[ORAL ARGUMENT NOT SCHEDULED]

No. 23-5220

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

CIGAR ASSOCIATION OF AMERICA, et al.,

Plaintiffs-Appellees,

v.

FOOD & DRUG ADMINISTRATION, et al.,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR APPELLANTS

Of Counsel:

SAMUEL R. BAGENSTOS
General Counsel
Department of Health & Human Services

MARK RAZA
Chief Counsel

WENDY S. VICENTE
Deputy Chief Counsel for Litigation

PETER DICKOS
Associate Chief Counsel
Office of the Chief Counsel
U.S. Food & Drug Administration

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MARK B. STERN
LINDSEY POWELL
(202) 616-5372
Attorneys, Appellate Staff
Civil Division, Room 7531
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), counsel certifies as follows:

A. Parties and Amici. Defendants-appellants are the U.S. Food and Drug Administration (FDA); the U.S. Department of Health and Human Services (HHS); Xavier Becerra, in his official capacity as HHS Secretary; and Robert M. Califf, MD, in his official capacity as FDA Commissioner. Plaintiffs-appellees are Cigar Association of America, Cigar Rights of America, and Premium Cigar Association.

The following entities participated as amici at an earlier stage of these proceedings:

- American Academy of Pediatrics
- American Cancer Society Cancer Action Network
- American Heart Association
- American Lung Association
- American Thoracic Society
- Campaign for Tobacco-Free Kids
- Cause of Action Institute
- Cynthia Fishman
- David Myles
- Leah Brasch
- Linda Goldstein
- Maryland Chapter – American Academy of Pediatrics
- Steven Hirsch
- The States of Arizona, Louisiana, Michigan, and Texas

- Tobacco Control Legal Consortium
- Truth Initiative

The following entities moved to intervene in district court at an earlier stage of these proceedings but later withdrew their motion:

- A. Fuente & Co.
- Alec Bradley Cigar Distributors, Inc.
- Ashton Distributors, Inc.
- Crowned Heads, LLC
- Holt Cigar Co., Inc.
- Oliva Cigar Co., Inc.
- Piloto Cigars, Inc.
- Rocky Patel Premium Cigars

B. Rulings Under Review. The rulings under review are the following orders of the United States District Court for the District of Columbia (Mehta, J.) in case number 16-1460: (1) the July 5, 2022, opinion and order granting in part and denying in part the parties' cross-motions for summary judgment (available at 2022 WL 2438512); (2) the August 9, 2023, opinion denying the government's request for remand without vacatur (available at 2023 WL 5094869); and (3) the August 9, 2023, order vacating FDA's final deeming rule insofar as it applies to premium cigars (unpublished).

C. Related Cases. Unrelated issues in this case have previously been on appeal and were decided by this Court in No. 18-5195 (published at 964 F.3d 56 (D.C. Cir. 2020)), and No. 20-5266 (published at 5 F.4th 68 (D.C. Cir. 2021)). Counsel is unaware of any related cases within the meaning of Circuit Rule 28(a)(1)(C).

/s/ Lindsey Powell
LINDSEY POWELL

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GLOSSARY

APA	Administrative Procedure Act
AR	Administrative Record
FDA	U.S. Food and Drug Administration
JA	Joint Appendix
TCA	Family Smoking Prevention and Tobacco Control Act

INTRODUCTION

Through the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA), Congress established a comprehensive framework for the regulation of tobacco products, and it authorized the U.S. Food and Drug Administration (FDA) to deem subject to the Act's requirements any "tobacco product" that meets the statutory definition. Recognizing that such products are inherently dangerous and addictive, Congress gave FDA "broad authority to address the public health and societal problems caused by" their use. *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 438 (5th Cir. 2020) (quotation marks omitted).

In exercising its authority to deem products subject to the Act's framework, FDA solicited comments as to whether certain products present reduced risks that might justify a difference in regulatory treatment. 79 Fed. Reg. 23,142, 23,143 (Apr. 25, 2014). Some commenters argued, for example, that e-cigarettes should be excluded from regulation based on claims that they may help smokers reduce their use of combusted tobacco products. Other commenters similarly argued that "premium" cigars should be exempted because they may pose less risk to users who smoke them infrequently or do not inhale.

After reviewing the scientific literature and comments on the proposed rule, FDA concluded that deeming all products that meet the statutory definition of "tobacco product" (other than accessories of such products) will best promote the public health. 81 Fed. Reg. 28,974, 28,975 (May 10, 2016). FDA explained that "[t]here is inherent risk in all tobacco-derived products," *id.* at 29,025, and deeming gives the agency important tools for mitigating that risk, *id.* at 28,984, 29,020.

Plaintiffs contend that in declining to create a special carveout for premium cigars, FDA did not fully address two pieces of evidence that suggest that many premium-cigar smokers use such products infrequently and that infrequent cigar use confers less risk. In so urging, plaintiffs do not contend that premium cigar products themselves are different or safer than other cigars. Their claim is instead that because some consumers of these products use them infrequently, premium cigars should be singled out among all tobacco products and exempted from the comprehensive scheme established by Congress.

The record shows that FDA amply considered these comments and reasonably concluded that, even though "cigar smokers generally smoke at a lower frequency," "deeming all cigars, rather than a subset, more

completely protects the public health." 81 Fed. Reg. at 29,020. The record shows that "[a]ll cigar use is harmful and potentially addictive," *id.* at 29,022, and "no amount of smoking is safe," *id.* at 29,020. Cigar smoke contains many of the same toxins and carcinogens as cigarette smoke, and users absorb large quantities of nicotine and other harmful substances even if they do not inhale. *Id.* at 29,022. "The fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others." *Id.* at 29,020. Nor does plaintiffs' argument account for the many people who smoke premium cigars frequently.

FDA also found that, despite these well-established risks, many people wrongly perceive cigars as safer alternatives to cigarettes, 81 Fed. Reg. at 29,024, and rates of cigar use have persisted even as cigarette use has declined, *id.* at 29,023. The evidence "clearly indicate[s] that youth and young adults are using premium cigars." *Id.* And exempting premium cigars could increase youth use by giving a false impression that they are safer than other tobacco products, *id.* at 29,021, and by excluding them from federal minimum-age-of-sale laws and other restrictions.

In holding that FDA insufficiently addressed two pieces of evidence, the district court failed to consider the totality of the agency's analysis and did not give due deference to the agency's scientific judgments. The court further erred in rejecting FDA's arguments for remand without vacatur, thereby exempting premium cigars from federal regulation and significantly unsettling the comprehensive federal scheme. For the reasons that follow, both decisions should be reversed.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction pursuant to 28 U.S.C. § 1331. JA 238. On July 5, 2022, the district court granted plaintiffs' motion for summary judgment with respect to count V, JA 34, and on August 9, 2023, the court entered an order vacating FDA's deeming rule in pertinent part, JA 3. On September 29, 2023, the government filed a timely notice of appeal. JA 1; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether FDA reasonably determined that exempting premium cigars from federal regulation would not promote the public health given

that all cigars are dangerous and potentially addictive, and the record does not show that patterns of premium-cigar use eliminate that risk of harm.

