No. 20-850

In the Supreme Court of the United States

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

v.

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

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

REPLY BRIEF

JERAD WAYNE NAJVAR
Counsel of Record
AUSTIN M.B. WHATLEY
NAJVAR LAW FIRM, P.L.L.C.
2180 North Loop West, Ste. 255
Houston, TX 77018
(281) 404-4696
jerad@najvarlaw.com

Counsel for Petitioners

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Becker Gallagher · Cincinnati, OH · Washington, D.C. · 800.890.5001

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The Government's[1] response here only serves to further illustrate the urgent need for this Court's review. Despite the ease with which Congress could have provided the requisite policy guidance in the Tobacco Control Act (TCA) to avoid an unconstitutional delegation under current jurisprudence, the FDA's response reflects that *even this* complaisant standard is too much for the "deeming" authority to bear. This is clear because the FDA still cannot defend the deeming authority without ignoring the facts—and, therefore, the actual holdings—of this Court's prior nondelegation cases.

The FDA's superficial treatment of this Court's leading nondelegation cases merely buttresses what Petitioners have said all along: the deeming authority cannot be upheld without ignoring and negating even the modest limits that should still apply under *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). Just like the Fifth Circuit, the FDA is emboldened to offer such a superficial and dismissive defense of the statute only because this Court's refusal to enforce the nondelegation doctrine in the last 85 years has invited the attitude that the doctrine is dead. The Court's inaction in this case will not merely preserve the status quo, but will permit the further expansion of permissible delegations and, thus, the further degradation of a core structural feature of our Constitution.

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[1] Petitioners sometimes refer to Respondents, collectively, as "the Government" or "FDA."

I. The Government Cannot Defend the Deeming Authority Without Contradicting *Panama Refining* and Ignoring Material Factors in This Court's Other Nondelegation Decisions.

Petitioners argued that the deeming provision is unconstitutional because the TCA imposes no operative standard guiding the agency's determination as to which additional tobacco products shall be regulated, and none can be fairly discerned from the TCA's preface because Congress's general statements of purpose are diverse and in actual tension with one another. Pet. 22-32. In such circumstances, *Panama Refining* precludes courts from prioritizing among these various interests in order to concoct a standard that Congress declined to impose. 293 U.S. at 416-19.

Incredibly, Respondents attempt to avoid this part of *Panama Refining* by re-writing it. Respondents repeatedly posit what they call the National Industrial Recovery Act's "central goal," or "overarching purpose," Resp. at 19, 20, and claim that *Panama Refining* held the delegation excessive because "[v]irtually any invocation of the President's power therefore would have been in substantial tension with the Recovery Act." Resp. at 19.

That is not at all what *Panama Refining* held. Instead, the Court recognized the tension inherent in the competing interests identified by Congress, and held that such broad statements of purpose cannot provide a sufficient guide to executive action without some operative standard in the statute. *Panama Refining*, 293 U.S. at 418-19; *id.* at 418 ("Among the numerous and diverse objectives broadly stated, the

President was not required to choose."). To the extent that *Panama Refining* did recognize a "general policy," as Respondents posit, this only makes it worse for the FDA because, despite identifying such "general policy," the Court *still* held the delegation excessive for lack of an operative standard. *Id*. at 418-19. The deeming authority fails for the same reason. *See Gundy*, 139 S. Ct. at 2134 (Gorsuch, J., dissenting) ("The framers understood, too, that it would frustrate 'the system of government ordained by the Constitution' if Congress could merely announce vague aspirations and then assign others the responsibility of adopting legislation to realize its goals.") (quoting *Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1892)).

Respondents also rely heavily on the fact that the deeming authority is limited to the field of "tobacco products," a term defined by Congress, and that the TCA provides the substantive requirements applicable to a product *once it is deemed to be subject to the statute*. Resp. at 18. These are arguments that Petitioners have anticipated, and addressed, at every iteration of this litigation since initial arguments in the trial court. At every juncture, Petitioners have explained why these aspects of the TCA do not obviate the delegation question, because they provide no guidance regarding when or in what circumstances the FDA should "deem" any additional segment of "tobacco products" to be subject to the watchful eyes of federal bureaucrats. *See* Pet. at 30-32. If defining the field of *potential* regulation were sufficient, then *Panama Refining* could have stopped with the observation that "[t]he subject to which th[e President's] authority relates is defined." 293 U.S. at 414. Likewise, the fact

that the TCA lays out the restrictions applicable to products *subjected to it* does not substitute for the lack of any standard to guide the Secretary in deciding *whether* these restrictions will apply. If that were the case, this Court certainly wasted a lot of ink in *Touby v. United States*, 500 U.S. 160 (1991), examining the Controlled Substances Act for relevant limitations on the Attorney General's temporary scheduling decisions. Respondents' refusal to engage these specific points is an indication that they have no good response.

