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ESCAPING PETITION PURGATORY: REFORMING FDA CITIZEN PETITION REVIEW TO SAFEGUARD SCIENTIFIC DECISIONMAKING FROM JUDICIAL OVERREACH

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ABSTRACT

Judicial review of the FDA's decisionmaking has long been legally permissible, but courts generally had not engaged in substantive review of the scientific bases for drug approval until 2023, when advocacy organizations filed suit against the FDA to oppose approval of the abortion drug mifepristone. Although most of the attention on the Alliance for Hippocratic Medicine v. FDA *(*AHM*) case has centered around the complex politics surrounding mifepristone's approval and use, this Article explores* AHM *as a test case for how the FDA's failure to effectively respond to two citizen petitions provided an opportunity for judicial overreach into the FDA's science-based decisions on the approval of mifepristone. The Article reviews the history of FDA citizen petition review and discusses the interplay of citizen petition review with judicial review procedures. The Article then turns to* AHM*, by reviewing the citizen petitions and litigation tactics used to bring judicial review in* AHM *and explaining how these tactics remain viable despite the Supreme Court's ultimate determination that the plaintiffs in* AHM *lacked standing. After exploring the significant risks of overreach in potential future judicial review of FDA drug approval decisions and the FDA's potential options in the face of a court order, the Article provides concrete suggestions for the FDA and Congress to improve the citizen petition process.*

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I. INTRODUCTION

Following the Northern District of Texas's April 2023 decision to stay the FDA's approval of the abortion drug mifepristone,[1] expansive media coverage focused on the potential impacts of the decision on the medication's availability and on wider concerns about reproductive rights in the United States.[2] Along with the drug misoprostol, mifepristone is one of two medications typically prescribed in a treatment regimen for medication abortions in the United States.[3] Mifepristone is the only drug in this regimen explicitly approved by the FDA for pregnancy termination.[4] The wide availability of mifepristone is undoubtedly important in the fight for reproductive justice, so changes in its availability—as contemplated in the *Alliance for Hippocratic Medicine v. FDA* (*AHM*) case[5]—posed significant issues that could have had an effect far beyond the regulatory status of mifepristone.

More importantly, judicial review of drug approval in *AHM* was triggered in an unprecedented fashion—through challenge of a set of citizen petitions filed with the FDA. This case revealed flaws in both the FDA's citizen petition procedures, and issues arising from the petitioners' ability to select a specific desired judge to hear the case despite dubious standing claims—issues that could render more FDA approvals and decisions subject to judicial review.

The FDA's citizen petition process is the formal administrative avenue for the public to request specific actions or changes to FDA-regulated products or proposed FDA rulemaking. When any member of the public submits a citizen petition, the FDA is required by statute to respond within 180 days.[6] In practice,

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[1] All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507 (N.D. Tex. 2023).

[2] *See, e.g.*, Rachel M. Cohen, *A Texas Judge Just Issued a National Ruling Against Medication Abortion. What Now?*, VOX (Apr. 8, 2023), https://www.vox.com/policy/2023/4/7/23593396/medication-abortion-pills-mifepristone-misoprostol-pregnancy-texas [https://perma.cc/98V6-RFGP]; Sarah McCammon, *Judges' Dueling Decisions Put Access to a Key Abortion Drug in Jeopardy Nationwide*, NPR (Apr. 8, 2023), https://www.npr.org/2023/04/07/1159220452/abortion-pill-drug-mifepristone-judge-texas-amarillo [https://perma.cc/CB7Z-U3RF].

[3] *See* U.S. Food & Drug Admin., *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation [https://perma.cc/N6AT-N4N4] (noting that mifepristone is approved, in a regimen with misoprostol, to end an intrauterine pregnancy through ten weeks gestation); *see also* Danco Laboratories, LLC, *A Private Choice for Early Abortion*, https://www.earlyoptionpill.com/ [https://perma.cc/42ND-PN55] (noting that Mifeprex (mifepristone) "is used in a regimen with another prescription medicine called misoprostol, to end an early pregnancy").

[4] *See* U.S. Food & Drug Admin., *supra* note 3; *see also* U.S. Food & Drug Admin., Mifeprex (Mifepristone) Tablets, for Oral Use (2000) (noting that Mifeprex "is used . . . to end an early pregnancy" and that the "Medication Guide has been approved by the U.S. Food and Drug Administration").

[5] *See* All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507 (N.D. Tex. 2023); All. for Hippocratic Med. v. U.S. Food & Drug Admin., 78 F.4th 210 (5th Cir. 2023); U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367 (2024).

[6] Citizen Petition, 21 C.F.R. § 10.30(e)(2) (2016).

however, the FDA frequently provides a substantive response only belatedly or fails to respond substantively at all.[7] Should the FDA not respond on time, or if a petitioner is dissatisfied with the FDA's response, the petitioner may seek judicial review. Underlying the *AHM* case are two extreme examples of the FDA's delay in responding to citizen petitions addressing mifepristone's approval: the FDA took *fourteen years* to substantively reply to a 2002 citizen petition filed by various anti-abortion organizations, and two years to reply to a second citizen petition submitted in 2016 by the same groups.[8] Following the FDA's delays in addressing these petitions, the plaintiff groups sought judicial review of FDA's approval of mifepristone—a drug that has been approved in the United States since 2000.[9]

This Article examines how the *AHM* plaintiffs capitalized on the FDA's inefficient citizen petition responses and predicts that similar issues will likely arise in the future unless the FDA and Congress act to improve the citizen petition process, enact needed judicial reform, and facilitate improved avenues for citizen input at the FDA. Part I explains the FDA's authority to regulate and monitor food, drugs, and medical devices; the citizen petition process; and the nexus between the Administrative Procedure Act and citizens' prerogative to seek judicial review of FDA decisions. This Part also explores the difficulty inherent in balancing science-based expert agency decisionmaking with review by generalist courts. Finally, this Part posits that, if correctly implemented, the citizen petition process can further the FDA's mission of protecting public health.

Part II explains how the recent litigation surrounding mifepristone's regulatory approval serves as a test case for judicial review of FDA drug approval decisions. This Part describes the history of medication abortion in the United States and the FDA's regulatory actions relating to mifepristone, including its significantly delayed actions on two citizen petitions brought by anti-abortion groups. It also describes the progress of *AHM* through the United States District Court for the Northern District of Texas, the United States Court of Appeals for the Fifth Circuit, and the Supreme Court.

Part III of this Article explains how, even though the Supreme Court ultimately determined that the plaintiffs in *AHM* did not have standing to bring their various claims, judicial review of citizen petition decisions on drug approvals (and indeed, on the FDA's science-based decisionmaking) remains highly viable and likely in future cases. This Part explores how *AHM* might

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[7] *See, e.g.*, Bradley Merrill Thompson, *Unpacking Averages: FDA's Extraordinary Delay in Resolving Citizen Petitions*, EPSTEIN BECKER GREEN HEALTH L. ADVISOR (Oct. 2, 2023), https://www.healthlawadvisor.com/unpacking-averages-fdas-extraordinary-delay-in-resolving-citizen-petitions [https://perma.cc/62G2-WN5D]; Adrienne R. Lenz & Lisa M. Baumhardt, *FDA Law Blog Citizen Petition Tracker*, HYMAN, PHELPS & MCNAMARA PC (Feb. 14, 2025), https://www.thefdalawblog.com [https://perma.cc/F9QY-4EMB].

[8] All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507, 522 (N.D. Tex. 2023).

[9] Letter from Center for Drug Evaluation and Research to Sandra P. Arnold, Vice President, Corp. Affairs, Population Council (2000); Complaint at 11, 240–54, All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507 (N.D. Tex. 2023) (No. 2:22-CV-223-Z).

incentivize forum shopping by litigants seeking specific results and could encourage litigants to bring standing claims that have historically been rejected by courts. Furthermore, it explores perhaps the most impactful substantive aspect of the Fifth Circuit's decision: this judicial ruling could have imposed new requirements on sponsors that were not previously required by the FDA. The ruling would have required sponsors to isolate certain clinical parameters for protocol amendments and continue to collect data for non-fatal adverse events. The Fifth Circuit effectively suggested new requirements for the FDA that would go above and beyond the FDA's statutory duties for required evidence to amend a drug's protocol,[10] marking a departure from the usual deference courts give to expert agencies in their scientific decisionmaking. Part III also details the FDA's potential responses to a court order limiting or rejecting its authority to approve a drug—both of which have major drawbacks. This Part argues that the FDA should be able to exercise its discretion to not comply with a judicial order limiting its authority to approve a drug, and that few consequences could be effectively levied against the FDA should it not comply with a court order. Furthermore, if the FDA were to comply with a court order withdrawing approval of a drug, this action does not necessarily bar reintroduction of the drug on the market in the United States.

Finally, Part IV of this Article recommends FDA and congressional action to prevent a flawed citizen petition process from undermining the FDA's ability to approve drugs and promote public health. First, this Part encourages creation of additional internal review processes at the FDA to enhance scientific decisionmaking in complex cases (and to bolster the administrative record on review). This Part also suggests that Congress enact reforms to increase oversight of the citizen petition process and allow for further transparency into FDA decisions. Second, this Part explores alternative strategies for ensuring exhaustion of an issue within the agency before the issue may be brought before a generalist court. Drawing from approaches by the Environmental Protection Agency (EPA), the U.S. Patent and Trademark Office (USPTO), and the FDA's own history, this Part examines how administrative judges and director review could be used to resolve the highly technical issues brought before the FDA.

II. THE FDA AS A SPECIALIST AGENCY: JUDICIAL REVIEW, CITIZEN PETITIONS, AND SCIENTIFIC EXPERTISE

The FDA plays a crucial role in promoting public health in the United States through the regulation and monitoring of food, drugs, and medical devices.[11] The FDA has long possessed broad authority to oversee the development, manufacturing, and distribution of these products to ensure their

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[10] Serious adverse event reporting for nonprescription drugs, 21 U.S.C. § 379aa (2006); All. for Hippocratic Med. v. Food & Drug Admin., 78 F.4th 210, 256 (5th Cir. 2023) (vacating in part and affirming in part).

