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 & 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, Southern Division (Gulfport)

PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 28.2.1, the undersigned counsel of record certifies that the following listed persons and entities 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.

1. Plaintiffs-Appellants

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

Plaintiffs Big Time Vapes, Inc. and United States Vaping Association, Inc. do not have any corporations requiring disclosure pursuant to Fed. R. App. P. 26.1 and 5TH CIR. R. 28.2.1.

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RULE 35(B) STATEMENT

In 2009, Congress imposed a new regulatory regime on cigarettes and smokeless tobacco via the Family Smoking Prevention and Tobacco Control Act ("TCA" or "the Act").[1] Notably, Congress left other types of tobacco—including such widely-used products as cigars and hookah—unregulated. Congress punted to the Secretary of Health and Human Services the authority to "deem" any other "tobacco products" to be subject to the TCA, with no guidance as to the circumstances under which the Secretary should regulate additional products.

While the Supreme Court has certainly upheld delegations under broadly worded standards, it has also considered a statute that—like the TCA—imposed *no* standard. *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). In that case, the Court refused to concoct a standard based on the broad purposes in the Act's preface, and held the law unconstitutional. Although exceedingly rare, the TCA is another statute imposing *no* discernible standard, and *Panama Refining* controls. Yet the panel did not even attempt to grapple with *Panama Refining*'s holding and reconcile it with subsequent cases—it simply treated the case as obsolete, as if overruled *sub silentio*. In refusing to respect *Panama Refining* as a

[1] Pub. L. No. 111-31, 123 Stat. 1777 (2009) (codified at 21 U.S.C. § 387, *et seq.*).

coherent part of the Court's nondelegation jurisprudence, the panel not only renders Article I's vesting clause an absolute nullity, but also violates the fundamental requirement under *Agostini v. Felton*, 521 U.S. 203 (1997), to treat like cases alike and not presume the Supreme Court has overruled one of its precedents.

The panel also misread the analysis in *Gundy v. United States*, 139 S. Ct. 2116 (2019), which *supports Plaintiffs*, because the *Gundy* plurality only avoided a serious nondelegation question by reading the statute to *avoid* conferring the precise type of discretion that is clearly provided to the Secretary in the TCA.

This case further warrants review by the full Court because there can be nothing more important than ensuring our Constitution's structural separation of powers remains intact.

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ISSUES PRESENTED

1. Where the TCA admittedly lacks a limiting principle in its operative text, was it appropriate for the panel to discern a standard based on the TCA's general statements of purpose when, the only other time the Supreme Court has confronted such a statute, it refused to do so? Or, on the other hand, have the Plaintiffs stated a plausible claim under the nondelegation doctrine sufficient to survive a motion to dismiss?

2. Even assuming, *arguendo*, that the panel was justified in attempting to discern a standard based on the general statements of purpose, is the standard the panel identifies a workable standard that meaningfully constrains the Secretary's discretion?

3. Even assuming, *arguendo*, that the panel was justified in discerning a standard and the standard the panel identified would be sufficient *if applied prospectively*, does such a judicially-created standard support dismissal where the Secretary already *irreversibly* exercised his "deeming" authority in 2016—extending the TCA to *all* products that meet the definition of "tobacco products" now or in the future—stating in the Final Rule that *no* substantive standard limited the Secretary's discretion, and successfully defending the Final Rule based on the same view?

COURSE OF PROCEEDINGS

Plaintiffs alleged a violation of the nondelegation doctrine and moved for a preliminary injunction; the Defendants moved to dismiss for failure to state a claim. The district court dismissed the case pursuant to Rule 12(b)(6), and denied the injunction motion. ROA.715-26. Plaintiffs appealed. ROA.727.

The panel set this case for oral argument, but argument was canceled due to coronavirus concerns, and the panel decision issued, affirming the district court. App.

