ORAL ARGUMENT NOT YET 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.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Columbia
(No. 16-cv-1460, Hon. Amit P. Mehta)

BRIEF OF AMICUS CURIAE AMERICANS FOR PROSPERITY FOUNDATION IN SUPPORT OF PLAINTIFFS-APPELLEES

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CERTIFICATE OF PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

Under Circuit Rule 28(a)(1), the undersigned counsel certifies:

A. Parties and *Amici*

All parties, intervenors, and *amici* that have entered an appearance in this court and the district court are listed in the Brief for Defendants-Appellants and Brief for Plaintiffs-Appellees, except for *amicus curiae* Americans for Prosperity Foundation.

Amicus curiae Americans for Prosperity Foundation is a nonprofit corporation. It has no parent companies, subsidiaries, or affiliates that have issued shares or debt securities to the public.

B. Rulings Under Review

References to the rulings at issue appear in the Brief for Defendants-Appellants and Brief for Plaintiffs-Appellees.

C. Related Cases

Counsel is unaware of any related cases within the meaning of Circuit Rule 28(a)(1)(C).

/s/ Michael Pepson

CERTIFICATE UNDER CIRCUIT RULE 29(D)

Under Circuit Rule 29(d), undersigned counsel for Americans for Prosperity Foundation ("AFPF") states that, to AFPF's knowledge, the other *amici curiae* supporting Plaintiffs-Appellees of which it is aware may file are the Commonwealth of Virginia *et al*., the Heartland Institute, and the New Civil Liberties Alliance.

AFPF's brief focuses on the broader values protected by, and the importance of rigorously enforcing, the Administrative Procedure Act's procedural requirements as a vital check against administrative excess.

/s/ Michael Pepson

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Amicus curiae Americans for Prosperity Foundation ("AFPF") is a nonprofit corporation. It has no parent companies, subsidiaries, or affiliates that have issued shares or debt securities to the public.

Under D.C. Circuit Rule 26.1(b), AFPF further states that it is a 501(c)(3) nonprofit organization committed to educating and training Americans to be courageous advocates for the ideas, principles, and policies of a free and open society. Some of those key ideas are the separation of powers and constitutionally limited government. As part of this mission, it appears as *amicus curiae* before federal and state courts.

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Americans for Prosperity Foundation ("AFPF") is a 501(c)(3) nonprofit organization committed to educating and training Americans to be courageous advocates for the ideas, principles, and policies of a free and open society. Some of those key ideas are the separation of powers and constitutionally limited government. As part of this mission, it appears as *amicus curiae* before federal and state courts.

Here, AFPF writes to highlight the importance of rigorous arbitrary and capricious review, particularly where, as here, unelected officials within an administrative body issue a legislative rule expanding the agency's jurisdiction to impose a burdensome and costly regulatory regime backed by draconian civil penalties and other sanctions to restrict the economic liberty of private businesses.

SUMMARY OF ARGUMENT

To protect liberty, the Constitution establishes a system of checks and balances, not only limiting the scope of federal power but also imposing guardrails on *how* the federal government exercises its powers, such as making lawmaking

[1] All parties have consented to the filing of this brief. Under FRAP 29(a)(4)(E), *amicus curiae* states that no counsel for a party other than AFPF authored this brief in whole or in part, and no counsel or party other than AFPF made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* or its counsel made a monetary contribution to its preparation or submission.

deliberately difficult by design to ensure that federal legislation would be the product of consensus. Much of the modern administrative state stands in irreconcilable tension with the Constitution. Most prominently, today most "law" is not made by Congress through duly enacted legislation, subject to the Constitution's bicameralism and presentment requirements; it is instead made by unelected bureaucrats housed within a warren of administrative bodies.

To provide at least some guardrails against administrative absolutism, Congress enacted the Administrative Procedure Act ("APA"). The APA's procedural requirements, including those that apply to notice and comment rulemaking, are key checks against administrative excess. For that reason, it is of utmost importance that agencies honor and take these requirements seriously. And when agencies fail to do so, it is equally important that courts rigorously enforce the APA's prohibition against arbitrary agency decisions.

