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; BRETT P. GIROIR, Admiral, Acting Commissioner of Food and Drug Administration; 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' PRINCIPAL BRIEF

———————————————————————

Jerad Wayne Najvar
Tex. Bar No. 24068079
jerad@najvarlaw.com
Austin M.B. Whatley
Tex. Bar No. 24104681
austin@najvarlaw.com
NAJVAR LAW FIRM, PLLC
2180 North Loop West, Ste. 255
Houston, Texas 77018
[Tel.] (281) 404-4696
[Fax] (281) 582-4138
Counsel for Appellants

CERTIFICATE OF INTERESTED PERSONS

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

1. *Big Time Vapes, Incorporated* and *United States Vaping Association, Incorporated* – Plaintiffs-Appellants. They are represented in the Fifth Circuit and in the district court by:

   Jerad Wayne Najvar
   Austin M.B. Whatley
   NAJVAR LAW FIRM, PLLC
   2180 North Loop West, Ste. 255
   Houston, TX 77018

   Additional counsel in district court, but not attorney of record on appeal:

   Spencer M. Ritchie
   210 E. Capitol St., Ste. 2200
   Jackson, MS 39225

2. *Food and Drug Administration; Brett P. Giroir*, *Admiral, Acting Commissioner of Food and Drug Administration; Alex M. Azar, II, Secretary, U.S. Department of Health and Human Services, in his official capacity* – Defendants-Appellees. These defendants-appellees are represented in the Fifth Circuit as follows:

Lindsey Powell
Civil Division, U.S. Dep't of Justice
950 Pennsylvania Ave., NW, Room 7226
Washington, DC 20530

Defendants-Appellees' counsel of record in the district court are as follows:

Joseph H. Hunt, Asst. Attorney General
D. Michael Hurst, Jr., United States Attorney
Eric B. Beckenhauer, Asst. Director
Stephen M. Pezzi, Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005

Emily S. Nobile, Asst. United States Attorney
Office of the United States Attorney
Southern Dist. of Mississippi

Of counsel in district court:

Robert P. Charrow, General Counsel
U.S. Dep't of Health and Human Services

Stacy Cline Amin, Chief Counsel
Food and Drug Administration
Deputy General Counsel
Dep't of Health and Human Services

Perham Gorji, Deputy Chief Counsel for Litigation

Wendy S. Vicente, Senior Counsel

Noah T. Katzen, Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

s/ Jerad W. Najvar
Jerad W. Najvar
Attorney of record for Appellant

STATEMENT REGARDING ORAL ARGUMENT

Appellant respectfully requests oral argument. While the challenged deeming provision of the Tobacco Control Act (TCA) is extreme, and even more standardless than the provision struck down by the Supreme Court in *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), Defendants will seek to minimize *Panama Refining*'s holding in light of the ensuing decades of nondelegation jurisprudence. Oral argument will provide the opportunity to address the Court's questions and explain why *Panama Refining* applies here and compels a judgment for Plaintiffs.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Constitutional Provisions & Statutes

Regulations

STATEMENT OF JURISDICTION

Plaintiffs-Appellants brought this action asserting that the "deeming" authority conferred upon the Secretary of Health and Human Services under the Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1777 (2009) ("Tobacco Control Act" or "TCA"), and Defendants-Appellees' actions taken pursuant to such authority, violate Plaintiffs' rights under the separation of powers set out in the United States Constitution. ROA.9-31. The complaint invoked the district court's jurisdiction pursuant to 28 U.S.C. §§ 1331 (federal question jurisdiction), and invoked relief under the Declaratory Judgment Act, 28 U.S.C. § 2201, and injunctive relief under 28 U.S.C. § 2202 and Federal Rule of Civil Procedure 65. ROA.11 (Compl. at ¶6).

On December 16, 2019, the district court entered its order granting Defendants' motion to dismiss, dismissing the suit with prejudice, and denying Plaintiffs' motion for preliminary injunction. ROA.715-25. The district court entered judgment the same day. ROA.726. Plaintiffs filed their notice of appeal the following day, December 17, 2019. ROA.727. This Court has jurisdiction over this appeal pursuant to 28 U.S.C. § 1291.

STATEMENT OF ISSUES

1. Whether the district court erred in holding that Plaintiffs failed to state a plausible claim that the deeming provision of the Tobacco Control Act transfers legislative authority to the Executive Branch, in violation of the nondelegation principle, where the deeming provision authorizes the Secretary of Health and Human Services to decide whether any given "tobacco product" shall be subject to the restrictions of the Tobacco Control Act, or shall remain unregulated, without providing any guidance or parameters to limit the Secretary's deeming discretion.
2. Whether the district court erred in holding that Plaintiffs had failed to establish likelihood of success on the merits of their nondelegation claim.

STATEMENT OF THE CASE

I. Statutory and Regulatory Background

a. Tobacco Control Act of 2009

In 2009, Congress amended the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FD&C Act"), by passing the Tobacco Control Act.[1] The Act mandates that "[t]obacco products ... shall be regulated by the Secretary [of Health and Human Services] under this subchapter and shall not be subject to the provisions of subchapter V." 21 U.S.C. § 387a. (Subchapter V of the FD&C Act governs "drugs" and "devices.").

"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).

Various "tobacco products" were in widespread use when Congress enacted the TCA—including cigarettes, cigars, smokeless tobacco, pipe tobacco, and hookah. *See* ROA.15-16. But Congress did not choose to impose the Act's requirements on all of them. Instead, the statute provides

---

[1] 123 Stat. 1777 (2009). The TCA comprises subchapter IX of the Food, Drug, and Cosmetic Act (FDCA), which is codified in chapter 9 of title 21 of the United States Code.

that "[t]his 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). "Roll-your-own tobacco" is defined to mean "any tobacco product which ... is suitable for use and likely to be offered to, or purchased by, consumers as tobacco *for making cigarettes*." 21 U.S.C. § 387(15) (emphasis added).

Therefore, Congress itself imposed the TCA only upon cigarettes and cigarette tobacco, and "smokeless tobacco," which is limited to "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." *Id.* § 387(18). Left unregulated—but subject to regulation at the Secretary's discretion—were all other forms of tobacco products, including such widely used products as cigars (premium and all other varieties), pipe tobacco, and hookah.[2]

The TCA imposes a variety of regulatory requirements on tobacco products subject to it.

---

[2] While the statute delegates deeming authority to "the Secretary [of HHS]," through a staff manual, the Secretary sub-delegated this power to the FDA Commissioner, who, in turn, sub-delegated this power to the Associate Commissioner for Policy. FDA Staff Manual Guide 1410.21 (authorizing the Associate Commissioner for Policy to assume the FDA Commissioner's authority to issue "proposed and final regulations").

Many of the most onerous burdens apply to "tobacco product manufacturers," a term[3] that, as applied in the Deeming Rule,[4] captures the vast majority of "e-cigarette retail stores and vape establishments." 81 Fed. Reg. at 28,979. FDA explained that "establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for direct sale to consumers are tobacco product manufacturers under the definition set forth in the FD&C Act and, accordingly, are subject to the same legal requirements that apply to other tobacco product manufacturers." *Id.*

The Act requires each covered manufacturer, including Plaintiff Big Time Vapes and many of the businesses represented by the USVA, to provide FDA a list of all ingredients and compounds added to its products, as well as any and all documentation pertaining to the products' health and related effects. 21 U.S.C. § 387d(a)-(b). The Act also requires manufacturers to register their places of business and their product listing

---

[3] A "tobacco product manufacturer" is "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).

[4] "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," No. FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule" or "the Rule"). The Rule went into effect 90 days after its publication. 81 Fed. Reg. at 28,976.

with the agency. *Id.* § 387e. Plaintiff Big Time Vapes and the USVA's "manufacturer" members have complied with these requirements. ROA.373.

The Act also prohibits, among other things, the marketing of any covered "new tobacco product" without the FDA's approval, unless the product is grandfathered. *Id.* § 387j. The effect of this provision is that any covered tobacco product that was "not commercially marketed in the United States as of February 15, 2007" is banned from the marketplace without prior FDA approval. *See id.* § 387j(a).

There are two main pathways for FDA approval to market a "new tobacco product" covered by the TCA. FDA has acknowledged that ENDS products must seek FDA approval through the most arduous pathway, the "premarket tobacco application," sometimes referred to as a "PMTA." ROA.20-21. This process requires the development and submission of substantial amounts of data, *see* 21 U.S.C. § 387j(b), as discussed further below.