STATEMENT OF FACTS

I. The TCA and the Deeming Rule

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

> 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). A great variety of products "made or derived from tobacco" and "intended for human consumption" were in widespread use in 2009, including cigarettes, chewing tobacco, premium and nonpremium

cigars, hookah (waterpipe) tobacco, and pipe tobacco. However, Congress only applied the TCA to cigarettes and snuff,[2] and punted the authority to expand its application, providing:

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

21 U.S.C. § 387a(b).

In 2016, the Food and Drug Administration seized upon its "deeming" authority to apply the TCA to any product meeting the "tobacco product" definition—that is, to (i) *everything* Congress itself had declined to regulate in 2009, plus (ii) *any* future "tobacco products." FDA explained the breadth of the Deeming Rule:[3]

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

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[2] "[R]oll your own tobacco" is defined as tobacco intended for *cigarettes*, and "[s]mokeless tobacco" means "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity." 21 U.S.C. §§ 387(15), (18).

[3] 81 Fed. Reg. 28,973 (May 10, 2016).

81 Fed. Reg. 28,976. It must be recalled that, while the FDA in fact "deemed" all products meeting the statutory definition at the same time, it was free to deem some, all, or none, in its unilateral discretion. The FDA initially proposed leaving "premium" cigars unregulated, but ultimately decided to include them. *Id.* at 29,020.

Based solely on "compliance costs," the FDA estimated that applying the TCA to ENDS would cause 87.5% of e-liquids to "exit the market." Deeming Rule ref. 204 (Final Regulatory Impact Analysis 2016) 78-79.[4] By contrast, FDA estimated only 5% of combusted tobacco products (cigars, pipes, and hookah) would exit the market. *Id.*

During the comment period required by the Administrative Procedures Act, a commenter had the temerity to suggest that the FDA is required to "establish that deeming [a product] will benefit public health." 81 Fed. Reg. at 28983. The FDA gently corrected the commenter, accurately explaining that the suggestion of such limitation "*attempted to impose a standard for the application of FDA's deeming authority that is not created by statute or otherwise*." *Id.* (emphasis added). The FDA reiterated this position in defending against an APA challenge in the

[4] https://www.regulations.gov/document?D=FDA-2014-N-0189-83108

District Court for the District of Columbia, writing that "Congress authorized the FDA to subject 'any' tobacco product … to the [TCA] as it 'deems' fit, *without articulating any standards to cabin the agency's discretion*." ROA.338-39 (FDA's legal memorandum, filed in *Nicopure Labs, LLC v. Food and Drug Admin.*, 266 F. Supp. 3d 360, 393 (D.D.C. 2017), *aff'd*, 944 F.3d 267 (D.C. Cir. 2019)); *see also id.* (FDA writing that "Congress's choice of the deferential word 'deems' *and the absence of any standard*—beyond the requirement that the product meet the definition of a 'tobacco product'—demonstrate that Congress committed the exercise of this authority to the agency's broad discretion.") (emphasis added). The court agreed with the FDA, recognizing that "the statute did not provide standards for when and how the agency was to exercise its discretion to deem[.]" *Nicopure Labs, LLC*, 266 F. Supp. 3d at 393.[5]

When the deadline to file premarket review applications ("PMTAs") was radically accelerated in July 2019, Plaintiffs sued. Plaintiff Big Time Vapes is a Mississippi corporation wholly owned by Belinda Dudziak, who smoked one-and-a-half to three packs of cigarettes every day for 26 years until she was able to quit entirely within *days* of trying her first e-cigarette.

[5] Nicopure did not assert a violation of the nondelegation doctrine.

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

II. Panel Opinion

The panel acknowledged that the TCA lacked an express standard limiting the FDA's deeming discretion, App. 11, 12, but detected one based on "the TCA's purpose and the relevant factual background," and noted that the scope of the deeming authority was limited by the definition of "tobacco products" and the fact that the TCA supplies the substantive requirements applicable to *regulated* products. App. 12-15. The panel also claimed that the decision in *Gundy* "compel[s] affirmance here," because—according to the panel— "[i]n both statutes, Congress delegated … the power to determine *whether* th[e statutory] requirements applied to other non-covered classes." App. 17 (emphasis added).