The U.S. Food and Drug Administration's ("FDA") Deeming Rule makes a mockery of the APA's procedural protections, moving the regulatory goalposts without explanation, ignoring evidence contrary to the agency's position, and "obscur[ing] the real math." JA 31. The FDA's decision to "deem" premium cigars subject to the Family Smoking Prevention and Tobacco Control Act's ("TCA") regulatory regime is not the product of reasoned decision making or agency expertise. It is instead a results-driven policy decision divorced from the data the

FDA specifically requested—and received. The FDA failed to follow the science here—indeed it denied the existence of a key study "whose *lead author* was [an] *FDA scientist*[.]" JA 21 (emphasis added). And its arbitrary and capricious "deeming" decision unjustifiably subjects a niche industry populated with small business manufacturers and retailers to a regulatory regime designed for products that are different in kind from the premium cigars at issue in this case.

"As the Supreme Court has said, 'the Government should turn square corners in dealing with the people.'" *GPA Midstream Ass'n v. U.S. Dep't. of Transp.*, 67 F.4th 1188, 1202 (D.C. Cir. 2023) (quoting *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020)). That did not happen here. Instead, the FDA "cut corners to the prejudice of the [premium cigar industry], the administrative process, and thus the public." *Id.* This Court should reject the FDA's flawed approach to rulemaking and "hold the agencies governed by the [APA's] rule-making procedure strictly to its requirements and not allow them to play fast and loose as the [FDA] apparently likes to do." *NLRB v. Wyman*, 394 U.S. 759, 779 (1969) (Douglas, J., dissenting).

For the foregoing reasons, this Court should affirm the district court.

ARGUMENT

I. Rigorous Enforcement of the APA's Procedural Protections Is a Critical Safeguard Against Administrative Overreach.

A. The Constitution Does Not Contemplate a Fourth Branch of Government.

The administrative state sits uneasily in our constitutional Republic. And much of it stands in irreconcilable tension with the separation of powers required by the Constitution. *See FTC v. Ruberoid Co*., 343 U.S. 470, 487 (1952) (Jackson, J., dissenting) (Administrative bodies "have become a veritable fourth branch of the Government, which has deranged our three-branch legal theories much as the concept of a fourth dimension unsettles our three-dimensional thinking.").

"Our Constitution was adopted to enable the people to govern themselves, through their elected leaders." *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd*., 561 U.S. 477, 499 (2010). In that document, the People agreed on a system of checks and balances. "The Constitution sets out three branches of Government and provides each with a different form of power—legislative, executive, and judicial." *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2216 (2020) (Thomas, J., concurring) (citations omitted). "[T]he legislature makes, the executive executes, and the judiciary construes the law[.]" *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 46 (1825). "That is the equilibrium the Constitution demands." *Tiger Lily, LLC v. HUD*, 5 F.4th 666, 673 (6th Cir. 2021) (Thapar, J., concurring).

The Constitution prohibits Congress from transferring any of its legislative power to other entities. U.S. Const. art. I, § 1. Nor did the Framers grant Congress plenary legislative power. *See Murphy v. NCAA*, 584 U.S. 453, 471 (2018) ("The Constitution confers on Congress not plenary legislative power but only certain enumerated powers."); U.S. Const. amend. X. Instead, "our Constitution establishes a system of dual sovereignty between the States and the Federal Government." *Gregory v. Ashcroft*, 501 U.S. 452, 457 (1991). "In our federal system, the National Government possesses only limited powers; the States and the people retain the remainder." *Bond v. United States,* 572 U.S. 844, 854 (2014).

"The administrative state makes hash out of this basic allocation of constitutional powers." Steven G. Calabresi & Gary Lawson, *The Depravity of the 1930s and the Modern Administrative State*, 94 Notre Dame L. Rev. 821, 852 (2019). "The most blatant way in which the administrative state violates the constitutional separation of powers is the vast subdelegation of legislative authority that permeates modern government." *Id.* at 853. "The administrative state allows for the creation of law outside constitutional channels and the imposition of nationwide directives controlling the health, safety, and government-defined moral well-being of the people." Hon. Naomi Rao, Speech: The Province of the Law, 46 Harv. J.L. & Pub. Pol'y 87, 92 (2023). "[M]any 'laws' emanate not from Congress but from administrative agencies[.]" *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 951 (D.C.

Cir. 1987) (Starr, J., concurring in part, dissenting in part). "The administrative degradation of consensual lawmaking is eating away at our government's legitimacy." Philip Hamburger, *Nondelegation Blues*, 91 Geo. Wash. L. Rev. 1083, 1108 (2023).

