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)

APPELLANTS' REPLY BRIEF

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INTRODUCTION

The TCA allows the Secretary of Health and Human Services to unilaterally decide which segments of the nationwide tobacco-product industry are regulated and which are not, without any standards to guide his discretion. In promulgating the Deeming Rule, the FDA rejected a commenter's suggestion that the FDA is required to "establish that deeming [a product] will benefit public health," accurately explaining that the commenter "attempted to impose a standard for the application of FDA's deeming authority that is not created by statute or otherwise." 81 Fed. Reg. at 28983. The FDA vigorously reiterated this position in 2017, and a federal district court agreed that "the statute did not provide standards for when and how the agency was to exercise its discretion to deem." *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).

Now, defending against this challenge, the FDA scrambles to identify the kind of limiting "intelligible principle" that it has consistently denied exists. However, because the FDA's original position was and is correct, Defendants can only defend the deeming provision by re-casting it into something different. Defendants characterize § 387a(b) as if it imposed a standard fact-finding task, like the statute at issue in *United States v.*

Womack, 654 F.2d 1034 (5th Cir. 1981). Defendants also attempt to minimize the authority to regulate, or not regulate, entire industries as if it were no more than the standard exercise of enforcement discretion or the authority to grant specific exceptions to statutory requirements. Defendants cite no authority for the latter proposition, and none of the statutes they cite as examples have been challenged on nondelegation grounds. Moreover, even though those statutes are decidedly small-bore compared to the authority to unilaterally regulate entire tobacco industries, even those statutes contain minimal (and, in some cases, very detailed) parameters to guide discretion. Plaintiffs reply to these and other points below. In short, none of the Defendants' arguments are availing. The deeming provision is unconstitutional, and this Court should not hesitate to say so.

ARGUMENT

I. Plaintiffs State a Claim Under the Nondelegation Doctrine.

Plaintiffs have explained that the TCA's deeming provision violates the separation of powers because it sets forth no standard or policy to guide the Executive's discretion as to which "tobacco products" shall be regulated. *See Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). Defendants' brief does not undermine this conclusion.

a. Plaintiffs state a claim that the TCA's unbounded delegation of "deeming" authority violates the Constitution.

Seven years *after* the Court referred to the requisite "intelligible principle" in *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928), Section 9(c) of the National Industrial Recovery Act (NIRA) was declared unconstitutional in *Panama Refining*. Congress had defined a narrow subject matter (oil produced in excess of state-law allowances), and "authorized" the President "to prohibit [its] transportation in interstate or foreign commerce," at his discretion. 293 U.S. 388, 406 (1935). *Panama Refining* held that "the question whether that transportation shall be prohibited by law is obviously one of legislative policy," and proceeded, as the plurality in *Gundy v. United States* describes the test, to "figure out…what instructions [the statute] provides" to guide the delegated decision. 139 S. Ct. 2116, 2123 (2019). Section 9(c) was an unconstitutional delegation because it did "not state whether or in what circumstances or under what conditions the President is to prohibit the transportation" of hot oil, "establish[ed] no creterion to govern the President's course," and "require[d no] finding by the President as a condition of his action." *Panama Refining*, 293 U.S. at 415. Instead, it gave him "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.*

Just as in *Panama Refining*, the choice whether to regulate any given tobacco product, or not, is a legislative choice for which Congress has provided no policy, standard, or even factors for consideration.

b. FDA still has not identified a case upholding a standardless delegation, and none exist.

Defendants' various efforts to escape the holding of *Panama Refining* are unavailing. They lead off with the bold claim that the Supreme Court "has approved many delegations of authority far broader than the one presented here," FDA Br. at 12 (referring to *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 474-75 (collecting cases)), and write, four pages later, that "[t]he statute falls well within the range of delegations approved by the Supreme Court," *id.* at 16. Notably absent from the brief is a single case substantiating this claim.

