the Court considered Section 9(c), which authorized the President "to prohibit the transportation in interstate and foreign commerce" of certain petroleum products. And *Schechter*, 295 U.S. at 521–22, evaluated Section 3, which empowered "the President to approve 'codes of fair competition'" that were submitted by "one or more trade or industrial associations or groups." NIRA outlined exceedingly broad legislative purposes, including (1) "remov[ing] obstructions to the free flow of interstate and foreign commerce," *Pan. Ref.*, 293 U.S. at 418, and (2) disfavoring "monopolies [and]

monopolistic practices," *Schechter*, 295 U.S. at 523. But in both cases, Congress erected no guide rails to limit how the President should exercise his authority.[27]

The Court found both delegations to be unconstitutional. *See Pan. Ref.*, 293 U.S. at 433; *Schechter*, 295 U.S. at 542. That's not surprising, given that NIRA placed almost no limits on how the President—and in *Schechter*'s case, private groups—could wield their delegated authority. Section 9(c) "provided literally no guidance for the exercise of discretion," and Section 3 "conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *Am. Trucking*, 531 U.S. at 474.

By contrast, the TCA's delegation to the Secretary is circumscribed, and Congress provided far more signposts to direct the exercise of the authority it delegated. The TCA's targeted statements of purpose and voluminous fact-finding make that incontrovertible.

Instead, the TCA's deputizing of the Secretary mirrors SORNA's delegation to the Attorney General.

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[27] *See Pan. Ref.*, 293 U.S. at 417–418 (observing that Congress "la[id] down no policy of limitation" in Section 9(c), and its general policy statement "contain[ed] nothing as to the circumstances or conditions in which transportation of petroleum or petroleum products should be prohibited"); *Schechter*, 295 U.S. at 541 (noting that the Section 3 was "without precedent," because it "sets up no standards" to guide the President's exercise of his authority outside of NIRA's "general aims of rehabilitation, correction, and expansion" of the economy).

In enacting SORNA, Congress sought "to combat sex crimes and crimes against children" by creating "'more uniform and effective' . . . sex-offender registration systems." *Gundy*, 139 S. Ct. at 2121 (plurality) (quotation marks omitted). For sex offenders convicted after SORNA, the statute provided a detailed framework outlining their obligations to register. *Id.* at 2122. SORNA didn't specify, however, how it would apply to pre-Act offenders, leaving that decision up to the Attorney General:

> The Attorney General shall have the authority to specify the applicability of the requirements of this subchapter to sex offenders convicted before the enactment of this chapter . . . and to prescribe rules for the registration of any such sex offenders . . . .

34 U.S.C. § 20913(d). But beyond the text of that provision, the plurality observed that SORNA's purposes,[28] statutory context, and legislative history all pointed in one direction: Congress meant for SORNA to apply to pre-Act offenders as soon as feasible. *Gundy*, 139 S. Ct. at 2126–29 (plurality). Given that backdrop, the plurality had little trouble determining that SORNA's delegation was constitutionally permissible. *See id.* at 2129–30.

In all material respects the TCA's statutory scheme parallels SORNA's. Both SORNA and the TCA established detailed regulatory frameworks that

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[28] Like the TCA's, SORNA's purposes were enacted as part of the positive law. *See* Pub. L. No. 109-248, § 102, 120 Stat. 587, 590-91 (2006) (codified at 34 U.S.C. § 20901).

automatically applied to certain classes of persons or products. In both statutes, Congress delegated to an executive branch official the power to determine whether those requirements applied to other non-covered classes. And in both instances, Congress outlined specific purposes to inform the executive officer's exercise of the discretion so afforded. Although a less-than-full-strength Court fractured in *Gundy*, five Justices elected to affirm SORNA's delegation.[29] Those votes compel our affirmance here.

* * * * *

The Court might well decide—perhaps soon—to reexamine or revive the nondelegation doctrine. But "[w]e are not supposed to . . . read tea leaves to predict where it might end up." *United States v. Mecham*, 950 F.3d 257, 265 (5th Cir. 2020), *cert. denied*, 2020 WL 3405899 (U.S. June 22, 2020) (No. 19-7865). The judgment of dismissal is therefore AFFIRMED.

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[29] *See Grundy*, 139 S. Ct. at 2121 (plurality); *see also id.* at 2131 (Alito, j., concurring in the judgment) ("Because I cannot say that the statute lacks a . . . standard that is adequate under the approach this Court has taken for many years, I vote to affirm.").

