No. 23-235, 23-236

IN THE

Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

MOTION FOR LEAVE TO FILE BRIEF OUT OF TIME AND BRIEF OF AMERICAN BAR ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF OUT OF TIME

Pursuant to Supreme Court Rules 21.1 and 37.2, the American Bar Association ("ABA") respectfully seeks leave to file a brief as amicus curiae in support of Petitioners after the deadline for filing such briefs. The ABA has notified all parties of its intent to file this motion and amicus brief. Petitioner Danco Laboratories, L.L.C. consents; Petitioner the FDA has not yet responded; Respondent Alliance for Hippocratic Medicine has not yet responded.

For the foregoing reasons, this motion should be granted.

The Petition was granted in this case on December 13, 2023, and consolidated with case 23-236. According to the original schedule, Petitioners' merits briefs were

due to be filed January 29, 2024 (pursuant to Supreme Court Rule 25.1, since January 27 fell on a Saturday) and, assuming filing on that date, any amicus brief in support of Petitioners would be due February 5, 2024 (pursuant to Supreme Court Rule 37.3).

The ABA has a rigorous and extensive process for authorizing and filing amicus briefs, *see* ABA Policy and Procedures Handbook, 2023-2024, pp. 61-64, that is designed to ensure that any such brief is consistent with the ABA's official positions. Typically, pro bono counsel submits a detailed application to file an amicus brief to the Standing Committee on Amicus Curiae Briefs (the "Amicus Committee"). *Id.* at p. 62. If the application is accepted, the Amicus Committee works with the drafters in preparing the proposed brief. *Id.* Once approved by the Amicus Committee, the Executive Committee of the Board of Governors must review and authorize the amicus brief. *Id.* at p. 61 (citing section 25.2 of the ABA Bylaws). The Board of Governors meets at four scheduled meetings each year. *Id.* at p. 10.

In this case, on the same day this Court granted the Petition, December 13, 2023, an ABA section committee immediately recruited pro bono counsel, who by the next day began the process of writing the requisite application to the ABA Amicus Committee as well as developing and drafting a brief. Counsel, in consultation with the Amicus Committee and ABA staff, established a number of fixed internal deadlines consistent with the expected filing date of February 5, 2024. Final approval by the Amicus Committee was set in time for presentation to and consideration by the Executive Committee at its prescheduled ABA Midyear Meeting on February 1, 2024. The Executive

Committee put consideration of the proposed amicus brief on its agenda for that meeting.

Once it became apparent that Petitioners filed their brief before the January 29, 2024 due date, and that amicus briefs supporting Petitioners were due on January 30, 2024, the ABA explored emergency measures to try to approve and file its brief that day, but was unable to accelerate its internal process. Final approval thus required the ABA to wait for Executive Committee review at its February 1, 2024 meeting. The ABA filed this motion immediately after the Executive Committee formally approved the brief.

As discussed in more detail in the accompanying brief, this case presents an issue of significant importance to the ABA, the largest professional association in the world—namely, advancing and preserving the rule of law. Judicial review of agency action serves as a cornerstone of the rule of law by guarding against arbitrary or unlawful actions and promoting predictability and stability. However, to play that role, courts must conduct judicial review consistent with this Court's longstanding precedent. When courts depart from those principles—whether by affording too much or too little deference (as the courts below did in this case) to an agency's adjudicative judgments—it can result not only in an erroneous outcome in the particular case but also in broader deleterious consequences for public confidence in the objectivity of the judicial system and the predictability that is necessary for the rule of law.

In light of the accelerated filing schedule in this case, the ABA's rigorous internal review process, and the importance of this issue, the ABA respectfully requests this Court grant its motion to file this brief out of time.

Respectfully submitted,

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INTEREST OF AMICUS CURIAE [1]

The American Bar Association ("ABA") is the largest voluntary professional association in the world, spanning all fifty states and the full spectrum of legal professionals.[2]

Founded in 1878, the ABA has long been committed to advancing the rule of law in America and abroad. Domestically, the ABA aims to increase public understanding of and respect for the rule of law and the legal process – including by providing educational content, resources for legal professionals, law school accreditation, and model ethics codes. Internationally, the ABA promotes its mission through the Rule of Law Initiative, which was established in 1990 after the fall of the Berlin Wall.