2. Whether any error by FDA in not addressing certain studies more fully could be readily addressed on remand without upending the comprehensive federal scheme of tobacco-product regulation, making remand without vacatur the appropriate remedy.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

1. The Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387 *et seq.*), established a comprehensive scheme for the regulation of tobacco products, which include "any product made or derived from tobacco . . . that is intended for human consumption." 21 U.S.C. § 321(rr)(1). "Based on decades of research, Congress made extensive findings about the public health risks of tobacco use: 'A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.'" *Nicopure Labs, LLC v. FDA*, 944

F.3d 267, 272 (D.C. Cir. 2019) (quoting TCA § 2(2), 123 Stat. at 1777). And tobacco use is "the foremost preventable cause of premature death in America." *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 438 (5th Cir. 2020) (quoting TCA § 2(13), 123 Stat. at 1777).

"To advance its public-health purpose, Congress established a detailed framework for regulating tobacco," and it gave FDA "broad authority to address 'the public health and societal problems caused by the use of tobacco products.'" *Big Time Vapes*, 963 F.3d at 438 (quoting TCA § 2(7), 123 Stat. at 1777). "Because more limited approaches had failed to curb tobacco use, including by adolescents, Congress insisted on 'comprehensive restrictions on the sale, promotion, and distribution' of tobacco products." *Nicopure Labs*, 944 F.3d at 272 (quoting TCA § 2(6), 123 Stat. at 1777). The Tobacco Control Act thus requires tobacco product manufacturers to disclose a variety of information about the composition, manufacture, and effects of their products, 21 U.S.C. § 387d(a), and it prohibits the marketing of a "new tobacco product" without FDA authorization, *id.* § 387j(a). The Act also authorizes FDA to "impose additional rules by regulation, such as minimum-age restrictions,

mandatory health warnings, method-of-sale limits, and advertising constraints." *Big Time Vapes*, 963 F.3d at 439 (citing 21 U.S.C. § 387f(d)).

Congress did not make the Tobacco Control Act immediately applicable to all "tobacco products." As enacted, its provisions applied to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," and "to any other tobacco products" that FDA "by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b).[1]

In 2014, FDA issued a notice of proposed rulemaking that would deem most products meeting the statutory definition of "tobacco product" and thus bring them within the regulatory framework of the Tobacco Control Act. 79 Fed. Reg. 23,142. FDA acknowledged that different types of tobacco products might present different degrees of risk, and the agency solicited comments regarding the extent of those risks and their regulatory implications. *Id.* at 23,143. For example, FDA noted that some interested parties "have advanced views that certain new tobacco products that are noncombustible (such as e-cigarettes) may be less hazardous than

[1] In 2022, Congress also made these provisions applicable to "any tobacco product containing nicotine that is not made or derived from tobacco," bringing synthetic nicotine products under FDA's authority. Pub. L. 117-103, 136 Stat. 49 (2022).

combustible products given the carcinogens in smoke and the dangers of secondhand smoke from combustible products." *Id.* Accordingly, FDA sought comments on "how e-cigarettes should be regulated based on the continuum of nicotine-delivering products." *Id.*

FDA also sought comments on how broadly to regulate cigars. Cigars come in a number of forms and include any "roll of tobacco wrapped in leaf tobacco or any substance containing tobacco" that is "not a cigarette." 21 C.F.R. § 1143.1. The principal varieties of cigars include little cigars, which resemble cigarettes; moderately sized cigarillos; and large traditional cigars. Among traditional cigars, certain more expensive products are sometimes referred to as "premium" cigars.

FDA noted in the proposed rule that, although "all cigars are harmful and potentially addictive," comments from some stakeholders "suggested that different kinds of cigars may have the potential for varying effects on public health, based on possible differences in their effects on dual use, youth initiation[,] and frequency of use by youth and young adults." 79 Fed. Reg. at 23,143. Accordingly, FDA sought comments on two options, the first of which would deem all tobacco products, including all cigars, subject to the requirements of the Tobacco Control Act, while the second

would exclude "premium" cigars from the scope of the regulation. *Id.* at 23,150-52. Because the Tobacco Control Act does not define the term "premium cigar" (nor is it subject to any other widely recognized definition), FDA also solicited comments on a possible definition of that term for purposes of the second option. *Id.* at 23,150. FDA received over 135,000 comments on the proposed rule. *See* 81 Fed. Reg. at 28,982.

2. In May 2016, FDA issued a final rule that adopted the first of the options above and deemed all products meeting the statutory definition of "tobacco product"—including all cigars and e-cigarettes, as well as pipe tobacco, hookah tobacco, and nicotine gels and dissolvables—subject to the Tobacco Control Act. 81 Fed. Reg. at 28,975.[2] As a result of the deeming rule, all products meeting the statutory definition of tobacco product became subject to a variety of federal requirements, including minimum age-of-sale restrictions, 21 U.S.C. § 387f(d)(5), prohibitions on free samples and vending machine sales, 21 C.F.R. §§ 1140.14(b)(3), 1140.16(d), and

[2] Deemed products include any "component or part" of a tobacco product but exclude "accessor[ies]" of such products, even though the latter fall within the statutory definition of "tobacco product." *See* 81 Fed. Reg. at 28,975 (explaining these distinctions). References in this brief to FDA's decision to deem all "tobacco products" are subject to the caveat that FDA excluded accessories of such products.

restrictions on false or misleading advertising and unauthorized modified-risk claims, 21 U.S.C. §§ 387c(a)(1), (7)(A), 387k. The deeming rule also made certain categories of tobacco products, including cigars, subject to statutory user fee obligations that fund federal tobacco regulation. *Id.* § 387s(b)(2)(B); *see* 81 Fed. Reg. 28,707 (May 10, 2016) (implementing the user fee statute for those tobacco products).

In determining the appropriate scope of the deeming rule, FDA acknowledged "a continuum of risk" within the broader category of tobacco products. 81 Fed. Reg. at 29,027. For example, "some evidence suggests that [e-cigarettes] may potentially promote transition away from combusted tobacco use among some current users and it is possible that there could be a public health benefit." *Id.* at 29,011. But FDA explained that "[w]hether [e-cigarettes] generally may eventually be shown to have a net benefit on or harm to public health at the population level—and there have not yet been long-term studies conducted to support either claim at this time—*regulation* of [e-cigarettes] will still benefit public health." *Id.* at 28,984. Deeming "affords FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use," allowing the agency to access information about the manufacture and

composition of tobacco products and enabling the agency to take appropriate action, *id.* at 28,975, and these tools serve the public health even as applied to lower-risk tobacco products, *id.* at 28,984.

FDA reached a similar conclusion with respect to premium cigars, which it directly addressed in over eight pages of the Federal Register (among other places in the final rule). 81 Fed. Reg. at 29,020-27. The agency noted evidence suggesting that, as compared to cigarette smokers, "cigar smokers generally smoke at a lower frequency and tend not to inhale the smoke, thus reducing (but not eliminating) their exposure to its toxic substances." *Id.* at 29,020. The evidence established, however, that all cigars present serious health risks and can be addictive. *Id.* at 29,025. And FDA found evidence indicating "increased disease risk and nicotine dependence [even] among infrequent cigar users and those reporting they do not inhale." *Id.* at 29,024.

"[A] cigar can contain as much tobacco as a whole pack of cigarettes, and nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette[.]" 81 Fed. Reg. at 29,022. Cigar smoke also contains many of the same harmful constituents as cigarette smoke and may have higher levels of certain harmful compounds. *Id.* at

29,020, 29,022. As a result, cigar smokers have an increased risk of a variety of fatal diseases relative to nonsmokers, including lung cancer, oral cancer, laryngeal cancer, esophageal cancer, stomach cancer, heart disease, aortic aneurysm, stroke, and chronic obstructive pulmonary disease. *Id.* at 29,020-21, 29,024. And exposure to secondhand cigar smoke "can cause the same or similarly dangerous effects as exposure to secondhand cigarette smoke," *id.* at 29,071, including heart disease and lung cancer, *see id.* at 29,020. Therefore, FDA explained that premium cigar use patterns do not "sufficiently reduce the health risks to warrant exclusion" from all regulation. *Id.* at 29,020.

