NO. 25-40135

In the United States Court of Appeals for the Fifth Circuit

KEALANI DISTRIBUTION, L.L.C.; UNITED STATES VAPING ASSOCIATION, INCORPORATED; DIAMOND VAPOR, L.L.C.; JOHNNY COPPER, L.L.C.; SWT GLOBAL SUPPLY, INCORPORATED; CAROLINA VAPOR MILL, L.L.C.; CAROLINA VAPOR MILL WOODRUFF ROAD; CVM3, L.L.C.,
Plaintiffs-Appellants/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, COMMISSIONER OF FOOD AND DRUGS; ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendant-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Eastern District of Texas, Sherman Division

BRIEF OF APPELLANTS

Jerad Wayne Najvar
CHALMERS, ADAMS, BACKER & KAUFMANN, LLC
2180 North Loop West, Ste. 255
Houston, Texas 77018
(281) 404-4696 – Telephone
jnajvar@chalmersadams.com
Counsel for Appellants

CERTIFICATE OF INTERESTED PERSONS

Appellant 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:

Petitioners and Owners of Petitioners:

United States Vaping Association, Inc.

Kealani Distribution LLC

Tracy Jones

Michael Whitehead

Diamond Vapor LLC

Keith Fairman

Sarah Fairman

Johnny Copper LLC

Justin Marlin

SWT Global Supply Inc.

William Thomas

Carolina Vapor Mill LLC

Carolina Vapor Mill Woodruff Road

CVM3 LLC

Lee Lance

Counsel for Petitioner:

Jerad Najvar

Respondent:

U.S. Food and Drug Administration

Marty Makary, Commissioner of Food and Drug Administration

Robert F. Kennedy, Jr., Secretary, Health and Human Services

Counsel for Respondent:

Scott P. Kennedy

Kimberly R. Stephens

Lindsey E. Powell

Michael S. Raab

Sophia Shams

/s/ Jerad Najvar
Jerad Najvar
Counsel for Plaintiff-Appellant

STATEMENT REGARDING ORAL ARGUMENT

This case presents a challenge under a statute, the Regulatory Flexibility Act, that has not frequently been applied, in this Circuit or in other Circuits. While Appellees strive to present Plaintiffs' arguments as nothing other than a run-of-the-mill objection to an agency's factual decisionmaking, the circumstances here in fact reflect a federal agency's fundamental misapprehension of the RFA and its duties to assess regulatory alternatives to a formal rule that might satisfy statutory objectives with less burden on small entities. The district court accepted FDA's characterization; Plaintiffs-Appellants believe oral argument would help illuminate the true, and deficient, nature of FDA's certification.

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STATEMENT OF JURISDICTION

Plaintiffs brought this action under the judicial review provision of the Administrative Procedure Act and Regulatory Flexibility Act. ROA.10; 5 U.S.C. § 611(a). The complaint, filed October 4, 2022, invoked the district court's federal question jurisdiction pursuant to 28 U.S.C. §§ 1331. Plaintiffs sought declaratory and injunctive relief under 28 U.S.C. §§ 2201-02 and Federal Rule of Civil Procedure 65. ROA.10.

Defendants-Appellees Food and Drug Administration, Robert M. Califf, M.D., in his official capacity as the Commissioner of the Food and Drug Administration, and Xavier Becerra, in his official capacity as Secretary of Health and Human Services, filed their answer on December 23, 2022. ROA.51-62.[1] After entry of a protective order requested by FDA to protect certain proprietary information in the administrative record, FDA filed the Index to the Administrative Record on September 8, 2023. ROA.155.

Plaintiffs filed their motion for summary judgment in January 2024. ROA.201-225. FDA filed a combined cross-motion for summary judgment and opposition to the Plaintiffs' motion in February 2024. ROA.226-253. Plaintiffs filed a response and reply brief in March 2024. ROA.260-274.

[1] Califf and Becerra have since been substituted by the current holders of their respective offices.

FDA filed a reply in support of its motion for summary judgment in April 2024, ROA.282-299, and the parties' Joint Appendix was filed in May 2024, ROA.300 et seq.

Without setting any hearing for argument, the district court issued a memorandum opinion and order on February 12, 2025, ROA.1120-1136, and a judgment the same date. ROA.1137. Plaintiffs' notice of appeal was timely filed March 14, 2025. ROA.1138.

This Court has jurisdiction over this appeal pursuant to 28 U.S.C. § 1291.

STATEMENT OF ISSUES

1. Whether the FDA's "certification" that the 2021 PMTA Final Rule would not "have a significant economic impact on a substantial number of small entities" was arbitrary and capricious.

STATEMENT OF THE CASE

I. The "Tobacco Control Act"

In 2009, Congress amended the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA") by passing the Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1777 (2009) (the "Tobacco Control Act" or "TCA"), *codified at* 21 U.S.C. 387 *et seq*.[2] The Tobacco Control Act mandates that "[t]obacco products … shall be regulated by the Secretary [of Health and Human Services] under this subchapter," rather than the FDCA subchapters governing "drugs" and "devices." 21 U.S.C. § 387a. "Tobacco product" is defined to mean:

> any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

21 U.S.C. § 321(rr)(1).[3]

While tobacco products fitting the statutory definition were extant in many and long-established forms when Congress enacted the TCA—including cigarettes, cigars, smokeless tobacco, and hookah—Congress

[2] 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.

[3] The terms "component," "part," and "accessory" are not further defined by statute.

did not choose to impose the Act's requirements on all such forms of tobacco products. Instead, Section 901 of the TCA provides 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." *Id.*, *codified at* 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* were all other forms of tobacco products, including products as the vapor products manufactured by Plaintiffs, as well as cigars and hookah.

While Congress itself declined to impose the TCA's requirements on anything other than cigarettes or "smokeless tobacco," it vested the Secretary of Health and Human Services with the authority 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).

II. The Regulatory Flexibility Act

This authority delegated to the Secretary sat latent for nearly a decade. Before discussing the two rulemakings relevant to this litigation, a review of pertinent provisions of the Regulatory Flexibility Act is in order.

The RFA amended the Administrative Procedures Act (APA) with specific provisions aimed at ensuring agency consideration of regulatory impact on small business. *See* PAUL R. VERKUIL, A CRITICAL GUIDE TO THE REGULATORY FLEXIBILITY ACT, 1982 Duke L.J. 213, 226-69. However, the scope of the RFA is limited: it applies only to notice-and-comment rulemaking. Particularly pertinent to the case at bar, the RFA requires an initial and final "regulatory flexibility analysis."