In furtherance of its mission to advance the rule of law, in 2006, the ABA adopted a Statement of Core Principles underscoring that the "ABA has adopted a wide range of policies supporting fundamental principles associated with the Rule of Law" and "strongly supporting the efforts of bar associations

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[1] Pursuant to Supreme Court Rule 37.6, counsel for amicus curiae states that no counsel for a party authored this brief in whole or in part. No counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and no person other than amicus or its counsel made such a contribution.

[2] Neither this brief nor the decision to file it should be interpreted as reflecting the views of any judicial member. No member of the ABA Judicial Division Council participated in this brief's preparation or in the adoption or endorsement of its positions.

worldwide to promote the Rule of Law. . . ."[3] *See also* ABA Goal IV, ABA Resolution 08A121 (adopted 2008) (setting forth objectives to advance the rule of law). The ABA has also submitted several amicus briefs in this Court and others urging faithful application of rule-of-law principles to preserve the integrity of, and public confidence in, our judicial system. *See, e.g.*, Br. of Amicus Curiae American Bar Association in Support of Respondents, No. 20-303, 2022 WL 16552943, *Moore v. Harper*, 600 U.S. 1 (Sept. 7, 2021).

The ABA respectfully offers its perspective on the rule of law in this case, *see* Report to ABA Resolution 23A509 at 2 (adopted Aug. 2023), particularly as this Court considers the second question presented by the petition of the United States.

SUMMARY OF ARGUMENT

The ABA seldom takes a position about particular instances of judicial review of administrative action, whether in the Supreme Court or the courts of appeals. Nor does the ABA normally get involved as amicus in litigation about the Food and Drug Administration's ("FDA's") approval or reconsideration of any particular pharmaceutical drug. But in this case, the court of appeals departed markedly from settled principles of judicial review enshrined in both the Administrative Procedure Act ("APA") and in this Court's precedent.

Judicial review of agency action serves as a cornerstone of the rule of law by guarding against arbitrary or unlawful actions and promoting predictability and stability. But to play that role, courts must conduct judicial review consistent with

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[3] ABA Resolution 06M111 (adopted 2006), *available at* https://www.americanbar.org/content/dam/aba/directories/policy/midyear-2006/2006_my_111.pdf.

the well-settled standard of "arbitrary and capricious" review required by the APA and this Court's longstanding precedent. In some cases, when courts depart from those principles—whether by affording too much or too little deference to an agency's adjudicative judgments—it can result not only in an erroneous outcome in the particular case but also in broader deleterious consequences for public confidence in the objectivity of the judicial system and the predictability that is necessary for the rule of law.

This is one such case. Unlike most cases in which courts invalidate agency action, a court's substitution of its own judgment for that of the FDA on the specific question of drug safety can raise broader rule-of-law implications. Congress exercised its prerogative to delegate authority over those decisions to the FDA, not to the courts, and, unlike the FDA, courts have none of the scientific or medical expertise needed to make those judgments. For these reasons, this Court has repeatedly called for heightened deference to the "complex chemical and pharmacological considerations" that are "within the peculiar expertise" of the FDA. *Weinberger v. Bentex Pharmaceuticals, Inc.,* 412 U.S. 645, 654 (1973). In that specific context of drug-safety determinations, those considerations pose a unique concern that a court decision disagreeing with the FDA's scientific judgment will not carry the appearance or reality that the court is "doing law."

The Fifth Circuit's decision illustrates these dangers. As the Petitioners have demonstrated, the court of appeals rested its decision on criticisms of the FDA's scientific judgments and methodology—second-guessing the agency's determinations as to the type and quantum of evidence necessary before a drug can be deemed safe or a prior safety decision should be

reevaluated. That approach overrode Congress's decision to assign responsibility for scientific judgments regarding drug safety to the FDA, which is staffed by thousands of doctors and scientists who pored over decades of data and dozens of medical studies in approving mifepristone. By comparison, "[a] court is ill-equipped to second-guess that kind of agency scientific judgment under the guise of the APA's arbitrary and capricious standard." *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 722, 727 (D.C. Cir. 2013) (Kavanaugh, J.).