B. The APA's Procedural Requirements Provide a Key Check Against Arbitrary Agency Action.

This state of affairs makes rigorous enforcement of the APA's procedural protections, including those that apply to notice and comment rulemaking, all the more important. *See* 5 U.S.C. § 553. "No principle is more important when considering how the unelected administrators of the Fourth Branch of Government treat the American people." *Wages & White Lion Invs., LLC v. FDA*, 90 F.4th 357, 362 (5th Cir. 2024) (en banc), *cert. pending*, No. 23-1038.

"The broader liberal tradition, which is the dominant tradition in American constitutional law, 'emphasizes limited government, checks and balances, and strong protection of individual rights.' By adopting the APA, the Congress intended to apply that tradition to governance of the administrative state." Douglas H. Ginsburg and Steven Menashi, *Our Illiberal Administrative Law*, 10 NYU J.L. & Liberty 475, 477 (2016) (quoting Michael W. McConnell, *Active Liberty: A Progressive Alternative to Textualism and Originalism?*, 119 Harv. L. Rev. 2387, 2391 (2006)).

The APA "was framed against a background of rapid expansion of the administrative process as a check upon administrators whose zeal might otherwise

have carried them to excesses not contemplated in legislation creating their offices. It created safeguards even narrower than the constitutional ones, against arbitrary official encroachment on private rights." *United States v. Morton Salt Co*., 338 U.S. 632, 644 (1950); *see also Wyman,* 394 U.S. at 778 (Douglas, J., dissenting) ("The multiplication of agencies and their growing power make them more and more remote from the people affected by what they do and make more likely the arbitrary exercise of their powers."). It "was intended to give the public a way to get relief from administrative excess." Ginsburg & Menashi, 10 NYU J.L. & Liberty at 521.

One of the "basic purposes" of the APA is "[t]o provide for public participation in the rule making process." Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act 9 (1947) [hereinafter "1947 Attorney General's Manual"]. The APA's "rule-making provisions . . . were designed to assure fairness and mature consideration of rules of general application." *Wyman*, 394 U.S. at 764. "Whether successful or not, the aim is to ensure 'that agency "rules" are also carefully crafted (with democratic values served by public participation) and developed only after assessment of relevant considerations.'" *In re MCP No. 165*, 21 F.4th 357, 391 (6th Cir. 2021) (Larsen, J., dissenting) (quoting *Cmty. Nutrition Inst.*, 818 F.2d at 951 (Starr, J., concurring in part, dissenting in part)).

It is "important for APA procedures to be followed before an agency pronouncement is deemed a binding legislative rule not merely because the APA

says so, but because in saying so the APA is protecting a free people from the danger of coercive state power undergirding pronouncements that lack the essential attributes of deliberativeness present in statutes." *Cmty. Nutrition Inst.*, 818 F.2d at 951 (Starr, J., concurring in part, dissenting in part). Notice and comment rulemaking is said to "promote[] public deliberation and serves to reconcile agencies' democratic deficit with their immense power. Public participation procedures thus provide an oversight mechanism for the public and Congress." James Yates, *Good Cause Is Cause for Concern*, 86 Geo. Wash. L. Rev. 1438, 1450–51 (2018) (cleaned up).

This Court has said that "by mandating openness, explanation, and participatory democracy in the rulemaking process, these procedures assure the legitimacy of administrative norms." *Air Transp. Ass'n v. Dep't of Transp.*, 900 F.2d 369, 375 (D.C. Cir. 1990) (cleaned up). Justice Douglas put it more plainly: "Public airing of problems through rule making makes the bureaucracy more responsive to public needs and is an important brake on the growth of absolutism in the regime that now governs all of us." *Wyman*, 394 U.S. at 778 (Douglas, J., dissenting). *Cf. City of Arlington v. FCC,* 569 U.S. 290, 315 (2013) (Roberts, C.J., dissenting).

"[T]hese procedural requirements are intended to assist judicial review as well as to provide fair treatment for persons affected by a rule." *Home Box Office, Inc. v. FCC,* 567 F.2d 9, 35 (D.C. Cir. 1977); *see also Dep't. of Commerce v. New York*,

139 S. Ct. 2551, 2573 (2019) ("[I]n order to permit meaningful judicial review, an agency must disclose the basis of its action." (cleaned up)); *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56, 64 (D.C. Cir. 2020) ("final rule['s] . . . 'general statement of . . . basis and purpose,' . . . forms the basis for judicial review" (citations omitted)). "Notice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision." *Azar v. Allina Health Servs*., 587 U.S. 566, 582 (2019) (citing 1 K. Hickman & R. Pierce, Administrative Law §4.8 (6th ed. 2019)).