FDA found that, although the health risks of cigars are well established, many people inaccurately think cigars are safer alternatives to cigarettes. 81 Fed. Reg. at 29,024. "Such confusion and misinformation about the harmfulness and addictiveness of cigars are particularly troubling given the increasing popularity of cigars . . . among youth . . . ." 79 Fed. Reg. at 23,158. Cigar use in the United States has persisted even as the use of cigarettes has declined. Between 2000 and 2011, overall consumption of large cigars increased by 233.1%. *Id.* at 23,147. And "youth cigar use has not declined when compared to use of other tobacco

products." 81 Fed. Reg. at 29,023. In 2014, 8.2% of high school students—some 1.2 million youth—were current cigar users, similar to the 9.2% of high school students who smoked cigarettes. *Id.* at 28,985. The record evidence indicated that tens of thousands of youth were current users of premium cigars in particular. *See* JA 321-23;[3] *see also* 81 Fed. Reg. at 29,023 (finding that youth cigar use is likely underreported).

FDA also determined that an exemption for premium cigars could have implications for broader patterns of tobacco use, which "may change over time and in response to regulation." 81 Fed. Reg. at 29,025. For example, exempting such products could increase youth use by "mislead[ing] consumers to believe that premium cigars are safe," *id.* at 29,021, and increasing the relative availability of such products by excluding them from federal minimum-age-of-sale rules and other restrictions, *see id.* at 29,022 (noting that "easier availability" influences youth tobacco use). FDA also noted that the availability of combustible tobacco products could affect the extent to which smokers switch to non-

[3] *See* Federal Interagency Forum on Child and Family Statistics, *Child Population* (table), *available at* https://www.childstats.gov/americaschildren/tables/pop1.asp (estimating 25 million U.S. youth ages 12-to-17).

combustible options, like e-cigarettes, that potentially present less risk. *See id.* at 28,984. Based on these considerations, FDA concluded that "there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule." *Id.* at 29,020.[4]

B. Procedural Background

Plaintiffs, three cigar industry associations, filed suit in July 2016, alleging as relevant to this appeal that FDA's decision to include premium cigars among the tobacco products made subject to federal regulation was arbitrary and capricious because FDA did not adequately address evidence suggesting that many premium-cigar users smoke infrequently and that infrequent cigar use may entail less risk.[5]

In July 2022, the district court granted summary judgment for plaintiffs on the ground that FDA's notice of proposed rulemaking made the relative risk of premium-cigar use a central question, and FDA did not adequately consider evidence bearing on that question. JA 20. The court

[4] FDA later issued an advance notice of proposed rulemaking inviting further comment on the regulation of premium cigars, 83 Fed. Reg. 12,901 (Mar. 26, 2018), but it subsequently withdrew that notice, JA 129-31.

[5] This Court addressed unrelated issues in earlier appeals. *Cigar Ass'n of Am. v. FDA*, 5 F.4th 68 (D.C. Cir. 2021); *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56 (D.C. Cir. 2020).

observed that it was already well established at the time of the proposed rule that premium cigars, like other cigars, contain nicotine and other harmful components. JA 26 (citing 79 Fed. Reg. at 23,143). The question raised by the agency was "whether premium cigar smokers used the product in a materially different way from non-premium cigar smokers" such that "those potential differences might warrant a different regulatory approach." JA 26-27.

The district court concluded that, "[d]espite this ask for evidence, the FDA said it received none," JA 21, stating in the final rule that "no . . . evidence was submitted" showing "how the potential different patterns of use for premium cigars might result in different or decreased health impacts," 81 Fed. Reg. at 29,022. The court agreed with plaintiffs that FDA failed to address the significance of two studies that can be read together to support an inference on the topic for which the agency had solicited evidence. JA 25. One of those studies, a 2014 report by the Centers for Disease Control and Prevention (referred to as the Corey study), JA 436-40, found that "only a small fraction of survey respondents who identified themselves as premium cigar users admitted to smoking on a daily basis." JA 22. One chapter in the other study, a 1998 National Cancer Institute

report titled "Cigars: Health Effects and Trends Monograph No. 9" (referred to as Monograph 9), found "no statistically significant difference in the 'all-cause' mortality rate as between 'neversmokers' and those who smoked no more than two cigars per day." *Id.*

The court concluded that the two studies, taken together, suggest that many premium-cigar users smoke infrequently and are thus exposed to less risk, and it agreed with plaintiffs that FDA inadequately addressed the studies. JA 22. The court focused on FDA's statement that "there were *no data* provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks." JA 23 (quoting 81 Fed. Reg. at 29,020), when, "in fact, there was record evidence showing a connection between less frequent use among premium cigar smokers and reduced public health risks," JA 21.

Plaintiffs also argued that FDA misinterpreted evidence about youth use of premium cigars, and the district court agreed that the deeming rule's discussion of that evidence "obscures the real math." JA 31. The court ultimately declined to decide whether FDA "misunderstood" a certain study and therefore acted arbitrarily and capriciously "in finding that youth 'are using premium cigars,'" noting that the "court trusts that any

action by the agency on remand will view the [relevant] study in its proper light." JA 32 (quoting 81 Fed. Reg. at 29,023).

On August 9, 2023, following supplemental briefing as to the appropriate remedy, the district court vacated the deeming rule insofar as it applies to premium cigars and remanded to the agency. Stating that remand without vacatur is reserved for exceptional cases, the court rejected FDA's arguments that the nature of the cited deficiencies and the disruptive consequences of vacatur warranted a departure from the default rule. JA 12-13.

For purposes of its ruling, the court defined "premium cigars" as those that: "(1) are wrapped in whole tobacco leaf; (2) contain a 100 percent leaf tobacco binder; (3) contain at least 50 percent (of the filler by weight) long filler tobacco; (4) are handmade or hand rolled; (5) have no filter, nontobacco tip, or nontobacco mouthpiece; (6) do not have a characterizing flavor other than tobacco; (7) contain only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weigh more than 6 pounds per 1,000 units." JA 15 n.7.

SUMMARY OF ARGUMENT

I. "There is inherent risk in all tobacco-derived products," 81 Fed. Reg. at 29,025, and FDA reasonably determined that bringing all such products under the Tobacco Control Act will benefit the public health by giving FDA important tools for mitigating potential harms, *id.* at 28,984, 29,020; *see Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 439-40 (5th Cir. 2020).

Consistent with that determination, FDA "concluded that deeming all cigars, rather than a subset, more completely protects the public health." 81 Fed. Reg. at 29,020. The evidence makes clear that "no amount of smoking is safe," *id.*, and that "cigar use of all types can lead to negative health effects" for smokers as well as bystanders, *id.* at 29,022. "The fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others." *Id.* at 29,020.

The available data also "clearly indicate that youth and young adults are using premium cigars." 81 Fed. Reg. at 29,023. And the evidence shows that rates of cigar use, including among youth, have persisted even as cigarette use has declined. *See id.* FDA determined that exempting a

subset of cigars from regulation could have implications for youth use by "mislead[ing] consumers to believe that premium cigars are safe," *id.* at 29,021, and by increasing the availability of such products relative to those that are subject to federal minimum-age-of-sale laws and other restrictions. Based on these considerations, FDA concluded that "there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule and that it is appropriate to deem them." *Id.* at 29,020.