Failure to comply with the above-described provisions can result in a variety of serious consequences for manufacturers and retailers, including designation of one's products as misbranded or adulterated, *see* 21 U.S.C. §§ 387b, 387c, which in turn can trigger substantial civil penalties and

imprisonment, 21 U.S.C. §§ 331, 333, as well as seizure of the offending products, 21 U.S.C. § 334. *See* ROA.19.

b. Electronic Nicotine Delivery Systems (ENDS)

Vapor devices, also known as "electronic cigarettes," "e-cigarettes," or "electronic nicotine delivery systems (ENDS)," are handheld electronic devices used to heat and aerosolize a liquid mixture ("e-liquid") that includes flavoring and various levels of liquid nicotine, including zero nicotine. ROA.374. Once the liquid is aerosolized, the user inhales the "vapor" in a manner similar to that of inhaling actual tobacco smoke, but without setting any tobacco on fire. Id.

Vapor devices come in "closed" or "open" systems. In a so-called "closed system," either the device itself or interchangeable pods or cartridges intended for use with that device come pre-filled with a particular type of e-liquid. *See* ROA.136 (definition of "E-cigarette"). In a so-called "open system," the device will not come pre-filled; rather, the user will separately buy bottled e-liquid(s) and use them to fill the device's e-liquid reservoir, or "tank," with the e-liquid and nicotine level of his or her choice. *Id.*

Former FDA Commissioner Scott Gottlieb, M.D., recognized 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." ROA.183; *see also id.* ("While it's the addiction to nicotine that keeps people smoking, it's primarily the combustion, which releases thousands of harmful constituents into the body at dangerous levels, that kills people.").

c. The Deeming Rule issued

FDA published the Deeming Rule in the Federal Register on May 10, 2016. In the Deeming Rule, FDA exercised its authority under 21 U.S.C. § 387a(b), decreeing that it "deems 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 chapter IX" of the FD&C Act. 81 Fed. Reg. 28,976 (emphasis added). FDA explained the breadth of the Rule:

> 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," except accessories of such newly deemed products, to be subject to FDA's authorities under chapter IX of the FD&C Act. For example, FDA envisions that there could be

> tobacco products developed in the future that provide nicotine delivery through means (e.g., via dermal absorption or intranasal spray) similar to currently marketed medicinal nicotine products, but which are not drugs or devices. These products would be "tobacco products" and subject to FDA's chapter IX authorities in accordance with this final deeming rule.

81 Fed. Reg. 28,976.

Application of the TCA to ENDS (and cigars, and all other newly-deemed products) imposed certain obligations and restrictions upon the regulated community effective as of August 8, 2016. *See* ROA.20. These include the requirement that any ENDS manufacturer, or retail establishment "mixing or preparing e-liquids or creating or modifying" ENDS devices for direct sale to consumers, register as "manufacturers" under the TCA and submit a list of all distinct products (including each distinct flavor/nicotine combination), and list all ingredients. *See* Deeming Rule, 81 Fed. Reg. at 29046.[5] The industry was also frozen as of the effective date of the Deeming Rule, in that "manufacturers" were permitted to continue marketing those product variations that were on the market as of the effective date of the Rule (pending timely submission of PMTAs), but

[5] Other provisions of the TCA prohibit the sale or distribution of products bearing 'modified risk' descriptions (such as 'light,' 'low,' or 'mild') without FDA approval (subject to a separate "Modified Risk" approval process), and a prohibition on distribution of free samples. *See* Deeming Rule, 81 Fed. Reg. at 28,976.

could not introduce new variations. *Id.* at 28,978. FDA also imposed an immediate prohibition on the sale of any covered tobacco products to individuals under age 18, and required all product labels and advertising to prominently state: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." 81 Fed. Reg. at 28979.

d. Premarket Review requirements under the TCA and shifting compliance deadlines.

The TCA also would have authorized FDA to halt sales of newly-deemed products until the TCA-required premarket review applications were processed and approved. *See* ROA.20; 21 U.S.C. § 387b (finding a tobacco product is "adulterated" if it is required to have a premarket review order but does not have one); *id.* § 331(a) (making it unlawful to introduce an adulterated tobacco product into interstate commerce). But as part of the Deeming Rule, FDA opted to implement the premarket review requirement more gradually, establishing a "staggered initial compliance period" discussed below. *See* 81 Fed. Reg. at 28978.

Because ENDS products are effectively ineligible for grandfathering or the less burdensome "substantial equivalence" pathway, the FDA acknowledged that "nearly all ENDS products will be subject to premarket review," and the FDA candidly predicted "considerable product consolidation and [market] exit" for ENDS products. ROA.20-21 (quoting

FDA, *Regulatory Impact Analysis*, AR 23,912-24,067 ("RIA")). This is because any variation, however slight, of any ingredient or component of either an e-liquid or an ENDS delivery device, such as variations in flavor, nicotine content, or quantity, would render the product a unique "new tobacco product" as defined in the TCA, and therefore require its own unique premarket review application. ROA.21; *see also* ROA.206-98 (U.S. Food and Drug Administration, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50566, 50573 (Sept. 25, 2019) ("Proposed Final PMTA Rule") (discussing proposed final definition of "new tobacco product")).[6]

FDA itself estimated that an initial premarket review application for e-liquids would cost between $181,686 and $2,014,120 per application, and applications for delivery devices it estimated would cost between $285,656 and $2,622,224 per application. *See* ROA.21 (citing RIA, AR 23,998 (Table 11a), AR 24,001-02 (Table 12a)).

Under the "staggered compliance policy," a manufacturer submitting a premarket review application was initially required to do so by August 8, 2018, *i.e.*, 24 months after the Rule became effective. *Id.* at 28,977-78

[6] The Proposed Final PMTA Rule's comment period was extended through December 16, 2019. 84 Fed. Reg. 65044. The final rule has not yet been published.

(describing compliance periods for the different pathways). FDA stated that it would then allow an additional 12-month period for review and approval of the PMTA before enforcement would commence, and would defer enforcement even further on a case-by-case basis. *Id.* at 28,978 ("However, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.").

FDA subsequently extended the compliance deadlines. First, in May 2017, it extended the deadlines outlined in the Deeming Rule by three months. ROA.378. Then, in August 2017, FDA announced another extension applying "only to compliance deadlines relating to premarket review requirements." ROA.192-205 ("August 2017 Guidance"). The August 2017 Guidance amended the FDA's prior compliance approach in substantive ways.

For example, whereas the Deeming Rule's "staggered compliance schedule" set out different deadlines for submission of applications by *application type* (substantial equivalence, exception to substantial

equivalence, or premarket review), the August 2017 Guidance distinguished between *product type*. The deadline for any type of application regarding a newly deemed combustible tobacco product was established as August 8, 2021, and the deadline for any type of application for a noncombustible product was established as August 8, 2022. ROA.196.

Additionally, the August 2017 Guidance "revis[ed] the compliance policy relating to the period after FDA receipt" of product applications. *Id.* In the Deeming Rule, FDA had established a 12-month compliance period for FDA review. The August 2017 Guidance reverted to a less definite compliance period pending review of submitted applications. *Id.* ("Under this new compliance policy, there will be a continued compliance period pending review of [marketing] applications ... [t]his compliance period will continue until the agency renders a decision on an application ... or the application is withdrawn.").

However, FDA has now been ordered by the federal district court for the District of Maryland to severely accelerate the compliance deadlines. In *American Academy of Pediatrics v. Food and Drug Administration*, the district court held that the FDA had failed to abide by the Administrative Procedures Act's notice and comment requirements in issuing the August 2017 Guidance. 379 F. Supp. 3d 461 (D. Md. 2019).

After the parties' remedy briefs, in a subsequent order issued July 12, 2019, the District Court for the District of Maryland vacated FDA's August 2017 Guidance, and ordered as follows:

> 1. [T]he FDA shall require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule ("New Products"), applications for marketing orders must be filed within 10 months of the date of this Memorandum Opinion and Order;
>
> 2. New Products for which applications have not been filed within this period shall be subject to FDA enforcement actions, in the FDA's discretion;
>
> 3. New Products for which applications have been timely filed may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application;
>
> 4. The FDA shall have the ability to exempt New Products from filing requirements for good cause on a case-by-case basis.

American Academy of Pediatrics v. Food and Drug Administration, No. 8:18-cv-00883-PWG, 2019 WL 3067492, at *7 (D. Md. Jul. 12, 2019), appeal docketed, No. 19-2130 (4th Cir.).

In other words, FDA has been ordered to require the submission of ENDS PMTAs a full *twenty-seven months earlier* than planned, by May 2020.[7] This severely accelerates the period within which Plaintiffs and others similarly situated are expected to prepare and file the complex

[7] The district court's order erroneously states the date as August 2022. ROA.719. This appears to have been a scrivener's error.