In rejecting the FDA's scientific judgment about mifepristone, the Fifth Circuit also failed to properly and faithfully apply the APA and this Court's precedents about "arbitrary and capricious" review, particularly in the context of FDA drug approvals. The Fifth Circuit did not even attempt to apply the traditional factors that this Court has set out. Instead, it fixated on precise types of evidence that it would have preferred the FDA to consider in approving mifepristone. By taking on for itself the role of making a fundamentally scientific judgment that a court is so ill-equipped to make, the Fifth Circuit's approach threatens to erode the appearance of objectivity and the predictability and stability that are critical — not only for Americans choosing what drugs to consume and pharmaceutical companies deciding what to research and where to invest — but also to the rule of law and public confidence in our system of judicial review.

ARGUMENT

I. TO ADVANCE THE RULE OF LAW, JUDICIAL REVIEW OF ADMINISTRATIVE AGENCY DECISIONS MUST ADHERE TO SETTLED PRINCIPLES.

Judicial review is a basic pillar of the rule of law.[4] Judicial review of government actions advances the rule of law by ensuring fidelity to constitutional and statutory commands and precluding arbitrariness or abuse. *See, e.g.*, *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 180 (1803).[5] Such judicial review preserves the predictability that the rule of law requires, including when administrative agencies act. *See* Antonin Scalia, *The Rule of Law is the Law of Rules*, 56 U. Chi. L. Rev. 1175, 1179 (1989) ("Predictability . . . is a needful

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[4] *See, e.g.*, Justice Sandra Day O'Connor, *Remarks at the Inaugural Sandra Day O'Connor Distinguished Lecture Series*, 41 Tex. Tech L. Rev. 1169, 1170 (2009); Stephen Breyer, *Making Our Democracy Work: A Judge's View* 3-12 (2010); Administrative Office of the U.S. Courts, *Overview – Rule of Law*, *available at* www.uscourts.gov/educational-resources/educational-activities/overview-rule-law (last visited Jan. 10, 2024); American Bar Association, *What is the rule of law*, *available at* www.americanbar.org/advocacy/rule_of_law/what-is-the-rule-of-law/ (last visited Jan. 10, 2024).

[5] *See also United States v. Nixon*, 418 U.S. 683, 705 (1974) ("it is the province and duty of this Court 'to say what the law is'" and "[a]ny other conclusion would be contrary to the basic concept of separation of powers and [] checks and balances") (citing *Marbury* and The Federalist No. 47); *New York State Bd. of Elections v. Lopez Torres*, 552 U.S. 196, 212 (2008) (Kennedy, J., concurring in the judgment) ("The rule of law, which is a foundation of freedom, presupposes a functioning judiciary respected for its independence, its professional attainments, and the absolute probity of its judges."); Scott D. Gerber, *The Political Theory of an Independent Judiciary*, 116 Yale L.J. Pocket Part 223, 225 (2007).

characteristic of any law worthy of the name.").[6] But judicial review can play that critical role in advancing the rule of law only if courts conduct their review of agency action in a manner consistent with settled, objective principles, including this Court's precedent establishing the proper standards of review.

These key principles of judicial review and their role in supporting the rule of law are firmly embedded in American law. First, it is beyond question that when "Congress makes the policy decisions, it may authorize another branch to 'fill up the details'" in determining how to apply statutory commands. *Gundy v. United States*, 139 S. Ct. 2116, 2136 (2019) (Gorsuch, J., dissenting) (quoting *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 43 (1825) (Marshall, C.J.)).[7] But as Congress itself recognized in enacting the Administrative Procedure Act (APA), courts can and should provide a check against "arbitrary and capricious" exercises of such delegated authority. 5 U.S.C. § 706(2)(A).

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[6] *See, also, e.g.*, Thomas W. Merrill, *The Essential Meaning of the Rule of Law*, 17 J. L. Econ. & Pol'y 673, 700 (2022) ("[A] broad right of judicial review of executive action is critical in creating and sustaining the rule of law. If the ultimate purpose of the rule of law is to make the use of coercive force by the executive predictable, and if the judiciary's penchant for enforcing settled law is the lynchpin in creating such a condition, then the executive must be answerable to the courts.").