The district court nevertheless set aside FDA's determination on the ground that the agency failed to address adequately two studies that, together, suggest that many premium-cigar users smoke infrequently and that infrequent cigar use may entail less risk. The court was mistaken. FDA addressed comments and evidence to this effect, including the studies at issue, and it amply explained why deeming all cigars benefits the public health even if patterns of premium-cigar use may entail less risk for some users.

II. If the Court were to conclude that FDA needed to further consider the two studies, the appropriate remedy would be remand without vacatur. *See Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d

146, 150-51 (D.C. Cir. 1993). Any explanatory error was minor within the broader scope of the rulemaking, and FDA could readily address the issue on remand by setting out its reasoning in greater detail. Vacating the rule in the interim tears a hole in the comprehensive regulatory scheme established by Congress and creates risks to the public health by leaving a category of harmful and potentially addictive products wholly unregulated—making it legal under federal law to sell premium cigars to young adults under age 21; to distribute premium cigars in vending machines and as free samples; and to ignore restrictions on false or misleading labeling and advertising. Vacating the rule also significantly disrupts the operation of the statutory user fee scheme that Congress established to fund federal tobacco regulation. *See* 21 U.S.C. § 387s.

STANDARD OF REVIEW

This Court reviews de novo the district court's review of agency action under the Administrative Procedure Act (APA). *Cigar Ass'n of Am. v. FDA*, 5 F.4th 68, 74 (D.C. Cir. 2021). The agency's decision must be upheld unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In undertaking such review, the Court "is not to substitute its judgment for

that of the agency, but instead to assess only whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Cigar Ass'n*, 5 F.4th at 74 (quoting *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020). Courts "give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise." *West Virginia v. EPA*, 362 F.3d 861, 871 (D.C. Cir. 2004) (quoting *Hüls Am. Inc. v. Browner*, 83 F.3d 445, 452 (D.C. Cir. 1996)). The Court reviews the district court's vacatur decision for abuse of discretion. *Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs*, 985 F.3d 1032, 1051 (D.C. Cir. 2021).

ARGUMENT

I. FDA Reasonably Concluded that There Is No Public Health Justification for Leaving Premium Cigars Entirely Unregulated.

A. The Tobacco Control Act gave "FDA broad authority to address 'the public health and societal problems caused by the use of tobacco products.'" *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 438 (5th Cir. 2020) (quoting TCA § 2(7), 123 Stat. at 1777). This "detailed framework for regulating tobacco" did not immediately apply to all forms of tobacco. *Id.* Instead, Congress made the Act applicable "to all cigarettes, cigarette

tobacco, roll-your-own tobacco, and smokeless tobacco," and "to any other tobacco products that [FDA] by regulation deems to be subject to [the Act]." 21 U.S.C. § 387a(b).

1. In comprehensive notice-and-comment rulemaking, FDA concluded that deeming all products that meet the statutory definition of "tobacco product" would best promote the public health. 81 Fed. Reg. at 28,975. As FDA explained, "[t]here is inherent risk in all tobacco-derived products." *Id.* at 29,025. "A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 272 (D. C. Cir. 2019) (quoting TCA § 2(2), 123 Stat. at 1777).

FDA further observed that, within this category of inherently dangerous products, there is a "continuum of risk"—as indicated, for example, "by the lower levels of toxicants in [e-cigarettes] in comparison to cigarettes." 81 Fed. Reg. at 29,027. The agency determined, however, that even tobacco products at the lower end of the continuum pose significant health risks, and it rejected the contention of some commenters that "it is

appropriate for FDA not to regulate certain tobacco products by virtue of their potential for varying effects on public health." *Id.* at 29,020-21.

FDA explained that even for tobacco products that "may eventually be shown to have a net benefit . . . to public health at the population level," "*regulation* of [the products] will still benefit public health" by giving the agency important tools to mitigate the potential for harm inherent in all tobacco products. 81 Fed. Reg. at 28,984. Thus, for example, although e-cigarettes "may potentially promote transition away from combusted tobacco," *id.* at 29,011, they present a risk of harm that warrants regulation as a deemed tobacco product, *id.* at 28,984; *see Nicopure Labs*, 944 F.3d at 271 (finding it "entirely rational and nonarbitrary to apply to e-cigarettes the Act's baseline requirement[s]"). The agency discussed at length why it would be contrary to the purposes of the Tobacco Control Act and inconsistent with the scientific evidence to wholly exclude certain tobacco products from regulation because they are lower on the continuum of risk.

2. In contrast to e-cigarettes, there is no contention that cigars might provide a net public health benefit. Plaintiffs claim, instead, that FDA was required to exempt premium cigars—and only premium cigars—from the comprehensive federal scheme for the regulation of tobacco products

because patterns of use might reduce health risks for some users. The agency addressed such contentions and amply explained its conclusion that an approach that subjects all tobacco products to regulation will better protect the public health than an option that creates a unique carveout for premium cigars. FDA determined that "(1) all cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults." 81 Fed. Reg. at 29,020.

FDA recognized that usage patterns affect smokers' precise level of risk from cigar use. As the agency noted, there is some evidence that "those who use a pipe or cigar usually smoke at a lower frequency" than cigarette smokers, 81 Fed. Reg. at 29,022, and that exposure to lower levels of cigar smoke for shorter periods of time may decrease the adverse health risks, *id.* at 29,020. But the evidence also shows that patterns of less frequent use "do not preclude [cigar] users from experiencing negative health effects" so as to obviate the potential for public harm. *Id.* at 29,024 (capitalization omitted). To the contrary, "[a]ll cigars expose users to toxic and cancer-causing substances and increase the risk of harm." *Id.* at 29,025.

And the "science is clear that cigar use of all types can lead to negative health effects," *id.* at 29,022—both for smokers and for those exposed to secondhand smoke, *see id.* at 29,020.

As with e-cigarettes, FDA found that deeming all cigars subject to the Tobacco Control Act will provide significant benefits even if patterns of less frequent use might entail less risk for some users. "For example, the adulteration and misbranding provisions . . . will protect consumers because FDA will be able to take enforcement action against any non-compliant tobacco product, such as a product with false or misleading labeling or advertising," and ingredient listings and reports of harmful and potentially harmful constituents "will assist FDA in better understanding the contents" and potential health risks of these products "and determining if future regulations" are warranted. 81 Fed. Reg. at 29,020. In addition, "FDA will be able to conduct biennial inspections of tobacco product manufacturers" and to "monitor product development and changes." *Id.* If premium cigars were instead exempted from deeming, they would not be subject to any federal regulations, including those designed to prevent youth access, such as federal minimum-age-of-sale restrictions and prohibitions on free samples and vending machine sales.

In addition, FDA explained that an exemption for premium cigars "could mislead consumers to believe that premium cigars are safe, which contradicts the available evidence that all cigars are harmful and potentially addictive." 81 Fed. Reg. at 29,021. By contrast, "[d]eeming all tobacco products, including premium cigars . . . will help to alleviate mistaken beliefs that certain tobacco products are safer alternatives to cigarettes by virtue of the fact that they are not subject to FDA regulation." *Id*. at 29,024.