"Whenever an agency is required by section 553 of this title, or any other law, to publish general notice of proposed rulemaking for any proposed rule … the agency shall prepare and make available for public comment an initial regulatory flexibility analysis." 5 U.S.C. § 603(a). The initial regulatory flexibility analysis (IRFA) "shall describe the

impact of the proposed rule on small entities." *Id.* This analysis must be published in the Federal Register with the general notice of proposed rulemaking, and shall be transmitted directly to "the Chief Counsel for Advocacy of the Small Business Administration." *Id.* Each IRFA shall include certain general components such as "a description of the reasons why action by the agency is being considered," the objectives and legal basis for the rule, and "a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply." 5 U.S.C. § 603(b). It "shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities." *Id.* § 603(c).

Upon publishing a final rule, the agency must publish a "final regulatory flexibility analysis." 5 U.S.C. § 604(a) (emphasis added). This final analysis shall include, *inter alia*, "a statement of the need for, and objectives of, the rule"; discussion of any "significant issues raised by public comments" and the agency's response to same; and "the response of the agency to any comments filed by the Chief Counsel for Advocacy of the [SBA]." *Id.* Also required is

> a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

5 U.S.C. § 604(a)(6).

An agency can avoid the requirements of the initial and/or final regulatory flexibility analysis by certifying that the rule will not have a significant impact on small business. Section 605(b) provides:

> Sections 603 [regarding the IRFA] and 604 [regarding the final regulatory flexibility analysis] of this title shall not apply to any proposed or final rule *if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities*. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration.

5 U.S.C. § 605(b) (emphasis added).

The RFA includes a limited provision for judicial review. "[A] small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements

of sections 601, 604, 605(b), 608(b), and 610 in accordance with [APA] chapter 7." *Id.* § 611(a)(1). The RFA specifically provides:

> In granting any relief in an action under this section, the court shall order the agency to take corrective action consistent with [APA chapter 6] and chapter 7, including, but not limited to--
>
> (A) remanding the rule to the agency, and
>
> (B) deferring the enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest.

5 U.S.C. § 611(a)(4).

III. Deeming Rule

In 2016, the Secretary, for the first time, exercised the "deeming" authority conferred by the FDCA. The Deeming Rule[4] applied the TCA to all products meeting the statutory definition of "tobacco product," including the vapor products manufactured by Plaintiffs here. 81 Fed. Reg. 28,976.

The TCA imposes a variety of regulatory requirements on tobacco products subject to it. As particularly relevant here, the TCA prohibits

[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"). The Rule went into effect 90 days after its publication. 81 Fed. Reg. at 28,976.

the marketing of any covered "new tobacco product" without the FDA's approval, unless the product is grandfathered. 21 U.S.C. § 387j. For products that are not grandfathered (such as Plaintiffs' products), there are two main pathways for FDA approval to market a "new tobacco product" covered by the TCA. The less onerous pathway is to demonstrate that the new product is "substantially equivalent" to a product that was being commercially marketed in the United States on the February 2007 grandfather date. 21 U.S.C. § 387j(b). Substantial equivalence is demonstrated if the product "(i) has the same characteristics[5] of the predicate tobacco product; or (ii) has different characteristics and the information submitted [in the substantial equivalence report] contains information … that demonstrates that it is not appropriate to regulate the product … because the product does not raise different questions of public health." *Id.* § 387j(a)(3)(A). If the FDA concludes that the new product is substantially equivalent to the predicate product, it must issue an order allowing the product to be commercially marketed. *Id.* § 387j(c). The "substantial equivalence"

[5] "Characteristics" means "the materials, ingredients, design, composition, heating source, or other features of a tobacco product." 21 U.S.C. § 387j(a)(3)(B).

pathway was and is not available for Plaintiffs' products (or any e-liquids for vapor devices) because there were no such products being commercially marketed before February 2007. Consequently, Plaintiffs must seek FDA approval through a "premarket tobacco application," referred to as a "PMTA."[6] ROA.1123, 1123 n.8.

The TCA sets out certain categories of information that a PMTA must contain. 21 U.S.C. § 387j provides:

> (b) Application
>
> (1) Contents
>
> An application under this section shall contain--
>
> (A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;
>
> (B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;
>
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

[6] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry* at 1 (Jun. 2019), https://www.fda.gov/media/127853/download.

> (D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;
>
> (E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;
>
> (F) specimens of the labeling proposed to be used for such tobacco product; and
>
> (G) such other information relevant to the subject matter of the application as the Secretary may require.

The statute does not elaborate further on the content requirements for each identified category of information, but it does provide some broad guidelines of sorts for the FDA's action on an application. 21 U.S.C. § 387j provides, in relevant part:

> (c) Action on application
>
> …
>
> (2) Denial of application
>
> The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application *and any other information before the Secretary with respect to such tobacco product*, the Secretary finds that--
>
> (A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

…

(4) Basis for finding

For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account--

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action

(A) Investigations

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, *when appropriate*, be determined on the basis of well-controlled investigations, which *may* include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) *Other evidence*

> If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, *the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence*.

21 U.S.C. § 387j(c) (emphasis added).

One of the costliest requirements of the PMTA process—as implemented in the PMTA Final rule challenged here—is the requirement for reports of "health risk investigations" under subsection (2)(A). As reflected above, the statute vests broad discretion in the FDA to flesh out these requirements. When the FDA issued the Deeming Rule, it had not even begun to decide important issues, including the question of when it would be "appropriate" to require applicants to submit certain "investigations" of their own (including, *inter alia*, potential requirements for human clinical trials or other long term studies), or under what circumstances FDA might rely on its own studies or studies already in the public domain.