PMTAs that even the FDA acknowledges are prohibitively expensive, and predicted would prompt "considerable product consolidation and [market] exit." RIA, AR 23,989-90 (FDA itself assuming that "54 percent of delivery systems and somewhere between 50 and 87.5 percent of e-liquids [would] not submit a marketing application and will exit the market after the initial compliance period ... ends.").

On January 2, 2020, FDA issued a new guidance document.[8] As particularly relevant here, the document states that FDA will "prioritize enforcement of any ENDS product that is offered for sale after May 12, 2020, and for which the manufacturer has not submitted a premarket application[.]" Id. at 3.[9] While FDA has appealed the Maryland district court order, FDA argues that the Maryland order has been "superseded" by the January 2020 guidance, and FDA intends to enforce the May 12, 2020 deadline independent of the court order. *See* FDA Brief at 2-3 (filed Jan. 23, 2020), in *Am. Academy of Pediatrics v. FDA*, Nos. 19-2130, -2132, -2198, & -2242 (4th Cir.).

e. Premarket Review Application (PMTA) Particulars

---

[8] FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization: Guidance for Industry (Jan. 2, 2020), https://www.fda.gov/media/133880/download.

For every "[n]ew tobacco product" subject to the TCA that was not on the market as of February 15, 2007, Section 910 of the FD&C Act requires obtaining a "marketing authorization order" from FDA permitting the marketing of such products before they can be sold legally in the United States. *See* 21 U.S.C. § 387j. Unlike cigarettes, which were grandfathered and therefore exempt from the PMTA process, ENDS products must submit a PMTA and receive FDA authorization. *Id.* § 387j(a)(2)(A).

i. FDA explains for years that more time is required to develop "rules of the road" for ENDS PMTAs.

The content requirements for a PMTA are stated in broad terms in the TCA itself. 21 U.S.C. § 387j(b)(1)). Yet the specific requirements for ENDS PMTAs were not elaborated for years after the Deeming Rule was announced.

On June 28, 2017, in a speech announcing the FDA's comprehensive tobacco regulation plan, then-Commissioner Scott Gottlieb, M.D., acknowledged that FDA did not yet have the proper regulations in place for ENDS products, stating: "One area of emphasis will be to make sure we have the foundational regulatory architecture to ensure proper oversight of ENDS .... Part of this will be developing regulations that we have not yet

pursued because the Agency's tobacco program itself is so new." ROA.382. Elaborating on this, the FDA stated in an official release that it

> plans to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers, while upholding the agency's public health mission. Among other things, the FDA intends to issue regulations outlining what information the agency expects to be included in Premarket Tobacco Applications (PMTAs), Modified Risk Tobacco Product (MRTP) applications and reports to demonstrate Substantial Equivalence (SE). The FDA also plans to finalize guidance on how it intends to review PMTAs for ENDS.

ROA.382.

The following month, FDA issued the August 2017 Guidance extending the initial PMTA submission deadline for ENDS products to August 2022. Then, for the next two years, Commissioner Gottlieb continued to emphasize that "[t]he foundational regulations for the tobacco program were never put in place and so we're going to take the time to put those in place so we have a firm foundation from which to regulate." ROA.382 (citing Nov. 3, 2017 statement); see id. (collecting additional statements).

And again in February 2019, then-Commissioner Gottlieb, in sworn testimony before Congress, defended and affirmed that extending the PMTA deadline to August 2022 was necessary "to give [FDA] the time to put in place the implementing regulations and guidance that would ...

provide the rules of the road for how to effectively traverse the PMTA process[.]" ROA.383-84.

A few months later, in July 2019, the Maryland district court issued its order accelerating the PMTA submission deadline to May 2020.

ii. Proposed final rule for PMTA technical requirements

Two months later—and *less than eight months* before the radically accelerated May 12, 2020 submission deadline—FDA finally released a proposed final rule establishing the actual requirements for PMTAs. ROA.206-98. Completing a PMTA requires a comprehensive assessment of each new vapor product, including evaluations of the short- and long-term human health effects of the product on the population. This requires reviews of existing scientific literature, extensive product testing, toxicological studies and analysis, stability testing, materials testing, environmental assessments, and clinical studies of human subjects regarding various aspects of the use and effects of the product on both the user and non-users of each product. *See, generally*, ROA.128-82 (FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery*

Systems: Guidance for Industry).[10] Every requirement of the PMTA must be separately satisfied with respect to every variant of a product: "FDA considers each ENDS product with a differing flavor variant and/or nicotine strength to be a different product." ROA.148-49.

The onerous burdens imposed by this process are illustrated by a review of some representative requirements. One central component of a PMTA is the requirement to state all "constituents" of the particular product, including "harmful or potentially harmful constituents" (HPHCs), and conduct rigorous and varied tests for them. Proposed Final PMTA Rule, 84 Fed. Reg. at 50585. The list of HPHCs for which testing is required is not yet even final. Id. (discussing evolving list of HPHCs). Additionally, several different types of "Health risk investigations" are required, involving "double-blind, placebo-controlled" studies of human subjects. Id. at 50604. FDA repeatedly warns that PMTAs will not be accepted for filing if they do not include all the required testing and reports. *E.g., id.* at 50605. This snapshot elucidates the substantial costs of preparing and submitting a PMTA that FDA itself estimated in its

[10] This updated Guidance for Industry was issued in June 2019 (immediately before the Maryland district court entered its remedy order). ROA.128. This guidance document, itself only a high-level summary, runs 52 pages.

Regulatory Impact Analysis accompanying the Deeming Rule, which estimates FDA reiterates again in the proposed rule. 84 Fed. Reg. at 50568.

II. Plaintiffs File Suit

Plaintiffs filed this lawsuit on August 19, 2019. ROA.9-31. Plaintiff United States Vaping Association (USVA) is a trade association organized in July and August 2019 to represent small-business vaping manufacturers (who make e-liquid) and retail vape shops. ROA.12. USVA counted approximately three dozen paid members at filing, and brought this action to further its members' interests. *Id.* Plaintiff Big Time Vapes, Inc., one of USVA's members, is a retailer and manufacturer of e-liquid, established in 2015, that operates a single location in Picayune, Mississippi. Its sole owner is Belinda Dudziak, who smoked one-and-a-half to three packs a day for twenty-seven years, until she quit smoking cigarettes entirely only three or four days after trying her first e-cigarette in 2012. ROA.12. Big Time Vapes produces its own proprietary flavors—350 of them—which can be sold in varying levels of nicotine content (0-24 mls), and in six different bottle sizes. Big Time Vapes has 4,000 customers, 98% of whom have quit smoking traditional cigarettes completely. Id.

The complaint raised a single argument: that the Secretary's "deeming" authority under the TCA violates the principle of nondelegation.

Plaintiffs alleged injury from the aspects of the TCA effective immediately upon deeming (including the registration, reporting, recordkeeping, and labeling requirements), the fact that regulated "manufacturers" have their product lines frozen in time as of August 2016, and the PMTA application requirements, which they cannot meet but which would require severe diversion of resources if they attempt to meet them. ROA.9, 12-13, 17, 24-25 (Compl. ¶¶ 1, 8-9, 25-28, 33, 46-51). Plaintiffs sought declaratory relief and a permanent injunction.[11]

III. Plaintiffs Move for a Preliminary Injunction After the Executive Unilaterally Threatens a Ban on Flavored E-Liquids.

On September 11, 2019, the Executive branch announced that it intended to change its enforcement priorities to remove all flavored ENDS products (other than tobacco flavors) from the United States market within thirty days after issuing a revised guidance document, which was expected to be released within weeks. ROA.299-301, 312. This was announced in a

[11] Plaintiffs elaborated regarding their current and impending injuries in support of their motion for preliminary injunction. *See* ROA.389-90, 405-10, and exhibits cited therein; ROA.592-93. While not strictly before the lower court for purposes of resolution of the motion to dismiss, this evidence was and is relevant to any inquiry into Plaintiffs' standing. Plaintiffs' standing for this pre-enforcement challenge is clear, as illustrated in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), and *Texas v. EEOC*, 933 F.3d 433 (5th Cir. 2019), and Defendants have not challenged it.

televised press conference at the White House, with President Trump joined by Defendants Azar and Sharpless. ROA.387.

An FDA statement issued September 20, 2019 stated again that the Agency "intend[ed] to finalize [this] compliance policy in the coming weeks[.]" ROA.388. Acting Director Sharpless testified to the same effect in a Congressional hearing September 25. Id.

In light of the Administration's threat, Plaintiffs filed a motion for preliminary injunction on October 10, 2019, ROA.123-27, arguing that looming PMTA submission deadline and the flavor ban each independently threatened irreparable harm. ROA.389-93.