FDA also determined that exempting certain products would have implications for patterns of use—including among youth—which "may change over time and in response to regulation." 81 Fed. Reg. at 29,025; *see Prohibition Juice Co. v. FDA*, 45 F.4th 8, 26 (D.C. Cir. 2022) (noting the fluidity of youth tobacco-use patterns). The data "clearly indicate that youth and young adults are using premium cigars," and the extent of youth use is likely underreported. 81 Fed. Reg. at 29,023. Youth use of such products is likely to increase if premium cigars are singled out for exemption from regulation, making it lawful for 18-to-20-year-olds to purchase such products in many States. *See id.* at 29,021, 29,022 (noting that "easier availability" influences youth tobacco use). The availability of

combustible tobacco products could also affect the extent to which smokers switch to noncombustible options, like e-cigarettes, that potentially present less risk. *Id.* at 28,984. Such considerations are among the reasons why "Congress meant for the FDA to attack [the problems associated with tobacco use] *comprehensively*, that is, in an 'all-encompassing or sweeping' fashion." *Big Time Vapes*, 963 F.3d at 445 (footnote omitted) (quoting *Gundy v. United States*, 139 S. Ct. 2116, 2127 (2019) (plurality opinion)).

B.1. In setting aside FDA's determination, the district court declared that FDA had not adequately addressed patterns of premium-cigar use, focusing on findings contained in two studies suggesting that many premium-cigar users smoke less frequently than smokers of other cigars (the Corey study), and that infrequent cigar users do not have statistically significantly higher all-cause mortality than non-users of tobacco products (Monograph 9). JA 21-26. The court held that FDA did not adequately address the import of these studies, and that the agency's analysis was thus insufficiently "responsive to the contention that less frequent use of premium cigars reduces the public health risks of that product." JA 26.

As the foregoing discussion shows, however, FDA repeatedly acknowledged the main point for which plaintiffs cited these studies—that

patterns of infrequent use may entail lower risk for many premium-cigar smokers. *See, e.g.*, 81 Fed. Reg. at 29,022 (noting evidence that cigar smokers "usually smoke at a lower frequency" and that those who smoke cigars exclusively "have a lower risk for many smoking-related diseases"); *id.* at 29,024 (noting comments stating "that a majority of cigar users are occasional smokers (two to six cigars per week) and do not inhale"). FDA also repeatedly cited the relevant studies in its discussion of cigar risks. *See id.* at 29,020-25 (citing Monograph 9 (Ref. 69) sixteen times and the Corey study (Ref. 90) five times). And the agency explicitly acknowledged the Monograph 9 finding that "data for the lowest level of cigar users (one to two cigars per day) do not reveal mortality rates that are significantly different from nonsmokers." *Id.* at 29,024; *see id.* at 29,021 (same).[6]

After acknowledging these comments and evidence regarding the diminished risks of infrequent use by some users, FDA explained its

[6] Notably, although plaintiffs and the district court relied on Monograph 9 as a basis for distinguishing premium cigars, the study is not specific to premium cigars, and its findings regarding the risks of infrequent cigar use refer to the risks of cigar use generally, rather than premium cigars in particular. *See* JA 354 (noting that the "level of exposure to cigar smoke is usually measured in cigars per day, which is an imprecise measure because of the varying sizes of cigars" (emphasis omitted)).

determination that "the cited studies or critiques are not persuasive" as a basis for excluding premium cigars from regulation. 81 Fed. Reg. at 29,021. FDA also noted countervailing evidence "suggesting increased disease risk and nicotine dependence among infrequent cigar users and those reporting they do not inhale." *Id.* at 29,024. Monograph 9 found that those who smoke 1-2 cigars a day are almost twice as likely to die from aortic aneurysm as non-smokers are. JA 403. Another study— a "systematic review of cigar smoking and mortality [that] summarized the results of 22 published studies," including data from Monograph 9, 81 Fed. Reg. at 29,024 (Ref. 82), also reported that "elevated risks of oral, esophageal, laryngeal cancers, and aortic aneurysm were observed among primary cigar users who smoked 1-2 cigars per day, although most of these risks did not reach statistical significance due to small sample size." JA 431; *see also* JA 337, 403.

After considering this and other evidence, FDA determined that although less frequent cigar use may entail less risk to individual users, "all cigar smoking is harmful." 81 Fed. Reg. at 29,024. FDA discussed the systematic review's finding that "primary cigar smoking [i]s associated with increased risk of mortality from all causes, several types of cancers,

coronary heart disease, and aortic aneurysm compared to nonsmokers[.]" *Id.* And it noted that, "[w]hile exposure to higher levels of cigar smoke for a longer period of time increases the adverse health risks due to cigar smoking (just as it does for cigarettes), the Surgeon General has stated that no amount of smoking is safe." *Id.* at 29,020.

FDA also addressed comments arguing that patterns of non-inhalation among premium cigar smokers obviates the risk to such users, explaining that "[w]hile inhaling cigar smoke poses much higher morbidity and mortality rates than not inhaling, significant risk still exists for those who do not inhale." 81 Fed. Reg. at 29,024. The evidence shows that "among primary cigar smokers reporting that they do not inhale, relative mortality risk was still highly elevated for oral, esophageal, and laryngeal cancers" as well as stomach cancer. *Id.* Thus, "[r]egardless of whether cigar smokers inhale, they are still subject to the addictive and other adverse health effects of the product through absorption of nicotine and harmful constituents." *Id.* at 29,024-25.

Ultimately, FDA found no evidence showing that patterns of infrequent use or reported non-inhalation "preclude premium cigar users from experiencing the negative health effects of these products" so as to

make their use safe. 81 Fed. Reg. at 29,024. As Monograph 9 explains, it is possible that "differences in frequency of exposure translates into lower disease risks," but "quitting is the only way to eliminate the documented harm that can result from cigar smoking." JA 330. Indeed, Monograph 9 rejects the claim that "cigar smokers who smoke few cigars or do not inhale have no increased risk of disease," and it explains that "[a] more accurate statement would be that the risks experienced by cigar smokers are proportionate to their exposure to tobacco smoke." JA 339. The study also notes that, due to their size and the duration of use, large cigars (including premium cigars) tend to present significant risks of harm to non-smokers from the large quantity of secondhand smoke generated. JA 330.

Similarly, although the Corey study indicates that many premium-cigar users smoke infrequently, it also shows that a significant number of people regularly smoke premium cigars—and are thus undisputedly exposed to greater risk. The percentages reported in the Corey study indicate that approximately 120,000 adults in the United States smoke

premium cigars at least daily. *See* JA 436-38.[7] Moreover, many cigar smokers, including a significant proportion of premium-cigar smokers, also use other tobacco products, which increases their overall risk. 81 Fed. Reg. at 29,022 (citing the Corey study's finding that 35.1% of adult premium-cigar smokers—or roughly 1.3 million people nationwide—also smoke cigarettes). Monograph 9 also raises concerns that former cigarette smokers who become occasional cigar smokers are at risk of re-initiating their nicotine addiction due to their exposure to the nicotine in cigars, JA 343, 353—underscoring the complex public health considerations of tobacco product use. *See also* JA 344 (noting the "likelihood of cigar smoking leading to initiation of cigarette smoking").

2. Without crediting the agency's broader analysis, the district court focused narrowly on statements in the final rule indicating that "there were no data provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks.'"

[7] The study found that, of the 7.3% of U.S. adults who smoke cigars, 19.9% usually smoke premium cigars, and 3.3% of those smoke every day. *See* JA 436-38; U.S. Census Bureau, *Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States: April 1, 2010 to July 1, 2019*, https://perma.cc/436E-LBHE (adult population was over 249 million in 2016).

JA 19, 21, 23, 29 (quoting 81 Fed. Reg. at 29,020); *see* JA 29 ("FDA specifically sought comment on how the potential different patterns of use for premium cigars might result in different or decreased health impacts, but no such evidence was submitted." (quoting 81 Fed. Reg. at 29,022)).