The FDA undertook a preliminary analysis of the costs of preparing a PMTA at that time, which FDA expressly acknowledged was incomplete in relevant respects. FDA acknowledged that the Deeming Rule's final regulatory impact analysis ("Deeming Rule Final RIA")

"accounted for the costs to comply with the format and content requirements of a PMTA *as described in the TCA*." ROA.880 (PMTA Preliminary RIA at 22 (Sept. 24, 2019)) (emphasis added). As one illustrative example, in the discussion of potential "Human Studies," FDA spoke as if it expected applicants to be able to rely substantially on public information or 70 studies the FDA *itself* was conducting at the time. *See* ROA.451 (Deeming Rule Final RIA at 149-50). As another example, in discussing "market adjustment costs," FDA acknowledges that subjecting vapor product manufacturers to the PMTA requirement will cause many firms to exit the market to avoid the compliance costs. FDA predicted a mass exit of small manufacturers from the market, but said the scope of such "adjustment" was too uncertain to estimate at that time. ROA.406-07. Indeed, in one place, FDA expressly acknowledged the fact that it "cannot predict the costs or benefits of future rulemaking before the contents of the rules themselves have been established." ROA.355-56.[7]

[7] The TCA generally requires the FDA to approve or deny a PMTA within 180 days. 21 U.S.C. § 387j(c)(1)(A), although the period may be extended to allow for certain necessary supplementation. 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.

Given that the Agency was not establishing, with the Deeming Rule, specific PMTA content requirements or standards—but would do so in a subsequent rulemaking—the FDA's regulatory flexibility analysis for the Deeming Rule did not consider "significant alternatives" to PMTA content requirements that could minimize the impact on small businesses. *See* 5 U.S.C. §§ 603(c), 604(a)(6). The Agency did consider "regulatory alternatives" as relevant to the Deeming decision in its 2016 analysis, but these had nothing to do with potentially less burdensome means of *satisfying the PMTA form and content requirements* to accommodate small business. *See* ROA.424-29 (Deeming Rule Final RIA Sec. III.G, "Assessment of Regulatory Alternatives"); ROA.435-36 (Sec. IV.C., "Regulatory Alternatives for Small Entities"). FDA considered four regulatory alternatives to the policy issued in the Deeming Rule, which only included consideration of exemption of certain cigars from deeming, changing labeling compliance dates, and not extending its delayed-enforcement "compliance policy" to new flavored tobacco products. ROA.424-28. The FDA also considered, under "small entity

§§ 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.

effects," extension of the compliance policy for labeling for a period of time, and exempting premium cigars from regulation. ROA.430-36. In other words, there was no consideration of less-burdensome PMTA requirements or processes to determine whether the objects of the statutory application and premarket review process could be sufficiently achieved with less cost to small businesses.

FDA published the Deeming Rule in the Federal Register on May 10, 2016. One of the immediate effects of the Deeming Rule was to effectively freeze the vapor market in place as of August 8, 2016 (the effective date of the rule). For any covered product that was already being commercially marketed as of August 8, 2016, FDA stated that it would withhold enforcement until PMTAs could be submitted and reviewed according to a staggered set of deadlines announced in the Deeming Rule. While extant products could thus remain on the market during this compliance review period, no products not already commercially marketed as of August 8, 2016 could be offered unless a PMTA for such product was actually approved.[8]

[8] Application of the TCA to ENDS (and all other newly-deemed products) imposed other immediate restrictions upon the effective date of the Deeming Rule (August 8, 2016), including the required submission of ingredient listing, "manufacturer" registration and product listing, prohibition of the sale or distribution of products

IV. FDA Delays Enforcement and PMTA Filing Requirements for Years After Deeming While Attempting to Settle on the "Rules of the Road" for Vapor PMTAs.

Under the "compliance policy" announced at the time, PMTA submissions were originally required by August 8, 2018. 81 Fed. Reg. at 29009-29015.[9] FDA emphasized that, as it gained experience regulating ENDS products, it expected to provide more guidance and regulations specifying what information an applicant could include in a PMTA to satisfy Section 910's standard of showing that marketing a given ENDS product would be "appropriate for the protection of the public health." *Id*. at 28997, 29012, 29051-52.

Along with the Deeming Rule, FDA published draft guidance for ENDS manufacturers titled "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Draft Guidance." FDA, Draft Guidance, Premarket Tobacco Product Applications for ENDS, 81 Fed. Reg. 28781 (May 10, 2016). FDA would go on to repeatedly confirm that it would publish further guidance and a formal "foundational rule" to

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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.

[9] FDA stated that ENDS products on the market as of August 8, 2016, would not be subject to FDA enforcement action for failure to submit a PMTA before the August 8, 2018, deadline. 81 Fed. Reg. at 28977-78, 29011.

provide the "rules of the road" so that vapor manufacturers could comply with the yet-to-be-determined PMTA filing requirements.

In late July 2017, FDA stated that it planned to issue foundational rules regarding PMTAs to "make the product review process more efficient, predictable, and transparent for manufacturers . . . . Among other things, the FDA intends to issue regulations outlining what information the agency expects to be included in [PMTAs]." *See* Press Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 27, 2017).[10]

In August 2017, FDA issued guidance extending the compliance deadline for PMTA submissions from August 8, 2018, to August 8, 2022. *See* FDA, Guidance for Industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (August 10, 2017), at 8. While it postponed the deadline, this guidance did not provide any new guidelines or direction from FDA on the requirements for PMTAs or FDA's planned PMTA review process.

[10] https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death (last accessed January 2, 2024).

On November 3, 2017, then-FDA Commissioner Scott Gottlieb stated 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." FDA Comm'r S. Gottlieb, Remarks at the National Press Club (Nov. 3, 2017).

By the end of 2017, FDA had advised stakeholders that it was pursuing a new comprehensive plan, that there would be new rules forthcoming, and that FDA would take the time necessary to get the process for PMTAs for ENDS products right.

On March 15, 2018, then-Commissioner Gottlieb stated:

> "For example, our plan demonstrates a greater awareness that nicotine, while highly addictive, is delivered through products on a continuum of risk, and that in order to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources. To that end, the agency's regulation of both novel nicotine delivery products such as e-cigarettes and traditional tobacco products will encourage the innovation of less harmful products while still ensuring that all tobacco products are put through an appropriate series of regulatory gates to maximize any public health benefits and minimize their harms. This will be achieved through our ongoing regulatory work to develop several foundational rules, guidances, product standards and other regulations.
>
> . . . .