Most of the cases the government cites here are cases the Plaintiffs already volunteered as "representing the outer bounds of permissible delegations under current law," Plfs' Br. at 59, and which are all distinguishable because, "broad as [they] may be[,] the statute[s] at issue incorporate[] some limiting principle beyond the fact that the authority

operates within a given field of activity." *Id.* (referring to *National Broadcasting Co. v. United States*, 319 U.S. 190 (1943); *New York Cent. Sec. Corp. v. United States*, 287 U.S. 12 (1932); *Yakus v. United States*, 321 U.S. 414 (1944), *FPC v. Hope Natural Gas Co.*, 320 U.S. 591 (1944), and *Whitman*, 531 U.S. at 472). In response, the FDA had the opportunity to challenge Plaintiffs' assertion on this point, but failed to identify any substantive guide or limitation in the text of the Tobacco Control Act analogous to the standards that sufficed in these other cases. Any additional cases the FDA has referenced are distinguishable for the same reason. The deeming authority is devoid of anything like the "excessive profits" standard in *Lichter v. United States*, 334 U.S. 742, 785 (1948), or the requirement that the 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." *Whitman*, 531 U.S. at 472 (punctuation in original).

Therefore, despite having litigated this case since August 2019, Defendants still have failed to identify a case upholding a standardless delegation. And when Defendants, later in the brief (Br. at 22), liken the deeming authority to other delegations that are supposedly "commonplace and have never been held to raise constitutional concerns," citing *National*

Wildlife Fed'n v. Gorsuch, 693 F.2d 156 (D.C. Cir. 1982), and *Pattison sand Co. v. Federal Mine Safety & Health Review Comm'n*, 688 F.3d 507, 513 (8th Cir. 2012), what they mean is that the parties in those cases did not raise any delegation challenge and the courts did not address it.[1]

The Defendants fail to identify any case upholding a delegation like this one because none exist. The FDA itself touted its standardless discretion right in the Deeming Rule, specifically rejecting the suggestion that deeming must be guided by a public health standard. Then again in 2017, the FDA argued to the federal court in *Nicopure* that "Congress authorized the FDA to subject 'any' tobacco product … to the Tobacco Control Act 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. FDA*, No. 16-0878 (ABJ), No. 16-1210 (ABJ) (D.D.C.);[2] *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

[1] The plaintiffs in those cases raised statutory construction arguments, and, in *Pattison*, a due process challenge under the Fifth Amendment, but did not raise delegation doctrine. Whether the authorities at issue in those cases would survive a nondelegation challenge—if one is filed—would be a question for another court.

[2] The decision in *Nicopure* is reported at 266 F. Supp. 3d 360, 393 (D.D.C. 2017), *aff'd*, 944 F.3d 267 (D.C. Cir. 2019).

exercise of this authority to the agency's broad discretion.") (emphasis added). The federal district 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.[3]

The fact that the FDA only pauses long enough to make this general statement, but devotes the substance of its brief to other arguments, is a reliable indication that—just as Plaintiffs have asserted from the beginning—there is *no case* upholding a delegation as extreme as the deeming provision. The FDA was right when it explained that no standard limited its discretion, and the *Nicopure* district court was right to agree. *Panama Refining* compels the conclusion that the deeming provision is unconstitutional as a standardless delegation. In the present posture of this case, therefore, the district court erred in dismissing Plaintiffs' claims.

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[3] The *Nicopure* court made this statement in the course of holding that the only substantive limitation on the Secretary's deeming authority, and thus justiciable for purposes of Nicopure's APA challenge, is that deeming extends only to "tobacco products." 266 F. Supp. 3d at 393. Nicopure did not allege that the statute violates the nondelegation principle and, as explained herein and in Plaintiff's brief, defining the field of potential regulation without setting parameters for when and whether regulation should be imposed is insufficient.

c. The fact that the Secretary's deeming authority operates within the field of "tobacco products" does not provide the sufficient "intelligible principle" required to guide discretion whether to deem any given product.

Lacking precedent upholding a standardless delegation like the deeming provision, the FDA argues that the delegation is valid because Congress defined "tobacco product," and "set forth in detail the requirements applicable to such products." FDA Br. at 16. These points are emphasized together at least four times. FDA Br. at 13, 16, 17, 25. Plaintiffs have already explained that neither of these considerations excuses the fact that the FDA retains the unbridled discretion to determine whether any given product shall be regulated or not. Plfs' Br. at 60-64.