The court's focus on those statements failed to account for the entirety of FDA's reasoned explanation and the information that FDA considered. Indeed, the two other "no data" statements that the district court referenced, *see* JA 21, provide clarifying context about what FDA considered deficient about the submitted information. The agency explained that "the comments did not include data indicating that premium cigar smokers are not subject to disease risk and addiction," 81 Fed. Reg. at 29,024," and they provided "no data indicating that premium cigar users are not susceptible to health risks," *id*. at 29,020. These statements comport with FDA's explanation that "commenters have not substantiated their claims that the patterns of use for premium cigars preclude users from negative health effects." *Id*. at 29,027. Contrary to the district court's suggestion, JA 26, FDA's determination that premium cigar use presents health risks to both users and bystanders is a reasonable basis

for concluding that all cigars, like all other tobacco products, should be subject to the provisions of the Tobacco Control Act.

When the agency's statements are considered in context, it is clear that FDA did not ignore the evidence that plaintiffs cite, it simply gave the evidence different weight. *Cf. FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1159 (2021). This Court has explained that an agency's decision need not "be a model of analytic precision to survive a[n APA] challenge." *Dickson v. Secretary of Def.*, 68 F.3d 1396, 1404 (D.C. Cir. 1995). Rather, an agency is "entitled to summary judgment if the path of its reasoning is sufficiently discernable in light of the record." *Settles v. U.S. Parole Comm'n*, 429 F.3d 1098, 1108 (D.C. Cir. 2005). When an agency "is evaluating scientific data within its technical expertise," the degree of deference owed to the agency's judgments is at its peak. *West Virginia v. EPA*, 362 F.3d 861, 871 (D.C. Cir. 2004) (quoting *Hüls Am. Inc. v. Browner*, 83 F.3d 445, 452 (D.C. Cir. 1996)).

The district court failed to adhere to these principles in focusing on FDA's "no data" statements in isolation and failing to consider the agency's broader analysis, including its express consideration of whether evidence of infrequent use of premium cigars might warrant different

treatment. Having addressed that question, FDA concluded that regulating premium cigars—rather than creating a special exemption for such products that would leave them free from federal oversight—will benefit the public health. 81 Fed. Reg. at 29,020. That conclusion is amply supported by the record. FDA's determination that even lower-risk tobacco products, like e-cigarettes, should be subject to regulation indicates that any error in failing to further address the risks of premium-cigar use was harmless. *See Prohibition Juice Co.*, 45 F.4th at 24 (noting that the Court will not grant a claim for relief when "an agency's mistake plainly 'had no bearing' on the substance of its decision" and emphasizing that "'the burden of showing that an error is harmful normally falls upon the party attacking the agency's determination'" (quoting *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009))).

3. FDA's reliance on considerations of youth premium-cigar use was likewise reasonable. The agency explained at length its conclusion that "youth and young adults are using premium cigars," 81 Fed. Reg. at 29,023, as well as its concern that an exemption for premium cigars would "lead[] more youth and young adults to initiate use of premium cigars," *id.* at 29,021.

In district court, plaintiffs urged that FDA misinterpreted key evidence about premium-cigar use among youth. FDA noted that in one study (the Delnevo study), researchers used data from "a study sample consisting of 6,678 past 30-day cigar smokers who reported smoking a usual brand of cigars." 81 Fed. Reg. at 29,023. Explaining the study findings, FDA stated that, "[w]hile many youth identified a mass market cigar as the brand they used most often, this analysis reveals that 3.8 percent of youth aged 12 to 17 and 12.1 percent of young adults aged 18 to 25 also identified certain premium cigars to be the brand they smoked most often." *Id.* That statement describes the use patterns of study participants and conveys that 3.8% of youth past 30-day cigar smokers who reported smoking a usual brand of cigars reported a premium cigar as the brand they smoked most often.

Although the district court did not hold that this discussion was arbitrary and capricious, it found that it "obscured the real math" by failing to spell out more clearly that 3.8% of youth cigar smokers smoke a premium cigar as their usual brand, as opposed to 3.8% of all youth. JA 30-32. But FDA's discussion of the study results is clear in context. *See* 81

Fed. Reg. at 29,023. And the study fully supports FDA's determination that "youth and young adults are using premium cigars." *Id.*

II. If the Court Were Nevertheless To Find the Deeming Decision Insufficiently Reasoned with Respect to Premium Cigars, the Proper Remedy Would Be Remand Without Vacatur.

If the Court were nevertheless to find that FDA failed to sufficiently consider two studies before deeming premium cigars, the appropriate remedy would be to remand to the agency without vacatur, rather than issuing an order that judicially defines the category of premium cigars and exempts them from regulation. "Although 'vacatur is the normal remedy' under the APA" in this Court,[8] the Court's precedents allow for "remand without vacating the agency's action in limited circumstances." *American*

[8] Contrary to that practice, a court's invalidation of a regulation in an APA action should not have the effect of a nationwide vacatur. There is no sound reason to conclude that Congress "meant to upset the bedrock practice of case-by-case judgments with respect to the parties in each case" by adopting the "unremarkable" "set aside" language in 5 U.S.C. § 706(2). *Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring); *cf. Georgia v. President of the U.S.*, 46 F.4th 1283, 1303-08 (11th Cir. 2022) (listing the reasons to be "both weary and wary of" nationwide relief). The extraordinary consequences of the claimed judicial authority strongly counsel against interpreting the APA's delegation so expansively. *Cf. West Virginia v. EPA*, 597 U.S. 697, 723 (2022) (reasoning that "[e]xtraordinary grants of . . . authority are rarely accomplished through 'modest words,' 'vague terms,' or 'subtle device[s]'" (third alteration in original)).

Great Lakes Ports Ass'n v. Schultz, 962 F.3d 510, 518 (D.C. Cir. 2020) (quoting *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014)). "To determine whether to remand without vacatur, this court considers first, 'the "seriousness of the [action's] deficiencies,"' and, second, the 'likely "disruptive consequences" of vacatur.'" *Id.* 518-19 (alteration in original). Both considerations counsel against vacatur in these circumstances.

First, the alleged shortcomings in the agency's analysis are not grave and can readily be addressed on remand. *See Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009) ("When an agency may be able readily to cure a defect in its explanation of a decision, the first factor . . . counsels remand without vacatur."). FDA amply explained its determination that "[t]here is inherent risk in all tobacco-derived products," 81 Fed. Reg. at 29,025, and that regulating all such products irrespective of their relative risk gives the agency important tools for curbing underage use and preventing misleading advertising, among other benefits, *id.* at 28,984, 29,020, 29,027. In reaching that conclusion, FDA directly acknowledged the evidence cited by the district court suggesting that patterns of infrequent premium-cigar use entail less risk. *See id.* at 29,921, 29,024. But the same study, as well as copious other evidence,

confirms that "[a]ll cigars pose serious negative health risks," and FDA reasonably concluded that subjecting all cigars to regulation would best protect the public health. *Id.* at 29,020. To the extent this Court determines that FDA should have addressed Monograph 9 or the Corey study in more detail or explained how the "no data" statements relied on by the district court comport with the agency's findings, FDA could easily provide the explanation on remand.