> Finally, we also plan to take new steps to make sure that our policies and processes for the regulation of tobacco products are efficient and predictable, and consistent with the mandate Congress gave us under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). We're committed to making sure that we have transparent regulatory policies and best practices in place to maximize our public health impact. To these ends, we plan to issue a series of foundational rules and guidance documents that will delineate key requirements of the regulatory process, such as the demonstration of substantial equivalence and the submission of applications for new tobacco products.[11]

In October 2018, FDA held a public meeting to "improve public understanding . . . on the process for the submission and review of [PMTAs]." Tobacco Product Application Review – A Public Meeting (October 22, 2018). In relaying the types of studies that could support a PMTA, an FDA representative stated: "No specific studies are required for a PMTA; it may be possible to support a marketing order for an ENDS product without conducting new nonclinical or clinical studies given other data sources can support the PMTA." Premarket Tobacco Product Application Content Overview: Iilun Murphy – OS/Division of Individual Health Science (October 23, 2018). FDA made similar statements at a public meeting held in 2019, describing reviewing a PMTA as a "[m]ulti-

[11] *Statement from FDA Comm'r S. Gottlieb, M.D., on pivotal public health step to dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or non-addictive levels* (Mar. 15, 2018) (emphasis added).

disciplinary approach," and citing numerous factors that must be considered for determining whether a product is appropriate for protection of the public health, including health risks and marketing plans. *See* Deemed Tobacco Product Applications – A Public Meeting (October 28- 29, 2019).

V. The PMTA Rule Challenged Here

FDA finally published the proposed final PMTA rule on September 25, 2019. The rule does several things. For one, it sought to "codify the general procedures FDA would follow when evaluating PMTAs, including application acceptance, application filing, and inspections, and would also create postmarket reporting requirements for applicants that receive marketing orders." ROA.1127 (Mem. Op.) (citing 84 Fed. Reg. at 50567). But it also "interpret[s] and set[s] forth requirements related to the content and format of PMTAs." *Id.*

While the FDCA provides substantial discretion, the PMTA Rule formalized FDA's open-ended requirement for reports and "investigations" respective to each product. While the Deeming Rule's RIA had prominently suggested potential cost-saving utility of dozens of studies the FDA itself was supposedly conducting, ROA.451, no mention

of such studies appears in the PMTA rule. The Rule requires each applicant to supply its own health risk investigation presentation.

With the proposed rule, FDA published an IRFA. ROA.859-914 ("PMTA Rule IRFA"). In that document, FDA proposed to certify that the PMTA Rule "would not have a significant economic impact on a substantial number of small entities." ROA.864. Despite the fact that this new Rule takes over 100 pages to describe the PMTA requirements for vapor products, by FDA's rationale, this new Rule would actually "generate net benefits or negligible costs for most affected small entities." *Id.* FDA reasoned that it had "already included the costs to submit and review PMTAs for deemed tobacco products in the final [RIA] for the Deeming Rule" in 2016. ROA.865.

As authorized by statute, the Small Business Administration's Office of Advocacy ("SBA Advocacy") filed official comments objecting that FDA's proposed certification that the PMTA Rule would have no significant impact on a substantial number of small entities lacked an adequate factual basis. ROA.915. Advocacy observed that the FDA had not "detail[ed] all requirements for [PMTAs], nor adequately assessed costs for the Deeming Rule." ROA.915. The letter noted that "[t]he

Deeming Rule itself … included no specific requirements on the procedure or information to be included in a PMTA," and that where estimates of the costs were discussed, they were "prefaced" by equivocal terms and by FDA's express statement that PMTA costs could not be assessed until the PMTA rule was devised. ROA.917, ROA.919. Advocacy specifically observed that "the FDA assumed in the Deeming Rule that public dockets of research would be available to assist in the development of PMTAs, 'potentially reducing the time for preparation of a particular application,'" ROA.919 (quoting Deeming Rule Final RIA at 56), but that "[t]hese resources … do not appear to be available." ROA.919.

Noting that "[s]mall businesses drive the ENDS industry," and citing industry sources reflecting that there were "approximately 14,000 ENDS firms located across the country," ROA.918, Advocacy advised that the RFA required the Agency to publish an initial regulatory flexibility analysis for the PMTA Rule which would adequately assess costs "and that would include consideration of significant alternatives to the proposed rule that will accomplish the stated objectives of applicable

statutes while minimizing the proposed rule's economic impact on small entities." ROA.915-16.

Notwithstanding SBA Advocacy's objection, FDA published the PMTA Final Rule in the Federal Register on October 5, 2021, certifying no significant impact on a substantial number of small entities. 86 Fed. Reg. 55300, 55405-06. Consequently, FDA did not perform or publish any final regulatory flexibility analysis with the PMTA Final Rule, and therefore did not conduct any analysis of potential alternatives or modifications to the PMTA content requirements that could lessen the burden on small entities while still satisfying the statutory requirements. ROA.1104.

VI. Manufacturers Challenge FDA's Certification

Plaintiffs are seven small-business manufacturers of e-liquids and a trade association, the United States Vaping Association, Inc. (USVA), organized in 2019 to represent small-business vapor product manufacturers and retailers. ROA.11-14. Kealani Distribution LLC is located in Collin County, Texas. ROA.11; ROA.274. Diamond Vapor LLC and Johnny Copper LLC are located in Florida; SWT Global Supply, Inc. (SWT) is located in Missouri; and Carolina Vapor Mill LLC, Carolina

Vapor Mill Woodruff Road, and CVM3 LLC, are related entities located in South Carolina. ROA.12-14; ROA.222-225.[12] The USVA has dozens of member businesses subject to the premarket tobacco product application requirements. ROA.223. No USVA member has more than 75 employees; the vast majority, if not all, of the USVA's members have fewer than 25 employees, and many have fewer than ten employees. ROA.223.

Plaintiffs filed suit in the Eastern District of Texas on October 4, 2022, bringing a single claim for relief: that the PMTA Final Rule was promulgated in violation of the RFA. ROA.25-27. Plaintiffs argued that—since the FDA refused to consider the costs associated with the PMTA content requirements as codified and explained in the PMTA Final Rule—"the Agency lacks any factual basis for the certification" that the Rule would have no substantial economic impact on small businesses. ROA.217 (Plfs' Mtn. for Summ. Judg. at 17, 17 n.11).

[12] All of the individual business plaintiffs are "small entities" for purposes of the RFA judicial review provision, as reflected in the record evidence, which is undisputed. See ROA.1104 (table reflecting 93% of "tobacco manufacturers" per Census data qualified as small businesses).