Plaintiffs argued that they were likely to succeed on the merits of their nondelegation claim. Plaintiffs argued that the question whether any given "tobacco product" or category of such products shall be subject to the TCA constitutes a quintessential question of legislative decisionmaking, and that delegating that decision to the Executive without providing a standard to guide the deeming decision violates Article I just as the Supreme Court held in *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). When the TCA passed Congress in 2009, a broad spectrum of products in widespread use met the definition of "tobacco product" in the Act. ROA.395. Despite defining "tobacco product" broadly, Congress itself only applied *the TCA's*

requirements to cigarettes and smokeless tobacco, leaving the Secretary the authority to impose the Act on "any other tobacco products that the Secretary by regulation deems to be subject to [the TCA]." 21 U.S.C. § 387a(b). In other words, Plaintiffs pointed out, Congress left cigars, hookah, pipe tobacco, and all other tobacco products unregulated and punted the question whether to extend the TCA to the Secretary, without providing any parameters or guidance whatsoever. ROA.395.

IV. Defendants Move to Dismiss Before Status Conference or Discovery

Defendants filed a Rule 12(b)(6) motion to dismiss (ROA.441) contemporaneously with their response to Plaintiffs' injunction request (ROA.507), and a combined memorandum arguing both (ROA.443-506). The combined memorandum leads off with eighteen pages of "introduction" and "background" material, replete with references to various sources nowhere mentioned in Plaintiffs' complaint. ROA.455-72. These sources include media reports, enforcement letters, selected representations of fact from the congressional record, and even quotes from evidence presented in separate litigation involving different parties. *E.g.*, ROA.466.

Summarizing its argument on the merits, FDA writes that "the [TCA], interpreted as a whole, plainly satisfies th[e] lenient [nondelegation]

standard[] by delegating narrow authority to the Executive Branch to *implement* one statutory term—"tobacco product"—that Congress already defined with precision." ROA.474 (italics added). FDA made two primary arguments. First, FDA relied heavily on this Court's decision in *United States v. Womack*, 654 F.2d 1034 (5th Cir. 1981), upholding a conviction for possession of certain firecrackers which the Secretary of the Treasury had determined to qualify as "explosives" as defined by Congress for purposes of a criminal statute. ROA.481. Second, FDA argued that the delegated authority is sufficiently limited when read in context with other provisions of the TCA, including the "recitation of … purposes" included in the Act's preface. ROA.486-87 (citing Pub. L. No. 111-31 § 3). FDA therefore argued that the Complaint should be dismissed for failure to state a claim, and the request for injunction denied as moot. ROA.473-74.[12]

Plaintiffs first addressed the merits, arguing that not only had they stated a *plausible* claim for relief, but that they had established likelihood of success on the merits, given that "the Complaint sufficiently alleges that the deeming provision here is even more unbounded than the authority struck down in" *Panama Refining*. ROA.608-09. Plaintiffs pointed out

[12] FDA also argued that Plaintiffs failed to carry their burden as to the remaining preliminary injunction factors, but these elements are not at issue in this brief.

that *Womack* was materially distinct in that—unlike the HHS Secretary's "deeming" authority—the criminal offense in *Womack* applied to *all* "explosives," and there was no suggestion that the Treasury Secretary had the discretion to *decline to list* some compound that was nonetheless an "explosive" under the statutory definition. ROA.584. Plaintiffs also explained why the FDA could not rely on the prefatory statements of purpose in this case, ROA.586-90, as explained in further detail below.

Secondarily, Plaintiffs argued that even if the sufficiency of their allegations were in doubt, the Court should deny the motion to dismiss because Plaintiffs are entitled to reasonable discovery for identified issues. ROA.609-14.

V. District Court Disposition

The district court first addressed FDA's motion to dismiss. The court concluded that "discovery is not necessary to determine whether the plaintiffs have stated plausible claims for relief," "[b]ecause the Court has not considered any documents outside the pleadings." ROA.721 n.4. In a single paragraph, the district court then characterized Plaintiffs' nondelegation argument as not plausible. ROA.723-24.

The court first stated that "Congress did not give the FDA unlimited discretion but restricted the FDA's discretion with a controlling definition

of 'tobacco product.'" ROA.723. The district court made no attempt to explain why—if merely limiting the field of *potential* regulation to a certain subject matter suffices—the Supreme Court went to so much unnecessary trouble searching for additional limits on the President's discretion in *Panama Refining* and other cases.

The district court also claimed that Congress "presented detailed policies behind its enactment of the TCA." ROA.723. "For example," the court wrote, "Congress clearly expressed a desire to protect the public health and to prevent, to the extent possible, underaged persons from having access to tobacco products." ROA.723-24. Assuming this is a reference to certain goals included in the purposes of the Act (*see* ROA.716), the court does not acknowledge Plaintiffs' argument that several of the listed purposes are in tension with others, or explain how the Secretary is supposed to prioritize among such purposes in deciding which "tobacco products" to regulate.

Lastly, the district court concluded that this case is "analogous" to the situation in *Womack*, "wherein ... Congress provided a definition of the term 'explosives' and gave an illustrative list of explosives subject to the Act." ROA.724.

Moving to the injunction motion, the court held that, because Plaintiffs had not stated a plausible claim, they could not establish likelihood of success on the merits, and denied the motion. ROA.724. The court declined to consider the other preliminary injunction elements. Id.

SUMMARY OF THE ARGUMENT

Determining the conditions that shall trigger the regulation of something by the federal government is a quintessential exercise of legislative policy. While the Supreme Court has upheld broad delegations, it has always required the statute to include *some* standard reflecting Congress's chosen policy. The deeming provision challenged here is a rare statute that imposes *no* standard to guide the Executive's discretion. Congress vested the Secretary with the authority to decide whether this or that "tobacco product" shall be regulated by the TCA, *or not*, at his complete whim. *Panama Refining* remains binding precedent marking the outer boundaries of current law, and the deeming provision is an excessive delegation under the analysis in *Panama Refining*. As such, it must be held unenforceable even under the current permissive standard.

Limiting the Secretary's discretion to the field of "tobacco products" is not alone sufficient, as every delegation case involves discretion that is already circumscribed within a given field of regulation. Nor is it possible to extract meaningful limitations on deeming discretion form the TCA's varied, ambiguous statements of purpose, which are at odds with one another. The Secretary is not at liberty to choose how to prioritize those

purposes—to the extent they are even understandable—in the absence of Congressional guidance.

While the district court accepted FDA's invitation to misread *Womack v. United States*, the statute at issue there applied the offense to all explosives, whereas Congress in the TCA deliberately omitted several categories of "tobacco products" from regulation, and punted to the Secretary the authority to regulate others, without any guidance. None of the Defendants' attempts to escape the binding holding of Panama Refining are availing, and Plaintiffs have not only stated a plausible claim, but have established likelihood of success on the merits. Nondelegation is an issue for the courts, and this Court has not shied away from enforcing the separation of powers where necessary. If this delegation is upheld, it will not mark fidelity to current jurisprudence but will stake new territory further undermining the separation of powers.

However, if there is any doubt about the strength of the claim, it was error to dismiss the case without allowing an opportunity to build a record. Plaintiffs have identified at least three issues on which discovery is relevant, including to undermine one of the central assumptions cited in defense of broad delegations (disinterested expert decisionmaking), and to demonstrate that deeming worked a major policy change, which speaks to a

specific issue touched upon recently by several justices of the Supreme Court.

ARGUMENT

I. Standard of Review

"A motion to dismiss under rule 12(b)(6) is viewed with disfavor and is rarely granted." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000) (internal quotation omitted). To survive a motion to dismiss for failure to state a claim, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "The court must accept all well-pleaded facts as true, and view them in the light most favorable to the plaintiff." *Inclusive Communities Project, Inc. v. Lincoln Prop. Co.*, 920 F.3d 890, 899 (5th Cir. 2019) ("*ICP*") (cleaned up; internal quotations omitted). Further, "[a]ll questions of fact and any ambiguities in the controlling substantive law must be resolved in the plaintiff's favor." *Id.* (quoting *Lewis v. Fresne*, 252 F.3d 352, 357 (5th Cir. 2001)). "On the other hand, courts are not bound to accept as true a legal conclusion couched as a factual allegation.'" *Id.* (*quoting Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Further, the court's analysis is "limited to (1) the facts set forth in the complaint, (2) documents attached to the complaint, and (3) matters of

which judicial notice may be taken under Federal Rule of Evidence 201." *Id.* "When a defendant attaches documents to its motion that are referenced in the complaint and are central to the plaintiff's claims, however, the court can also properly consider those documents." *Id*.