The fact that Congress defined "tobacco product" merely defines the field subject to the FDA's unilateral decisionmaking power, but provides no guidance as to when or why the FDA should exercise its delegated power over any given tobacco product. FDA's continued reliance on this point simply ignores the fact that *every* delegation is circumscribed within some field of activity.[4] Section 9(c) of the National Industrial Recovery Act, struck down

[4] The only apparent delegation ever considered that was not already limited within a given field of activity was, of course, held unconstitutional, *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935). The fact that every other delegation ever considered by the Court was circumscribed within a defined field did not mean the Court was relieved

in *Panama Refining*, conferred discretion within only a narrowly-defined subject area. *Panama Refining* began its analysis by observing that "[t]he subject to which this authority relates is defined. It is the transportation in interstate and foreign commerce of petroleum and petroleum products which are produced…in excess of the amount permitted by state authority." 293 U.S. at 414-15. The Court specifically rejected the argument that defining the narrow field of potential presidential action was sufficient, writing that the reference to oil withdrawn in violation of state law "simply defines the subject of the prohibition which the President is authorized to enact or not to enact as he pleases." *Id.* at 420. Justice Cardozo dissented in *Panama Refining*, arguing 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; *see also A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 552 (Cardozo, J., concurring) ("This court has held [in *Panama Refining*] that delegation may be unlawful,

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of the responsibility to determine whether Congress had imposed sufficient parameters for the specific discretion conferred, as discussed below.

though the act to be performed is definite and single, if the necessity, time, and occasion of performance have been left in the end to the discretion of the delegate.").

Thus, 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. Similarly, the fact that SORNA's challenged authority was limited to the narrow field of "sex offenders" as defined in the statute, *Gundy*, 139 S. Ct. at 2122 (acknowledging SORNA's "sex offender" definition), did not obviate the need to analyze whether Congress had sufficiently limited the Attorney General's discretion to determine SORNA's applicability to pre-Act offenders, *id.* at 2123. Plaintiffs already made these points in their briefing below and in their principal brief here. Plfs' Br. at 60-61 ("If the fact that the deeming authority was limited to the field of 'tobacco products' was sufficient in and of itself, then *Gundy*, and all other nondelegation cases, would have been much easier for the Court to dispatch by simply noting that the authority only operates within the field at issue."). FDA has not attempted to respond.

d. 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.

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. Plfs' Br. at 61-64. The Supreme Court has consistently described the task of "defin[ing] *the circumstances in which* [Congress's] command is to be effective" as the exercise of core legislative power. *Opp Cotton Mills v. Admin. of Wage and Hour Division of Dep't of Labor*, 312 U.S. 126, 144 (1941) (emphasis added). For this reason, the Court in *Touby* 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). Similarly, the binary nature of the authority in *Panama Refining* did not substitute for a standard.

e. Neither statutory context nor Congress's broad, contradictory purpose statements substitute for the lack of a standard.

The FDA argues that the congressional findings and statements of purpose in the prefatory sections of the TCA provide a sufficient statement

of policy guiding the deeming decision. FDA Br. at 17-21. The FDA's appeal to purpose and context actually ignores purpose and context. Even setting that aside, purpose and context cannot provide sufficient guidance in the absence of at least a broadly-stated primary standard.

i. Defendants' appeal to context ignores the context.

As an initial matter, the statement from *Womack* prominently quoted by the FDA for this principle (Br. at 17-18) is worth reciting in its full context:

> Congressional legislation which prescribes essential standards and basic legislative policy and delegates to an administrator authority for promulgation of rules and regulations is constitutionally permissible, provided the standards are "sufficiently definite and precise to enable Congress, the courts and the public to ascertain whether the Administrator ... has conformed to those standards." 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. American Power & Light Corp. v. Securities & Exchange Comm'n, 329 U.S. 90, 105 (1946).

Womack, 654 F.2d at 1037 (citations omitted; cleaned up; underlining added).