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

CAUSE NO. 1:19cv531-LG-JCG

[Filed: December 16, 2019]

BIG TIME VAPES, INC. and UNITED STATES VAPING ASSOCIATION, INC.	)
PLAINTIFFS	)
v.	)
FOOD AND DRUG ADMINISTRATION, et al.	)
DEFENDANTS	)

MEMORANDUM OPINION AND ORDER GRANTING DEFENDANTS' MOTION TO DISMISS AND DENYING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

BEFORE THE COURT are the [15] Motion for Preliminary Injunction filed by the plaintiffs Big Time Vapes, Inc., and United States Vaping Association,

Inc., and [24] Motion to Dismiss filed by the defendants Food and Drug Administration, Admiral Brett P. Giroir, M.D. in his official capacity as Acting Commissioner of Food and Drug Administration, and Alex M. Azar, II, in his official capacity as Secretary of Health and Human Services. The parties have fully briefed both Motions. The plaintiffs raise a constitutional delegation challenge to part of the Family Smoking Prevention and Tobacco Control Act ("TCA"), and the defendants counter that the plaintiffs have failed to state a plausible claim for relief. After reviewing the submissions of the parties, the record in this matter, and the applicable law, the Court finds that the defendants' Motion to Dismiss should be granted, and the plaintiffs' Motion for Preliminary Injunction should be denied.

BACKGROUND

In 2009, Congress amended the Federal Food, Drug, and Cosmetic Act to include the TCA, which vests the FDA with regulatory authority over the design, production, marketing, and advertising of tobacco products. Congress listed the following purposes of the Act:

> (1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act . . . by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division . . . ;
> (2) to ensure that the Food and Drug

Administration 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;

(3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) 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;

(5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) in order 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;

(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and

> (10) to strengthen legislation against illicit trade in tobacco products.

Pub. L. No. 111-31, 123 Stat. 1778 (2009). Congress clarified, however, that the TCA is not intended to affect the growing, cultivation, or curing of raw tobacco. *Id.*

Congress specified that the TCA "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).[1] Congress 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).

On May 10, 2016, the FDA issued a final rule deeming electronic nicotine delivery systems ("ENDS") to be subject to the Federal Food, Drug, and Cosmetic Act.[2] Deeming Tobacco Products to be Subject to the

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[1] The Secretary referred to in the statute is the Secretary of Health and Human Services. 21 U.S.C. § 321(d). The Secretary redelegated his authority to the FDA Commissioner, who in turn redelegated his authority to the Associate Commissioner for Policy. FDA Staff Manual Guide 1410.10, 1410.21.

[2] ENDS include e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973-01, 29,028 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143).

Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973-01 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143). This deeming rule clarified that "establishments that mix or prepare e-liquids or create of modify aerosolizing apparatus for direct sale to consumers are tobacco product manufacturers under the definition set forth in the FD&C Act and, accordingly, are subject to the same legal requirements that apply to other tobacco product manufacturers." *Id.* at 28,979. As a result, these establishments must obtain premarket approval of all products not commercially marketed in the United States as of February 15, 2007. 21 U.S.C. § 387j. Any products not preapproved by the FDA are banned. *See* 21 U.S.C. § 387b; 21 U.S.C. § 387c.

The deeming rule went into effect on August 8, 2016, but the FDA provided time periods during which the FDA did not intend to enforce compliance with premarket review requirements. *Id.* at 29,006. In August 2017, the FDA issued *Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* (Aug. 2017), which is available at https://www.fda.gov/media /105346 /download, stating that it did not intend to enforce the Act's premarket review provisions "as a matter of enforcement discretion" until August 2022. 2017 Guidance at 3-4.

The American Academy of Pediatrics and others filed a lawsuit against the FDA in the United States District Court for the District of Maryland, arguing that the 2017 Guidance violated the Administrative Procedure Act, exceeded the FDA's statutory authority,

and violated U.S. Const. art. II, § 3. *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461, 490 (D. Md. 2019). The plaintiffs alleged that the FDA violated the APA by failing to comply with the notice and comment requirements for rule-making when it issued the 2017 Guidance. *Id.* The court held that the Guidance was "tantamount to an amendment to the Tobacco Control Act," such that the FDA was required to comply with the APA's notice and comment requirements. *Id.* at 497-98. As a result, the court vacated the 2017 Guidance. *Id.* at 498. In a subsequent order dated July 12, 2019, the court established a ten-month deadline for submitting marketing order applications for new tobacco products and a one-year deadline for products for which applications were already filed to remain on market without enforcement action. *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 399 F. Supp. 3d 479 (D. Md. 2019). As a result, premarket review applications for ENDS products must be submitted by August 2022. The *American Academy of Pediatrics* decision is currently on appeal before the United States Court of Appeals for the Fourth Circuit.