Plaintiffs explained that the FDA's position—that the costs of the PMTA process are attributable to the statute rather than the Final Rule—"fails because it ignores the very significant policy discretion FDA exercised in determining *how* the capacious statutory requirements are to be implemented, and contradicts its own statements made in its Deeming economic analysis." ROA.217. The Deeming Rule RIA expressly accounted only for the costs to comply with the format and content requirements for PMTAs "as described in the [Tobacco Control Act]" itself. ROA.880. But the most expensive components of the PMTA statutory requirements are expressly made contingent upon the FDA's regulatory determination as to whether and to what extent certain "investigations" are necessary as components of an application or whether applicants may rely on (or the Agency may consult on its own initiative) other data available to it. Indeed, Plaintiffs noted—just as SBA Advocacy had done during the comment period—that in promulgating the Deeming Rule, FDA suggested that a public docket of studies (some of which the FDA itself claimed to be engaged in) may be available by the time applications are required to substantially reduce

application costs, but that such references were absent from the PMTA Final Rule. ROA.218-19.

In response, FDA reiterated its view that its certification under § 605(b) that the PMTA Final Rule would have no significant economic impact on a substantial number of small entities was appropriate because the PMTA costs were already estimated in 2016, based on the FDCA statutory requirements. *See* ROA.242 ("[T]he [PMTA] Final Rule RIA explained that the significant costs associated with submitting PMTAs were traceable to the Deeming Rule; the new administrative burdens imposed by the Final Rule were incremental and modest compared to the baseline costs the agency had already considered in the Deeming Rule RIA; and those new costs would be offset by greater efficiencies and earlier revenues for most affected entities.").

FDA argued, in the alternative, that even if a final regulatory flexibility analysis were required for the PMTA Final Rule (that is, even if the Agency's certification were erroneous), "the Final Rule RIA *did* address each topic delineated in § 604(a)." ROA.248 (emphasis in original). FDA argued that the Final Rule satisfies the requirement in § 604 to discuss "steps … to minimize" the Final Rule's impact on small

entities, and to explain the Agency's "reasons for selecting the alternative adopted in the final rule and why … other … alternatives were rejected." ROA.249 (quoting § 604(a)(6)). But the only regulatory alternative considered with the promulgation of the PMTA Final Rule was the option of "dispensing with 'postmarket reporting.'" *See* ROA.249; ROA.807-808. FDA did not consider any "regulatory alternatives" to the *substantive PMTA content requirements*. Indeed, in its cross-motion for summary judgment, with respect to the comments (by Advocacy and others) suggesting that PMTA costs, and regulatory alternatives to substantive PMTA requirements, should be considered, FDA reiterated that it considered such criticisms "out-of-scope" regarding the PMTA Final Rule, because "[w]e attribute any costs that result from the requirement to prepare and submit PMTAs for deemed new tobacco products to the Deeming … Rule and not this rule." ROA.1074; ROA.249.

In reply, Plaintiffs argued that FDA's attempted reliance on the 2016 cost estimates "only further illustrates the deficiency here." ROA.267. Plaintiffs wrote that the "qualifications and conditions [characterizing the 2016 cost estimates] are further confirmation that the FDA was acutely aware of the very wide discretion it possesses to

interpret and flesh out the bare-bones statutory content and review standards," but FDA neither adopted nor (publicly) considered any alternatives to the substantive PMTA standards before promulgating the PMTA content requirements. "In other words," Plaintiffs argued:

> there was no consideration of less-burdensome PMTA requirements or processes to determine whether the objects of the statute could be sufficiently achieved with less cost to small businesses. This made sense at the time [of the Deeming Rule], given that the FDA itself expressly recognized and anticipated that it would flesh out PMTA requirements in a subsequent rulemaking. What does not make sense, nor satisfy the RFA, is for FDA to retroactively advert to the incomplete economic forecast from 2016 to satisfy the RFA, and forever avoid the requisite consideration of regulatory alternatives.

ROA.268-69.

VII. District Court Decision

The district court granted summary judgment for the FDA and dismissed Plaintiffs' claims. ROA.1136. To the district court, the analysis was simple. "Because the RFA imposes only procedural requirements, judicial review is limited to whether an agency followed the proper procedure while promulgating its rule." ROA.1132. According to the court, "FDA followed the RFA's procedural requirements for the 2021 Final Rule" because FDA (i) "published its certification in the

Federal Register" (ii) "and offered 'a statement providing the factual basis for such certification,'" namely, "the 2021 Final Rule explained that the significant costs associated with submitting PMTAs were traceable to the Deeming Rule." ROA.1133 (quoting § 605(b)) (some internal punctuation omitted). The district court observed that the FDA further accounted for the costs imposed by the Final Rule's "new administrative requirements," which "would be incremental and modest compared to the baseline costs already imposed on small manufacturers by the Deeming Rule." ROA.1133.

Turning to the Plaintiffs' argument, the district court characterizes Plaintiffs' objection to "the FDA's attribution of PMTA-related costs to the Deeming Rule" merely as a challenge to "a *substantive factual conclusion* underlying [FDA's] certification." ROA.1134 (emphasis supplied by court). Explaining its view, the court acknowledged Plaintiffs' argument that the PMTA costs "should have been recalculated … in the context of the regulated industry at the time the 2021 Final Rule was proposed and issued," but concluded that such argument was "on its face" a "disagreement with the substance of the FDA's factual basis" rather than a procedural defect. ROA.1134-35.

In a long footnote, the district court sought to distinguish two cases reflecting insufficient factual predicates for a § 605(b) certification. Even if "an agency must have supporting evidence to certify that a regulation will have no economic impact," rather than "a simple conclusory statement," ROA.1135 (citing *N.C. Fisheries Ass'n v. Daley*, 16 F.Supp.2d 647 (E.D. Va. 1997) ("*Daley I*")), "the 2021 Final Rule includes twenty pages of analysis on the effects of the rule's compliance-related costs." ROA.1135 (referring to FDA's estimation "that incremental costs of no more than $2,000 per affected entity would result from the 2021 Final Rule"). And even if an agency may run afoul of the RFA by "consciously ignore[ing] its own data," refusing "to recognize the economic impact of its regulatory actions," or suggesting that it was "under no statutory duty to consider alternatives," ROA.1135 (quoting *N.C. Fisheries Ass'n v. Daley*, 27 F.Supp.2d 650 (E.D. Va. 1998) ("*Daley II*")), there were no such deficiencies here, because FDA had dutifully "quantified the economic effects of its policy choices through the Deeming Rule RIA and the 2021 Final Rule RIA," and "the 2021 Final Rule RIA provided reasons for selecting the alternative it chose and rejecting the other alternatives."