After quoting the second sentence from this paragraph, FDA Br. at 17-18, FDA notes that "Congress made extensive findings regarding the unique dangers posed by tobacco products and the particular risks they present to children, TCA § 2(1) – (49) ... [and] concluded that 'comprehensive restrictions on the sale, promotion, and distribution of such products are

needed.' *Id.* § 2(6)." FDA Br. at 18. After quoting some of the express purposes of the Act, the Defendants argue that the

> FDA's determination that products falling within the statutory definition of "tobacco product" should be subject to the Act's requirements thus comports with the general policies set forth in the statute's findings and statement of purpose. ... Congress plainly contemplated such inclusive regulation of tobacco products under this "comprehensive" scheme, TCA § 2(6), and that congressional intent properly factors in this analysis.

FDA Br. at 20 (underlining added).

Defendants' argument is unavailing. First, it seeks to impart a meaning on the reference to "comprehensive restrictions" in TCA § 2(6) that it clearly cannot bear in context. Given that Congress only applied the TCA to cigarettes and smokeless tobacco in 2009, this reference to "comprehensive restrictions on the sale, promotion, and distribution of such products" is a reference to the breadth of the *topics* covered by the TCA (marketing, distribution, etc.), and not to the scope of *products* to which the TCA applied. *See* SCALIA & GARNER, READING LAW 218 (2012) (explaining that "an expansive purpose in the preamble cannot add to the specific dispositions of the operative text"); *Nat'l Wildlife Federation*, 693 F.2d at 178 ("[A]s any student of the legislative process soon learns, it is one thing for Congress to announce a grand goal, and quite another for it to mandate full implementation of that goal."). Certainly, the Defendants cannot argue that

the Secretary was *required* to regulate all (or any) other tobacco products, either then or at any time in the future. The FDA initially considered not deeming premium cigars, which was its prerogative under the statute.

This highlights the fundamental problem with the Defendants' argument based in select parts of the Act's preface. Their position requires the Court to ignore the very structure of the TCA and Congress's choice to selectively apply it only to cigarettes and smokeless tobacco in the first instance.

It is critical to recall that, in 2009, many tobacco products were in long and widespread use and yet Congress did not subject them to the TCA. This includes cigars (both premium and non-premium varieties), hookah, and pipe tobacco. Moreover, while animated by the desire to address the negative health effects of nicotine addiction and tobacco use (primarily combusted tobacco), Congress did *not* ban even traditional cigarettes. Instead, they (and anything else on the market as of 2007) were grandfathered—subjected to the marketing and distribution restrictions but not required to submit PMTAs. This reflects a legislative determination that some products should be regulated, but not all of them, and that Congress stopped short of regulating *even cigarettes* too harshly. 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.

Thus, while Congress defined the field of *potential* regulation broadly ("tobacco products"), it simultaneously declined to apply the TCA to anything other than cigarettes and smokeless tobacco, unless the Secretary of HHS decided to expand it. Ironically, then, the FDA's argument—purportedly grounded in reading the statute as a whole—requires the Court to ignore the fact that, despite its recitation of broad principles, Congress itself strictly circumscribed the application of the TCA to a sub-set of tobacco products. It cannot be simplified as if Congress's overriding purpose was the broadest coverage possible.

Defendants' arguments simply elide this reality. FDA writes that all tobacco products "contain or are related to the use of nicotine and thus raise many of the same public health concerns as the products enumerated by Congress." Br. at 20. To the extent newly deemed products share characteristics with cigarettes and smokeless tobacco, that was true in 2009

as well. Moreover, as the FDA acknowledges, the "risks, and any arguable benefits, vary by product." FDA Br. at 20. The Deeming Rule is replete with discussion of the distinctions between the types of tobacco products, including health factors (repeatedly states that the FDA is "particularly" concerned about combusted products), 81 Fed. Reg. at 29022, 29023, and differences in youth use of cigars versus youth use of vapor products, for example. The economic and market effects of deeming also vary widely among different categories. E-liquids are particularly hard hit; the FDA acknowledged that essentially all vapor products would have to proceed through the most burdensome (PMTA) pathway, while new cigar and deadly cigarette varieties are eligible for the less burdensome substantial equivalence pathway. *See* Plfs' Br. at 21. The FDA itself predicted in 2016 that 95% of all "baseline" cigar, pipe tobacco, pipes, and hookah products would either be grandfathered or submitted for premarket review, only 12.5-50% of E-liquids would. This is why the FDA frankly acknowledged that up to 87.5% of E-liquids would have to "exit the market."[5]

[5] Plaintiffs are confident that the evidence adduced on remand regarding the actual percentage of all vapor products on the market now that would be able to file a PMTA is, in actuality, very near zero.