"The notice-and-comment requirement forces the agency to take note of complexities and realities of which it might otherwise be unaware. In this way, the requirement aids the agency in exercising an informed judgment." Ginsburg & Menashi, 10 NYU J.L. & Liberty at 507–08. Through this process, "[a]gencies [are supposed to] discover that they are not always repositories of ultimate wisdom; they [are supposed to] learn from the suggestions of outsiders and often benefit from that advice." *Wyman*, 394 U.S. at 777–78 (Douglas, J., dissenting) (citing H. Friendly, The Federal Administrative Agencies 45 (1962)).

These protections, coupled with judicial review, serve as at least some check on administrative overreach—or at least are supposed to.

C. At the Least, the APA Requires that Binding Legislative Rules Must Be Reasonable and Reasonably Explained.

Arbitrary agency actions "cannot carry the force of law." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (citations omitted). The APA provides that "court[s] shall" "hold unlawful and set aside agency action, findings, and conclusions found to be [] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706(2)(a). Arbitrary and capricious review under the APA "is not toothless[.]" *Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1013 (5th Cir. 2019). "While it is a forgiving standard, it does not create a rubberstamp." *BNSF Ry. Co. v. Surface Transp. Bd.*, 741 F.3d 163, 167 (D.C. Cir. 2014). "In fact, after *Regents*, it has serious bite." *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1136 (5th Cir. 2021) (citing *Regents*, 140 S. Ct. at 1907–15).

"The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). This requires that an agency "reasonably considered the relevant issues and reasonably explained the decision." *Id.*; *see Grayscale Invs., LLC v. SEC,* 82 F.4th 1239, 1245 (D.C. Cir. 2023). "[A]gency action is lawful only if it rests on a consideration of the relevant factors[.]" *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (citation omitted)); *see Getty v. Fed. Sav. & Loan Ins. Corp.*, 805 F.2d 1050, 1055 (D.C. Cir. 1986) ("Stating that a factor was considered, however, is not a substitute for considering it."). "[T]he agency must examine the relevant data and articulate a

satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (cleaned up). An agency cannot offer "an explanation for its decision that runs counter to the evidence before . . . [it], or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

Of course, "[t]he APA . . . imposes no general obligation on agencies to produce empirical evidence." *Am. Great Lakes Ports Ass'n v. Schultz*, 962 F.3d 510, 516 (D.C. Cir. 2020). But it does require that "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments[.]" 5 U.S.C. § 553(c); *see also* 1947 Attorney General's Manual, *supra*, 31 ("Each agency is affirmatively required to consider 'all relevant matter presented' in the proceeding[.]"). And "an agency cannot ignore evidence contradicting its position." *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) (cleaned up); *see Stellar IT Sols., Inc. v. U.S. Citizenship & Immigration Servs.*, No. 18-cv-2015 (RC), 2018 WL 6047413, at *9 (D.D.C. Nov. 19, 2018) ("[T]he agency cannot base its decision on a supposed lack of evidence when evidence was not actually lacking.").

Nor may an agency ignore "comments which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency's

proposed rule cast[.]" *Home Box Office*, 567 F.2d at 35 n.58. It "must do more than simply ignore comments that challenge its assumptions[.]" *ALLTEL Corp. v. FCC*, 838 F.2d 551, 558 (D.C. Cir. 1988).

This means "the agency's mind must be open to considering" comments it receives. *Grand Canyon Air Tour Coal. v. FAA*, 154 F.3d 455, 468 (D.C. Cir. 1998). It "need not address every comment, but it must respond in a reasoned manner to those that raise significant problems." *Covad Communs. Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006). Failure to do so is arbitrary and capricious. *See, e.g.*, *Sierra Club v. EPA*, 863 F.3d 834, 838 (D.C. Cir. 2017); *BNSF Ry. Co.*, 741 F.3d at 168. (

"An agency's response to public comments [] must [also] be sufficient to enable the courts 'to see what major issues of policy were ventilated . . . and why the agency reacted to them as it did.'" *Carlson v. Postal Regulatory Comm'n*, 938 F.3d 337, 344 (D.C. Cir. 2019). After all, "the opportunity to comment is meaningless unless the agency responds to significant points raised by the public." *Home Box Office*, 567 F.2d at 35–36 (citation omitted).