Regarding other authorities the FDA cites, the Government simply closes its eyes to the facts of these cases, elevating isolated phrases but ignoring the material aspects of the statutes this Court relied upon in rejecting nondelegation challenges. *See* Resp. at 16-17. Predictably, the FDA points to several cases frequently cited as examples illustrating the outer bounds of permissible delegations. *See, e.g.*, *Gundy*, 139 S. Ct. at 2129 (citing, *inter alia*, *Whitman v. American Trucking Assocs.*, 531 U.S. 457, 474-75 (2001), *National Broadcasting Co. v. United States*, 319 U.S. 190, 216 (1943), and *Federal Power Com'n v. Hope Natural Gas Co.*, 320 U.S. 591 (1944)). Yet these authorities reflect that, even in the most extreme cases, the statutes at issue were upheld only because the Court identified some substantive standard that, although broadly worded, manifested a Congressionally-determined policy and imposed some limit on the delegee's discretion. *National Broad. Co.*, 319 U.S. at 216 (Federal Communications Commission's power to regulate radio airwaves in the "public interest"); *Federal Power Comm'n*, 320 U.S. at 600 (Federal Power Commission's authority to

determine "just and reasonable" rates for wholesale sales of natural gas)); *American Trucking*, 531 U.S. at 472 (Environmental Protection Agency's authority to set nationwide air-quality standards limiting pollution to the level "requisite" "to protect the public health"). The TCA lacks any such standard, which is why the FDA is forced to attempt to cobble something together from the TCA's amorphous and competing statements of purpose in contravention of *Panama Refining*.[2]

The FDA's decision to rely so heavily on *Mistretta v. United States*, 488 U.S. 361 (1991) (Resp. at 18, 19, 24), is puzzling, because the Court in *Mistretta* was able to identify multiple levels of express parameters and limitations guiding the Sentencing Commission's discretion. Several paragraphs would be required

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[2] In fact, in many of these oft-cited examples of capacious delegations, this Court identified and relied upon far more detailed guidance than is reflected in the superficial quotations from these cases that are repeatedly recited by the government (and even subsequent opinions of this Court and lower courts). For example, in *National Broadcasting*, the Court relied on the fact that the statute fleshed out "public interest" to mean "the interest of the listening public in 'the larger and more effective use of radio.'" 319 U.S. at 217 (citing an additional substantive provision of the statute at issue). In *American Trucking*, the statute did not simply allow unlimited discretion "to protect the public health," but required the EPA Administrator to 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). See also *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*). Thus has the Court referred to *additional*, *consistent* indications of statutory purpose to flesh out *the underlying standard*.

merely to summarize the Court's summary of those provisions. *See id.* at 375-77. Suffice it to say that *Mistretta* observed that Congress had "legislated a full hierarchy of punishment-from near maximum imprisonment, to substantial imprisonment, to some imprisonment, to alternatives-and stipulated the most important offense and offender characteristics to place defendants within these categories." 488 U.S. at 377. The TCA identified no parameters or characteristics to limit the Secretary's discretion in determining which additional products should be federally regulated, when, or for what reasons.

Notably absent from the Response is any real attempt to grapple with the fact that Congress only applied the TCA to cigarettes and smokeless tobacco, leaving any other "tobacco products" to be regulated only at the Secretary's discretion. Much like its treatment of *Panama Refining*, FDA attempts to sidestep the implications of Congress's narrow application of the TCA by re-writing the statute. FDA invites the Court to pretend that the four types of tobacco products subjected to the TCA by Congress in 2009 were actually just a list of examples, as if § 387a(b) said that "this chapter shall apply to tobacco products, including" the four listed products, serving to illustrate what Congress meant by "tobacco product." *See* Resp. at 10, 14. Of course, that is not what § 387a(b) says. And the four products enumerated by Congress in § 387a(b) are—quite plainly—not illustrative examples. Cigars and pipe tobacco clearly fit the "tobacco product" definition (*cf.* Resp. at 14) and yet were not regulated by Congress. Instead, Congress deliberately limited the application of the TCA, and the

Secretary was indisputably not under any duty to regulate any other "tobacco product" at any time.