Given that one of Congress's stated purposes was to "promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases," TCA § 2(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 of requiring a PMTA for every single product variation—acknowledged by the FDA—will be to decimate the vast majority of the market of products that so many adult smokers have found to have helped them *quit cigarettes* entirely. *See* ROA.12 (alleging that Plaintiff Big Time Vapes "has approximately 4,000 customers, 98% of whom have quit smoking cigarettes entirely").[6] *See also* Plfs' Br. at 18-19, 28, 67 (Fmr. Comm'r Gottlieb contrasting danger of combusted tobacco from vapor products, and need to maintain vapor on the market). Former Commissioner Gottlieb candidly acknowledged that in devising an enforcement strategy under the Deeming Rule, the FDA was "grappling with" "hard tradeoffs," specifically, between addressing youth use on the one hand, and maintaining ENDS on the market for adults transitioning from

[6] Plaintiffs provided additional evidence on this point in support of their injunction motion. *See* ROA.317-331 (USVA member owners describing their success quitting smoking nearly immediately upon beginning to vape).

traditional cigarettes on the other. *See* ROA.28. These are two of the broadly-stated purposes in the TCA's prefatory section, and Congress failed to instruct the Secretary how to prioritize among them.

i. *Gundy* and *Whaley* distinguished

Congress' decision to limit the application of the TCA to cigarettes and smokeless tobacco distinguishes this case from the situations in *Gundy* and *United States v. Whaley*, 577 F.3d 254 (5th Cir. 2009).

While Defendants are correct that the *Gundy* plurality looked to SORNA's statement of purpose, FDA Br. at 20, the plurality concluded that Congress's express intent to create a "comprehensive" regime aided the interpretation of the otherwise ambiguous operative provision of SORNA (instructing the Attorney General to "specify the applicability" of SORNA to pre-Act offenders). The plurality thus reiterated what the Court had already (according to the plurality) held in *Reynolds v. United States*, 565 U.S. 432 (2012): that SORNA "*require[d]* the Attorney General to apply SORNA to *all* pre-Act offenders *as soon as feasible*[.]" 139 S. Ct. 2116, 2123 (emphasis added). After *Reynolds*, the plurality wrote, "'[s]pecify the applicability' … does not mean 'specify *whether* to apply SORNA' to pre-Act offenders at all, even though everything else in the Act commands their coverage. The phrase instead means 'specify *how* to apply SORNA' to pre-Act offenders if

transitional difficulties require some delay." *Id.* at 2128. The plurality thus identified the delegation question as: "Did Congress make an impermissible delegation when it instructed the Attorney General to apply SORNA's registration requirements to pre-Act offenders as soon as feasible?" *Id.* at 2129. Prior to *Gundy*, this Circuit employed a similar analysis of SORNA, holding that Congress's intent to create a "comprehensive" regime sufficiently informed the Attorney General's discretion in "specifying the applicability" of SORNA to pre-Act offenders. *Whaley*, 577 F.3d at 264.

Unlike with SORNA, there is no way to read the deeming provision as if it *required* (or even suggested) that the Secretary must deem any particular product, or category of products, to be subject to the requirements of the TCA, subject merely to otherwise minor practical considerations of implementation. Reliance on the reference to a "comprehensive" tobacco regulation regime in the TCA's preface 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 smokeless tobacco and left any other products unregulated, except at the Secretary's whim, without providing any parameters to guide that decision.