[11] *See, e.g.*, ASSISTANT SEC'Y FOR PUB. AFFS. (ASPA), *Health and Human Services Agencies and Offices* (July 29, 2024), https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html [https://perma.cc/U24J-XLR9] (noting that the FDA "ensures that food is safe, pure, and wholesome; human and animal drugs, biological products, and medical devices are safe and effective; and electronic products that emit radiation are safe").

safety and efficacy.[12] Although much of the FDA's decisionmaking relies on internal expert analysis, the citizen petition process is the primary formal mechanism through which the public may request specific actions or changes by the FDA to its processes and procedures. Unfortunately, the citizen petition process has not always worked as intended: substantive responses to petitions are often delayed or effectively abandoned, and there is little motivation for the FDA to improve on this process.

This Part describes the history of the FDA and introduces the governing statutes that guide both the FDA and administrative agencies more generally. It then explores the process by which petitioners can seek judicial review of the FDA's decisions, and the evolving requirements for exhaustion of administrative remedies at the FDA. This Part then explains the FDA's citizen petition process, intended to allow citizens the opportunity to directly engage with the FDA on its decisions. Finally, this Part addresses the tension inherent in squaring expert decisionmaking with broad governing statutes and discusses how the judiciary is often ill-equipped to address agency-specific scientific and public health concerns.

A. The FDA's History and Origins

The modern era of the FDA began in 1906 when Congress passed the Federal Food and Drug Act.[13] The FDA's current structure began taking shape in 1938, however, when Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA).[14] When Congress amended the Act in 1962, it required, for the first time, that manufacturers demonstrate the safety of their proposed drug products to the FDA before receiving approval to market in the United States.[15] This Act marked a major shift in the regulation of pharmaceutical products in the United States, significantly affecting the roles of manufacturers and the FDA. The FDCA required manufacturers to provide the FDA with evidence demonstrating the safety of their proposed products and directed the FDA to assess this safety information in its approval decisions.[16]

At the time that Congress passed the FDCA, no uniform body of law shaped the actions of administrative agencies. In the 1930s, most administrative

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[12] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399(d), § 1002(a), Pub. L. 111-31, 21 U.S.C. § 355(a)–(b); *see also* United States v. Article of Drug Bacto-Unidisk, 394 U.S. 784, 798 (1969).

[13] *Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN. (Apr. 24, 2019), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement [https://perma.cc/P54Z-37ZK].

[14] *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Nov. 27, 2018), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act [https://perma.cc/JN4P-5NC8].

[15] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., Pub. L. 75-717, 52 Stat. 1040 (1938). It was not until 1962 that Congress required manufacturers to demonstrate the efficacy of their drugs to the FDA. Drug Amendments of 1962, 21 U.S.C. § 301 et seq., Pub. L. 87-781, 76 Stat. 780 (1962).

[16] U.S. PHARMACOPEIA, *1938 Food, Drug, and Cosmetic Act (FDCA)* (Oct. 7, 2010), https://www.usp.org/sites/default/files/fda-exhibit/legislation/1938.html [https://perma.cc/QYK8-LURQ].

law arose from specific statutory requirements tailored to an agency's purpose, rather than overarching standards for all agencies.[17] In 1946, Congress passed the Administrative Procedure Act (APA), which, among other requirements, directs government agencies to give the public the right to petition in order to issue, amend, or repeal agency rulings.[18] Under the APA, an agency must provide "interested persons an opportunity to participate in the rule making through the submission of written data, views, or arguments."[19]

In addition, the APA outlined a statutory scheme for judicial review of agency action, requiring that there must be "final agency action" on a petition before a petitioner may seek judicial review.[20] The judiciary can compel agency action that has been "unlawfully withheld or unreasonably delayed," and "set aside agency action, findings, and conclusions" if the action is, among other things: arbitrary, capricious, or an abuse of discretion; in excess of the statutory authority or jurisdiction granted to an agency; unsupported by substantial evidence; or unwarranted by the facts (after a de novo review of the facts by the reviewing court).[21] The APA outlines two instances where judicial review is impermissible: (1) when "statutes preclude judicial review;" and (2) "where agency action is committed to agency discretion by law."[22]

Before seeking judicial review, generally petitioners must exhaust available administrative remedies; put another way, only final agency actions can be appealed.[23] Requirements for exhaustion have evolved over time, however. After enacting the APA in 1946, Congress subsequently amended the FDCA so that consumers adversely affected by an administrative regulation could seek judicial review without any provision that required intra-agency "exhaustion" of a remedy.[24] This amendment meant that, after the FDA denied a public request for a hearing, judicial review could be sought to challenge the adverse effects of regulatory rulemaking.[25]

After 1966, the FDA revised its procedures for citizen petitions and began publishing the petitions it had received and accepted in the Federal Register for public comments.[26] Once the comment period (thirty days following publication in the Federal Register) had expired, the FDA Commissioner then published an order responding to the petition and proposing any amendments,

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[17] *See, e.g.*, ATT'Y GEN.'S COMM. ON ADMIN. PROC., FINAL REPORT OF THE ATTORNEY GENERAL'S COMMITTEE ON ADMINISTRATIVE PROCEDURE, at 7–10 (1941); Securities and Exchange Commission, 15 U.S.C. § 78(d); Social Security Board, 42 U.S.C. § 903; National Labor Relations Board, 29 U.S.C. §§ 151–169; *see also* Roni Elias, *The Legislative History of the Administrative Procedure Act*, 27 FORDHAM ENV. L. REV. 207, 215 (2015).

[18] Administrative Procedure Act of 1946, Pub. L. No. 79-404, 60 Stat. 237 (codified as 5 U.S.C. §§ 551–559 (2012)).

[19] 5 U.S.C. § 553(c) (internal quotations omitted); *see also* Elias, *supra* note 17, at 219.

[20] 5 U.S.C. § 704.

[21] *Id.* at § 706.

[22] *Id.* at § 701(a)(1)–(2).

[23] *See, e.g.*, *id.* at § 704; McCarthy v. Madigan, 503 U.S. 140, 145 (1992).

[24] 21 U.S.C. § 371(f)(1); *see* James R. Baird, Jr., *The Right to Judicial Review: An Analysis of Section 701(f)(1)*, 10 FOOD DRUG COSMETIC L.J., 285, 296 (1955).

[25] 21 U.S.C. § 371(f)(1); *see* Baird, *supra* note 24, at 297.

[26] 21 C.F.R. § 2.66 (1968).

repeals, or issues relating to the petition's subject matter.[27] Any member of the public who could be "adversely affected" by the order then had thirty days to submit any objections to the FDA Commissioner, and/or to request a public hearing with a presiding officer; otherwise, the FDA's proposal constituted final agency action.[28] When a member of the public requested a hearing, once the presiding officer completed the hearing, unsatisfied petitioners could seek review by the FDA Commissioner to determine whether an interlocutory appeal was necessary to resolve the issue presented in the citizen petition.[29] The FDA Commissioner had discretion to decide whether to conduct an oral argument upon review.[30] Following the FDA Commissioner's review or oral argument, the FDA Commissioner published a final order in the Federal Register,[31] marking final exhaustion of a petitioner's administrative remedies and thus allowing a petitioner to seek judicial review.[32]

In 1979, the FDA amended its citizen petition regulations to clarify that the FDA Commissioner would rule on a petition within 180 days of receipt by approving the petition, denying the petition, or providing a tentative response.[33] Under this amendment, the FDA Commissioner had discretion to use conferences, meetings, evidentiary public hearings, and regulatory hearings as part of the decisionmaking process, but petitioners could no longer request a hearing.[34] Upon a final decision by the FDA Commissioner, the petition would be docketed publicly or noticed in the Federal Register.[35] Within thirty days of a decision's release, any interested person could file a petition for reconsideration or a petition to stay the action proposed by the FDA Commissioner.[36] If a petitioner did not file for reconsideration, or if the FDA did not grant reconsideration, the action was considered final—allowing the petitioner to seek judicial review.[37] Further, petitioners were not required to file for reconsideration before seeking judicial review.[38]

Although these regulations have been amended since 1979, the condition to trigger judicial review is still effectively the same: the FDA's published decision on a petition constitutes final agency action.[39] A dissatisfied petitioner must then seek judicial review of the final agency action within six years after

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[27] *Id.* at § 2.66(c) (1968).
[28] *Id.* at § 2.67(a) (1968).
[29] *Id.* at § 2.89 (1968).
[30] *Id.*
[31] *Id.* at § 2.98 (1968).
[32] *See id.* at § 2.101 (1938).
[33] *Id.* at § 10.30 (1979).
[34] *Id.*; 44 Fed. Reg. 22323, 22318–22 (Apr. 13, 1979).
[35] 21 C.F.R. § 10.30(e)(2) (1979).
[36] *Id.* at §§ 10.33, 10.35 (1979).
[37] *Id.* at § 10.45 (1979).
[38] *Id.*
[39] U.S. FOOD & DRUG ADMIN. CTR. FOR DRUG EVALUATION & RSCH. (CDER), *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry*, 14 (Sept. 2019), https://www.fda.gov/media/130878/download [https://perma.cc/WM7C-ZS52].

the cause of action accrues, or the claim may be time-barred.[40] Once an action is subject to judicial review, the APA allows the judiciary to compel action from an agency if the agency has abused its discretion or has taken action unsupported by evidence.[41]

B. The Modern FDA Citizen Petition Process

The FDA's current citizen petition procedures allow "any interested person" to voice concerns to the FDA about scientific, safety, or legal issues under the FDA's purview.[42] Petitions must contain at least the following information: the action requested; a statement of factual and legal grounds for the petition; where relevant, the environmental impact of an action and the economic impact of an action; and a certification that the petition includes all pertinent information, including any information not favorable to the petition.[43] Petitioners can comment on essentially any topic falling under the FDA's purview, such as: the approval of a drug or medical device; product labeling requirements; health claims associated with food and supplements; permitted food additives; food processing permits; FDA proposed rulemaking or guidance; and warnings on carcinogens or certain chemicals.[44]

Three categories of petitioners typically file citizen petitions: (1) members of the general public (including engaged citizens as well as researchers, doctors, universities, hospitals, and other organizations such as advocacy organizations); (2) generic drug manufacturers; and (3) innovator drug manufacturers.[45] Members of the general public (including researchers and doctors) tend to submit petitions requesting either that (1) the FDA take action on a safety issue; or (2) the FDA reconsider its preexisting guidelines for

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[40] 24 U.S.C. § 2401(a); *see* Susan C. Morse & Leah R. Butterfield, *Out of Time at the Fifth Circuit: Why (Most of) the Mifepristone Challenge in Alliance for Hippocratic Medicine is Time-Barred*, YALE J. ON REG. (Mar. 2023), https://www.yalejreg.com/nc/out-of-time-at-the-fifth-circuit-why-most-of-the-mifepristone-challenge-in-alliance-for-hippocratic-medicine-is-time-barred-by-susan-c-morse-leah-r-butterfield/ [https://perma.cc/P83F-X46Z]. On July 1, 2024, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the Supreme Court held that challenges to agency regulation are untimely if filed more than six years after the cause of action accrued (in that case, when the plaintiff was first harmed by the action). 603 U.S. 799 (2024).