Finally, the FDA cannot avoid Petitioners' nondelegation claim by arguing that the agency confined its deeming discretion within parameters that it imposed upon itself. *Cf.* Resp. at 21-22; *id.* at 22 ("The agency further explained [in the Deeming Rule] that, 'although FDA is not required to meet a particular public health standard to deem tobacco products, regulation of the newly deemed products will be beneficial to public health.'") (quoting 81 Fed. Reg. at 28, 983). This Court has already rejected "[t]he idea that an agency can cure an unconstitutionally standardless delegation of power by declining to exercise some of that power." *Whitman v. American Trucking Assocs.*, 531 U.S. 457, 473 (2001). As *Whitman* observed, "[t]he very choice of which portion of the power to exercise—that is to say, the prescription of the standard that Congress had omitted—would itself be an exercise of the forbidden legislative authority." *Id.*; *see also United States v. Stevens*, 559 U.S. 460, 480 (2010) ("We would not uphold an unconstitutional statute merely because the Government promised to use it responsibly."). Moreover, FDA's assertion that "all products meeting the statutory definition of tobacco product implicate serious public health concerns, according to Congress's findings and statements of purpose" (Resp. at 15), *precludes* any superficial appeal to "public health" as a sufficient guide to when or why federal regulation should extend to additional categories.

II. This Case Presents a Particularly Compelling Vehicle for the Renewed Enforcement of the Nondelegation Doctrine.

Petitioners argued that this case presents an especially compelling need for enforcement of the nondelegation doctrine because the statute confers a particularly broad and standardless delegation of power to decide major policy questions regarding subject matter that is outside of any inherent authority of the President. Pet. at 32-39. The FDA offers no satisfying rebuttal.

FDA first resorts to the general principle that Congress must be able to obtain "the assistance of its coordinate Branches" and retain sufficient flexibility to regulate appropriately. Resp. at 24-25. This is true enough, but it is no excuse for Congress to avoid the responsibility vested in it under article I to provide constitutionally sufficient guidance in the statutes to be administered. This Court recognized the need for "flexibility and practicality" in *Panama Refining* itself, but held that such recognition "cannot be allowed to obscure the limitations of the authority to delegate, if our constitutional system is to be maintained." 293 U.S. at 421. Even if it were true that "the government needs to be able to adapt to the ever-changing market for tobacco products" because "manufacturers develop new products … at a rapid rate," Resp. at 24-25, this is obviously no license to ignore the separation of powers. The government's interest here can certainly be no greater than it was with respect to the Attorney General's authority to temporarily schedule "designer drugs" under the Controlled Substances Act (CSA),

which incurred this Court's careful scrutiny, and was upheld only because the CSA contained a raft of substantive limitations of a type that are completely absent in the TCA. *See Touby*, 500 U.S. at 166-67; Pet. at 31. And the FDA's denial that the unilateral discretion to decide whether entire segments of tobacco products will be subject to federal regulation implicates major policy questions (Resp. at 25-26) is belied by the FDA's own estimates regarding the impact such regulation would have on the ENDS industry alone, *see* Pet. at 12-13, and the very public and controversial manner in which the Administration has handled the enforcement decisions necessitated by the Deeming Rule, *see* Pet. at 13-15, 16-17. Determining whether a segment of the economy shall be regulated or unregulated, as the deeming provision allows, is materially different than delegating authority to fine-tune the parameters of a requirement that Congress has mandated.

CONCLUSION

The FDA has said about as much as can be said in defense of an indefensible delegation. None of it is persuasive. The government ignores material distinctions in the relevant caselaw, pleading, effectively, for the erasure of the only limits remaining under current jurisprudence. The deeming authority cannot be constitutional unless *Panama Refining* has been neutered, subsilentio. If, instead, the separation of powers is indeed a bulwark of liberty and a fundamental aspect of our Constitution, *Gundy*, 139 S. Ct. at 2133-34 (Gorsuch, J., dissenting), then this Court must grant review and reverse the decision below.

Respectfully submitted,

JERAD WAYNE NAJVAR
Counsel of Record
AUSTIN M.B. WHATLEY
NAJVAR LAW FIRM, P.L.L.C.
2180 North Loop West, Ste. 255
Houston, TX 77018
(281) 404-4696
jerad@najvarlaw.com

Counsel for Petitioners