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Prefatory statements of purpose and statutory context can only aid in fleshing out a statutory standard where (i) there *is* a statutory standard and (ii) the statutory purposes and context paint a consistent picture, usefully limiting the agency's discretion. Plfs' Br. at 64-69. The delegation here is unconstitutional both because there is no standard, leaving the Secretary free "to choose" "[a]mong the numerous and diverse objectives broadly stated." *Panama Refining*, 293 U.S. at 418.

f. *Womack* is distinguishable

Defendants' continued attempt to suggest that the TCA's deeming provision merely delegates fact-finding authority—as if the Secretary were under a duty to "deem" anything that qualifies as a tobacco product, using the four products Congress itself enumerated as "illustrative" examples—simply evades the issue and further demonstrates the weakness of the FDA's position.

Summarizing the core of its argument, the FDA writes that "[i]t is commonplace for Congress to provide definitions and standards and task agencies with determining their application." FDA Br. at 13. Re-characterizing the only four products that Congress itself subjected to the TCA in 2009 as illustrative "examples," FDA likens the deeming authority to the statute at issue in *Womack*. *Id.* at 23-25. The problem with this analogy

is that the four products enumerated by Congress in § 387a(b) are—quite plainly—not illustrative examples. Instead, they represent Congress's deliberate limitation of the application of the TCA, and the Secretary is indisputably not under any duty to regulate any other product, under any congressionally-mandated parameters, even if it constitutes a "tobacco product."

The statute in *Womack* applied the operative offense to all "explosives," provided a definition with illustrative examples, and tasked the Treasury with the job of listing products that meet the definition. The TCA is structured materially differently; the statute defines "tobacco product" broadly, but § 387a(b) states that the regime "shall apply" only to the four enumerated products, and to any others deemed by the Secretary, without explaining which additional products should be deemed or why. *Womack* is therefore distinguishable. *Womack* would only be applicable if FDA could convince this Court that either the TCA requires 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 declined to list it anyway, in its unilateral discretion.

The Court cannot accept the government's invitation to read *Womack* as if the statute conferred that second-level discretion because the parties in *Womack* did not argue that such authority existed, and the court's opinion does not contemplate such discretion. Plfs' Br. at 58. 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. Plaintiffs explained this in their brief (p. 58), and the FDA has not argued otherwise.

g. Unilateral authority to decree which tobacco product industries shall be regulated cannot be likened to standard enforcement discretion.

Lastly, FDA argues that, because certain statutes grant administrative agencies authority to confer exceptions to otherwise-applicable requirements, Congress could have done so with the TCA, and the fact that Congress chose a "different default rule for most tobacco products" (*i.e.*, leaving most of them *un*regulated, but subject to regulation at the agency's whim) does not change the scope of agency authority. FDA Br. at 22-23. This argument is strained at best, and the FDA cites no authority for it.

First, this argument is based on the questionable premise that a statutory regime characterized by limited coverage but authorizing an agency to unilaterally extend coverage (over vast swaths of economic activity) is

analytically the same as a regime in which Congress provides blanket coverage with agency discretion to make exceptions. FDA certainly cannot equate the sort of case-by-case enforcement discretion that agencies typically enjoy with the monumental delegation at issue here, by which the Secretary determines in the first instance whether whole industries shall be subjected to a comprehensive statutory regime.

But even if one accepts, *arguendo*, the proposition that Congress's chosen "default" rule does not affect the delegation analysis, the FDA's argument is nothing less than the bold suggestion that *this* delegation must be constitutional simply because *other* delegations exist in the law. None of the examples cited by the FDA (Br. at 23 n.4.) have been challenged on nondelegation grounds, much less upheld. The fact that statutes exist does not mean they are constitutional.

Third, and tellingly, even the examples of small-bore enforcement discretion authority cited by the Defendants incorporate the kind of policy parameters limiting agency discretion that are entirely absent in the deeming provision.[7] Far from undermining Plaintiffs' case, these examples serve to

[7] 7 U.S.C. § 1637b(b)(2)(D) (authorizing exemptions from reporting requirements for "any manufacturer that processes and markets less than 1,000,000 pounds of dairy products per year"); 15 U.S.C. § 78u-5(g) (authorizing Securities and Exchange Commission to provide exemptions from certain requirements "if and to the extent that any such

demonstrate how easy it would have been for Congress to incorporate some kind of parameters to guide the Secretary's deeming discretion.