ARGUMENT

I. The Panel Opinion Contradicts and Ignores Supreme Court Precedent.

The authority to decide the circumstances under which a given activity or product shall be subjected to federal regulation is quintessentially one of legislative policy. *Field v. Clark*, 143 U.S. 649, 693 (1892) ("Legislative power was exercised when *congress* declared that the suspension should take effect *upon a named contingency*."); *Opp Cotton Mills v. Admin. of Wage and Hour Division of Dep't of Labor*, 312 U.S. 126, 144 (1941); *Yakus v. United States*, 321 U.S. 414, 424 (1944). In accordance with this established principle, the plurality in *Gundy* recognized that, if the Sex Offender Registration and Notification Act (SORNA) conferred authority on the Attorney General to determine *whether* SORNA applied to pre-Act offenders at all, it would have presented a serious constitutional question. 139 S. Ct. at 2123 ("If that were so, we would face a nondelegation question."). The plurality avoided that question, because it held that the "Court has [in an earlier case] already interpreted § 20913(d) to say something different—to require the Attorney General to apply SORNA to all pre-Act offenders as soon as feasible." *Id.*

In *Panama Refining*, the Court likewise recognized that "the question whether … transportation [of hot oil] shall be prohibited" or not "is

obviously one of legislative policy," 293 U.S. at 415, and held the delegation unconstitutional because

> Section 9(c) [of the National Industrial Recovery Act of 1933 ("NIRA")] does not state whether or in what circumstances or under what conditions the President is to prohibit the transportation of the amount of petroleum or petroleum products produced in excess of the state's permission. It establishes no creterion to govern the President's course. It does not require any finding by the President as a condition of his action. The Congress in section 9(c) thus declares no policy as to the transportation of the excess production. So far as this section is concerned, it gives to the President an unlimited authority to determine the policy and to lay down the prohibition, or not to lay it down, as he may see fit.

Id. at 415.

The Court held this delegation unconstitutional despite expressly acknowledging that the scope of authority was narrowly circumscribed to the particular subject matter ("hot oil") and despite the binary nature of the President's authority. In a portion of *Panama Refining* that the panel here never acknowledges, much less distinguishes, the Court examined NIRA's surrounding provisions and statements of purpose, but found they did not establish a discernible standard. *Id.* at 417-18. This aspect of the decision warrants discussion in some detail, because it should compel a judgment for Plaintiffs, but the panel opinion does not account for it.

Prohibiting transportation of oil withdrawn in violation of state quotas would have furthered several of the purposes expressed in the prefatory section of the Act, such as the conservation of natural resources or eliminating "unfair competitive practices." *See id.* On the other hand, prohibiting such transportation might also undermine other purposes, such as "removing obstructions to the free flow of interstate and foreign commerce." *See id.* The Court refused to read the general statements of purpose to impose a discernible standard. *Id.* at 418. The Court continued:

> *Among the numerous and diverse objectives broadly stated, the President was not required to choose*. The President was not required to ascertain and proclaim the conditions prevailing in the industry which made the prohibition necessary. The Congress left the matter to the President without standard or rule, to be dealt with as he pleased. The effort by ingenious and diligent construction to supply a criterion *still permits such a breadth of authorized action as essentially to commit to the President the functions of a Legislature rather than those of an executive or administrative officer executing a declared legislative policy*.

Panama Refining, 293 U.S. at 418–19 (emphasis added).

The TCA presents the Secretary with the same kind of binary authority as NIRA § 9(c), with even vaguer statements of purpose, some of which are in actual tension. While one purpose is to "address the use of tobacco by young people and dependence on tobacco," Pub. L. 111-31 § 3(2), another is "to continue to permit the sale of tobacco products to adults" and

"promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases," *id.* §§ 3(7), (9). It is certainly not a given that the Congress that passed the TCA, grandfathering cigarettes and leaving other products entirely unregulated, would support "deeming" vapor products, where the practical effect would be to extinguish nearly 90% of the products that so many adult smokers have used to quit cigarettes entirely. *Supra* at 12; ROA.183 (Fmr. FDA Commissioner Gottlieb recognizing that "what primarily causes death and disease from tobacco use isn't the nicotine" but "the act of lighting tobacco on fire to free that drug for inhalation," and "E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products."); Plfs' Br. at 18-19, 28, 67. Moreover, federal law still contains a provision expressly recognizing Congress's interest in protecting "commerce and the national economy … to the maximum extent," 15 U.S.C. § 1331 (regarding cigarette labeling and advertising), which the Supreme Court observed in 2000 "reveal[s] [Congress's] intent that tobacco products remain on the market." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 139. That statute remains on the books, and Congress's limited application of the TCA in 2009 reflects similar legislative tradeoffs.

Ignoring all this, the panel did what the Supreme Court in *Panama Refining* refused to do. The panel evades all distinctions and internal tension by mashing the entire "purpose" list into a still more generalized "general policy," claiming that, "[o]bviously, the TCA's purpose sounds in (1) protecting public health and (2) preventing young people from accessing (and becoming addicted to) tobacco products." App. 13.

This adventure in judicial legislation is novel. The panel makes no attempt to distinguish *Panama Refining*, and cites no case fabricating a standard in the absence of some kind of operative statutory standard. The panel's authority for this point, *American Power & Light Co. v. SEC*, 329 U.S. 90 (1946), featured both a primary statutory standard and what the Court called "*a veritable code of rules* … for the Commission to follow in giving effect *to the standards of s 11(b)(2)*." *Id.* at 104-05 (emphasis added). The TCA has neither. Even more puzzling is the fact that the panel imagines a (meaningless) standard "sounding in" public health, despite the fact that the FDA itself eschewed any public health standard *in the Final Rule*. Oddly, then, in the supposed service of facilitating necessary discretion in executive agencies, a panel of three judges overruled the agency's own contemporaneous view of the statute it administers.

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

And contrary to the panel's suggestion (App. 14), *United States v. Womack*, 654 F.2d 1034 (5th Cir. 1981), would only be relevant if the TCA *required* the Secretary to deem anything constituting a "tobacco product" to the TCA (we know that it does not), or if the statute in *Womack* had delegated to the Treasury the prerogative to recognize that something qualified as an explosive but then *decline to list it anyway*, in its unilateral discretion. Even if *Womack* were ambiguous on the latter point, the Court cannot assume the statute conferred discretion *not* to list an "explosive" because the parties in *Womack* did not argue that such authority existed, and the court's opinion does not contemplate such discretion. Thus, even if one wanted to read the "explosives" statute as if it allowed similar discretion in the Treasury, established principles of stare decisis prohibit ascribing any holding to *Womack* that the panel did not even contemplate. *De La Paz v. Coy*, 786 F.3d 367, 373 (5th Cir. 2015) (cited at Plfs' Br. at 58, collecting authorities).

The fact that the deeming provision confers discretion only with respect to the field of "tobacco products" does not save the TCA any more

than the fact that NIRA § 9(c) was strictly circumscribed to a subset of petroleum products withdrawn in violation of state law. The *Panama Refining* majority rejected NIRA § 9(c) over Justice Cardozo's dissent, in which he argued that the president's discretion was sufficiently limited by the fact that he had only a binary choice (to prohibit the transportation, or not), regarding a "particular commodity," further limited to when such commodity was withdrawn in violation of another legal standard (state law). 293 U.S. at 434-35 (Cardozo, J., dissenting); *see also A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 552 (Cardozo, J., concurring).

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

subjected to it. 500 U.S. 160, 160-65 (1991).[6] *Panama Refining* and *Touby* foreclose the panel's blinkered claim that vesting a cabinet official with the unilateral authority to decide whether a given segment of the economy is regulated or not is merely a "finishing touch" under the TCA. *Cf.* App. 15. Deciding whether cigars (or any other product) shall be regulated, after Congress left them unregulated, is not a "finishing touch."