[7] *See also, e.g.*, Congressional Research Service, *Organizing Executive Branch Agencies: Who Makes the Call?* (June 27, 2018) ("Congress may act pursuant to its specific, enumerated authorities to establish [executive branch] agencies" and their "power to establish agencies may be enhanced by the Necessary and Proper Clause . . . ."), *available at* https://crsreports.congress.gov/product/pdf/LSB/LSB10158.

Faithful application of this arbitrary-and-capricious standard promotes the rule of law by respecting Congress's decision to empower agencies, on the one hand, while requiring rational decision-making and reason-giving on the other. *See* Kevin M. Stack, *An Administrative Jurisprudence: The Rule of Law in the Administrative State*, 115 Colum. L. Rev. 1985, 2010 (2015). As this Court has explained, "[r]eview under the arbitrary and capricious standard is deferential." *National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658 (2007). A court "will not vacate an agency's decision unless it 'has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" *Id.* (quoting *Motor Vehicles Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S 29, 43 (1983)).

This Court has directed that arbitrary-and-capricious review limits a court's consideration to whether "the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).[8] *See also Biden v. Missouri et al.*, 595 U.S. 87, 96 (2022) (per curiam) (holding it was not was not arbitrary and capricious

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[8] *See generally* Congressional Research Service, An Introduction to Judicial Review of Federal Agency Action, R44699 at 18-21 (Dec. 7, 2016) (summarizing *Motor Vehicle Manufacturers Association v. State Farm Auto Mutual Insurance Co.*, 463 U.S. 29, 43 (1983) and other case law about the arbitrary-and-capricious standard).

for Secretary of Health and Human Services to issue an interim rule requiring COVID-19 vaccination in facilities participating in Medicare and Medicaid); *FERC v. Electric Power Supply Ass'n.*, 577 U.S. 260, 292-295 (2016) (holding it was not arbitrary and capricious for FERC to issue a rule compensating electricity users at the same rate as electricity generators, provided that users commit to reduce their electricity use during peak periods and pass a net-benefits test); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513-14 (2009) (holding it was not arbitrary and capricious for the FCC to change its previous policy regarding enforcement of its indecency ban). And in the specific context of "complex chemical and pharmacological considerations" that are "within the peculiar expertise" of the FDA, this Court has emphasized that judges exercise only "'limited functions of review.'" *Bentex,* 412 U.S. at 654 (quoting *Far East Conference v. United States*, 342 U.S. 570, 574 (1952)).

Consistent adherence to this Court's precedents governing arbitrary-and-capricious review likewise advances the stability and predictability that is necessary to the rule of law. The "greatest purpose" of stare decisis "is to serve a constitutional ideal—the rule of law." *Citizens United v. FEC*, 558 U.S. 310, 378 (2010) (Roberts, C.J., concurring)); *see also* Stanford Encyclopedia of Philosophy, *The Rule of Law* (June 22, 2016) ("The Rule of Law envisages law operating as a relatively stable set of norms available as public knowledge.").[9] While this Court, of course, has discretion to revisit its own precedent when appropriate, the rule of law requires that the lower

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[9] *Available at* https://plato.stanford.edu/entries/rule-of-law/#RuleLawRuleLaw (last visited Jan. 16, 2024).

federal courts practice absolute fidelity to this Court's precedents. "[V]ertical stare decisis"—that is, the lower courts' obligation to faithfully follow the precedents of this Court—is "absolute, as it must be in a hierarchical system with 'one supreme Court.'" *Ramos v. Louisiana*, 140 S. Ct. 1390, 1416 n.5 (2020) (Kavanaugh, J., concurring in part) (quoting U.S. Const., Art III, § 1); *see also Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 136 (2023) (reiterating that "'[i]f a precedent of this Court has direct application to a case,' . . . a lower court 'should follow the case which directly controls . . . .'") (quoting *Rodriguez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989)); Kurt T. Lash, *Originalism, Popular Sovereignty, and Reverse Stare Decisis*, 93 Va. L. Rev. 1437, 1454 (2007) (noting that "vertical stare decisis . . . provides maximal rule of law benefits").