Moreover, even if the FDA could identify some standardless authority to grant exceptions in other contexts, unilateral agency authority to determine which parts of the national tobacco industry should be regulated is delegation on a materially different plane, as noted above. The massive economic and social policy impacts from regulation of the vapor industry alone is evident from the fact that it was the subject of a press conference televised live nationally from the White House, along with continuing

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exemption is consistent with the public interest and the protection of investors, as determined by the Commission"); 15 U.S.C. § 78j-1(m)(3)(C) (authorizing Securities and Exchange Commission to authorize case-by-case exemptions from the "independence" requirement for members of the audit committee of an "issuer"); 15 U.S.C. § 5711(a)(5) (authorizing the Federal Trade Commission to provide exemptions from the requirement that pay-per-call service providers include an introductory message on each call, describing the services and costs, for "(A) calls from frequent callers or regular subscribers using a bypass mechanism to avoid listening to the disclosure message … or … (B) pay-per-call services provided at nominal charges, as defined by the Commission in such regulations"); 16 U.S.C. § 823a(b) (authorizing Fedreral Power Commission to exempt certain facilities below a certain capacity and subject to several other standards and requirements); 29 U.S.C. 1112(e) (Labor Sec'y may exempt employee benefit plans from bonding requirements "where he finds that (1) other bonding arrangements or (2) the overall financial condition of the plan would be adequate to protect the interests of the beneficiaries and participants"); 46 U.S.C. § 4305 (Secretary may authorize exemptions from certain recreational vessel regulations if "safety will not be adversely affected"); 49 U.S.C. § 20306 (Transportation Sec'y may exempt certain railroad equipment from safety regulations "when those requirements preclude the development or implementation of more efficient … equipment or other transportation innovations," and only under certain conditions); 49 U.S.C. § 47528(b) (authorizing applications for waivers of "civil subsonic turbojet" noise limits, but only if a carrier meets those requirements for 85% of its fleet by a certain date).

modifications to Administration enforcement policies as reflected during the pendency of this litigation. *See, generally*, Plfs' Br. at 27-30, 32-34.

II. Standardless Delegation is Unconstitutional Under Current Law, and This Court Should Not Hesitate to Enforce the Constitution.

"Time and again[,]" the Supreme Court has "reaffirmed the importance in our constitutional scheme of the separation of governmental powers into three coordinate branches," *Morrison v. Olson*, 487 U.S. 654, 693 (1988), and it "has not hesitated to enforce the principle of separation of powers … when its application has proved necessary for the decisions of cases or controversies properly before it." *Buckley v. Valeo*, 424 U.S. 1, 123 (1976) (per curiam).

Neither has the Fifth Circuit hesitated to enforce these bedrock principles. In *Collins v. Mnuchin*, discussing the separation of powers, the Court of Appeals noted that "[t]he Constitution's unique architecture is 'the central guarantee of a just government' and essential to protecting individual liberty." 896 F.3d 640, 659 (5th Cir. 2018) (quoting *Freytag v. C.I.R.*, 501 U.S. 868, 870 (1991)), *reinstated in part by* 938 F.3d 553, 588 (5th Cir. 2019) (en banc), pet. filed, Nos. 19-422, 19-563. In *Collins*, a panel held that the structure of the Federal Housing Finance Agency violated the separation of powers, and its holding and analysis was reinstated by the full Fifth Circuit

following rehearing en banc. *Collins v. Mnuchin*, 938 F.3d at 588. The en banc Court vigorously endorsed the judiciary's duty to enforce the structural principles of the Constitution, reiterating, "[t]he warning that 'if we are to continue a government of limited powers, these agencies must themselves be regulated' remains fresh as ever." *Id.* at 576-77 (quoting *New York v. FERC*, 535 U.S. 1, 18 (2002)). In another recent case, a panel of the Fifth Circuit granted a stay against an order issued by an administrative law judge of the Federal Deposit Insurance Corporation, after concluding that the movant demonstrated a "strong showing" that he was likely to succeed on his separation of powers challenge under the Appointments Clause. *Burgess v. Federal Deposit Ins. Corp.*, 871 F.3d 297, 301 (5th Cir. 2017).