The broader context of the agency's analysis confirms that any error in not further addressing the studies in question was minor. FDA identified a number of harms associated with premium-cigar use that are not mitigated by infrequent use. For example, the agency explained concerns about the cumulative risk presented by secondhand smoke, "which causes negative health effects such as heart disease and lung cancer in bystanders," 81 Fed. Reg. at 29,022; the risks of "dual and polyuse of cigars and other tobacco products," *id.*; and the likely increase in youth initiation if a subset of cigars is exempted from regulation, *id.* at 29,021. These separate grounds for regulation underscore that any error in not further addressing the studies in question was not serious in the broader scope of the rulemaking. To the extent the district court's 2023 vacatur

decision relied on speculation about what the agency might do on remand based on a report published in March 2022, nearly six years after the deeming rule was promulgated, the court's reliance was in error. JA 10.

Second, remand without vacatur is also warranted because vacatur hampers Congress's efforts to address the public health harms caused by tobacco products. "Congress meant for the FDA to attack those [harms] *comprehensively*," *Big Time Vapes*, 963 F.3d at 445 (quoting *Gundy*, 139 S. Ct. at 2127 (plurality opinion)), and deeming all tobacco products subject to the Tobacco Control Act is a necessary prerequisite for any regulation of those products. Vacatur makes the deeming rule inapplicable to premium cigars, leaving them essentially unregulated at the federal level. They are no longer subject to the federal minimum-age-of-sale requirement for tobacco products, *see* 21 U.S.C. § 387f(d)(5), or to prohibitions on free samples and vending machine sales, 21 C.F.R. §§ 1140.16(d), 1140.14(b)(3). And vacatur leaves premium-cigar manufacturers free "to mislabel their products without consequence." *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 394 (D.D.C. 2017); *see* 21 U.S.C. §§ 387c(a)(1), (a)(7)(A), § 387k. FDA explained that the predictable result of leaving premium cigars uniquely free from these federal restrictions will be an increase in youth and young adult

use—and the associated disease and addiction. *See* 81 Fed. Reg. at 29,021; *Prohibition Juice*, 45 F.4th at 26 (noting the fluidity of youth tobacco-use patterns).

Vacatur also creates other forms of disruption. Exempting premium cigars from regulation means exempting them from FDA enforcement for sales to buyers under the age of 21. Although forty States and the District of Columbia have enacted their own laws raising the tobacco purchasing age from 18 to 21, ten States have not.[9] In those States, retailers must determine whether products meet the district court's eight-part definition of "premium cigar"—something that cannot be ascertained just by looking at the product and its packaging—to determine whether they may lawfully be sold to 18-to-20-year-olds. Similarly, in all 50 States, FDA must determine whether a product meets the court's definition to know if its sale to an underage purchaser would violate federal law and thus be subject to federal enforcement action.

[9] Ctrs. for Disease Control & Prevention, *State System Minimum Legal Sales Age (MLSA) Laws for Tobacco Products Fact Sheet*, https://perma.cc/KK47-L7AC (last updated May 26, 2023).

In addition, vacatur has already caused substantial disruption to FDA's years-long administration of the "detailed user fee scheme" that Congress established to fund federal tobacco regulation. *Cigar Ass'n*, 5 F.4th at 78 (discussing the scheme). The scheme requires FDA to issue quarterly invoices to manufacturers and importers of applicable "classes" of tobacco products based on their market share, and for manufacturers and importers to pay their proportionate share of the total amount established by Congress. 21 U.S.C. § 387s(b)(2)(B). Each tobacco manufacturer or importer's share is thus dependent on what every other manufacturer or importer owes. *See id.*; *Cigar Ass'n*, 5 F.4th at 79-80. Consistent with this statutory obligation, FDA for seven years (until the district court's vacatur decision) assessed user fees on manufacturers and importers of premium cigars, as with other cigar manufacturers and importers, through a series of complex and interlocking formulas. *See* 81 Fed. Reg. at 28,713.[10]

In contemplating the regulation of cigars and the related collection of user fees, Congress did not provide for the possibility that certain subsets

[10] Plaintiffs' separate challenges to the user fee rule were denied. *Cigar Ass'n*, 5 F.4th at 78.

of the cigar class might be regulated differently, leaving no mechanism for administering a judicial carveout for premium cigars. The Act defines the user fee cigar "class" as "cigars, including small cigars and cigars other than small cigars." 21 U.S.C. § 387s(b)(2)(B)(i)(II). And the statutory user fee calculation methodology is based on excise taxes, but neither excise tax law nor the excise tax information currently submitted to FDA by rule distinguishes between "premium" cigars and other cigars. 21 U.S.C. § 387s(b)(5); 26 U.S.C. § 5701(a); 21 C.F.R. § 1150.5(b)(2); *see* 81 Fed. Reg. at 28,713. FDA is still evaluating how to administer an exception that Congress never contemplated. *See American Great Lakes*, 962 F.3d at 519 (holding that remand without vacatur was warranted in light of the substantial disruption that vacatur would cause to a federal fee-collection scheme); *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993) (same).

In contrast to the substantial harms caused by vacatur, maintaining the status quo as it existed for the seven years prior to the district court's vacatur order while FDA further considers the relevant evidence would impose no significant regulatory burdens on premium-cigar manufacturers because the requirements triggered by deeming largely consist of one-time

obligations that manufacturers have already satisfied, relatively modest user fees (totaling less than one cent per cigar), or prohibitions that impose no out-of-pocket costs.[11]

Moreover, vacatur is particularly improper in these circumstances because it transfers to the district court the agency's authority to craft the proper scope of a regulation. The Tobacco Control Act does not acknowledge any subclasses of cigars, and FDA has never adopted a definition of "premium cigar" for purposes of deeming. Accordingly, in order to create an exemption for such cigars, the district court had to define them.[12] In doing so, the court adopted an eight-part definition that departed from the definition that FDA suggested in the proposed rule.

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[11] The requirements to include health warnings and to obtain premarket authorization for new tobacco products have already been vacated or enjoined as to premium cigars. *See Cigar Ass'n of Am. v. FDA*, 964 F.3d 56 (D.C. Cir. 2020); *Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d 256, 280-82 (D.D.C. 2020).

[12] The district court first adopted this definition an earlier ruling that enjoined FDA from enforcing the Tobacco Control Act's premarket-review requirements with respect to a court-defined category of premium cigars. *Cigar Ass'n*, 480 F. Supp. 3d at 281 (relying on a definition the government proposed in a separate context). To comply with the court's order, FDA relied on that definition for purposes of excluding premium cigars from rules addressing premarket review. *See* 86 Fed. Reg. 55,300, 55,308 & n.8 (Oct. 5, 2021); 86 Fed. Reg. 55,224, 55,228 & n.3 (Oct. 5, 2021).

Compare JA 15 n.7, *with* 79 Fed. Reg. at 23,150. The lack of agreement on the definition of "premium cigars" and the absence of clear standards for identifying them underscores the error of the district court's decision. At a minimum, the court should have remanded without vacatur to allow the agency to determine an appropriate definition of premium cigars.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

Of Counsel:

SAMUEL R. BAGENSTOS
General Counsel
Department of Health & Human Services

MARK RAZA
Chief Counsel

WENDY S. VICENTE
Deputy Chief Counsel for Litigation

PETER DICKOS
Associate Chief Counsel
Office of the Chief Counsel
U.S. Food & Drug Administration

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MARK B. STERN
/s/ Lindsey Powell
LINDSEY POWELL
(202) 616-5372
Attorneys, Appellate Staff
Civil Division, Room 7531
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief uses a proportionately spaced, 14-point font and contains 9,232 words according to the count of this office's word processing system, and thus complies with Rule 32(a)(7)(B)(i) of the Federal Rules of Appellate Procedure.