Faced with accelerated deadlines for complying with the TCA, Big Time Vapes, Inc., and United States Vaping Association, Inc., filed this lawsuit on August 19, 2019, against the FDA, the Secretary of Health and Human Services, and the Acting Commissioner of the FDA. The plaintiffs assert that 21 U.S.C. § 387a(b) violates the United States Constitution by impermissibly delegating legislative authority to the

executive branch.[3] See U.S. Const., art. I, § 1 ("All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.") The plaintiffs seek a declaratory judgment that 21 U.S.C. § 387a(b) violates the Constitution, such that the deeming rule is invalid. The plaintiffs also ask the Court to enjoin the defendants from enforcing the TCA against the plaintiffs or any other similarly situated businesses. The plaintiffs have filed a motion for preliminary injunction, and the defendants have filed a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6).

DISCUSSION

I. DEFENDANTS' MOTION TO DISMISS

When considering a motion under Rule 12(b)(6), the "court accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.'" *Martin K. Eby Constr. Co. v. Dall. Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004) (quoting *Jones v. Greninger*, 188 F.3d 322, 324 (5th Cir. 1999) (per curiam)). But "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere

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[3] Big Time Vapes is a Mississippi corporation that sells and manufactures vaping products in Picayune, Mississippi. United States Vaping Association is a trade association "organized in July and August 2019 to represent small-business vaping manufacturers (who make e-liquid) and retail vape shops that sell e-liquid manufactured by other firms and mix and produce their own in-house e-liquid." (Compl. 4-5, ECF No. 1.)

conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). To overcome a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations and footnote omitted).

Ordinarily, in considering a motion to dismiss under Rule 12(b)(6), the Court "must limit itself to the contents of the pleadings, including attachments thereto." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000). An exception to this rule exists for "matters of public record," of which the Court may take judicial notice. *Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007). Additionally, "[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to her claim." *Causey v. Sewell Cadillac-Chevrolet, Inc.*, 394 F.3d 285, 288 (5th Cir. 2004). "If . . . matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12. The Court has not considered any matters outside of the pleadings while deciding the defendants' Motion; therefore, it is not necessary to treat the defendants' Motion to Dismiss as a motion for summary judgment.[4]

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[4] The plaintiffs ask the Court to permit them to conduct discovery prior to ruling on the defendants' Motion to Dismiss, because the

Article I, section 1 of the Constitution provides, "All legislative powers herein granted shall be vested in a Congress of the United States . . . ." U.S. Const. art. I, § 1. As a result, "Congress generally cannot delegate its power to another Branch." *Mistretta v. United States*, 488 U.S. 361, 372 (1989). Nevertheless, this nondelegation doctrine does not prevent Congress from delegating "at least some authority that it could exercise itself." *Loving v. United States*, 517 U.S. 748, 758 (1996). "So long as Congress shall lay 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 (alterations in original). "Applying this 'intelligible principle' test to congressional delegations, our 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." *Id.* "The true distinction . . . is between the delegation of power to make the law, which necessarily involves discretion as to what it shall be, and conferring authority or discretion as to its execution, to be exercised under and in pursuance of the law. The first cannot be done; to the latter no valid objection can be made." *Loving*, 517

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plaintiffs contend that the defendants have relied on documents outside the pleadings in support of their Motion. Because the Court has not considered any documents outside the pleadings, discovery is not necessary to determine whether the plaintiffs have stated plausible claims for relief.

U.S. at 758-59. Apart from two 1935 cases, *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935), the Supreme Court has upheld every challenge to a congressional delegation of power that has been presented to it. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474 (2001).

Courts considering whether Congress has supplied an intelligible principle must "construe the challenged statute to figure out what task it delegates and what instructions it provides." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019). The delegation of legislative authority 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 *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)). "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." *United States v. Womack*, 654 F.2d 1034, 1037 (5th Cir. 1981) (citing *Am. Power & Light Corp.,* 329 U.S. at 105). "[T]he degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Am. Trucking Ass'ns*, 531 U.S. at 475.