II. The FDA Flouted the APA's Procedural Requirements.

The FDA's decision to "deem" premium cigars subject to the TCA's regulatory regime does not reflect the reasoned decision making the APA requires.

A. The FDA Denied the Existence of Data It Specifically Requested—Including a Key Study Whose Lead Author Was an FDA Scientist.

To begin, aspects of the FDA's rulemaking process could be described as Kafkaesque. The FDA asked for data on premium cigar usage patterns and safety. *See* 79 Fed. Reg. 23,142, 23,150 (April 25, 2014); 81 Fed. Reg. 28,974, 29,024 (May 10, 2016) ("[D]espite our explicit requests in the NPRM, the comments did not include data indicating that premium cigar smokers are not subject to disease risk and addiction."); *id.* at 29,022 ("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."). The FDA was then provided with the data it said it wanted. *See* JA 20–23 (discussing Catherine Corey et al., *Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults—United States*, 2012-2013, 63 Morbidity & Mortality Wkly. Rep. 650 (2014) [hereinafter "Corey Study"], and Nat'l Cancer Inst., *Cigars: Health Effects and Trends Monograph No. 9* (1998) [hereinafter "Monograph 9"]). The "lead author" of the Corey study "was FDA scientist Catherine Corey." JA 21.

But the FDA chose to studiously ignore this evidence and deny its existence. *See* JA 21 ("Despite this ask for evidence, the FDA said it received none."); JA 7 ("[T]here was data . . . in the record, but [] the agency simply ignored it."). Instead

of engaging with evidence that did not support its preferred policy outcome,[2] the FDA muddied the waters, stating: "[T]here 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." 81 Fed. Reg. at 29,020. As the district court found, "[t]hat statement was not accurate then, and . . . it is not accurate now." JA 29. "[W]aving away evidence of actual, current usage patterns based on the mere possibility of a change in behavior is not reasoned decisionmaking." JA 28.

"Shifting the regulatory goalposts without explanation is arbitrary and capricious." *Fontem US, LLC v. FDA*, 82 F.4th 1207, 1222 (D.C. Cir. 2023). This holds particularly true here because the FDA chose to "place[] these issues on the table," making it "'incumbent upon the agency' to address relevant, substantial comments to this effect."[3] *Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d 256, 280 (D.D.C. 2020) (quoting *Cigar Ass'n of Am. v. FDA*, 436 F. Supp. 3d 70, 89 (D.D.C. 2020)). The Deeming Rule should be set aside on this ground alone. *Cf. Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009) ("In the past we have not hesitated to

[2] The Corey study 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. "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." JA 22.

[3] The district court did not "fault[] the FDA for failing to connect the dots between disparate data points; the connection was already drawn for them." JA 25.

vacate a rule when the agency has not responded to empirical data or to an argument inconsistent with its conclusion.").

B. The FDA Fudged the Numbers To Support Its Policy Preference.

The FDA's inaccurate "no data" finding was not the only problem with its process. "[T]he Final Deeming Rule [also] obscures the real math," JA 31, on a core issue in this rulemaking: "the frequency of [premium cigar] use by youth and young adults[.]" 79 Fed. Reg. at 23,150. The FDA played fast and loose with the findings of a key study to blow a statistic out of proportion to support the agency's conclusion that youth "are using premium cigars" at a meaningful rate. *See* 81 Fed. Reg. at 29,023. Put charitably, the FDA failed to put the study's findings in proper context. *See* JA 30–32; *see also* JA 7.

The FDA subsequently acknowledged in this litigation that the "study shows that only 0.1 percent of youth (31,350/25,000,000) ages 12 to 17 have smoked a premium cigar within the last 30 days." JA 31. Yet "[n]owhere [in the Final Deeming Rule] did the agency say what it now admits: that only 3.8 percent of the only 3.3 percent of youth who reported smoking a cigar within the last 30 days, or 0.1 percent of all youth, identified a premium cigar as their preferred brand." JA 32. That is unacceptable. Although the district court did not make an arbitrary and capricious finding on this error, that, too, renders the FDA's "deeming" decision arbitrary and capricious. *Cf. R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1220 (D.C. Cir.