ROA.1135. Accordingly, the court dismissed Plaintiffs' challenge as "not a procedural attack cognizable under the RFA." *Id.*

SUMMARY OF ARGUMENT

This case illustrates the regulatory twilight zone that will be established if the government can certify that a final rule has no cognizable economic impact on small businesses in the circumstances here, obviating any need to perform the analysis required under the Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq*.

Plaintiffs argue that the FDA's § 605(b) certification (that the 2021 PMTA Final Rule has no significant impact on small entities) is erroneous as a matter of law because it effectively avoids grappling with the economic impact of the policy choices the FDA made in exercising its discretion under the statute. The FDA cannot avoid the fact that, in promulgating the 2021 Final Rule, it was engaging in substantive rulemaking with the force of law; this is why it was required to follow the formal notice-and-comment procedures. Accordingly, "by its very policy choices in the PMTA Rule, the Agency had the discretion to make the [application] process infinitely less—or more—burdensome in many ways." ROA.218. FDA's defense doubles down on the purported

sufficiency of the cost estimates accompanying the Deeming Rule in 2016, but this fails for two reasons. First, FDA's estimates regarding application costs in the Deeming Rule were made based on the text of the statute alone. Even if one assumes that all of the assumptions baked into FDA's 2016 PMTA cost estimates—based on the bare text of the Tobacco Control Act—were equally applicable under the language of the Final Rule (regarding the types of studies required, etc.), those estimates would still be categorically insufficient given the fact that five years had transpired in the interim. FDA's refusal to assess the costs as they pertain to the industry at the time of the Rule's promulgation renders the certification legally deficient.

But this case presents a problem far more fundamental than even this lapse of five years since the last cost assessment. Even if FDA's 2016 analysis were otherwise sufficient *as to predicted cost*, it is undisputed that FDA did not perform any analysis of potential regulatory alternatives to the *substantive PMTA requirements* with the Deeming Rule or with the 2021 PMTA Final Rule. This violates § 604(a)(6) of the Regulatory Flexibility Act. That provision requires the agency to consider "significant alternatives" to the final rule that might satisfy

statutory interests but minimize impact on small businesses, and explain why the agency "selected the alternative adopted in the final rule." In 2016, FDA omitted consideration of potentially less-burdensome application requirements, explaining that it anticipated a fuller cost assessment when issuing an actual PMTA rule. *See* ROA.219. However, when FDA promulgated that rule five years later, it again refused to consider regulatory alternatives to the substantive PMTA content requirements. FDA has therefore somehow promulgated a 139-page Final Rule governing PMTA content requirements without ever having considered regulatory alternatives to those content requirements that might impose less burden on small entities.

In other words, FDA posits a "heads I win, tails you lose" approach that would allow it to sidestep any obligation to seriously grapple with the potential economic impact of the specific PMTA requirements on small businesses *and* to consider regulatory alternatives to its chosen approach. The Agency did not consider regulatory alternatives *with respect to PMTA content requirements* when it "deemed" all "tobacco products" to be subject to the Tobacco Control Act in 2016, and it specifically acknowledged that its cost estimates were preliminary.

Later, when it did elaborate the PMTA content requirements in the rule at issue, it adverted to its earlier cost estimates, but still avoided any analysis of significant alternative content or processing requirements for applications as applied to small entities. ROA.1104 (rebuffing the Office of Advocacy's request to "prepare … an analysis of alternatives" "[b]ecause we certify that this final rule will not have a significant economic impact on a substantial number of small entities" and therefore "does not require a full Initial Regulatory Flexibility Analysis"). This gambit denudes the RFA. Summary judgment should be entered for Plaintiffs.

ARGUMENT

I. Standard of Review

Agency actions, including improper RFA certifications, are reviewed under the arbitrary and capricious standard of the APA. 5 U.S.C. §§ 611(a), 701 *et seq*.; *Alenco Communications, Inc. v. F.C.C.*, 201 F.3d 608, 625 (5th Cir. 2000); *see also Daley II*, 27 F. Supp. 2d at 658. "The APA's arbitrary-and capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). While the Court must not

"substitute" its "own policy judgment for that of the agency," it must ensure that "the agency has acted within a zone of reasonableness, and in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Id.*; *Alenco Comm's, Inc.*, 201 F.3d at 625 ("We review only to determine whether an agency has made a 'reasonable, good-faith effort' to carry out the mandate of the RFA.").

II. FDA Lacks a Factual Basis for its § 605(b) Certification.

"Arbitrary and capricious review focuses on whether an agency articulated a rational connection between the facts found and the decision made." *Mexican Gulf Fishing Co. v. United States Dep't of Com.*, 60 F.4th 956, 971 (5th Cir. 2023) (quoting *ExxonMobil Pipeline Co. v. U.S. Dept. of Transportation*, 867 F.3d 564, 571 (5th Cir. 2017)). "In reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Texas v. EPA*, 983 F.3d 826, 835 (5th Cir. 2020) (quoting *Motor Vehicle Mfrs. Assn. of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

The Tobacco Control Act provides a wide berth for FDA to regulate, especially with respect to content requirements of PMTAs. *See, generally*, ROA.204-07 (describing certain operative provisions). The ultimate determination the Secretary of HHS is required to make in approving or rejecting a PMTA is whether a proposed tobacco product would be "appropriate for the protection of the public health" (APPH). 21 U.S.C. § 387j(c)(2)(A). That capacious term is open to interpretation; there is no precise definition, but the TCA provides some broadly-worded categories of information to be included in an application and some high-level factors to be considered. *See* ROA.205-06. With respect to the category of "health risk investigations," Congress went out of its way to emphasize the Secretary's discretion to require "well controlled investigations" "*when appropriate*," 21 U.S.C. § 387j(c)(5) (emphasis added), but, even then qualifies this further by communicating that, if such investigations are to be required, clinical investigations are not the only type of "well controlled investigations," *id.* When FDA issued the Deeming Rule, it did not purport to flesh out the PMTA requirements (because it anticipated the later rulemaking now at issue), and it expressly premised the cost estimates on the "format and content

requirements of a PMTA *as described in the TCA*." ROA.880 (emphasis added). FDA's cost estimates were based on what was effectively the Agency's preliminary reading of the PMTA content requirements as stated in the statute, but without yet purporting to exercise its authority to flesh them out.