/s/ Lindsey Powell
LINDSEY POWELL

CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Lindsey Powell
LINDSEY POWELL

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21 U.S.C. § 387a(b) – FDA authority over tobacco products

(b) Applicability

This subchapter 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 subchapter. This subchapter shall also apply to any tobacco product containing nicotine that is not made or derived from tobacco.

21 U.S.C. § 387s – User fees

(a) Establishment of quarterly fee

Beginning on June 22, 2009, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to this subchapter. The fees shall be assessed and collected with respect to each quarter of each fiscal year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for such year, subject to subsection (c).

(b) Assessment of user fee

(1) Amount of assessment

The total amount of user fees authorized to be assessed and collected under subsection (a) for a fiscal year is the following, as applicable to the fiscal year involved:

(A) For fiscal year 2009, $85,000,000 (subject to subsection (e)).

(B) For fiscal year 2010, $235,000,000.

(C) For fiscal year 2011, $450,000,000.

(D) For fiscal year 2012, $477,000,000.

(E) For fiscal year 2013, $505,000,000.

(F) For fiscal year 2014, $534,000,000.

(G) For fiscal year 2015, $566,000,000.

(H) For fiscal year 2016, $599,000,000.

(I) For fiscal year 2017, $635,000,000.

(J) For fiscal year 2018, $672,000,000.

(K) For fiscal year 2019 and each subsequent fiscal year, $712,000,000.

(2) Allocations of assessment by class of tobacco products

(A) In general

The total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products shall be an amount that is equal to the applicable percentage of each class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

(B) Applicable percentage

(i) In general

For purposes of subparagraph (A), the applicable percentage for a fiscal year for each of the following classes of tobacco products shall be determined in accordance with clause (ii):

(I) Cigarettes.

(II) Cigars, including small cigars and cigars other than small cigars.

(III) Snuff.

(IV) Chewing tobacco.

(V) Pipe tobacco.

(VI) Roll-your-own tobacco.

(ii) Allocations

The applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under section 518d(c) of Title 7 for each such class of product for such fiscal year.

(iii) Requirement of regulations

Notwithstanding clause (ii), no user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 387a(b) of this title or is deemed by the Secretary in a regulation under section 387a(b) of this title to be subject to this subchapter.

(iv) Reallocations

In the case of a class of tobacco products that is not listed in section 387a(b) of this title or deemed by the Secretary in a regulation under section 387a(b) of this title to be subject to this subchapter, the amount of user fees that would otherwise be assessed to such class of tobacco products shall be reallocated to the classes of tobacco products that are subject to this subchapter in the same manner and based on the same relative percentages otherwise determined under clause (ii).

(3) Determination of user fee by company

(A) In general

The total user fee to be paid by each manufacturer or importer of a particular class of tobacco products shall be determined for each quarter by multiplying--

(i) such manufacturer's or importer's percentage share as determined under paragraph (4); by

(ii) the portion of the user fee amount for the current quarter to be assessed on all manufacturers and importers of such class of tobacco products as determined under paragraph (2).

(B) No fee in excess of percentage share

No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer.

(4) Allocation of assessment within each class of tobacco product

The percentage share of each manufacturer or importer of a particular class of tobacco products of the total user fee to be paid by all manufacturers or importers of that class of tobacco products shall be the percentage determined for purposes of allocations under subsections (e) through (h) of section 518d of Title 7.

(5) Allocation for cigars

Notwithstanding paragraph (4), if a user fee assessment is imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year.

(6) Timing of assessment

The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under this subsection for each quarter of each fiscal year. Such notifications shall occur not later than 30 days prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made by the last day of the quarter involved.

(7) Memorandum of understanding

(A) In general

The Secretary shall request the appropriate Federal agency to enter into a memorandum of understanding that provides for the regular and timely transfer from the head of such agency to the Secretary of the information described in paragraphs (2)(B)(ii) and (4) and all necessary information regarding all tobacco product manufacturers and importers required to pay user fees. The Secretary shall maintain all disclosure restrictions established by the head of such agency regarding the information provided under the memorandum of understanding.

(B) Assurances

Beginning not later than fiscal year 2015, and for each subsequent fiscal year, the Secretary shall ensure that the Food and Drug Administration is able to determine the applicable percentages described in paragraph (2) and the percentage shares described in paragraph (4). The Secretary may carry out this subparagraph by entering into a contract with the head of the Federal agency referred to in subparagraph (A) to continue to provide the necessary information.

(c) Crediting and availability of fees

(1) In general

Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2)(D). Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(2) Availability

(A) In general

Fees appropriated under paragraph (3) are available only for the purpose of paying the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this subchapter and the Family Smoking Prevention and Tobacco Control Act (referred to in this subsection as "tobacco regulation activities"), except that such fees may be used for the reimbursement specified in subparagraph (C).

(B) Prohibition against use of other funds

(i) In general

Except as provided in clause (ii), fees collected under subsection (a) are the only funds authorized to be made available for tobacco regulation activities.

(ii) Startup costs

Clause (i) does not apply until October 1, 2009. Until such date, any amounts available to the Food and Drug Administration (excluding user fees) shall be available and allocated as needed to pay the costs of tobacco regulation activities.

(C) Reimbursement of start-up amounts

(i) In general

Any amounts allocated for the start-up period pursuant to subparagraph (B)(ii) shall be reimbursed through any appropriated fees collected under subsection (a), in such manner as the Secretary determines appropriate to ensure that such allocation results in no net change in the total amount of funds otherwise available, for the period from October 1, 2008, through September 30, 2010, for Food and Drug Administration programs and activities (other than tobacco regulation activities) for such period.

(ii) Treatment of reimbursed amounts

Amounts reimbursed under clause (i) shall be available for the programs and activities for which funds allocated for the start-up period were available, prior to such allocation, until September 30, 2010, notwithstanding any otherwise applicable limits on amounts for such programs or activities for a fiscal year.

(D) Fee collected during start-up period

Notwithstanding the first sentence of paragraph (1), fees under subsection (a) may be collected through September 30, 2009 under subparagraph (B)(ii) and shall be available for obligation and remain available until expended. Such offsetting collections shall be credited

to the salaries and expenses account of the Food and Drug Administration.

(E) Obligation of start-up costs in anticipation of available fee collections

Notwithstanding any other provision of law, following the enactment of an appropriation for fees under this section for fiscal year 2010, or any portion thereof, obligations for costs of tobacco regulation activities during the start-up period may be incurred in anticipation of the receipt of offsetting fee collections through procedures specified in section 1534 of Title 31.

(3) Authorization of appropriations

For fiscal year 2009 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equal to the amount specified in subsection (b)(1) for the fiscal year.

(d) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of Title 31.

(e) Applicability to fiscal year 2009

If the date of enactment of the Family Smoking Prevention and Tobacco Control Act occurs during fiscal year 2009, the following applies, subject to subsection (c):

(1) The Secretary shall determine the fees that would apply for a single quarter of such fiscal year according to the application of subsection (b) to the amount specified in paragraph (1)(A) of such subsection (referred to in this subsection as the "quarterly fee amounts").

(2) For the quarter in which such date of enactment occurs, the amount of fees assessed shall be a pro rata amount, determined according to the number of days remaining in the quarter (including such date of enactment) and according to the daily equivalent of the quarterly fee amounts. Fees assessed under the preceding sentence shall not be collected until the next quarter.

(3) For the quarter following the quarter to which paragraph (2) applies, the full quarterly fee amounts shall be assessed and collected, in addition to collection of the pro rata fees assessed under paragraph (2).