2012) ("While APA review of final agency action is deferential, it surely does not require us to accept a flawed interpretation of Canadian survey data or the agency's own projected 0.088% decrease in the U.S. smoking rate as 'substantial evidence' that its warnings will advance its stated interest.").

"[A] regulation perfectly reasonable and appropriate in the face of a given problem may be highly capricious if that problem does not exist." *Home Box Office*, 567 F.2d at 36 (cleaned up). So too here. The FDA suggests that subjecting premium cigars to the TCA's regulatory regime is necessary to address the putative problem of youth use of premium cigars. *See* Gov't. Br. 3, 12–13, 18–19, 26, 35, 40–41. But the data in the administrative record indicates that that problem does not exist in any meaningful way. *See* JA 31–32; *see also* JA 7.

C. The FDA Shifted the Regulatory Goalposts for Evaluating Option 2.

More broadly, and related to the FDA's "no data" finding, the FDA's Final Deeming Rule pulled an unexplained switcheroo on the standard the agency used to evaluate whether premium cigars should be regulated under the TCA.

In the proposed rule, the FDA "propos[ed] two options (Option 1 and Option 2), which would provide two alternatives for the scope of the deeming provisions[.]" 79 Fed. Reg. at 23,143. "Option 1, if selected, would subject premium cigars to the TCA's requirements. Conversely, 'Option 2' would exclude premium cigars from the scope of the Final Deeming Rule." JA 18 (citation omitted). FDA then stated:

"[A]lthough all cigars are harmful and potentially addictive, it has been suggested that different kinds of cigars . . . may have the potential for varying effects on public health, if there are differences in their effects on youth initiation, the frequency of their use by youth and young adults, and other factors[.]" 79 Fed. Reg. 23,150. "The agency thus signaled that evidence of different usage patterns and their public health impacts would be a central consideration in deciding whether to exclude premium cigars from the scope of the final rule." JA 20–21; *see* JA 6, JA 26–27. The FDA received troves of evidence showing different usage patterns and public health impacts, which the agency studiously ignored. *See* JA 6–7.

The FDA then reversed course. While the proposed rule indicated that the FDA would evaluate Option 2 based on evidence regarding the comparative degree of risk associated with premium cigars, the Final Deeming Rule moved the regulatory goalposts, appearing to take an absolutist position and use an entirely different standard. *Compare* 81 Fed. Reg. at 29,020 ("[T]here are no data indicating that premium cigar users are not susceptible to health risks[.]"); *id.* at 29,025 ("[P]atterns of use for premium cigars do not preclude users from negative health effects."), *with* 79 Fed. Reg. at 23,150.

The FDA's decision to reject Option 2 appears driven not by data on comparative risk but by the agency's conclusion that "[a]ll cigar use is harmful[.]" 81 Fed. Reg. at 29,022; *see id.* at 29,020. But "[t]he relevant question [was] not

whether premium cigars, like standard cigars, produce toxic cigar smoke. The FDA already knew that to be the case" when it issued the proposed rule. JA 26 (citing 79 Fed. Reg. at 23,143, 23,150–51, 23,170). The FDA's unexplained refusal to answer the question it originally asked "suggest[s] too closed a mind." *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988). This Circuit does not "allow agencies to use the rulemaking process to pull a surprise switcheroo on regulated entities." *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005). And the FDA's unexplained shift in position during the notice and comment process was arbitrary and capricious. *Cf. Fontem*, 82 at 1222. This is yet another reason why the FDA's "deeming" decision cannot stand.

III. Waiving the "Expertise" Flag Cannot Excuse the FDA's APA Violations.

The FDA mistakenly suggests the district court "did not give due deference to the agency's scientific judgments." Gov't. Br. 4. But simply waiving the agency expertise flag cannot salvage the FDA's arbitrary "deeming" regulation. And as demonstrated above, the FDA did not adhere to the science and data but rather its own policy preferences. The FDA's pleas for deference based on its putative technical expertise should therefore be rejected. *See* Gov't. Br. 21, 34.

All too often rote appeal to putative agency expertise is a canard. As Judge Ginsburg and now-Judge Menashi have explained:

> Sometimes the claim to expertise is entirely fraudulent; the most well-documented case is that of the National Labor Relations Board[.] . . . Most often, however, expertise is simply a euphemism for policy judgments. The permanent staff of an agency may have a great deal of technical expertise, but the agency's ultimate decisions are made by the experts' political masters, who have sufficient discretion that they can make decisions based upon their own policy preferences, fearing neither that the expert staff will not support them nor that a court will undo their handiwork.