SBA Advocacy was therefore correct to point out that FDA improperly assumed the PMTA costs were due to the Deeming Rule rather than this rule, and that the 2016 cost estimates lacked the requisite factual basis to avoid the RFA analysis. ROA.915, 920. FDA here seeks to minimize the distinctions between the statute itself and the PMTA Rule, ROA.247 (*FDA Cross-Mtn.* at 17), but Advocacy's own letter from 2019 points out significant expansion of number of categories of topics covered and detail. ROA.917. FDA's certification lacks the requisite factual basis, and fails to account for relevant factors, because the 2016 cost estimates were expressly preliminary and incomplete, and inconsistent with the FDA's own admission that it "cannot predict the costs or benefits of future rulemaking before the contents of the rules themselves have been established." ROA.356; *see also* ROA.404 (cost of

"harmful or potentially harmful constituent" testing not presently estimable); ROA.406 (costs of market adjustment also not estimable).

The 2016 cost estimates, based on the *statutory* text, are an insufficient factual predicate for the certification because they fail to account for the specific requirements issued in the PMTA Rule, as applied to the regulated industry at the time the PMTA Rule was proposed and issued.

Despite the paucity of caselaw squarely addressing RFA challenges, *North Carolina Fisheries Ass'n, Inc. v. Daley*, 16, F. Supp. 2d 647, 652-53 (E.D. Va. 1997), found a violation of the RFA in materially similar circumstances. The district court held that the agency erred because it had assumed that the small business impact from the proposed flounder quota for 1997 would be the same as the impact from the quota imposed in 1996, because it was the same quota. *Id.* at 653. Despite application of the same quota, the agency had "entirely failed to consider an important aspect of the problem" by failing to analyze the quota as applied to the condition of the regulated industry *in 1997*. *Id.* (quoting *Motor Vehicles Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Similarly here, even if the FDA were correct that the

PMTA rule imposed materially the same requirements as the statute itself (which it does not), FDA still should have completed its cost analysis, and done so in the year of the proposed PMTA Rule, as required by the RFA. The FDA's mere adjustment of the dollars estimated in 2016 for inflation is clearly insufficient to this task, because it does not account for the state of the industry in 2021 (as opposed to 2016).

The cases cited by FDA, seeking to distance itself from *Daley*, are all inapposite, because they involve challenges to the agency's actual factual determination of an issue involved in the analysis, whereas here the FDA failed to undertake the relevant factual analysis (of the actual rule, at the appropriate time) at all. *See Council for Urological Interests v. Burwell*, 790 F.3d 212, 227 (D.C. Cir. 2015) (plaintiffs merely disputing Secretary's factual belief that "existing arrangements could be 'easily restructured' to meet the new rule); *Helicopter Ass'n Intern., Inc. v. FAA*, 722 F.3d 430, (D.C. Cir. 2013) (challenging agency's factual determination regarding negligible cost of rule, made at time rule was adopted); *Grocery Servs. Inc. v. USDA Food and Nutrition Service*, H-06-2354, 2007 WL 2872876 (S.D. Tex. 2007) (agency unable to determine small business impact because "small entities will be impacted

differently in each State depending upon how that State chooses to meet the requirements set forth here). For the same reason, the Fifth Circuit's decision in *Alenco Communications Inc.*, 201 F.3d 608 is not an obstacle to Plaintiffs' argument here. Plaintiffs in *Alenco* were challenging the FCC's factual findings and exercise of statutory discretion, not the utter lack of a relevant factual predicate as exists here. *See id.* at 625 ("Petitioners' RFA argument amounts to little more than a redressing of its earlier *Chevron* and APA claims.").[13]

III. Even Assuming the Sufficiency of the 2016 Cost Estimates, FDA Failed to Consider Less Burdensome Regulatory Alternatives Regarding PMTA Content Requirements.

FDA's argument that the 2016 cost estimates should suffice for its RFA obligations only further illustrates the deficiency here. FDA's 2016 cost estimates were premised on its then-reading of the (capacious and ambiguous) requirements of the statute itself. Those estimates are rife with qualifications and conditions. *See* ROA.917 (Advocacy ltr. quoting, *e.g.*, Deeming Rule Final RIA at p. 151). These qualifications and conditions are further confirmation that the FDA was acutely aware of

[13] *Alenco* is also not particularly instructive here, given the Court's repeated acknowledgment that the rules at issue were expressly transitional. *See id.* at 616 ("Because the provisions under review are merely transitional, our review is especially deferential."). The 2021 PMTA Final Rule is not transitional.

the very wide discretion it possesses to interpret and flesh out the bare-bones statutory content and review standards. If FDA were going to legitimately rely upon its 2016 cost estimates *regarding the PMTA content requirements* to satisfy the RFA, then it should have simultaneously done all that the RFA requires *regarding those content requirements*, including performing an analysis of regulatory alternatives required by § 604(a)(6). *See Alenco*, 201 F.3d at 625 ("[B]oth orders are accompanied by substantial discussion and deliberation, including consideration and reasoned rejection of significant alternatives which, in the Commission's judgment, would not have achieved with equivalent success its twin statutory mandates of universal service and local competition. The RFA requires no more.").

FDA performed no such analysis. The Agency did consider "regulatory alternatives" as relevant to the Deeming decision in its 2016 analysis, but these had nothing to do with potentially less burdensome means of satisfying the PMTA form and content requirements to accommodate small business. ROA.424-29, 435-36. FDA considered four regulatory alternatives to the policy issued in the Deeming Rule, which only included consideration of exemption of certain cigars from deeming,

changing labeling compliance dates, and not extending its delayed-enforcement "compliance policy" to new flavored tobacco products. ROA.424-28. The FDA also considered, under "small entity effects," extension of the compliance policy for labeling for a period of time, and exempting premium cigars from regulation. ROA.430-36. In other words, there was no consideration of less-burdensome PMTA requirements or processes to determine whether the objects of the statute could be sufficiently achieved with less cost to small businesses. This made sense at the time, given that the FDA itself expressly recognized and anticipated that it would flesh out PMTA requirements in a subsequent rulemaking. What does not make sense, nor satisfy the RFA, is for FDA to retroactively advert to the incomplete economic forecast from 2016 to satisfy the RFA, and forever avoid the requisite consideration of regulatory alternatives.