[41] 5 U.S.C. § 706.

[42] 21 C.F.R. §§ 10.25(a), 10.30(a) (2012). The First Amendment provides that "Congress shall make no law . . . abridging the freedom . . . to petition the Government for a redress of grievances." U.S. CONST. amend. I. The Constitutional right to petition one's government to act underlies the development of administrative agencies—Congress created specialized administrative agencies to receive petitions from the public urging action on a specific issue. *See* Maggie McKinley, *Petitioning and the Making of the Administrative State*, 127 YALE L.J. 1538, 1600 (2018).

[43] 21 C.F.R. § 10.30(b) (2012).

[44] *See* 21 C.F.R. §§ 10.30–31; Brian K. Chen, Y. Tony Yang, Xi Cheng, John Bian & Charles L. Bennett, *Petitioning the FDA to Improve Pharmaceutical, Device and Public Health Safety by Ordinary Citizens: A Descriptive Analysis*, 11 PLOS ONE e0155259, S1 (May 2016).

[45] *See* Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 101, 112 (2012).

approval of a drug or food additive.[46] Generic firms often use reference listed drug (RLD) designation petitions to request that the FDA list the drug as an RLD, so a generic manufacturer can begin the Abbreviated New Drug Application (ANDA) submission process towards generic drug approval.[47] All manufacturers may file discontinuation petitions to receive confirmation from the FDA on whether a drug was removed from the market for safety or efficacy concerns.[48] Finally, 505(q) petitions filed by innovator firms generally ask the FDA to take action that may potentially delay generic drug approval (e.g., requesting that the FDA adopt certain standards for a generic drug that may be more burdensome).[49] Third parties may also participate in creating the record of the citizen petition proceeding by submitting comments to the docket of a filed petition; these comments become part of the docket file.[50]

Petitions must receive a written response from the FDA "within 180 days of receipt of the petition," except for 505(q) petitions, which require a shorter response time of 150 days.[51] As described above, the FDA's administrative remedies must be exhausted before judicial review is sought.[52] If the FDA does not reply to a petition within the required time frame, the FDA's regulations, the APA, and, for 505(q) petitions, Congress's clarification of the meaning of "final action," make clear that the FDA's failure to respond constitutes final agency action, after which petitioners may seek judicial review.[53] The APA provides that agency actions may be compelled when "unreasonably delayed," and such actions may be subject to judicial review when they are "otherwise not in accordance with law."[54] Although the FDCA does not clearly state that failure to respond constitutes final agency action for all types of citizen petitions, the Food and Drug Administration Amendments Act (FDAAA) provided that for 505(q) petitions, "[t]he Secretary shall be considered to have taken final agency action [whether denied, adopted, or the 180-day period for review has elapsed] on a petition if . . . such [statutory review] period expires without the Secretary

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[46] *See* Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U.L. REV. 305, 327 (2017); *see also* Chen, *supra* note 44, at S1.

[47] *See* Carrier, *supra* note 46, at 327.

[48] *Id.*

[49] *Id.* Certain other procedures are relevant for citizen petitions arising under Section 505(q), including (1) determination of whether Section 505(q) applies to a specific petition; (2) determination of whether a petition would delay approval of an ANDA, 505(b)(2), or 351(k) application; (3) application of the certification requirements in Section 505(q)(1)(H); and (4) application of the verification requirements in Section 505(q)(1)(I). *See* CDER, *supra* note 39.

[50] 21 C.F.R. § 10.30(d) (2012).

[51] *Id.* at §§ 10.30(e)(4)–(5) (2012). Two different types of ANDA citizen petitions have a shorter reply period: the FDA must reply to 505(q) petitions within 150 days and to 505(j)(2)(c) petitions within ninety days. *Id.*

[52] *Id.* at § 10.45(b) (2012).

[53] 5 U.S.C. § 551(13); 5 U.S.C. § 706; *see* Biovail v. U.S. Food and Drug Admin., 448 F. Supp. 2d 154, 161 (D.D.C. 2006).

[54] 5 U.S.C. §§ 706(2)(A), (E).

having made such a final decision."[55] As noted, the petitioner must seek judicial review within six years or their claim may be time-barred.[56]

Despite the opportunity to meaningfully engage with the FDA that citizen petitions appear to provide, in a 1998 report the Department of Health and Human Services' Office of the Inspector General (OIG) determined that the FDA was managing the citizen petition process ineffectively.[57] A 1998 OIG investigation into the citizen petition process found that the FDA's response delays resulted from limited resources, a lack of written policy and procedures for addressing citizen petitions, ineffective screening and prioritizing, and lack of central monitoring.[58] A summary of the OIG's recommendations and the FDA's responses appears below in Table 1.

OIG Recommendation[59]	**FDA Response**	**Current FDA Process**
Centralize petition process	Rejected	No centralization of petitions.
Engage in continued correspondence with petitioners	Accepted	The FDA sends interim responses in response to some petitions.[60]
Provide petitioners with an estimated final response date	Rejected	It is not clear from recent petitions whether the FDA has implemented this process.
Notify the Office of the Commissioner of	Rejected	The FDA does not have an externally verifiable

[55] 21 U.S.C. § 355(q)(2)(a)(ii); *see* Food and Drug Administration Act, Pub. L. No. 110-85 § 914(a) (2007); Ctr. for Food Safety v. Hamburg, 954 F. Supp. 2d 965 (N.D. Cal. 2013) (holding that failure to comply with mandatory deadlines constituted a failure to act under the APA and ordering parties to work toward new deadlines, as the FDA was required to act, but should not release insufficiently considered regulations); Norton v. Utah Wilderness All., 542 U.S. 55, 62–64 (2004) (holding that claims under 5 U.S.C. § 706(1) can proceed where an agency "failed to take *a discrete* agency action that it *is required to take*," although that was not what was happening in this particular case).

[56] 28 U.S.C. § 2401(a); Texas v. Comm'r of Internal Revenue, 142 S. Ct. 1308 (2022) (concurring in denial of certiorari in part due to statutory limitations under 28 U.S.C. § 2401(a)). *But see* Nat'l Ass'n of Mfrs. v. Dep't of Def., 583 U.S. 109, 118–19 (2018) (stating that suits filed under the APA for judicial review generally need to be filed within six years after the claim accrues); Corner Post Inc. v. Bd. of Governors of the Fed. Rsrv. Sys., 144 S. Ct. 2440 (2024) (holding that the six-year statute of limitations for an APA claim under 28 U.S.C. § 2401(a) does not accrue until a plaintiff is injured by final agency action, rather than starting when the agency action became final). *See generally* Morse, *supra* note 40.

[57] OFF. OF INSPECTOR GEN., DEP'T. OF HEALTH & HUM. SERVS., REVIEW OF THE FOOD AND DRUG ADMINISTRATION'S CITIZEN PETITION PROCESS (1998), https://oig.hhs.gov/documents/audit/3317/A-15-97-50002-Complete%20Report.pdf [https://perma.cc/R8ZM-A5AE] [hereinafter OIG July 1998 Review].

[58] *Id.* at 4–8.

[59] *Id.* at Appendix B at 3–4.

[60] *See, e.g.*, Citizen Petition from Katherine Price Snedaker, Docket Number FDA-2022-P-0234 (July 28, 2022), https://downloads.regulations.gov/FDA-2022-P-0234-0004/attachment_1.pdf [https://perma.cc/WC6M-PNNN].

outstanding petitions after one year		process to track which petitions are left outstanding after a year. The Commissioner is not notified of outstanding petitions.
Establish time-based target dates for responses	Accepted	The FDAAA requires the FDA to resolve 505(q) petitions within 150 days of filing and submit annual reports to Congress. Petitions arising under 505(q) are all completed within 150 days.[61]

To date, it does not appear that the FDA has addressed all the concerns raised by the OIG. Currently, many petitions are substantively ignored long past the 180-day deadline,[62] and the FDA lacks a centralized, up-to-date tracker where the status of multiple petitions can be viewed simultaneously.[63] In fact, a private firm has attempted to track petitions based on publicly available information, but this tracker has not been updated since 2021.[64] Since the FDA provides little transparency about how petitions are prioritized for response, citizens have minimal reassurance that the FDA is addressing public concerns in a timely manner.

C. The FDA as a Scientific Specialist Agency: Impacts on Citizen Petitions and Judicial Review

The APA's exhaustion requirement reduces the number of petitions that reach the courts in an attempt to spare courts from overloaded dockets and

[61] FOOD & DRUG ADMIN., FIFTEENTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION (2022), https://www.fda.gov/media/172538/download?attachment [https://perma.cc/KQ4E-DCP5].

[62] *See Citizen Petition Tracker*, FDA LAW BLOG, https://www.thefdalawblog.com/ [https://perma.cc/U62K-SEMW]. In July 1998, the OIG for HHS conducted a review of the citizen petition process and found that the "FDA [did] not have an effective process for handling citizen petitions in a timely manner, as evidenced by a backlog of approximately 250 petitions that have not been fully answered, some dating back to the 1970's and early 1980's." OIG July 1998 Review, *supra* note 57, at 3. The efficiency of this process does not appear to have significantly improved in more recent times—as an example, the FDA has not responded to some petitions filed well over a decade ago, and some petitions from the early 2000s still await a response. *See, e.g.*, 2002 Chronological List of Petitions and Advisory Opinions, U.S. FOOD & DRUG ADMIN., https://wayback.archive-it.org/7993/20180125144317/https://www.fda.gov/RegulatoryInformation/Dockets/ucm090545.htm [https://perma.cc/N7LZ-T2XD].