The panel also misread *Gundy*. The panel writes that "in both statutes [SORNA and the TCA], Congress delegated to an executive branch official the power to determine *whether* those requirements applied to other non-covered classes." App. 17 (emphasis added). In fact, the *Gundy* plurality held that SORNA "*require[d]* the Attorney General to apply SORNA to *all* pre-Act offenders *as soon as feasible*[.]" 139 S. Ct. at 2123 (emphasis added), specifically to avoid a difficult constitutional question.

The unbridled discretion feared and avoided by the *Gundy* plurality is the precise discretion vested in the Secretary here. And unlike with SORNA, there is no way to read the deeming provision as if it *required* (or even suggested) that the Secretary deem any particular product to be

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

subject to the requirements of the TCA, at any time or for any reason. Reliance on the reference to a "comprehensive" tobacco regulation regime in the TCA's preface, App. 13 n.25, runs headlong into an obstacle that was not present in SORNA—*i.e.*, the same Congress that referred to comprehensive regulation also limited the regime to cigarettes and snuff and left any other products unregulated, except at the Secretary's whim.[7]

En banc review is necessary to conform Circuit law to Supreme Court precedent.

II. In Ignoring Supreme Court Precedent, the Panel Opinion Violates the Most Basic Tenet of Stare Decisis.

The panel's failure to reconcile binding precedent also violates established principles of stare decisis.

Stare decisis means treating like cases alike. BRYAN A. GARNER, ET AL., THE LAW OF JUDICIAL PRECEDENT (2016) 21. And a circuit court has a duty to reconcile and give effect to all vertical precedent. *Id.* §§ 15, 36. Thus, even in situations in which subsequent decisions directly refute the rationale of an earlier holding, the Supreme Court has repeatedly reminded appellate courts that they must apply the more directly applicable case.

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[7] Moreover, the referenced provisions obviously refer to the comprehensive nature of the *topics* addressed as to regulated products, not to the ultimate application of the TCA to as many *products* as possible.

Agostini, 521 U.S. at 237-38; *Rodriguez de Quijas v. Shearson/American Exp.*, 490 U.S. 477, 484 (1989). This Circuit has faithfully applied that principle. *E.g.*, *Texas Dem. Party v. Abbott*, 961 F.3d 389, 405-06 (5th Cir. 2020) (rejecting argument that early case can be disregarded as "too aged" because it "predates most of the Supreme Court's modern voting rights jurisprudence"); *Thomas v. Reeves*, 961 F.3d 800, 809-10 (5th Cir. 2020) (en banc) (Costa, J., concurring); *In re Crystal Power Co., Ltd.*, 641 F.3d 82, 84 n.5 (5th Cir. 2011) ("We note that the century-old Supreme Court cases prohibiting mandamus review of jurisdictional defects stand in sharp tension with the Court's more recent push to rigorously enforce jurisdictional limits and their "drastic" consequences. Nevertheless, these cases directly address the issue before us and are … controlling."); *Medellin v. Dretke*, 371 F.3d 270, 280 (5th Cir. 2004).

Not only has *Panama Refining*'s holding *not* been refuted, the Supreme Court has continued to reiterate its validity, *see Industrial Union Dept., AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 646 (1980), and it is easily reconcilable with all subsequent nondelegation decisions. The President's authority to prohibit transportation of hot oil was not cabined by any primary statutory standard, and the Court rejected the government's argument that one could be substituted by cobbling together

broadly-worded purposes that still left discretion in the executive to prioritize which particular purpose to pursue. All subsequent decisions rejecting nondelegation challenges—*all of them*—have done so only because—broad as it may be—the statue at issue incorporates a limiting principle beyond the fact that the authority operates within a given field of activity. The panel's own recitation of those cases (App. at 9 n.18), makes Plaintiffs' point, because Congress did not limit the Secretary's deeming discretion with the kind of statutory standard that the panel is able to so readily quote from every case in that footnote.