FDA here tacitly acknowledges that the "regulatory alternatives" considered in the Deeming Rule were *not* relevant to the PMTA content requirements, because, despite relying upon its cost estimates from 2016, it does not even purport to rely upon the regulatory alternatives considered with deeming. *See* ROA.248-49 (FDA MSJ at 18-19). FDA

instead argues (in its Sec. II, FDA MSJ at 18-19) that its analysis of the items in Section 604(a) satisfied the RFA. But the FDA does not suggest that it considered less burdensome alternatives *to the PMTA content requirements*; nor could it, given the fact that Advocacy's request to do so was expressly rejected on the record, as quoted above. The analysis FDA refers to here concerns other tangential items, but not the substantive requirements for PMTA applications. Indeed, the pages quoted by FDA itself confirm this. *See* ROA.1075 ("we only consider the incremental change in the costs of premarket review for ENDS products created by this rule in this analysis"). For this reason, the district court erred in citing FDA's consideration of regulatory alternatives as sufficient. ROA.1135. The FDA never considered *any* alternative means of satisfying the TCA's substantive PMTA requirements, despite the fact that the TCA itself offers up a clear alternative to the most expensive portion of PMTAs under the current rule. As summarized above, the statute gives the Agency the authority to rely on its own studies, or other publicly available information, to gauge APPH as to individual applications.

Plaintiffs do not challenge the FDA's factual expertise but its metaphysical deconstruction of the Regulatory Flexibility Act. The FDA has, perhaps unintentionally, backed itself into a scenario presenting a fundamental problem under the RFA, not the run-of-the-mill bickering over a particular calculation or factual dispute. FDA's certification, coupled with its attempted defense here, represent an erroneous legal interpretation of the operation of the RFA. An agency cannot avoid analysis of potential regulatory alternatives for small business by pointing back to an economic analysis done years earlier that was not only pockmarked with caveats but also devoid of the consideration of alternatives *to the substantive requirements now at issue*. *Alenco* upheld the FCC's analysis after specifically observing that the agency had in fact provided "substantial discussion and deliberation, including consideration and reasoned rejection of significant alternatives" to the substantive components issued in the rule under review. 201 F.3d at 625. This necessarily reflects that failure to so consider such alternatives would mark a material deficiency under the RFA. The Agency here failed to consider significant alternatives to the substantive PMTA content requirements, either in the Deeming Rule or in the PMTA Rule. This is

a failure to consider an express component of RFA review. SBA Advocacy specifically called out this failure to analyze regulatory alternatives in response to the PMTA proposed rule, and FDA specifically responded that it had no obligation to consider such alternatives. ROA.1104 (rejecting the Office of Advocacy's request to "prepare … an analysis of alternatives"); *see also* ROA.1074 (FDA considering substantive comments contesting the PMTA costs as "out-of-scope" because PMTA costs are considered to derive from the statute and deeming rather than the PMTA rule).

IV. FDA's Method Here Denudes the RFA.

The Regulatory Flexibility Act was surely not intended to be an empty exercise by the Congress that passed it and the President who signed it. It was enacted with a purpose. It was meant to ensure that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies … seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public." 5 U.S.C. § 601 n.7. It was passed specifically to protect small businesses from overreaching and oblivious government agencies. It tasked the Small Business Administration Office of

Advocacy with commenting on proposed rules to ensure that the voice of small businesses are taken into account. Its purposes would be entirely defeated if a federal agency with such sweeping powers as the FDA here can punt on any defensible estimate of the effects of application of a statutory requirement until a rule implementing the statute is passed, but then advert to its admittedly insufficient earlier analysis when the rule is adopted. Here is a unique case in which the Agency itself said that it "cannot predict the costs or benefits of future rulemaking before the contents of the rules themselves have been established," but then seeks to ignore this statement to avoid any real examination of the cost to small business of FDA's policy choices, and to forever dodge any responsibility to consider potentially effective but less-burdensome alternative means of regulation. FDA must, at least, be held to its own words, or the RFA is a dead letter.

V. The PMTA Final Rule Should Be Vacated.

A plaintiff who "prevails on its [APA] claim" is "entitled to relief under that statute, which normally will be a vacatur." *Am. Bioscience Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001); 5 U.S.C. § 706. "'[W]hen a reviewing court determines that the agency regulations are

unlawful, the ordinary result is that the rules are vacated.'" *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs.*, 145 F.3d 1399, 1409 (D.C. Cir. 1998); *Sierra Club v. Van Antwerp*, 719 F. Supp. 2d 77, 78 (D.D.C. 2010) ("[B]oth the Supreme Court and the D.C. Circuit Court have held that remand, along with vacatur, is the presumptively appropriate remedy for a violation of the APA."). "Exceptional circumstances" must be present to "warrant deviating from the ordinary rule of vacatur of an arbitrary and capricious rule." *Cigar Ass'n of America v. FDA.,* No. 16-CV-01460 (APM), 2023 WL 5094869, at *1 (D.D.C. Aug. 9, 2023) (vacating FDA decision to deem premium cigars). Therefore, in the event the Court rules for Plaintiffs, vacatur should be ordered, and FDA bears the burden to establish exceptional circumstances to warrant a different remedy.

CONCLUSION

Plaintiffs-Appellants respectfully request that the Court vacate the judgment below and render judgment for Plaintiffs-Appellants. Appellants request any further relief to which they may be entitled.

Respectfully submitted,

/s/ Jerad Wayne Najvar
Jerad Wayne Najvar
Tex. Bar No. 24068079

jnajvar@chalmersadams.com
CHALMERS, ADAMS, BACKER & KAUFMAN, LLC
2180 North Loop West, Ste. 255
Houston, Texas 77018
[Tel.] (281) 404-4696
Attorney for Plaintiffs-Appellants

CERTIFICATE OF SERVICE

I certify that the foregoing document was filed with the Court in electronic format through the CM/ECF system, on June 18, 2025. A copy of the document was served on counsel of record, as listed below, through the CM/ECF system, on the same date:

/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 9,645 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 2010 in 14-point Century Schoolbook type.

/s/ Jerad Wayne Najvar
Jerad Wayne Najvar

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Counsel also certifies that on June 18, 2025, the foregoing document was transmitted to Mr. Lyle W. Cayce, Clerk of the United States Court of Appeals for the Fifth Circuit, via the Court's CM/ECF system.

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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Jerad Wayne Najvar