II. Plaintiffs State a Claim Under the Nondelegation Doctrine.

Not only have Plaintiffs stated a plausible claim, but extant Supreme Court precedent compels a judgment in their favor. The district court erred in dismissing the suit.

a. Nondelegation standard

Article I of the Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. art. I, § 1. "This text permits no delegation of those powers[.]" *Whitman*, 531 U.S. at 472. At the same time, "the Constitution does not deny to the Congress the necessary resources of flexibility and practicality that enable it to perform its functions," and "Congress may obtain the assistance of its coordinate Branches—and, in particular, may confer substantial discretion on executive agencies to *implement* and *enforce* the laws." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (italics added; internal punctuation and citations omitted). "In a delegation challenge, the constitutional question is whether the statute has delegated legislative

power to the agency." *Whitman*, 531 U.S. at 912. "When Congress confers decisionmaking authority upon agencies *Congress* must 'lay down by legislative act an intelligible principle to which the person or body authorized to act is directed to conform.'" *Id.* (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)) (emphasis in original). Determining "whether Congress has supplied an intelligible principle ... requires construing the challenged statute to figure out what task it delegates and what instructions it provides." *Gundy*, 139 S. Ct. at 2123.

Further, the Supreme Court has said that "the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Whitman*, 531 U.S. at 913 (contrasting discretion to define "country elevators," which are to be exempt from new-stationary-source regulations governing grain elevators, from "setting air standards that affect the entire national economy").

b. The TCA delegates to FDA the unbounded authority to leave any particular tobacco product unregulated, or to deem it to be subject to the TCA, in its absolute discretion.

The TCA is a comprehensive and burdensome regime with respect to any "tobacco products" subjected to it. When the statute was enacted in June 2009, premium and nonpremium cigars, waterpipe tobacco (hookah), pipe tobacco, and other tobacco products were on the market and in

widespread use. The first ENDS products were already being marketed in the United States as well.[13] Still, Congress *itself* only applied the TCA to cigarettes and smokeless tobacco, leaving the Secretary the authority to impose the Act on "any other tobacco products that the Secretary by regulation deems to be subject to [the TCA]." 21 U.S.C. § 387a(b). In other words, Congress left cigars, hookah, pipe tobacco, ENDS, and all other tobacco products unregulated and punted the question whether to extend the TCA to the Secretary, without providing any parameters or guidance whatsoever. The statute does not require or even suggest a list of factors the Secretary should consider; it does not establish a factual trigger and task the Secretary with "deeming" in the event he or she finds such facts to be present; and did not even include a broadly-stated policy aim, such that the Secretary shall deem a given product if doing so was judged to be beneficial to the "public interest" or similar aim.

Indeed, the *FDA itself* is on record stating that its deeming authority is *not constrained by any policy parameters set by Congress*. In issuing

---

[13] In fact, in the twelve-month period before the TCA was enacted, the FDA had issued import refusal reports denying entry to nearly forty shipments of "electronic cigarettes" and their components, characterizing them as unapproved drug-device combinations under the FD&C Act, as they were apparently expressly marketed as a safer alternative to traditional cigarettes. *See Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 64-65 (D.D.C. 2010), *aff'd sub. nom. Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

the final Deeming Rule, FDA forcefully rejected a commenter's suggestion that the statute did not grant FDA authority to deem *all* products meeting the statutory definition of "tobacco product" "in sweeping manner," but rather must "deem" only on a product-by-product, or category-by-category, basis. 81 Fed. Reg. 28982 ("There is no provision in the statute that restricts FDA's authority to deem all tobacco products that meet the statutory definition or requires FDA to deem products on an individual or product category basis."). Rejecting arguments "largely from the ENDS industry" "that FDA is required to establish that deeming will benefit public health," FDA gently explained that "[t]hese comments attempted to impose a standard for the application of FDA's deeming authority that is not created by statute or otherwise." Id. at 28983. [14]

While the FDA is therefore unbound by any standard and can deem all "tobacco products" at once, it is also free to make distinctions—if it wants to make distinctions—as reflected by the fact that FDA considered

[14] This statement was also relied upon by the district court in *Nicopure*, in the course of holding that FDA was not required to accept any suggested regulatory alternatives under the APA. 266 F. Supp. 3d at 398; *see also id.* at 401 (holding that "[t]he statute does not limit the Secretary's authority to deem to when he finds it 'appropriate and necessary' to do so," and therefore there is "no source for a requirement that costs be taken into account when the deeming power is exercised").

leaving "premium cigars" unregulated when it proposed the Deeming Rule.[15]

Defending itself against an APA challenge to the Deeming Rule in 2017, the FDA wrote that "Congress authorized the FDA to subject 'any' tobacco product (except certain raw tobacco leaf) 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.);[16] *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 federal district court agreed with the FDA, recognizing that "the statute did not provide standards for when and

[15] Proposed Rules, 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;, 79 Fed. Reg. 23142-01, 23144 (Apr. 25, 2014) ("As noted previously, given that different kinds of cigars may have the potential for varying effects on public health, FDA is proposing two options for the categories of cigars that would be covered by this rule. FDA is specifically seeking comment on whether all cigars should be subject to deeming and what provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars.").

[16] 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).

how the agency was to exercise its discretion to deem[.]" *Nicopure Labs, LLC*, 266 F. Supp. 3d at 393.[17]

c. This unbounded delegation of "deeming" authority violates the Constitution.

i. *Panama Refining Co. v. Ryan*

Panama Refining Company v. Ryan involved a challenge to section 9(c) of the National Industrial Recovery Act (NIRA), dealing with "hot oil," or oil produced in excess of state allowances. 293 U.S. at 418. Congress "authorized" the President "to prohibit the transportation in interstate or foreign commerce" of petroleum products "produced or withdrawn from storage in excess of the amount permitted to be produced or withdrawn from storage by any State" law or regulation. *Id.* at 406. The Act was passed in June 1933, and less than a month later, President Roosevelt issued an executive order utilizing this authorization. The order prohibited transportation of oil produced or withdrawn in excess of state allowances, tracking the language of the statute. *Id.* at 405. Addressing the claim that

[17] 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. To counsel's knowledge, the nondelegation doctrine has not been asserted in any other litigation involving the Deeming Rule.

the statute worked "an unconstitutional delegation of legislative power," the Court introduced the analysis as follows:

> The subject to which [the President's] authority relates is defined. It is the transportation in interstate and foreign commerce of petroleum and petroleum products which are produced or withdrawn from storage in excess of the amount permitted by state authority. Assuming for the present purpose, without deciding, that the Congress has power to interdict the transportation of that excess in interstate and foreign commerce, the question whether that transportation shall be prohibited by law is obviously one of legislative policy. Accordingly, we look to the statute to see whether the Congress has declared a policy with respect to that subject; whether the Congress has set up a standard for the President's action; whether the Congress has required any finding by the President in the exercise of the authority to enact the prohibition.

293 U.S. at 414-15 (emphasis added). The Court examined the statute and found no such limits:

> Section 9(c) 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 (emphasis added).

Panama Refining distinguished NIRA § 9(c) from the provision upheld in *Field v. Clark*, 143 U.S. 649 (1892). That statute provided that, "'with a view to secure reciprocal trade' with countries producing certain articles," whenever the President ascertained that a country was imposing duties "'deem[ed] to be reciprocally unequal and unreasonable, he shall have the power and it shall be his duty,'" to issue a proclamation triggering the imposition of duties set out in the statute. 293 U.S. at 425 (quoting *Field, supra*, at 680). Because "'the suspension was *absolutely required* when the president ascertained the existence of *a particular fact*,'" the President was not making law but merely serving as the legislature's agent. *Id.* at 426 (quoting *Field, supra*, at 692-93) (emphasis added).[18]

While *Panama Refining* recognizes Congress's practical need for "flexibility and practicality" in order to function properly, the Court also held that this recognition "cannot be allowed to obscure the limitations of the authority to delegate, if our constitutional system is to be maintained."

---

[18] The statute considered in *Field* is also distinguishable because it overlaps with power regarding foreign affairs that is within President's own article II authority. *See Gundy v. United States*, 139 S. Ct. 2116, 2137 (2019) (Gorsuch, J., dissenting) (discussing line of cases involving delegations of discretion in matters "already within the scope of executive power"). *See also Brackeen v. Bernhardt*, 937 F.3d 406, 436-37 (5th Cir. 2019) (rejecting delegation challenge, holding that federal statute incorporated inherent tribal authority), *reh'g en banc granted*, 942 F.3d 287.