"Whether the statute delegates legislative power is a question for the courts[.]" *Whitman*, 531 U.S. at 472. While the Supreme Court has upheld broad delegations of authority, it has always required the statute to include *some* standard reflecting Congress's chosen policy. In the absence of such a standard—where there is no guidance for the exercise of discretion—it means the agency is legislating, rather than Congress, and the Constitution is violated. *Id.* at 474 (referring to *Panama Refining*). *Panama Refining* cannot simply be ignored as if it has been overtaken by subsequent cases; it

remains binding, and illustrates that there is a limit to Congress's authority to delegate, even under current law.

This is a truly rare nondelegation case, because the operative statute imposes no standard, a fact that the Defendants themselves have relied upon in prior litigation and another federal court has already acknowledged. The Court does not have to decide whether some broadly-stated standard is sufficient under current law; it need only apply the holding of *Panama Refining* that Congress exceeded its powers when it imposed no standard at all.

III. Even If Plaintiffs' Claim Were Doubtful, It Was Error to Dismiss Their Complaint Before Reasonable Discovery.

This is not a case in which dismissal on the pleadings is appropriate, especially after the government taints the trial court record with voluminous references to extraneous facts. Plaintiffs are within the class of parties with standing as the targets of regulation, and—at a minimum—they have a *plausible* claim against this standardless delegation in light of *Panama Refining*. Plaintiffs should be permitted the opportunity to adduce admissible evidence that refutes and contextualizes the Defendants' superficial factual presentation below.

The FDA referred selectively to material in the legislative record going back decades, nearly all of it pertaining to combustible tobacco products (primarily cigarettes), inviting the impression that deeming non-combustible vapor products falls in line with Congress's purposes in the TCA. *See* Plfs' Br. at 71-72.

The Defendants and the district court also acknowledge that the scope of the delegation is pertinent in determining the level of guidance Congress must provide, but would deny Plaintiffs the opportunity to adduce admissible evidence reflecting the size of the ENDS industry. Such data is relevant to the question, despite Defendants' claim to the contrary (FDA Br. at 27). *See* Plfs. Br. at 72. Another relevant area of data will be the number of former smokers who have transitioned away from smoking only because vaping exists as an alternative, which bears directly on the competing interests at play in the legislative decisions surrounding regulation.

Plaintiffs also believe that discovery may well yield evidence directly reflecting how, in the circumstances of this case, excessive delegation of policymaking authority actually and severely undermined the legitimate and important functions of HHS, including the FDA and CDC. For example, Plaintiffs believe the evidence will show that the FDA deliberately generalized the data regarding youth uptick in vaping over a period of

months. While it was clear all along that the vast majority of youth who report using vapor products use closed-system e-cigarettes (and, among them, a majority used a single brand, JUUL), the FDA ignored this distinction because generalizing the matter helped engender public support for its preferred policy of regulating even open-tank systems, used primarily by adult former smokers and *not* youth.

CONCLUSION

Plaintiffs respectfully request that the Court reverse the judgment below, hold that Plaintiffs are likely to succeed on the merits (or, in the alternative, that they have stated a plausible claim), and remand for further proceedings.

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 April 9, 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
Jerad Wayne Najvar

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of FED. R. APP. P. 32(a)(7)(B) because this brief contains 6,369 words, excluding the parts of the brief exempted by FED. R. APP. P. 32(a)(7)(B)(iii).
2. This brief complies with the type-volume limitation of FED. R. APP. P. 32(a)(5) and the type style requirements of FED. R. APP. P. 32(a)(6) because this brief has been prepared in proportionately spaced typeface using Microsoft® Word 2016 in 14-point Georgia type.

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CERTIFICATE OF ELECTRONIC COMPLIANCE

Counsel also certifies that on April 9, 2020, the foregoing brief 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.

Counsel further certifies that (1) the required privacy redactions have been made, 5th Cir. R. 25.2.13; (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 25.2.1; and (3) the document has been scanned and is free of viruses.

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