10 NYU J.L. & Liberty at 482–83.[4] That observation resonates here. *Compare* JA 21 ("FDA scientist" "lead author" of key study FDA ignored), *with* 81 Fed. Reg. at 29,106 (Rule issued by "Associate Commissioner for Policy").

This Court "do[es] not defer to the agency's conclusory or unsupported suppositions." *United Techs. Corp., Pratt & Whitney Div. v. U.S. Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) (cleaned up); *see Verizon v. FCC*, 740 F.3d 623, 663 (D.C. Cir. 2014) (Silberman, J., concurring in part, dissenting in part) ("deference to" an agency's predictive "judgment must be based on some logic and evidence, not sheer speculation"). This makes sense because "reliance on expertise and experience, like efficiency, is no substitute for 'reasoned decisionmaking.'" *Wages & White Lion Invs.*, 16 F.4th at 1137 (quoting *Michigan v. EPA*, 576 U.S. at 750); *see Bidi Vapor LLC v. FDA,* 47 F.4th 1191, 1204 (11th Cir. 2022) ("Experience fails as a justification for ignoring the marketing and sales-access-restrictions plans.").

[4] Making matters worse, unelected administrators often labor under confirmation, specialization, and size biases. *See* Hamburger, 91 Geo. Wash. L. Rev. at 1187–92.

And "[a]dministrative actions cannot survive solely on an agency's demand for policy deference." *Louisiana v. Dep't of Energy*, 90 F.4th 461, 469 (5th Cir. 2024).

"[A]n agency's 'experience and expertise' presumably enable the agency to provide the required explanation, but they do not substitute for the explanation, any more than an expert witness's credentials substitute for the substantive requirements applicable to the expert's testimony under Fed. R. Evid. 702[.]" *CS Wind Vietnam Co. v. United States*, 832 F.3d 1367, 1377 (Fed. Cir. 2016). To pass muster under Rule 702, an expert's testimony may not be "based on subjective belief or speculation" and "must be supported by appropriate validation." *Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 590 (1993). Similarly, under the APA, "mere conjecture and abstract theorizing offered in a vacuum" do not suffice to show "that the agency has engaged in reasoned decisionmaking." *Ariz. Pub. Serv. Co. v. United States*, 742 F.2d 644, 649 n.2 (D.C. Cir. 1984). The Deeming Rule fails this standard.

IV. Allowing the Rule to Stand Would Create a Perverse Incentive for Agencies to Play Fast and Loose With the APA's Requirements.

As discussed above, the FDA's Deeming Rule is infected by inaccurate statements, studiously ignores key data the agency itself requested, fudges the math, and thereby hides the ball from courts and the public. On top of this, the FDA's decision to "deem" premium cigars subject to the TCA's requirements has been fundamentally flawed from the start and it has demonstrated a pattern of flouting the

APA's procedural requirements in this rulemaking. *See* JA 16–17. *Cf. Wages & White Lion Invs.,* 90 F.4th at 362–63 (en banc).

Holding that this is good enough for government work would have implications far beyond this case. As Justice Douglas has observed: "[W]hen we are lax and allow federal agencies to play fast and loose with rule making, we set a precedent with dangerous repercussions." *Wyman*, 394 U.S. at 778 (dissenting). So too here. Allowing the FDA's "deeming" decision to stand would create perverse incentives for the FDA and other agencies. Such a result is particularly pernicious because the type of APA violations at issue here conceal from courts and the public the information they would need to assess whether a regulation is reasonable and reasonably explained, frustrating judicial review. That should not be allowed.

CONCLUSION

For the above reasons, this Court should affirm the district court.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of FRAP 29(a)(5) and FRAP 32(a)(7)(B) because it contains 5,082 words. This brief also complies with the typeface and type-style requirements of FRAP 32(a)(5)-(6) because it was prepared using Microsoft Word 2013 in Times New Roman 14-point font.

Dated: April 22, 2024

/s/ Michael Pepson

CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2024, I electronically filed the above Brief of Amicus Curiae Americans for Prosperity Foundation in Support of Petitioner with the Clerk of the Court by using the appellate CM/ECF system. I further certify that the participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Michael Pepson