Id. at 421. *Panama Refining* held that NIRA § 9(c) unconstitutionally delegated legislative power:

> As to the transportation of oil production in excess of state permission, the Congress has declared no policy, has established no standard, has laid down no rule. There is no requirement, no definition of circumstances and conditions in which the transportation is to be allowed or prohibited.
>
> If section 9(c) were held valid, it would be idle to pretend that anything would be left of limitations upon the power of the Congress to delegate its lawmaking function.

293 U.S. at 430.

ii. TCA § 387a(b) is unconstitutional under *Panama Refining*.

Panama Refining, and the longstanding conception of "legislative" power common to all the Court's nondelegation jurisprudence, compel the conclusion that the TCA violates the nondelegation doctrine.

First, it is important to note that the statute declared unconstitutional in *Panama Refining* did not confer limitless authority on the President to regulate any industry in any way he saw fit. Instead, the Court began 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 or withdrawn from storage in excess of the amount permitted by state authority." 293 U.S. at 415.

In the instant case, "[t]he subject to which" the challenged authority relates is the range of products meeting the TCA's definition of "tobacco products." This subject is itself even broader than the subject in *Panama Refining*, which at least was constrained to only a subset of petroleum products (those produced in excess of state-law limitations), defined in a way so as to include only a subset of products that could be said to be especially problematic (in that they violated another extant legal standard, albeit under state law).

After acknowledging the limited subject matter at issue, *Panama Refining* held that "the question whether ... transportation [of hot oil] shall be prohibited by [federal] law *is obviously one of legislative policy*." 293 U.S. at 415 (emphasis added). This holding reflects a principle that has animated the Court's nondelegation cases from *Field v. Clark* through *Gundy v. United States*: the authority to decide the factors or circumstances under which a given activity or product shall be subjected to a certain field of regulation is quintessentially one of legislative policy. In *Field*, the Court held that legislative power had not been delegated because Congress itself had established that the President must issue a proclamation if he ascertains that a covered country is imposing "reciprocally unequal and unreasonable" duties:

> As the suspension was absolutely required when the president ascertained the existence of a particular fact, it cannot be said that in ascertaining that fact, and in issuing his proclamation, in obedience to the legislative will, he exercised the function of making laws. Legislative power was exercised when congress declared that the suspension should take effect *upon a named contingency*.

143 U.S. at 693 (emphasis added). Similarly, the *Gundy* plurality only rejected the petitioner's nondelegation argument after interpreting the Sex Offender Registration and Notification Act (SORNA) "to *require* the Attorney General to apply SORNA to *all* pre-Act offenders *as soon as feasible*." 139 S. Ct. at 2123 (emphasis added). Gundy had argued that the operative provision "grants the Attorney General plenary power to determine SORNA's applicability to pre-Act offenders—to require them to register, or not, as she sees fit[.]" *Id.* The Court acknowledged that "[i]f that were so, we would face a nondelegation question," *id.*, but avoided it by holding that SORNA did not grant such discretion, *id.* at 2125.

By contrast, Congress unconstitutionally ceded legislative power when it vested the President with the authority to determine whether the transportation of hot oil should be prohibited by federal law without any guiding principles. *Panama Refining*, 293 U.S. at 415.

It follows that the question whether this or that tobacco product, or all of them, or none of them, shall be regulated under the TCA "is obviously

one of legislative policy." However, Congress failed to state "whether or in what circumstances or in what conditions" a product should be deemed, establish any criteria or broadly stated limiting principle, or require any factual finding. *See* 293 U.S. at 415.

The Supreme Court held NIRA § 9(c) unconstitutional even though the statute expressly "declare[d] that a national emergency exists which is 'productive of widespread unemployment and disorganization of industry,'" *id.* at 416-17,[19] and the relevant authority was merely to prohibit the interstate transportation of certain commodities already illegal under state law, and which the President exercised less than a month after the NIRA became law. The TCA's deeming provision extends substantially further, granting the Executive Branch unchecked authority to regulate, *or not regulate*, a whole swath of products, without limitation to any subset of such products in violation of other law (or any other limitations), and FDA exercised that authority nine years after the TCA was enacted, deciding—in its infinite discretion—to regulate not only all those products Congress itself refused to regulate, but also an entirely new industry of products that are materially different. Much more than a mere definition of "country

[19] *See also Panama Refining*, 293 U.S. at 443 (Cardozo, J., dissenting) (noting "[t]he statute was framed in the shadow of a national disaster").

elevators," an entire industry—or at least an entire nation's worth of small businesses in the industry, including Big Time Vapes and the USVA's members—are threatened with extermination pursuant to the FDA's unilateral policy choice. Moreover, affected businesses have no avenue for challenging the application of the TCA to their industry or business, *precisely because* the TCA lacks any substantive standard. *Cf. American Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946) (noting, after finding a sufficiently limiting principle, that "[p]rivate rights are protected by access to the courts to test the application of the policy in the light of these legislative declarations"); *Yakus*, 321 U.S. at 426.

The deeming provision therefore violates the principle of nondelegation under *Panama Refining* and, unlike in *Gundy*, there is no way to save the statute by interpreting § 387a(b) as if it *required* all, or any, tobacco products to be "deemed."

iii. *Womack* is distinguishable.

Womack considered a statute providing that "[i]t shall be unlawful for any person ... to engage in the business of importing, manufacturing, or dealing in explosive materials" without a license. 654 F.2d at 1036 n.1. The statute defined "explosive materials" to mean "explosives, blasting agents, and detonators," and defined "explosives" as follows:

> any chemical compound mixture, or device, the primary or common purpose of which is to function by explosion; the term includes, but is not limited to, dynamite and other high explosives, black powder, pellet powder, initiating explosives, detonators, safety fuses, squibs, detonating cord, igniter cord, and igniters. The Secretary shall publish and revise at least annually in the Federal Register a list of these and any additional explosives which he determines to be within the coverage of this chapter.

Id. (emphasis added).

Womack thus addressed a question materially distinct from the TCA. The federal statute in *Womack* applied the offense to *all* "explosives." The statute includes an illustrative list of items, but expressly states that the term "includes, but is not limited to" those items. *Womack* falls within the line of cases in which Congress delegated a fact-finding function to the agency—to determine which additional materials meet Congress's definition of "explosive" and, if so, list it. There was no suggestion that the Attorney General was authorized to (i) find that something fit the definition of "explosive," but then (ii) decline to list it in his discretion. The TCA's deeming provision would only be analogous if it stated that "this chapter shall apply to *all tobacco products*," followed by an inexhaustive list. Instead, Congress wrote that "this chapter shall apply" to identified *sub-categories* of tobacco products, even though there were—indisputably—other tobacco products that Congress deliberately omitted (*e.g.*, hookah

and cigars). The problem here is that the statutory definition is clearly not the only determinant, but Congress provided no further guidance.

Reading *Womack* otherwise—as if the statute vested the Attorney General with the discretion to simply decline to list something that qualified as an "explosive"—would place this Court's decision upholding the statute in clear tension with consistent Supreme Court precedent. *Field* held that the "[l]egislative power was exercised when congress declared that the suspension should take effect *upon a named contingency*," and relied on the fact that suspension was "*absolutely required* when the president ascertained the existence of a particular fact." 143 U.S. at 693. If the "named contingency" were not the definition of "explosive" itself, but some additional contingency thought to be important in the Attorney General's discretion—the parameters of which are nowhere discussed in *Womack*—it would have presented an obvious nondelegation problem. Yet there is no indication that Mr. Womack made any argument that such second-level discretion existed, nor did the Court give any such indication. Indeed, the FDA's invitation to read *Womack*'s statute as if it granted uncabined discretion to determine whether an "explosive" should be listed is an invitation to interpret the statute in precisely the manner that the *Gundy*

plurality expressly eschewed interpreting SORNA, in order to avoid the nondelegation question. *See* 139 S. Ct. at 2127.

Finally, even if the FDA's suggested interpretation of the statute in *Womack* were plausible, the parties in *Womack* did not argue such was the case and the Court's opinion does not address it. It is "black letter law" that "'a question not raised by counsel or discussed in the opinion of the court' has not 'been decided merely because it existed in the record and might have been raised and considered.'" *De La Paz v. Coy*, 786 F.3d 367, 373 (5th Cir. 2015) (quoting *United States v. Mitchell*, 271 U.S. 9, 14 (1926)); *see also Texas v. Cobb*, 532 U.S. 162, 169 (2001) ("Constitutional rights are not defined by inferences from opinions which did not address the question at issue."); *cf. Hagans v. Lavine*, 415 U.S. 528, 535, n.5 (1974) ("[W]hen questions of jurisdiction have been passed on in prior decisions sub silentio, this Court has never considered itself bound when a subsequent case finally brings the jurisdictional issue before us.").

d. The FDA's authority is inapposite.