[63] Citizen Petition Tracker, FDA LAW BLOG, https://www.thefdalawblog.com/ [https://perma.cc/U62K-SEMW].

[64] *Id.*

prevent generalist courts from having to grapple with complex scientific issues that may be prone to misunderstanding or misconstruction. One of the greatest challenges in trying to square the decisions of a specialist agency with the judicial system is that science and the judiciary are somewhat at odds in their fundamental purposes. Science is a process of learning that requires constant effort and reflection to prove prior information wrong in the pursuit of inching closer to the truth.[65] Significant scientific findings are also likely to be challenged *sua sponte* by other researchers in the field as part of the normal conduct of scientific research. In contrast, the judicial system is founded on consistency and finality—parties are prevented from bringing the same issues back to court under the principles of *res judicata* and collateral estoppel.[66]

The processes by which judges and juries typically approach complex scientific questions differ somewhat from those used by expert scientific agencies like the FDA. Judges and juries typically rely on expert testimony to elucidate scientific issues.[67] This can lead to a "battle of the experts," in which ultimately the fact finder makes decisions on scientific "truth" based on credibility determinations—determinations which can be related more to how the experts engage with the lawyers and share scientific knowledge, rather than the veracity of the testimony.[68] Conversely, although the FDA certainly uses expert panels and outside experts to augment its analysis, on many issues the FDA has sufficient expertise to evaluate scientific data and information without needing to rely on outside experts.[69]

To further complicate the challenges of combining science with judicial decisionmaking, agency science combines scientific knowledge with policy goals—making the review of agency decisionmaking more complex.

In the case of the FDA, science is used to approve medications and promote public health goals.[70] A citizen petition gives individuals or groups the ability to call a problem to the FDA's attention so the FDA may further investigate and make a final decision.[71] If the petitioner is unsatisfied by the FDA's decision on a citizen petition, then judicial review may be sought. Due to the specialist nature of the FDA, however, it is not clear whether or how a

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[65] *See* Radley Balko, *How Do We Reconcile Law and Science?*, WASH. POST (Aug. 6, 2019), https://www.washingtonpost.com/opinions/2019/08/06/how-do-we-reconcile-law-science/ [https://perma.cc/KZP2-XK4L].

[66] *Id.* This is not to say, however, that a court cannot revisit an issue in a later decision if the situation has fundamentally changed—put another way, *stare decisis* is not an absolute bar to reconsideration of a legal issue.

[67] *See, e.g.*, Fed. R. Evid. 702.

[68] *See* David L. Faigman, Christopher Slobogin & John Monahan, *Gatekeeping Science: Using the Structure of Scientific Research to Distinguish between Admissibility and Weight in Expert Testimony*, 110 NW. UNIV. L. REV. 859, 899 (2016).

[69] Congress and the courts have recognized this expertise through delegation of decisionmaking authority to the FDA and the deference given to the FDA in its scientific analysis. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., Pub. L. No. 75-717, 52 Stat. 1040 (1938); *see* sources cited *infra* note 199.

[70] *See* Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 740 (2011) ("When an agency is engaging in rulemaking or adjudication, formal or informal, the agency will base its decision-making on factual information and policy choices").

[71] 21 C.F.R. § 10.30(a) (2012).

court will come to a decision that ensures the FDA is acting in line with its duty.[72] Generalist courts may act as "translators" for an agency's highly scientific information.[73] But, given its expertise in considering public health implications and weighing various scientific and policy considerations, the FDA may be better positioned to advance the goals of the FDCA than a court that lacks this expertise. It is therefore in the FDA's best interest as a specialist agency to analyze citizen petitions with diligence, both to aid in its mission of protecting public health and to prevent future harms that could arise from the misinterpretation of scientific decisions.

The *AHM* litigation is the first example of judicial review of the FDA's substantive scientific decisionmaking in the citizen petition context, but it may not be the last. Historically, parties have sought reconsideration of initial FDA scientific decisionmaking at the agency level through filing a citizen petition. This practice is likely to continue, as President Donald J. Trump's Secretary of the Department of Health and Human Services, Robert F. Kennedy, Jr., has supported efforts by his attorney Aaron Siri to file citizen petitions seeking to pause distribution of numerous vaccines, including a polio vaccine approved by the FDA in 1990,[74] Hepatitis B vaccine, and thirteen other vaccines.[75] Just as with mifepristone, the FDA did not reply to some of these petitions on time,[76] or only provided Mr. Siri and his colleagues with an interim response.[77] Given Secretary Kennedy's familiarity with the citizen petition process, it is likely that the FDA (over which he has oversight as Secretary of HHS) will bring renewed focus to the citizen petition process.

III. WHY MIFEPRISTONE BECAME THE TEST CASE FOR JUDICIAL REVIEW OF FDA APPROVAL DECISIONS

[72] *See* 21 U.S.C. § 393(b).

[73] *See* Meazell, *supra* note 70, at 778–79.

[74] Requests that the FDA withdraw or suspend the approval for Poliovirus Vaccine Inactivated (IPOL) for infants, toddlers, and children until a properly controlled and properly powered double-blind trial of sufficient duration is conducted to assess the safety of this product and amend the product label for IPOL to note that: "IPOL does not prevent intestinal infection and therefore does not prevent poliovirus transmission." Food & Drug Admin., Citizen Petition from Siri & Glimstad LLP, Docket No. FDA-2022-P-1998 (July 28, 2022), https://www.regulations.gov/document/FDA-2022-P-1998-0001 [https://perma.cc/Q6D9-EVYA].

[75] Christina Jewett & Sheryl Gay Stolberg, *Kennedy's Lawyer Has Asked the F.D.A. to Revoke Approval of the Polio Vaccine*, N.Y. TIMES (Dec. 15, 2024), https://www.nytimes.com/2024/12/13/health/aaron-siri-rfk-jr-vaccines.html [https://perma.cc/NS2T-FHMJ].

[76] *See* Food & Drug Admin., Requests that the FDA amend the study design for the Phase III trial of ChAdOx1nCoV-19 (NCT04400838) to ensure that the control group will receive a placebo (saline injection); any and all adverse events and reactions will be documented for the entire duration of the trial; germline transmission tests are conducted for male participants, Docket No. FDA-2020-P-1768 (Aug. 18, 2020), https://www.regulations.gov/docket/FDA-2020-P-1768 [https://perma.cc/A48P-4MGZ].

[77] *See* Interim Response Letter from FDA CBER to Siri & Glimstad LLP, Docket No. FDA-2022-P-1998 (Feb. 16, 2023), https://www.regulations.gov/document/FDA-2022-P-1998-0008 [https://perma.cc/47FX-C3L9].

Judicial challenges to FDA approval for new drugs have historically been rare and unlikely to succeed.[78] The 2023 *Alliance for Hippocratic Medicine v. FDA* (*AHM*) case in the Northern District of Texas (later appealed to the Fifth Circuit and the Supreme Court) is a notable exception. This Part reviews the relevant regulatory and judicial review processes for this challenge to mifepristone's approval. First, this Part reviews mifepristone's complex path through the regulatory review process. Next, this Part discusses the FDA's review of two citizen petitions challenging mifepristone's approval and prescribing requirements—an initial citizen petition to stay mifepristone's approval in 2002 (the 2002 Petition) and a second petition in 2019 (the 2019 Petition) to urge the FDA to change prescriber and dosing requirements.[79] The FDA did not reply to the 2002 Petition until 2016,[80] or the 2019 Petition until 2021.[81] The FDA's failure to provide a timely response to these citizen petitions challenging mifepristone's approval allowed advocacy groups interested in removing mifepristone from the U.S. market to file suit, seeking judicial review of the FDA's citizen petition decisions.

Citing the FDA's failure to reply in a timely manner to these petitions, the plaintiffs filed suit in the Northern District of Texas, which resulted in the assignment of a notably anti-abortion judge, Judge Matthew Kacsmaryk.[82] This Part also discusses this district court case, in which the court issued an April 2023 ruling staying the FDA's approval of mifepristone.[83] On the same day, the Eastern District of Washington preliminarily enjoined any action by the FDA altering the drug's approval status in an attempt to prevent a nationwide action from occurring as a result of the Northern District of Texas's ruling.[84]

With conflicting rulings in place, the *AHM* plaintiffs appealed to the Fifth Circuit, where a panel ordered a partial stay of the Northern District of Texas's ruling. In August 2023, the Fifth Circuit vacated the part of the Northern District of Texas's ruling invalidating mifepristone's 2000 approval but upheld the part of the decision invalidating a change to the mifepristone dosing regimen

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[78] *See, e.g.*, Nicopure Labs, LLC v. Food & Drug Admin., 944 F.3d 267, 282 (D.C. Cir. 2019) (finding that the FDA was acting within its duties to subject an e-cigarette to a premarket authorization process before approving the product); Doe #1-#14 v. Austin, 572 F. Supp. 3d 1224, 1231 (N.D. Fla. 2021) (finding that the FDA's Emergency Use Authorization of COVID-19 vaccines for military personnel was exempt from review under the APA).

[79] *See generally* Complaint, All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507 (N.D. Tex. 2023) (No. 2:22-CV-223-Z).

[80] *All. for Hippocratic Med.*, 668 F. Supp. 3d at 522; Food & Drug Admin., Citizen Petition re: Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy through 49 Days' Gestation, at 3, 60 (Aug. 21, 2002), https://aaplog.org/wp-content/uploads/2021/01/2002-Aug-Citizen-Petition_Mifeprex-8.20.02.pdf [https://perma.cc/3UF9-63KV].

[81] *All. for Hippocratic Med.*, 668 F. Supp. 3d at 522 .