All of these elements—predictability, respect for appropriate congressional delegations to expert agencies, adherence to this Court's articulated standards of judicial review of agency action, and stare decisis—form the rule-of-law framework of American administrative law. And together they balance rule-of-law considerations that can point in different directions: If judicial review is hamstrung, then executive actions can be prone to excess or even lawlessness. But if judicial review becomes so aggressive that it appears arbitrary or rooted in personal or political preference, then it too can undermine public confidence in the judicial system and the predictability on which Congress, the Executive Branch, and the people appropriately rely.

II. BY DEFYING CONGRESS'S DELEGATION OF SCIENTIFIC JUDGMENTS TO THE EXPERT AGENCY AND THE DEFERENTIAL STANDARD OF REVIEW THIS COURT HAS MANDATED, THE FIFTH CIRCUIT UNDERMINED THE RULE OF LAW AND THE PREDICTABILITY IT FOSTERS.

The ABA rarely takes a position regarding specific instances of judicial review of administrative action, whether in the courts of appeals or this Court. Nor does the ABA typically weigh in as amicus in litigation about the FDA's approval or review of any given drug applications. But in this case, the courts below departed substantially from settled principles of judicial review to substitute their own judgment for that of the FDA on the specific question of drug safety and efficacy. In doing so, those decisions implicate broader rule-of-law concerns by eroding public confidence in the judicial system and the predictability and stability of the law. In particular, the Fifth Circuit: (1) overrode Congress's decision to delegate scientific judgments to the FDA and (2) failed to properly and faithfully apply this Court's precedent establishing the deferential standard of review for the FDA's decisions.

1. The Decision Below Defied Congress's Decision to Authorize the FDA, Not the Federal Courts, to Make Scientific Judgments Regarding Drug Safety and Efficacy

Congress created the FDA to implement its policy that Americans should have access to pharmaceutical drugs that are safe and effective for their intended uses. *See* 21 U.S.C. § 393. In doing so, Congress made

a considered decision—to which the courts owe deference—to "grant . . . primary jurisdiction" over the scientific and medical judgments necessary to ensure drug safety and effectiveness to an "expert agency." *Weinberger v. Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 627 (1973). The FDA is staffed by over 12,000 scientists, including "biologists, chemists, epidemiologists, nurses, pharmacists, [] physicians[,] social and behavioral scientists, statisticians, veterinarians, and engineers." FDA, *FDA STEM Outreach, Education and Engagement* (June 8, 2022).[10] It implements well-established and rigorous criteria and procedures for approving drugs, determining conditions for the prescription and dispensing of drugs, and removing drugs from the market if they are later shown not to be safe and effective. *See generally* FDA, *Development & Approval Process | Drugs* (Aug. 8, 2022).[11] The statute creating the FDA and authorizing its work is explicit that the FDA make its decisions based on scientific expertise and evidence. *See, e.g.*, 21 U.S.C. § 355; FDA, *Laws, Regulations, Policies and Procedures for Drug Applications* (Dec. 4, 2014).[12]

Consistent with the rule of law, Congress also provided for judicial review of agency decisions, like those of the FDA. *See generally* 5 U.S.C. Ch. 7 (establishing judicial review under the Administrative Procedure Act); *infra* p. 5-7. Moreover, Congress

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[10] *Available at* https://www.fda.gov/science-research/fda-stem-outreach-education-and-engagement (last visited Jan. 22, 2024).

[11] *Available at* https://www.fda.gov/drugs/development-approval-process-drugs (last visited Jan. 16, 2024).

[12] *Available at* https://www.fda.gov/drugs/development-approval-process-drugs/laws-regulations-policies-and-procedures-drug-applications (last visited Jan. 16, 2024).

determined that FDA decisions to approve drugs should be evaluated under the arbitrary-and-capricious standard of review. 5 U.S.C. § 706(2)(A). As this Court has explained, that review respects Congress's reliance on the FDA's expertise in evaluating medical and scientific evidence, precludes irrational decisions, and promises a stable regulatory framework.[13] In one of the earliest cases involving the FDA's authority, for example, this Court recognized that "[t]he determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations" that are "within the peculiar expertise" of the FDA, and over which courts exercise only "'limited functions of review.'" *Bentex,* 412 U.S. at 654 (quoting *Far East Conference*, 342 U.S. at 574). After all, as then-Judge Kavanaugh explained, "[a] court is ill-equipped to second-guess that kind of agency scientific judgment under the guise of the APA's arbitrary and capricious standard."*Cytori*