Defendants' various other efforts to escape the holding of *Panama Refining* are unavailing.

i. FDA cannot seek refuge in precedent upholding broadly-worded "intelligible principles" where TCA § 387a(b) incorporates *no* principle.

Predictably, Defendants made repeated and strenuous reference to the fact that, as observed most recently in *Gundy*, the Court has "over and over upheld even very broad delegations." 139 S. Ct. at 2129. This is true enough, but cases and controversies are not decided based on generalities.

Defendants can point to no case upholding a statute like the TCA's deeming provision. Every case rejecting a nondelegation argument has done so only because—broad as it may be—the statute at issue incorporates some limiting principle beyond the fact that the authority operates within a given field of activity. For example, *Gundy* cites cases upholding delegations to regulate "in the 'public interest,'" *id.* at 2129 (citing *National Broadcasting Co. v. United States*, 319 U.S. 190, 216 (1943), and *New York Central Securities Corp. v. United States*, 287 U.S. 12, 24 (1932)), "authorizations for agencies to set 'fair and equitable' prices and 'just and reasonable' rates," *id.* at 2129 (citing *Yakus v. United States*, 321 U.S. 414, 422 (1944), and *FPC v. Hope Natural Gas Co.*, 320 U.S. 591 (1944)), and "a delegation to an agency to issue whatever air quality standards are 'requisite to protect the public health,'" *id.* (citing *Whitman*, 531 U.S. at 472). These cases are among those most frequently cited as representing the outer bounds of permissible delegations under current law. *See, e.g.*, *Loving v. United States*, 517 U.S. 748, 772 (1996) (citing *NBC*); *Whitman*,

531 U.S. at 474 (citing *NBC* and *Yakus*, among others); *United States v. Whaley*, 577 F.3d 254, 263-64 (5th Cir. 2009) (citing *NBC*, *Yakus*, and *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)).

Thus, even the most extreme examples of upheld delegations included some basic standard manifesting Congressionally-determined policy and limiting the agency's discretion.[20]

ii. The fact that the Secretary's deeming authority is limited to the field of "tobacco products" does not substitute for the required "intelligible principle."

Panama Refining began its analysis by recognizing that "[t]he subject to which [the President's] authority relates is defined" as the narrow field of oil produced in violation of the limits allowable under state law and regulations. 293 U.S. at 414-15. The statute was nonetheless unconstitutional because it gave the President the authority to prohibit that transportation, or not prohibit it, without laying down any principles or standards to guide his discretion. *Every* delegation case involves a delegated task that operates within a certain field of activity; resolution of

---

[20] While the deeming provision is so standardless that it fails even the permissive review called for under the Court's current jurisprudence, Plaintiffs note that the current standard applied by courts is unduly permissive and the nondelegation doctrine should be more vigorously enforced by the judiciary, as required by the structural principles of the Constitution. *See Gundy*, 139 S. Ct. at 2131 (Gorsuch, J., dissenting). While the circuit court need not wade into that debate, because Plaintiffs prevail under current law, Plaintiffs note that argument for purposes of Supreme Court review.

the case requires determining "what task it delegates and *what instructions it provides*." *Gundy*, 139 S. Ct. at 2123 (emphasis added). 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. For example, in *Gundy*, while the challenged authority was circumscribed within the narrow field of "sex offenders" as defined in the statute, *id.* at 2122 (acknowledging SORNA's "sex offender" definition), the separation of powers required the Court to analyze whether Congress had sufficiently limited the Attorney General's discretion to determine SORNA's applicability to pre-Act offenders, *id.* at 2123.

iii. 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.

Defendants place much emphasis on the fact that Congress has articulated exactly what restrictions and requirements apply to any deemed tobacco products once they are subjected to the TCA. ROA.480-81, 483. This is true, but it does not remedy the lack of any standards to guide the

Secretary's decision whether to subject any product to these restrictions or not.

Plaintiffs wrote in their memorandum that "the authority to decide the factors or circumstances under which a given activity or product shall be subjected to a certain field of regulation is quintessentially one of legislative policy." ROA.400. This is a fundamental principle consistently reflected in nondelegation jurisprudence. *Field v. Clark* rejected the argument that the President's authority to issue a proclamation, upon finding the existence of certain predicate facts, violated the principle, because "Legislative power was exercised when *congress* declared that the suspension should take effect *upon a named contingency*." 143 U.S. at 693. In 1941, the Court wrote that "[t]he adoption of the declared policy by Congress *and its definition of the circumstances in which its command is to be effective*, constitute the performance, in the constitutional sense, of the legislation function." *Opp Cotton Mills v. Admin. of Wage and Hour Division of Dep't of Labor*, 312 U.S. 126, 144 (1941) (emphasis added). *Yakus v. United States*, 321 U.S. 414 (1944), noted that "[t]he essentials of the legislative function … are preserved when Congress has specified the basic conditions of fact upon whose existence or occurrence, ascertained from relevant data by a designated administrative agency, it directs that its

statutory command shall be effective." Commensurate with this principle, *Panama Refining* held that "the question whether ... transportation [of hot oil] shall be prohibited" or not "is obviously one of legislative policy," and struck down the statute because Congress had failed to provide any relevant guidance. 293 U.S. at 415. By failing to state any standard, Congress left to the Executive the legislative authority to determine whether or under what circumstances any given tobacco product should be regulated.

This deficiency is not rectified by the fact that Congress has written a detailed code that shall apply to any product the Secretary decides to deem. For example, in *Touby v. United States*, the plaintiff challenged § 201(h) of the Controlled Substances Act (CSA), granting authority to the Attorney General to temporarily assign substances presenting an "imminent hazard to the public safety" to one of the five categories (or "schedules") of substances under the CSA. 500 U.S. 160, 160-165 (1991). The nondelegation challenge was not answered merely by reference to the fact that, *once scheduled*, a detailed statutory scheme applied to the substance. Instead, the Court examined whether Congress had provided sufficient guidance to "meaningfully constrain" the Attorney General's discretion to temporarily schedule the substance in the first place. *Id.* at 166. 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.

iv. Congress' broad and contradictory statements of purpose do not provide meaningful policy guidance.

It is true that "[t]he standards of the [challenged] 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." *Womack*, 654 F.2d at 1037 (citing *American Power & Light*, 329 U.S. at 105). This does not save the TCA's deeming provision, for three reasons. First, there is *no statutory standard* to be fleshed out with reference to the general declarations of purpose. Second, the declarations of purpose are both amorphous and self-contradictory, as some purposes are in direct tension with other purposes. Third, even if one *could* discern a guiding principle from the statements of purpose, reading the statute as a whole requires recognizing that Congress limited the TCA's application to a subset of tobacco products, precluding any attempt to derive "meaningful content" from the prefatory section of the Act alone.

The Defendants' primary authority for this point, *American Power & Light Co. v. SEC*, 329 U.S. 90 (1946), is far afield. While broadly stated, the relevant provision of the Public Utility Holding Company Act of 1935 imposed the kind of substantive standard that is entirely lacking in § 387a(b). Section 11(b)(2) of that Act "provide[d] that the Commission shall act so as to ensure that the corporate structure or continued existence of any company in a particular holding company system does not 'unduly or unnecessarily complicate the structure' or 'unfairly or inequitably distribute voting power among security holders.'" 329 U.S. at 104. The Court held that "even standing alone, standards in terms of unduly complicated corporate structures and inequitable distribution of voting power cannot be said to be utterly without meaning, especially to those familiar with corporate realities." *Id.* It was then the Court provided the language Defendants here rely upon, stating that "*these standards* need not be tested in isolation." *Id.* (emphasis added). The Act's other provisions provided a *consistent* framework fleshing out what Congress had in mind by "unduly or unnecessarily complicated structures" and inequitable distribution of voting power, including not just the "general policy declarations," but also the "standards for new security issues set forth in s 7, the conditions for acquisitions of properties and securities prescribed in s 10, and the nature

of the inquiries contemplated by s 11(a)—a veritable code of rules ... for the Commission to follow in giving effect to the standards of s 11(b)(2)." *Id.* at 105.