[82] *All. for Hippocratic Med.*, 668 F. Supp. 3d at 519; Eleanor Klibanoff, *Federal Judge at Center of FDA Abortion Drug Case Has History with Conservative Causes*, THE TEX. TRIB. (Mar. 15, 2023), https://www.texastribune.org/2023/03/15/federal-judge-amarillo-abortion-fda/ [https://perma.cc/7M43-3T3B].

[83] *All. for Hippocratic Med.*, 668 F. Supp. 3d at 559.

[84] Wash. v. Food and Drug Admin., 668 F. Supp. 3d 1125, 1143 (E.D. Wash. 2023).

that occurred in 2016 and amendments to the drug's approval made in 2021.[85] Part III.D reviews the Fifth Circuit's decision in detail.

In December 2023, the Supreme Court announced that it would take the case but denied a cross-petition by the *AHM* plaintiffs to add the 2000 approval of mifepristone to the Court's review.[86] On June 13, 2024, a unanimous Supreme Court found that the plaintiffs lacked Article III standing to challenge the FDA's actions, and reversed and remanded the Fifth Circuit's decision, preventing future challenges from being brought by similarly situated plaintiffs. Part III.E discusses the Supreme Court's standing decision.

A. Mifepristone's Path to FDA Approval

In 2020, medication abortions constituted fifty-three percent of U.S. abortions.[87] The vast majority of medication abortions consist of a two-drug regimen containing mifepristone and misoprostol.[88] Patients first take mifepristone to block the hormone progesterone, and twenty-four to forty-eight hours later, patients take misoprostol to induce cramping and expel pregnancy tissue.[89] Significant scientific evidence indicates that this regimen is highly effective and safe—used together, these medications terminate first-trimester pregnancy in ninety-six percent of cases with a 0.3 percent risk of major complications.[90] As misoprostol alone has never been approved by the FDA for pregnancy termination, abortion opponents more commonly target mifepristone's FDA approval.[91]

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[85] All. for Hippocratic Med. v. Food & Drug Admin., 78 F.4th 210, 245, 254 (5th Cir. 2023).

[86] *See* Food & Drug Admin. v. All. for Hippocratic Med., No. 23-235, 144 S. Ct. 537, 537 (Dec. 13, 2023) (denying cross-motion).

[87] Rachel K. Jones, Marielle Kirstein & Jesse Philbin, *Abortion Incidence and Service Availability in the United States, 2020*, 54 PERSP. ON SEXUAL & REPROD. HEALTH 128, 136 (2022).

[88] *Id.*

[89] *See* FOOD & DRUG ADMIN., 3909592 MIFEPREX (mifepristone) tablets Label (2016), 1, 3, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf [https://perma.cc/6GCT-92MH]; Mara Gordon, *Medication abortion is still possible with just one drug. Here's how it works*, NPR (Apr. 10, 2023), https://www.npr.org/sections/health-shots/2023/04/10/1168857095/misoprostol-only-medical-abortion [https://perma.cc/34CB-5TCH].

[90] Elizabeth G. Raymond, Caitlin Shannon, Mark Weaver & Beverly Winikoff, *First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review*, 87 CONTRACEPTION 26, 26 (2013); FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RSCH., Medical Reviews Mifepristone (Jan. 27, 2000), 7, 13, 20–21, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf [https://perma.cc/HY6G-KTJE]; Laurie Sobel, Alina Salganicoff & Mabel Felix, *Legal Challenges to the FDA Approval of Medication Abortion Pills*, KFF (Mar. 13, 2023), https://www.kff.org/womens-health-policy/issue-brief/legal-challenges-to-the-fda-approval-of-medication-abortion-pills/ [https://perma.cc/2WY8-PSAH].

[91] *See* Haley Weiss, *The Most Common Abortion Method Is in Danger in Every State*, TIME (Feb. 15, 2023), https://time.com/6255625/abortion-pills-mifepristone-texas-lawsuit/ [https://perma.cc/KAT8-9KS6] (explaining that misoprostol is approved as an ulcer treatment while mifepristone is primarily used for abortions).

The FDA approved mifepristone (with the trade name Mifeprex) under 21 C.F.R. § 314 Subpart H (Subpart H), an accelerated approval pathway for medications treating serious or life-threatening illnesses that require certain restrictions to assure safe use. As part of these restrictions, the FDA mandated that the manufacturers of Mifeprex commit to Phase IV studies,[92] including a comparative study of safety and efficacy issues in medication versus surgical abortion, and a surveillance study on the continuing pregnancies of those for whom Mifeprex did not cause an abortion.[93]

In 2007, the FDAAA established the Risk Evaluation and Mitigation Strategies (REMS) framework for prescription drugs and biologics to allow safe use of products with certain serious risks.[94] In 2011, the FDA added REMS requirements to Mifeprex, requiring manufacturer Danco Laboratories, LLC (Danco) to track certification and decertification of medical providers authorized to dispense Mifeprex.[95] The REMS thus ultimately required that a patient be seen in-person prior to prescribing Mifeprex, precluding Mifeprex from being dispensed by mail or through a retail pharmacy.[96]

In 2016, the FDA approved amendments to the dosing regimen for Mifeprex (the 2016 Amendments). These amendments increased the gestational age limit, changed the dosing regimen, allowed Mifeprex to be given by a non-physician healthcare provider, and eliminated the requirement that prescribers report any serious adverse event to Danco.[97] Crucially, the 2016 Amendments did not alter the underlying approval of mifepristone or conclusions regarding

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[92] Phase IV studies "are post-marketing studies that are imposed upon a pharmaceutical firm as a condition for drug approval." FOOD & DRUG ADMIN., *Phase 4 Commitment Category*, https://www.fda.gov/drugs/data-standards-manual-monographs/phase-4-commitment-category [https://perma.cc/7J93-RVMX]. Conducted after marketing approval, Phase IV studies are "an important phase of drug development," in which the "real world effectiveness" of a drug may be assessed in a variety of ways (post-marketing surveillance, non-interventional studies to assess the safety, tolerance, and effectiveness of an approved medication in a clinical setting across a wider range of patients than those tested in pre-marketing approval clinical trials, and other trials mandated by the FDA to ensure safety and efficacy of marketed drugs). Viraj Suvarna, *Phase IV of Drug Development*, 1 PERSP. CLIN. RES. 57, 57–60 (2010).

[93] *See* FOOD & DRUG ADMIN., Approval Letter for Mifeprex, 2–3 (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf [https://perma.cc/CYY3-VRJ7] (listing Phase 4 commitments).

[94] *See* FOOD & DRUG ADMIN., *Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS)*, 9 (Sept. 2014), https://www.fda.gov/files/about%20fda/published/Standardizing-and-Evaluating-Risk-Evaluation-and-Mitigation-Strategies-(REMS).pdf [https://perma.cc/3QMG-M3FJ].

[95] KAISER FAM. FOUND., *The Availability and Use of Medication Abortion* (June 1, 2023), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/ [https://perma.cc/4KBM-8YE8]; FOOD & DRUG ADMIN., *NDA 020687 MIFEPREX® (mifepristone) Tablets, 200 mg Risk Evaluation and Mitigation Strategy* (Mar. 2016), https://www.fda.gov/media/164649/download [https://perma.cc/7VKZ-99NU].

[96] *See* KAISER FAM. FOUND., *The Availability and Use of Medication Abortion* (June 1, 2023), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/ [https://perma.cc/93YX-ECDG] (noting that "Mifeprex must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber").

[97] *See* GOV'T ACCOUNTABILITY OFF., Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts, at 12–15 (Mar. 2018), https://www.gao.gov/assets/gao-18-292.pdf [https://perma.cc/QZ2K-VN9F].

its safety, but rather corresponded with standard post-market oversight.[98] In April 2019, the FDA approved a generic version of Mifeprex.[99]

B. Citizen Petitions Preceding AHM *Litigation*

In 2002, the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and the Christian Medical and Dental Association (CMDA) submitted an FDA citizen petition (2002 Petition), urging the FDA to grant an immediate stay of Mifeprex's approval. Although some of the petition rested on critiques of the FDA's approval decisions and the use of Subpart H for approval, the petition raised other concerns related to six alleged post-approval adverse events in 2002 (uncontrolled fatal hemorrhage, serious bacterial infections, and a heart attack).[100] The initial Mifeprex clinical trials excluded women with ectopic pregnancies, but on approval the FDA did not require clinicians to rule out ectopic pregnancy before administering Mifeprex.[101] The petitioners thus urged that ultrasounds be required prior to Mifeprex administration to identify ectopic pregnancies.[102] The National Abortion Federation (NAF), Planned Parenthood, Danco, and The Population Council all filed comments opposing the petition.[103] NAF and Planned Parenthood asserted that routine ultrasounds were not necessary to rule out ectopic pregnancy and pointed out that other standard tools available to clinicians were generally effective to diagnose ectopic pregnancy while presenting less of an obstacle to medical abortion.[104]

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[98] *Id.* at 9.

[99] *See* U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RSCH., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, (Sep. 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation [https://perma.cc/4DH9-VNF8] (approving mifepristone).

[100] *See* AM. ASS'N OF PRO-LIFE OBGYNS, *Citizen Petition re: Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy through 49 Days' Gestation*, at 3 (Aug. 21, 2002), https://aaplog.org/wp-content/uploads/2021/01/2002-Aug-Citizen-Petition_Mifeprex-8.20.02.pdf [https://perma.cc/JT74-BL7L]; Jane Allen, *Abortion Pill Under Scrutiny After Deaths*, L.A. TIMES (Apr. 22, 2002), https://www.latimes.com/archives/la-xpm-2002-apr-22-he-abort22-story.html [https://perma.cc/L3TP-TJQ6].

[101] *See* U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RSCH., App. No.: 20-687, Medical Review(s) Mifepristone (Jan. 27, 2000), at 7, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf [https://perma.cc/HY6G-KTJE] [hereinafter Mifepristone Medical Review].

[102] *See* AM. ASS'N OF PRO-LIFE OBGYNS, *supra* note 100, at 60; Mifepristone Medical Review, *supra* note 101, at 7.