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[13] *See Hynson*, 412 U.S. at 624 ("FDA is indeed the administrative agency selected by Congress to administer the [Federal Food, Drug, and Cosmetic] Act"); *id.* at 627 ("The heart of the new procedures designed by Congress is the grant of primary jurisdiction to FDA, the expert agency it created"); *CIBA Corp. v. Weinberger*, 412 U.S. 640, 643-44 (1973) (where the question "involves a determination of technical and scientific questions by experts . . . the agency is therefore appropriately the arm of Government to make the . . . determination"); *id.* at 644 ("the Act does not create a dual system of control – one administrative, and the other judicial"); *Bentex*, 412 U.S. at 652 (the statutory drug approval provisions "strongly suggest that Congress desired that the administrative agency make" all drug regulatory determinations); *id*. at 653 ("Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background").

Therapeutics, Inc. v. FDA, 715 F.3d 722, 727 (D.C. Cir. 2013) (Kavanaugh, J.).

In this case, however, the Fifth Circuit did not follow Congress's direction. First, contrary to congressional design, the Fifth Circuit substituted its judgment for the FDA's expertise when it rejected conclusions the FDA drew from scientific evidence. For example, the Fifth Circuit claimed that because the FDA "failed to seek data on the cumulative effect" of several changes it made to the mifepristone risk evaluation and mitigation strategy (REMS) in 2016, its decision to allow those changes was arbitrary and capricious, Pet. 53a. Similarly, the Fifth Circuit held that the FDA did not have adequate evidence to support its decisions in 2020 and 2021 to allow remote prescription of mifepristone. Pet. 59a-63a. But in both instances, the FDA had substantial amounts of evidence, "including dozens of scientific studies and decades of safe use of mifepristone by millions of women in the United States and around the world," Pet. 12, from which it drew its conclusions.

The Fifth Circuit's second-guessing of the FDA's conclusions undermines Congress's decision to rely on the FDA's expertise and this Court's insistence on respecting that decision. This Court has long instructed that because the judiciary typically lacks scientific expertise, courts reviewing FDA decisions to approve drugs must respect the FDA's scientific determinations. *See, e.g., Bentex,* 412 U.S. at 464. To this day, members of this Court continue to insist on judicial deference to the FDA's expertise. For example, Justices Alito and Thomas, in a previous mifepristone case, criticized a district court judge "[who] took it upon himself to overrule the FDA on a question of drug safety . . . [d]isregarding the Chief Justice's admonition against judicial second-guessing of

officials with public health responsibilities." *FDA v. American Coll. Of Obstetricians and Gynecologists*, 141 S. Ct. 10, 12 (2020) (Alito and Thomas, JJ., dissenting). *See FDA v. American Coll. Of Obstetricians and Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring) (reiterating, in a case involving mifepristone, his previous admonition that "courts owe significant deference to the politically accountable entities with the background, competence, and expertise to assess public health").

Unlike the Fifth Circuit in this case, other lower courts have consistently heeded Congress's and this Court's mandate of judicial deference to the FDA's medical and scientific expertise. *See, e.g.*, *Pharm. Mfg. Rsch. Serv. v. FDA*, 957 F.3d 254, 265 (D.C. Cir. 2020) (Rao, J.) ("Meaningful review of the agency's actions does not require us to step into the FDA's shoes and reassess its scientific judgments"); *Cytori Therapeutics*, 715 F.3d at 727; *Serono Labs, Inc. v. FDA*, 715 F.3d 722, 727 (D.C. Cir. 1998) ("Neither we, nor the district judge, are scientists independently capable of assessing the validity of the agency determination – beyond holding it to the standards of rationality required by the Administrative Procedure Act"); *Premo Pharmaceutical Labs., Inc., v. United States*, 629 F.2d 795, 803 (2d Cir. 1980) ("[W]hether the product . . . is in fact safe and effective . . . is to be determined by the FDA which, as distinguished from a court, possesses superior expertise, usually of a complex scientific nature, for resolving the issue").