Here, by contrast, the TCA provides *no* standard to guide the Secretary's deeming decisions. That fatal deficiency places this case under the controlling authority of *Panama Refining*, which directly rejected the government's attempt to salvage a standardless statute by importing some broadly-stated principle cherry-picked from the act's prefatory section of "diverse objectives." 293 U.S. at 417-18. The Court observed that NIRA's "general outline of policy contains nothing as to the circumstances or conditions in which transportation of petroleum or petroleum products should be prohibited," and "[t]he Congress did not say that transportation of that oil was 'unfair competition,'" or "declare in what circumstances that transportation should be forbidden, or require the President to make any determination as to any facts or circumstances." *Id.* at 418. While prohibiting the transportation of hot oil might have furthered some of the policy aims identified in the law (*e.g.*, "eliminat[ing] unfair competitive practices" and "conserv[ing] natural resources" during a wartime emergency), it might have hindered other purposes (including "remov[ing] obstructions to the free flow of interstate and foreign commerce which tend

to diminish the amount thereof"). 293 U.S. at 418. The statute delegated legislative power because "[a]mong the various and diverse objectives broadly stated, the President was not required to choose" which policy to pursue. *Id.*

The TCA's listed purposes are likewise "various and diverse" and are in actual tension with one another. Commissioner Gottlieb candidly acknowledged the "hard tradeoffs … we're grappling with" between addressing youth use on the one hand, and maintaining ENDS on the market for adults transitioning from traditional cigarettes on the other. ROA.28. Regardless of what the evidence showed on any particular aspect of these issues, the Constitution does not permit the agency to decide unilaterally which particular ambiguous statutory purpose shall prevail, and make these decisions, without sufficient guidance.

Further illustrating the boundless deeming discretion is the fact that the FDA deemed all "tobacco products" in one fell swoop, including all those Congress deliberately omitted in 2009.

Lastly, and perhaps most importantly, even if one *could* discern some kind of workable principle from the TCA's prefatory statements of purpose, FDA cannot ignore the fact that, despite these general statements, Congress limited the application of the TCA to cigarettes and smokeless tobacco, and

failed to outline why or when the Secretary should deem anything else. Congress's careful circumscription of the TCA reflects a legislative determination to leave many types of tobacco products entirely unregulated except at the Secretary's whim.

The *Gundy* plurality supports Plaintiffs, not Defendants, on this point. The relevant provision of SORNA provided that "[t]he 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[.]" *Gundy*, 139 S. Ct. at 2122. The plurality began by explaining that the Court in *Reynolds v. United States*, 565 U.S. 432 (2012), had "already interpreted [the statute] to ... *require* the Attorney General to apply SORNA to *all* pre-Act offenders *as soon as feasible*," *id.* at 2123 (citing *Reynolds*, 565 U.S. at 442-43) (italics added). Unlike with SORNA, there is no way to read the deeming provision as if it *required* the Secretary to deem any particular product, or category of products, to be subject to the requirements of the TCA.

Congress's deliberate limitation of the TCA's reach (and standardless delegation) similarly precludes the FDA from seeking support in any other provisions that it has cited. So, while § 393(b)(1) (cited by FDA at ROA.487, 489, and 499) authorizes the FDA to "tak[e] appropriate action

on the marketing of *regulated* products in a timely manner," this authority is predicated on the FDA's unilateral decision to regulate ENDS in the first place.

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

Plaintiffs have easily stated a plausible claim for relief, especially given the binding authority of *Panama Refining*, and the district court erred in dismissing the case.[21] However, if the lower court had any doubts about the sufficiency of the claim, it should have permitted reasonable discovery.

To be clear, Plaintiffs have established likelihood of success on the merits, and should win on the merits if this case is remanded, without any discovery. But Plaintiffs do not have to concede their right to discovery just because they believe they should win as a matter of law. The trial phase is a litigant's only opportunity to build a merits record, and Plaintiffs believe that an appropriate discovery phase may yield evidence that this Court, or

---

[21] This is distinguishable from situations in which a complaint is properly dismissed where a plaintiff's claim, however factually elaborate, fails simply because there is no valid cause of action under the relevant substantive law. *See, e.g.*, *Collins*, 224 F.3d 496 (dismissing suit because plaintiff shareholders are not within the class of beneficiaries who have a right to sue in contract under New York law).

the Supreme Court, would find very relevant regarding the nondelegation claim.

Undermining the assumption that "expert" agencies make disinterested decisions. A standard refrain in delegation cases is the notion that broad delegations of authority are a practical necessity so that "experts" in the Executive Branch can deal with the minutiae that Congress cannot. *See, e.g.*, *Mistretta v. United States*, 488 U.S. 361, 372 (1989). This is a broad-based assumption that has come to be treated as an article of faith. The district court cited this principle below. ROA.722. But it is an assumption of fact; it assumes that agencies with experts will make disinterested decisions even when vested with ever-increasing authority over policy. As an assumption of fact, it is subject to refutation by evidence, both broadly and as-applied.

Plaintiffs contend that this case aptly illustrates that delegating *too much* authority not only short-circuits the legislative process *but also undermines the proper functioning of the experts and agencies of the Executive*.

Vesting HHS or FDA with unilateral authority to make legislative decisions skewed the agency's incentives, which had the effect of subjugating the science to the policy agenda. Plaintiffs expect to seek

documents and perhaps depositions that will reflect that the scientists at FDA/CDC recommended more precise (and useful) statements pinpointing the causes of EVALI, and the types of ENDS preferred by youth, but these statements were generalized by political staff in order to engender public support for FDA's preferred policy—the undifferentiated and heavy-handed regulation of ENDS.

Refuting Defendants' claims that Congress' intent in 2009 supports deeming ENDS and minimizing the economic impact of deeming. Defendants' combined memorandum is replete with references to factual material, including scientific studies, that are woven into Defendants' argument on the merits of the nondelegation claim but are wholly outside of Plaintiffs' complaint.[22] Fairness dictates that, if the government is going to proffer statements of fact and cite factual material in support of its motion, Plaintiffs have the opportunity to refute and contextualize those facts, especially to show that the dangers of combustible products referenced in the legislative record do not apply to ENDS (therefore undermining the argument that deeming ENDS is easily

[22] Even if a plaintiff attaches or incorporates parts of a certain document in his complaint, that does not open the door for a defendant to rely on other parts of even that same document to support a motion to dismiss over plaintiff's objection. *Scanlan*, 343 F.3d at 536-39.

consistent with Congress's purpose in 2009). *See, e.g.*, ROA.457-59 (Defendants citing dangers from combustible products); ROA.611 (Plfs' response regarding discovery).

Both parties cite the statement in *Whitman*, 531 U.S. at 475, that "the degree of agency discretion that is acceptable varies according to the scope of the power" delegated, ROA.395 (*Plfs' Mem.*), ROA.488 (*Defs' Mem*.), and the district court cited it as well. ROA.723. While it is obvious on its face that deeming several entire industries has a significant economic impact, imposing an even stricter requirement for Congress to provide sufficient guidance, to the extent there is any doubt on this issue, Plaintiffs are entitled to the opportunity to secure admissible evidence reflecting the size of the ENDS industry and other newly-deemed industries (cigars, etc.), the jobs at stake, the number of smokers transitioning, etc., before their case can be dismissed. *See, e.g.*, *Util. Air Regulatory Group v. E.P.A.*, 573 U.S. 302, 322-324 (2014) (relying on data as to impact of regulation); *Paul v. United States*, 140 S. Ct. 342 (KAVANAUGH, J., statement respecting denial of cert.) (indicating interest in consideration of "congressional delegations to agencies of authority to decide major policy questions" in light of *Gundy* dissent).

IV. The District Court Erred in Denying the Injunction.

As argued above, not only have Plaintiffs stated a plausible nondelegation claim, they have demonstrated that they are likely to succeed on the merits. Consequently, the district court's holding that Plaintiffs failed to meet their burden on this first element of injunctive relief (ROA.724) should be reversed. Because the district court did not analyze the remaining elements of injunctive relief, ROA.724, consistent with this Court's normal practice, the district court should consider the remaining elements in the first instance on remand. *See, e.g.*, *Sierra Club, Lone Star Chapter v. F.D.I.C.*, 992 F.2d 545, 551-52 (5th Cir. 1993).

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,

/s/ Jerad Wayne Najvar
Jerad Wayne Najvar
Tex. Bar No. 24068079
jerad@najvarlaw.com
Austin M.B. Whatley
Texas Bar No. 24104681
austin@najvarlaw.com
NAJVAR LAW FIRM, PLLC

2180 North Loop W., Ste. 255
Houston, Texas 77018
[Tel.] (281) 404-4696
[Fax.] (281) 582-4138
ATTORNEYS FOR APPELLANT

CERTIFICATE OF SERVICE

I certify that the foregoing document was filed with the Court in electronic format through the CM/ECF system, on February 20, 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 12,945 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.

s/ Jerad Wayne Najvar
Jerad Wayne Najvar

CERTIFICATE OF ELECTRONIC COMPLIANCE

Counsel also certifies that on February 20, 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.

s/ Jerad Wayne Najvar
Jerad Wayne Najvar