[103] *See* Nat'l Abortion Fed'n & Planned Parenthood Fed'n of Am., Comments of the National Abortion Federation and Planned Parenthood Federation of America in Opposition to Citizen Petition and Request for Administrative Stay Regarding Mifeprex® (Mifepristone), Docket No. 02P-0377, at 6–8 (May 20, 2004), https://www.prochoice.org/pubs_research/publications/downloads/public_policy/fda_comments.pdf [https://perma.cc/N9W8-3S72].

[104] *Id.* at 6.

The FDA replied to the 2002 Petition in 2016 (nearly fourteen years later),[105] but the FDA and the federal government had not ignored ongoing safety concerns for Mifeprex during this period. In 2008, the Government Accountability Office (GAO) conducted a study on Mifeprex,[106] finding that ectopic pregnancy with Mifeprex use was extremely rare—only 0.005% of women who had used Mifeprex had an ectopic pregnancy, despite the rate of ectopic pregnancy in the U.S. falling somewhere between 1.3 and 2%.[107] The GAO also detailed the FDA and CDC's investigation into deaths among Mifeprex patients—in six of the seven deaths reported between the drug's approval in 2000 and 2006, the patients had taken Mifeprex and misoprostol in a manner not approved by the FDA.[108] In 2011, the FDA introduced the Mifeprex REMS, which it later modified with the 2016 Amendments.[109] In March 2019, AAPLOG submitted another citizen petition (2019 Petition) to request that the FDA continue to limit the dispensing of Mifeprex to patients in clinics under the supervision of a physician.[110] In the 2019 Petition, AAPLOG again argued that Mifeprex should be administered only to patients confirmed not to have an ectopic pregnancy.[111]

Yet in 2020, during the early months of the COVID-19 pandemic, the American College of Obstetricians and Gynecologists (ACOG), other physicians, and reproductive justice advocates filed a lawsuit against the FDA to suspend the Mifeprex REMS in-person dispensing requirement.[112] The District Court of Maryland enjoined the in-person dispensing requirement. While the Fourth Circuit considered the appeal, the Supreme Court granted a stay on the order, maintaining the REMS requirement.[113] In a concurrence, Chief Justice Roberts stated that, "as in related contexts concerning government responses to the pandemic, [his] view is that courts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health'"—here, to the FDA's science-focused decisionmakers who responded to the citizen petition request.[114] In December 2021, the FDA finalized a decision removing the in-person dispensing

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[105] AM. ASS'N OF PRO-LIFE OBGYNS, *supra* note 100, at 60.

[106] This study described the approval of Mifeprex, compared the approval process for Mifeprex with other Subpart H drugs, and detailed the post market oversight procedure. U.S. GOV'T ACCOUNTABILITY OFF., *Approval and Oversight of the Drug Mifeprex*, (Aug. 2008), https://www.gao.gov/assets/gao-08-751.pdf [https://perma.cc/WCB2-KK8L].

[107] *Id.* at 39.

[108] *Id.* at 39–40.

[109] FOOD & DRUG ADMIN., *NDA 020687 MIFEPREX® (mifepristone) Tablets, 200 mg Risk Evaluation and Mitigation Strategy* (Mar. 2016), https://www.fda.gov/media/164649/download [https://perma.cc/7VKZ-99NU].

[110] AM. ASS'N OF PRO-LIFE OBGYNS, *Citizen Petition Final*, https://aaplog.org/wp-content/uploads/2021/01/Citizen-Petition-Final-FDA-Mif-REMS.pdf [https://perma.cc/H5CF-Y3UR].

[111] *Id.* at 4.

[112] Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., 472 F. Supp. 3d 183 (D. Md. 2020).

[113] U.S. Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 578 (2021).

[114] *Id.* at 579 (quoting S. Bay United Pentecostal Church v. Newsom, 140 S. Ct. 1613, 1614 (2020)).

requirements, stating that mifepristone could be dispensed by mail in an unofficial announcement on its webpage (2021 Actions).[115] The same day, the FDA replied to AAPLOG's 2019 Petition, clarifying that while it would maintain the mifepristone REMS, it would not amend the REMS to require in-person dispensing by a physician.

The 2021 Actions did not formally modify the mifepristone REMS program and allow mifepristone to be dispensed via mail.[116] The FDA did not formally modify the REMS until January 2023, affirming the requirement that mifepristone may only be dispensed by certified prescribers or pharmacies, and allowing certified prescribers to dispense mifepristone by mail.[117]

C. AHM *at the Northern District of Texas*

On November 18, 2022, the Alliance for Hippocratic Medicine, the AAPLOG, the American College of Pediatricians, the CMDA, and various doctors acting in their individual capacities filed a complaint in the Northern District of Texas, seeking to enjoin the FDA's approval of mifepristone.[118] Plaintiffs used the citizen petition process as a trigger for their suit, stating that they were entitled to judicial review because the FDA had left the 2002 Petition outstanding for fourteen years, and the 2019 Petition was left outstanding for two and a half years.[119] In the complaint, plaintiffs made multiple suggestions that the approval of mifepristone and the FDA's 2016 response to the 2002 Petition were "correlated" with elections, and that the FDA's actions relating to mifepristone were "relentless, politicized efforts to push these drugs throughout the country."[120]

On January 13, 2023, the Department of Justice (DOJ) filed its response to the preliminary injunction motion.[121] The DOJ acknowledged that the plaintiffs had filed citizen petitions, but it failed to acknowledge that the FDA's response to both citizen petitions was severely delayed.[122] Instead, the DOJ argued that plaintiffs' delay in seeking an injunction after the FDA's response to their petitions suggested that the harm was not so "imminent and irreparable" that it necessitated injunctive relief.[123]

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[115] Pam Belluck, *F.D.A. Will Permanently Allow Abortion Pills by Mail*, N.Y. TIMES (Dec. 16, 2021), https://www.nytimes.com/2021/12/16/health/abortion-pills-fda.html [https://perma.cc/U8VS-YEV5].

[116] *Id.*

[117] U.S. FOOD & DRUG ADMIN., Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG (Jan. 2023), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390 [https://perma.cc/S7HJ-HWE6].

[118] Complaint at 40, All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507 (N.D. Tex. 2023) (No. 2:22-CV-223-Z).

[119] *Id.* at 2–3.

[120] *Id.* at 2, 36.

[121] Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction, All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507 (N.D. Tex. 2023) (No. 2:21-CV-00067-Z).

[122] *Id.* at 6.

[123] *Id.* at 31–32.

On April 7, 2023, the Northern District of Texas granted the plaintiffs' preliminary motion in part, and reviewed plaintiffs' three challenges on the merits: (1) the FDA's 2016 substantive response to the 2002 Petition; (2) the 2019 Generic Approval; and (3) the April 2021 letter encompassing both a response to the 2019 Petition and the 2021 Actions.[124] The court first assessed whether plaintiffs could demonstrate either associational or organizational standing. First, the court found that plaintiffs had associational standing to bring suits on behalf of their individual members and patients.[125] Next, the court established the organizations also had organizational standing because the "FDA's actions have frustrated their ability to educate and inform their member physicians, their patients, and the public."[126] These injuries were considered "diversionary injury" by the court, and the finding of both types of standing relied on the doctors' allegations that mifepristone patients could overwhelm their clinics.[127]

Although the plaintiffs' claim related to the 2002 Petition fell beyond the six year statute of limitations (as the FDA responded in 2016, seven years before plaintiffs brought this challenge), the court ruled that the "reopening doctrine"[128] justified review of *both* the 2002 Petition and the 2019 Petition because the FDA's responses and actions in 2016 and 2021 "significantly departed from the agency's original approval of the abortion regimen."[129] The district court ultimately ruled to stay (and preliminarily vacate) the FDA's 2000 approval of mifepristone under Section 705 of the APA, which provided "less drastic relief" than an injunction as it permits a reviewing court to "issue all necessary and appropriate process to postpone the effective date of an agency action."[130] But, because the order stayed the FDA's 2000 approval of mifepristone, this decision impacted "all subsequent challenged actions related to that approval—i.e., the 2016 Changes, the 2019 Generic Approval, and the 2021 Actions."[131] Acknowledging that the APA § 705 stay might be reversed due to a pending appeal in *Texas v. Biden*,[132] the court clarified that it "alternatively would have ordered Defendants to suspend the chemical abortion approval and all subsequent challenged actions related to that approval until the Court can render a decision on the merits."[133]

On the same day that the Northern District of Texas issued its ruling, a coalition of seventeen states and the District of Columbia received a preliminary

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[124] *See* All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507, 520–25, 530–31 (N.D. Tex. 2023).

[125] *See id.* at 523–26.

[126] *Id.* at 526–27.

[127] *Id.*; *see* discussion *infra* Part V.

[128] *See id.* at 531–33. The reopening doctrine is a principle used to determine whether there is "an exception to statutory limits on the time for seeking review [of an agency decision]." United Transp. Union-Ill. Legis. Bd. v. Surface Transp. Bd., 132 F.3d 71, 75–76 (D.C. Cir. 1998).

[129] *All. for Hippocratic Med.*, 668 F. Supp. 3d at 533–34.

[130] *Id.* at 559–60.

[131] *Id.* at 560.

[132] *Id.*

[133] *Id.*

injunction from a judge in the Eastern District of Washington, preventing the FDA from taking any action to suspend regulatory approval of mifepristone.[134]

The case in the Northern District of Texas was appealed to the Fifth Circuit, and because of the conflicting rulings, the Supreme Court granted an emergency stay of the Northern District of Texas' vacatur order—permitting mifepristone to remain on the U.S. market while the appeal was pending.[135]

D. AHM *at the Fifth Circuit*

On appeal, in its preliminary ruling the Fifth Circuit vacated the part of the district court's ruling that stayed the effective date of the 2000 Approval (and the 2019 Generic Approval) but determined that the 2016 Amendments and the 2021 Actions may have violated the APA.[136]

The Fifth Circuit panel found that not all of plaintiffs' claims could be examined substantively by the court, as the statute of limitations had expired for the claims related to the 2002 Petition. The panel rejected use of the equitable tolling doctrine as there was no "extraordinary circumstance" that prevented the petitioners from filing within the six years since the FDA's reply to the 2002 Petition in 2016.[137] The panel found, however, that the plaintiffs had standing to bring the claims related to the 2016 Amendments and the 2021 Actions, relying on a similar analysis to that of the district court.[138] But, the panel found that the plaintiffs did not have standing to challenge the 2019 Generic Approval as the plaintiffs did not show that the generic approval "affect[ed] their risk of future harm."[139]

Importantly, on the merits of the plaintiffs' claims on the FDA's 2016 Amendments and the 2021 Actions, the Fifth Circuit recognized that neither decision constituted "serious, substantive reconsideration" of mifepristone's approval in 2000.[140] Therefore, the panel declined to address the plaintiffs' claims directed to the approval of mifepristone itself. The panel proceeded to consider only the FDA's subsequent regulatory actions.