Moreover, reading those cases in full, one finds that the statutes included more detail further limiting discretion beyond the standard quoted by the panel. *E.g.*, *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 472 (2001) (requiring EPA Administrator set "ambient air quality standards … which in the judgment of the Administrator, *based on [the] criteria [documents of § 108]* and *allowing an adequate margin of safety*, are *requisite* to protect the public health." (emphasis added); *Lichter v. United States*, 334 U.S. 742, 783-84 (1948) ("excessive profits," *as defined in prior administrative practice and written policies known to Congress*). In some of *those* cases, the Court has referred to *additional*, *consistent*

indications of statutory purpose to flesh out *the underlying standard*. *See American Power & Light*, *supra*; *Womack, supra*.

The government still has not identified a single case upholding a standardless delegation like that in *Panama Refining*. This case does not require the Court to opine on the constitutionality of a broadly-worded standard under current law; it requires only that it recognize that Congress exceeded its authority when it imposed no standard at all. Cases and controversies are not decided based on generalities, and the panel is not free to ignore easy distinctions in order to ignore and nullify Supreme Court precedent.

CONCLUSION

Rehearing en banc should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that the foregoing document was filed with the Court in electronic format through the CM/ECF system, on August 13, 2020. A copy of the document was served on counsel of record, as listed below, through the CM/ECF system, on the same date:

Lindsey Powell, Defendants-Appellees

/s/ Jerad Wayne Najvar
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s/ Jerad Wayne Najvar
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Counsel also certifies that on August 13, 2020, the foregoing document was transmitted to Mr. Lyle W. Cayce, Clerk of the United States Court of Appeals for the Fifth Circuit, via the Court's CM/ECF system.

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s/ Jerad Wayne Najvar
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IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
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Lyle W. Cayce
Clerk

No. 19-60921

BIG TIME VAPES, INCORPORATED;
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Plaintiffs–Appellants,

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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 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

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

[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."

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 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.

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[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).

[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).

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, 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, mandatory health warnings, method-of-sale limits, and advertising constraints. *See id.* § 387f(d). Failing to comply with the TCA's

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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.

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 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

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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 "e-cigarettes, 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 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.

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, 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,

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[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 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 (Apr. 30, 2020) (announcing the guidance).

and the United States Vaping Association, an ENDS industry trade association, sued the FDA, contending that the TCA unconstitutionally 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 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

[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 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.").

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 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 Court has "almost never

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[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 only to find gibberish." (cleaned up)); Gary Lawson, *Delegation and Original 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.").

[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

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

B.

"[A] nondelegation inquiry always begins (and often almost ends) with

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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 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).

[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.").

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.

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 nondelegation 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

[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 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.").

Supreme Court.[22]

1.

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 enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less

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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 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).

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 sweeping" fashion. *Gundy*, 139 S. Ct. at 2127 (plurality). Those findings, when coupled with

[25] *See, e.g.*, 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 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 begin 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)).

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 "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)

[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.

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 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. 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,

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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 that 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).

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 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.

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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).

[29] *See Gundy*, 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.").

* * * * *

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.

United States Court of Appeals

FIFTH CIRCUIT
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August 11, 2020

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No. 19-60921 Big Time Vapes, Incorporated, et al v. FDA, et al
USDC No. 1:19-CV-531

Dear Mr. Najvar and Mr. Whatley,

The following pertains to your rehearing en banc electronically filed on August 10, 2020.

We have filed your Petition for Rehearing En Banc. However, it has the following deficiency. Unless the deficiency is corrected within 10 days from this date, we will forward the document to the court to be stricken.

The Certificate of Interested Persons, Rule 25(B) Statement, and Certificate of Compliance needs to be listed on the Table of Contents.

A Statement of the Facts is missing. It will also needed to be added the Table of Contents.

Once you have prepared your sufficient rehearing, you must email it to: **Mary_C_Stewart@ca5.uscourts.gov** for review. If the rehearing is in compliance, you will receive a notice of docket activity advising you that the sufficient rehearing has been filed.

Sincerely,

LYLE W. CAYCE, Clerk

By: _____
Mary C. Stewart, Deputy Clerk
504-310-7694

cc:
Ms. Lindsey E. Powell