The plaintiffs argue that the TCA is unconstitutional, because it gives the FDA no guidance for determining whether a tobacco product should be governed by the TCA. Contrary to the plaintiffs' assertions, Congress did not give the FDA unlimited

discretion but restricted the FDA's discretion with a controlling definition of "tobacco product."[5] In addition, Congress, itself, designated certain tobacco products as governed by the TCA[6] and presented detailed policies behind its enactment of the TCA. 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. These listed policies and covered products provide additional guidance to the FDA for determining which additional tobacco products should be governed by the TCA. This case is analogous to *United States v. Womack*, wherein the Fifth Circuit held that Title XI of the Organized Crime Control Act of 1970 provided the Secretary of the Treasury with adequate standards for listing additional explosives covered by the Act where Congress provided a definition of the term "explosives" and gave an illustrative list of explosives subject to the Act. 654 F.2d at 1037. In the opinion of the Court the TCA does not violate the Constitution, and the plaintiffs have not stated a plausible claim for relief.

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[5] Congress 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).

[6] Congress specified that the TCA "shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco . . . ." 21 U.S.C. § 387a(b).

II. PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

A movant is entitled to a preliminary injunction only if he establishes:

> (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.

Byrum v. Landreth, 566 F.3d 442, 444 (5th Cir. 2009). The plaintiffs cannot demonstrate a substantial likelihood of success on the merits because they have not stated a plausible claim for relief. As a result, it is not necessary to consider the additional preliminary injunction elements. The plaintiffs' Motion for Preliminary Injunction is denied.

CONCLUSION

Congress provided sufficient guidance when it delegated authority to the FDA to designate which products should be governed by the TCA. Thus, the TCA does not violate the United States Constitution. The defendants' Motion to Dismiss is granted, and the plaintiffs' Motion for Preliminary Injunction is denied.

IT IS, THEREFORE, ORDERED AND ADJUDGED that the [24] Motion to Dismiss filed by the defendants, Food and Drug Administration, Admiral Brett P. Giroir, M.D. in his official capacity as

Acting Commissioner of Food and Drug Administration, and Alex M. Azar, II, in his official capacity as Secretary of Health and Human Services is **GRANTED**. This lawsuit is hereby **DISMISSED WITH PREJUDICE**. The Court will enter a separate judgment pursuant to Fed. R. Civ. P. 58.

IT IS, FURTHER, ORDERED AND ADJUDGED that the [15] Motion for Preliminary Injunction filed by the plaintiffs, Big Time Vapes, Inc., and United States Vaping Association, Inc., is **DENIED**.

SO ORDERED AND ADJUDGED this the 16th day of December, 2019.

s/ Louis Guirola, Jr.
LOUIS GUIROLA, JR.
UNITED STATES DISTRICT JUDGE

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

CAUSE NO. 1:19cv531-LG-JCG

[Filed: December 16, 2019]

BIG TIME VAPES, INC. and UNITED STATES VAPING ASSOCIATION, INC.	)
PLAINTIFFS	)
v.	)
FOOD AND DRUG ADMINISTRATION, et al.	)
DEFENDANTS	)

FINAL JUDGMENT

In accordance with the Memorandum Opinion and Order entered herewith, this Court finds that this lawsuit should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

IT IS, THEREFORE, ORDERED AND ADJUDGED that this lawsuit is hereby **DISMISSED WITH PREJUDICE**.

SO ORDERED AND ADJUDGED this the 16th day of December, 2019.

s/ Louis Guirola, Jr.
LOUIS GUIROLA, JR.
UNITED STATES DISTRICT JUDGE

APPENDIX D

United States Court of Appeals
for the Fifth Circuit

No. 19-60921

[Filed: August 25, 2020]

BIG TIME VAPES, INCORPORATED; UNITED STATES VAPING ASSOCIATION, INCORPORATED,	)
Plaintiffs – Appellants,	)
versus	)
FOOD & DRUG ADMINISTRATION, STEPHEN M. HAHN, COMMISSIONER OF FOOD AND DRUGS; ALEX M. AZAR, II, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN HIS OFFICIAL CAPACITY,	)
Defendant – Appellees.	)

Appeal from the United States District Court
for the Southern District of Mississippi
USDC No. 1:19-CV-531

ON PETITION FOR REHEARING EN BANC

(Opinion June 25, 2020, 963 F.3d 436)

Before SMITH, HIGGINSON, and ENGELHARDT, *Circuit Judges*.

PER CURIAM:

Treating the petition for rehearing en banc as a petition for panel rehearing, the petition for panel rehearing is DENIED. No judge in regular active service having requested that the court be polled on rehearing en banc (FEDERAL RULE OF APPELLATE PROCEDURE 35 and 5TH CIRCUIT RULE 35), the petition for rehearing en banc is DENIED.

ENTERED FOR THE COURT

/s/ Jerry E. Smith
United States Circuit Judge