For the claims based on the 2016 Amendments, the Fifth Circuit concluded that the "FDA failed to address the cumulative effect" of each change the FDA approved in the 2016 Amendments for the use of mifepristone,[141]

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[134] *See* Wash. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 1125, 1133, 1144–45 (E.D. Wash. 2023) (granting preliminary injunction preventing FDA suspension of mifepristone).

[135] *See* Danco Lab'ys, LLC v. All. for Hippocratic Med., 143 S. Ct. 1075 (2023) (granting application for stay). On April 21, 2023, Danco Laboratories (the manufacturer of Mifeprex) requested that the Supreme Court stay the District Court's order staying the approval of mifepristone. The stay was granted, pending disposition of the appeal to the Fifth Circuit and an eventual petition for writ of certiorari. *Id.*

[136] *See* All. for Hippocratic Med. v. U.S. Food & Drug Admin., 78 F.4th 210, 256 (5th Cir. 2023) (vacating in part and affirming in part).

[137] *See id.* at 245.

[138] *See id.* at 238–41.

[139] *Id.* at 241.

[140] *Id.* at 243.

[141] *Id.* at 246.

leading to a likely violation of the APA.[142] Additionally, the Fifth Circuit criticized one of the 2016 Amendments that removed the mandatory adverse event reporting requirement, and thus no longer required authorized prescribers to report all adverse events to manufacturer Danco.[143] As a result of the amendment, prescribers were encouraged (but not required) to report adverse events to the FDA's voluntary reporting system, the FDA Adverse Event Reporting System (FAERS).[144] The court found that this amendment made the FDA "responsible for its own inability to obtain probative data."[145] And, as the FDA only relied on this FAERS data as justification to enact the 2021 Actions, the court concluded that the FDA was "cit[ing] its lack of information as an argument in favor of removing further safeguards," rather than showing affirmative evidence of mifepristone's continued safety.[146] Therefore, according to the court, the FDA relied on "concededly limited data" to support "the notion that mifepristone would remain safe and effective even without the in-person dispensing requirement."[147] Furthermore, the Fifth Circuit found that the FDA had incomplete data from FAERS, as the reporting process was "cumbersome," and required "taking away significant time from a doctor to treat and meet with patients."[148]

The Fifth Circuit also rejected Danco's claim that it would face harm from the district court's order, concluding that harm from withdrawal of mifepristone from the market would be mitigated, as Danco would have adequate time to prepare to comply with the district court's order due to the Supreme Court's stay.[149] The FDA contended that the plaintiff organizations should have sought a stay via the FDA before proceeding to district court, but the Fifth Circuit rejected this argument, stating that "the record shows that the FDA would have denied any request for an administrative stay."[150] As the FDA denied the 2019 Petition on the same day the 2021 Actions were introduced (and later formalized this policy in 2023), the Fifth Circuit interpreted these actions as a commitment by the FDA to implement these changes regardless of any petitions it received on this issue.[151]

E. AHM *at the Supreme Court*

On September 8, 2023, both Danco and the FDA filed a petition for a writ of certiorari, challenging the Fifth Circuit's opinion.[152] On October 12, 2023, the Alliance for Hippocratic Medicine filed a cross-petition, urging the

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[142] *Id.*
[143] *Id.*
[144] *Id.* at 249.
[145] *Id.*
[146] *Id.*
[147] *Id.* at 250–51.
[148] *Id.* at 249.
[149] *Id.* at 252–53.
[150] *Id.* at 255.
[151] *Id.*
[152] Petition for a Writ of Certiorari, Danco v. All. for Hippocratic Med., 602 U.S. 367 (2024) (No. 23-236); Petition for a Writ of Certiorari, U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367 (2024) (No. 23-235).

Supreme Court to consider the 2000 Approval in its review, and alleging that the "FDA disregarded law, science, and safety in pursuit of a political end," and therefore approval of mifepristone under Subpart H violated the FDA's own regulations.[153] The Supreme Court granted the petitions from Danco and the FDA, but denied the cross-petition filed by the Alliance for Hippocratic Medicine.[154] Therefore, the Supreme Court only reviewed the Fifth Circuit's decisions on the 2016 Amendments and the 2021 Actions (while declining to review the 2000 Approval or the 2019 Generic Approval of mifepristone).

On June 13, 2024, the Supreme Court held that the plaintiff organizations lacked Article III standing to challenge the FDA's 2016 Amendments and 2021 Actions on the regulation of mifepristone.[155] More specifically, as the FDA's regulations "apply to doctors prescribing mifepristone and to pregnant women taking mifepristone," the Supreme Court concluded that the plaintiffs' admission that they neither prescribe nor use mifepristone was fatal to establishing standing.[156] As the Supreme Court explained, Article III of the Constitution does not permit a plaintiff standing where it "desire[s] to make a drug less available for *others*."[157]

The Supreme Court rejected the plaintiffs' causation arguments, as the plaintiffs failed to allege injuries that unregulated parties may assert to demonstrate causation (through monetary injury or injury to property) because the plaintiffs "do not prescribe, manufacture, sell, or advertise mifepristone or sponsor a competing drug."[158] The Court rejected the plaintiffs' contention that the FDA's more relaxed regulation of mifepristone under the 2016 Amendments and the 2021 Actions would cause conscience injuries, as the plaintiffs failed to demonstrate that they would be forced to perform abortions or provide abortion-related treatment under these revisions.[159] Also, the Court found no monetary or related injuries that would trigger causation sufficient to confer Article III standing, as the plaintiffs failed to present evidence suggesting that the FDA's actions either (1) caused an increase in the number of pregnant women seeking abortion services from the plaintiffs and caused resulting diversion of the plaintiff doctors' time and resources; or (2) caused additional malpractice suits or insurance costs from treatment of women with mifepristone complications.[160]

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[153] Cross-Petition for a Writ of Certiorari at 11–12, U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367 (2024) (No. 23-235, 23-236).

[154] All. for Hippocratic Med. v. U.S. Food & Drug Admin., 144 S. Ct. 537 (Dec. 13, 2023) (mem.).

[155] U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367 (2024).

[156] *Id.* at 385.

[157] *Id.* at 367 (emphasis in original).

[158] *Id.* at 385.

[159] *Id.* at 386. Federal and state conscience laws give strong protection to doctors who wish to not perform abortions or provide other medical treatment that violates their consciences. *See id.* The plaintiffs failed to show any instance where a doctor had been required to perform an abortion or provide other abortion-related treatment that violated the doctor's conscience. *Id.* at 387. Even in the case of emergency room treatment, doctors can simply refuse to provide abortion services if it violates their consciences. *Id.* at 388.

[160] *Id.* at 390–91. As explained by the Court, there is no "doctor standing" under Article III, to challenge government safety regulations based on the potential for additional emergency room admittances or follow-on injuries. *Id.*

Finally, the Court also found that the medical associations lacked organizational standing to bring these claims.[161] Although the medical associations claim to have incurred costs to oppose the FDA's regulatory actions for mifepristone, the Court explained that such spending cannot confer standing: "[a]n organization cannot manufacture its own standing" by "expending money to gather information and advocate against the defendant's action."[162]

Justice Clarence Thomas concurred in the opinion, writing separately to explain that he has "serious doubts that an association can have standing to vicariously assert a member's injury" under a theory of associational standing.[163]

In *AHM*, the plaintiffs asserted that they had associational standing to sue on behalf of their members' injuries, even though the members of the various plaintiff associations are other associations, not doctors.[164] Justice Thomas notes that Article III does not permit plaintiffs "to seek to vindicate someone else's injuries."[165] Under a theory of associational standing, there is no injury to redress for the plaintiff—the injured member is not a party to the suit.[166]

IV. CHALLENGES WITH JUDICIAL REVIEW OF CITIZEN PETITIONS: *AHM*'S POTENTIAL IMPACTS ON FUTURE JUDICIAL CHALLENGES OF FDA DECISIONS AND REGULATIONS

Ultimately, the orders in *AHM* did not impact the current availability of mifepristone in the United States market.[167] But, *AHM* demonstrates that citizen petitions can be used to trigger judicial review of substantive, science-based FDA decisionmaking, providing activists with a judicial strategy to attack approvals and policies falling under the FDA's purview. As new drugs are approved, particularly when those drugs are relevant to areas ripe for political controversy, the FDA should expect challenges to its decisions via judicial review mechanisms. Although the Supreme Court ultimately declined to find standing for the various claims brought in *AHM*, without improvements in the FDA's process to address citizen petitions, activists may use the FDA's delays to their benefit and seek out judicial review with judges or courts who they know will be favorable to their case.

This Part reviews the litigation strategies used by the *AHM* plaintiffs in seeking judicial review of these substantive decisions—judge shopping and

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[161] *See id.* at 369.

[162] *Id.* at 370.

[163] *See id.* at 400 (Thomas, J., concurring).

[164] *Id.*

[165] *Id.*

[166] *See id.*

[167] *Alliance for Hippocratic Medicine v. FDA*, CTR. FOR REPROD. RTS., https://reproductiverights.org/case/alliance-for-hippocratic-medicine-v-fda/ [https://perma.cc/WM2Q-T638]; Ann E. Marimow & David Ovalle, *Supreme Court Upholds Broad Access to Key Abortion Pill Mifepristone*, WASH. POST (June 13, 2024), https://www.washingtonpost.com/politics/2024/06/13/supreme-court-abortion-pill-ruling-mifepristone/ [https://perma.cc/MDK6-CM75]; Lauren Gardner & David Lim, *Awaiting Trump's Abortion Pill Posture*, POLITICO (Jan. 28, 2025), https://www.politico.com/newsletters/prescription-pulse/2025/01/28/awaiting-trumps-abortion-pill-posture-00200811 [https://perma.cc/4CUU-4NYJ].

expansive standing claims. This Part also discusses judicial review as a strategy to modify FDA approvals more generally, in light of the *AHM* decision and the recent Supreme Court decisions in *Loper Bright Enterprises v. Raimondo*[168] and *Ohio v. EPA*,[169] which together will likely reduce deference to the FDA's decisionmaking. Finally, this Part explores the various options that the FDA has in the face of a court order (non-compliance or withdrawal of approval), concluding that both options have significant drawbacks.