In contrast, in this case, the Fifth Circuit second-guessed the FDA's scientific findings and imposed its own conclusions instead of properly examining the extensive record before the FDA and applying the arbitrary-and-capricious standard as it applies to the drug approval context.

2. The Decision Below Defied this Court's Precedent Establishing the Arbitrary-and-Capricious Standard

The Fifth Circuit's decision also contravenes this Court's precedent as to the proper application of arbitrary-and-capricious review. As outlined above, *infra* p. 7-8, the term "arbitrary and capricious" has an established legal meaning that is distinct from *de novo* or reasonableness review.

Here, the Fifth Circuit did not even try to reason that the FDA "relied on factors which Congress had not intended it to consider, . . . offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise," *Motor Vehicles Mfrs. Ass'n*, 463 U.S at 43. Instead, the Fifth Circuit took the view that the FDA did not consider the cumulative effects of loosening restrictions on mifepristone in 2016, Pet. 53a, wrongly changed its collection of non-fatal adverse events, Pet. 54a-56a, and failed to gather evidence about the risks of remote prescription, Pet. 63a, 74a-75a.

This is problematic in at least three ways:

First, the Fifth Circuit effectively converted its inexpert, judicial conclusions that the FDA's evidence was inadequate into a claim that the FDA "entirely failed to consider an important aspect of the problem." 463 U.S at 43. While the Fifth Circuit might prefer additional or more precise types of data, that does not transform its judicial preferences into a legal conclusion that the FDA "entirely failed to consider" relevant factors in making a uniquely scientific judgment. The factual record indicates the contrary.

Second, the Fifth Circuit flouted this Court's frequent admonition that arbitrary-and-capricious review is not *de novo* review of the expert agency's conclusions and inferences. Rather, as this Court has explained, the question for the reviewing court is whether "the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 592 U.S. at 423. The Fifth Circuit's final published opinion identified no aspect of the FDA's determination or record that was outside this "zone of reasonableness."[14]

Third, the Fifth Circuit's approach would erode precedent by allowing a reviewing court to require highly specific evidence of the court's choosing rather than deferring to the FDA's more informed judgment as to what evidence is required and the agency's reasonable inferences and conclusions informed by the agency's scientific expertise. This Court has rejected such a demanding approach to arbitrary-and-capricious review. For example, in upholding the Federal Communications Commission's decision to tighten restrictions on profanity in broadcasts as part of its enforcement of Congress's "determination that indecency is harmful to children," the Court explained

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[14] *See also FERC v. Electric Power Supply Ass'n.*, 577 U.S. 260, 292 (2016) ("In reviewing [the agency's] decision, we may not substitute our own judgment for that of the Commission" because a "court is not to ask whether a regulatory decision is the best one possible or even whether it is better than the alternatives. Rather, the court must uphold a rule if the agency has 'examine[d] the relevant [considerations] and articulate[d] a satisfactory explanation for the action[,] including a rational connection between the facts found and the choice made.'") (citations omitted).

that empirical studies on precisely how much and what kind of profanity caused harm were unnecessary. *Fox,* 556 U.S. at 519. "[I]t suffices to know that children mimic the behavior they observe—or at least the behavior that is presented to them as normal and appropriate." *Id.* Neither the Administrative Procedure Act nor this Court's precedent on arbitrary-and-capricious review empowers the lower courts to demand that the FDA (or any other expert agency on which Congress relies to implement its policies) conduct any particular meta-analysis or collect particular data on medical risks.

* * *

While scientific research and agency decisions can evolve over time, courts must exercise a careful and steady hand, especially in the context of revisiting longstanding drug approvals. The rule of law is served when the judiciary properly reviews the decisions of a federal agency. The Administrative Procedure Act plays an important role in our governmental structure, and when appropriate, judicial invalidation of administrative rulings can serve as a valuable check on agency arbitrariness or overreach. Rule-of-law principles can be undermined, however, when a court that lacks any scientific expertise deploys the Administrative Procedure Act to selectively second-guess the FDA's exercise of scientific judgment without any valid basis. For all these reasons, the ABA respectfully urges the Court to give effect to Congress's decision to delegate scientific assessment of drug safety to the FDA and adhere to the proper standard of review established in this Court's precedent.

CONCLUSION

For the foregoing reasons, this Court should reverse.

Respectfully submitted,

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