A. Strategies for Substantive Judicial Review Used in AHM

There are two key procedural methods through which plaintiffs successfully received judicial review of their substantive claims: (1) seeking a potentially sympathetic judge through a practice known as "judge shopping;" and (2) proffering expansive standing claims. This Section reviews the application of both strategies in *AHM*.

1. Judge Shopping

As the plaintiffs in *AHM* demonstrated, forum shopping can be highly advantageous when seeking judicial review of an FDA decision, especially when a case involves a contentious medical intervention like abortion. Here, the *AHM* plaintiffs appear to have targeted review of their case by a notably anti-abortion judge, Judge Matthew Kacsmaryk, through filing suit in a single-judge division (Amarillo) in the Northern District of Texas.[170] Only one plaintiff (Alliance for Hippocratic Medicine) claimed any relationship with the Northern District of Texas, through registration with the Texas Secretary of State in August 2022[171] and an alleged office address in Amarillo, Texas.[172] The only judge in the federal courthouse in Amarillo for the Northern District of Texas is Judge Kacsmaryk, who has a record of opposition to access to contraception and abortion.[173]

Based on these facts, it appears that the *AHM* plaintiffs may have engaged in judge shopping to find a judge sympathetic to their arguments and willing to give credence to the plaintiffs' justifications for standing and arguments on the merits. Judge shopping allows plaintiffs to effectively select a specific judge to hear their case by filing in a district court division which only has one judge. Many district courts, including the Northern District of Texas, allow such assignments—in the Northern District of Texas, Local Civil Rule

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[168] 144 S. Ct. 2244 (2024).

[169] 144 S. Ct. 2040 (2024).

[170] All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507 (N.D. Tex. 2023); Eleanor Klibanoff, *Federal Judge at Center of FDA Abortion Drug Case Has History with Conservative Causes*, TEX. TRIB. (Mar. 15, 2023), https://www.texastribune.org/2023/03/15/federal-judge-amarillo-abortion-fda/ [https://perma.cc/L25Q-32NU].

[171] TEX. COMPTROLLER OF PUB. ACCTS., EXEMPTION VERIFICATION LETTER (Nov. 18, 2023), https://comptroller.texas.gov/taxes/exempt/verification-letter.php?tp_id=32085759861 [https://perma.cc/3ECA-EKF7].

[172] Klibanoff, *supra* note 170.

[173] *Id.*

83.3 explains that "district judges shall determine the method by which all cases are assigned to individual judges."[174] In practice, under the current process for case distribution in the Northern District of Texas, the *AHM* plaintiffs could predict with some certainty that their case would be heard by Judge Kacsmaryk—nearly all cases filed at the Amarillo courthouse are heard by Judge Kacsmaryk.[175]

2. Risks from Expansive Standing Claims

While the Supreme Court ultimately found that plaintiffs had not presented sufficient evidence to establish Article III standing,[176] in the future, savvy litigators might be able to bring forward a case where plaintiffs' standing is more robust.

At the district court, the *AHM* plaintiffs raised theories of both associational standing and organizational standing, citing potential "overwhelm" of the medical system, "increased exposure to allegations of

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[174] N.D. Tex. LOC. CIV. R. 83.3.

[175] Klibanoff, *supra* note 170. In light of *AHM* and the recent documented rise in cases resulting in nationwide vacatur orders and injunctions, Congress and scholars are currently considering a wide range of potential judicial reform options to modify when a solitary judge can issue nationwide remedies in future judicial review of agency actions. Harvard Law Review Editors, *District Court Reform: Nationwide Injunctions*, 137 HARV. L. REV. 1701, 1715–24 (2024) [hereinafter *District Court Reform: Nationwide Injunctions*]. The article points out that, in scenarios where judges elect to not issue nationwide injunctions, judges are turning to vacatur as an option to provide universal relief (as Judge Kacsmaryk elected in *AHM*). Many of the policy considerations for widespread use of vacatur or nationwide injunctions are the same: (1) in seeking both remedies, plaintiffs are incentivized to look for forums likely to be sympathetic to their views; and (2) vacatur or nationwide injunctive orders are both likely to "halt the proper development of law" and encourage a rush to the Supreme Court, without further factual development in the lower courts. *Id.* at 1715. As a threshold matter, although instituting a bar to judicial review of citizen petition decisions could increase efficiency and decrease the odds of delay in FDA responses (through allowing the FDA to focus its resources on responses rather than litigation), it is unlikely that a comprehensive bar of judicial review of FDA citizen petitions would gain traction, as it does not seem to be contemplated under the broad judicial review provisions of the APA. The subject matter of citizen petitions varies, but many petitions contend with issues of fact, and a recent study highlighted that judicial review bars on factual determinations are very rare. *See* Laura Dolbow, *Barring Judicial Review*, 77 VAND. L. REV. 307, 353 (2024) (reporting that only four percent of judicial review bars in the U.S. Code bar review of factual determinations). Although the Supreme Court unanimously found that the *AHM* plaintiffs' standing theories were insufficient, the risk of judge shopping in future cases is still acute. U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367, 368 (2024). Restraining judge shopping is the most targeted strategy to curb potential abuse of the citizen petition process, as it would curtail plaintiffs' ability to select a specific judge while still allowing the judiciary to check the power of the executive branch where needed. Judge shopping practices in cases requesting nationwide relief could be reformed in at least three ways: (1) ensuring the random assignment of judges, and potentially banning the filing of cases requesting nationwide relief in forums where only a single judge is available to hear a case; (2) automatic transfer to the District Court for the District of Columbia; or (3) creation of multi-judge panels to decide cases where nationwide relief has been requested. *District Court Reform: Nationwide Injunctions*, *supra* note 175, at 1722–23. Proposals that all suits seeking nationwide relief should be filed in the District Court for the District of Columbia are particularly appealing for citizen petition review, given that this court regularly hears cases involving the FDA.

[176] *See supra* Part II.E.

malpractice and potential liability," and diversion of "valuable resources away from advocacy and educational efforts to compensate for the lack of information."[177] The plaintiffs established that their associational injuries would stem from the costs they would incur while combatting the FDA's regulations, and their organizational injuries came from the fact that the FDA's actions forced them to spend energy, time, and resources writing to the FDA to contest the regulations.[178] The Supreme Court concluded that these theories were not substantiated by the facts the plaintiffs alleged, as for associational and organizational standing, plaintiffs still must show a concrete and particularized actual or imminent injury-in-fact.[179] But before the Supreme Court ruled in this case, both the district court and the Fifth Circuit upheld at least some portion of the plaintiffs' standing claims. The district court concluded that the plaintiffs' standing theories were supported by evidence from the Rafferty & Longbons study, a study of women who had regretted their abortions based on blog posts on a pro-life website.[180] Although this study of general themes in fifty-four anonymous blog posts of people who regretted their abortions might be relevant evidence if the court were to consider standing for *patients*,[181] the district court in *AHM* used this study's empirical data to support the *doctor-plaintiffs'* claim to standing.[182]

Although the Fifth Circuit's standing analysis was narrower than the district court's analysis, it still failed to address how the plaintiffs suffered an "actual or imminent injury" caused by the 2016 Amendments and the 2021

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[177] All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507, 524, 527 (N.D. Tex. 2023).

[178] *Id.* at 526–27.

[179] U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367, 385 (2024); *see Overview of Lujan Test*, LIBR. OF CONG., CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artIII-S2-C1-6-4-1/ALDE_00012995/ [https://perma.cc/F4CF-5ZPP]; *see also* Adam Unikowsky, *Mifepristone and the Rule of Law, Part II*, ADAM'S LEGAL NEWSLETTER (Apr. 9, 2023), https://adamunikowsky.substack.com/p/mifepristone-and-the-rule-of-law-9c4 [https://perma.cc/WSW9-YK24].

[180] Unikowsky, *supra* note 179, at 179.

[181] *See* Katherine A. Rafferty & Tessa Longbons, *#AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*, 36 HEALTH COMMC'N 1485 (2021). However, for patients to have standing against the FDA, this would require that a waiver to sovereign immunity applies, and the claim be based "upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government." Berkovitz v. United States, 486 U.S. 531, 535 (1988).

[182] All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507, 524–25 (N.D. Tex. 2023). The court also uses the Rafferty & Longbons study in support of its decision on the merits, arguing that this limited study provides concrete evidence that the majority of women reported a negative change in their lives after chemical abortion. *Id.* at 547. It may be that Judge Kascmaryk believed that this study constituted adequate factual evidence to overturn the FDA's scientific decisionmaking on mifepristone, but it may also be that this limited study provided evidence necessary to reach Judge Kascmaryk's preferred outcome on the availability of mifepristone in the U.S. market. Further, the Northern District of Texas's use of a small study with biased patient selection and questionable methodology illustrates how courts may be ill-equipped to deal with understanding the rigorous data analysis required to approve a drug.

Actions.[183] The Fifth Circuit instead relied on an expansive interpretation of *Havens Realty Corp. v. Coleman*, where a non-profit challenged a realty corporation's "racial steering" practices in violation of the Fair Housing Act, claiming that the violations made it more difficult and costly to perform their functions.[184] Per the Fifth Circuit's reading of *Havens*, "any time a government agency takes an action contrary to the mission of a public interest group, that group suffers an Article III injury."[185] Yet, while the statute in *Havens* authorized private suits to enforce the requirements of the FHA, there is no provision in the FDCA that would have allowed the plaintiffs in *AHM* to similarly allege standing.[186]

In its decision to reverse and remand in *AHM*, the Supreme Court directly countered the Fifth Circuit's interpretation of *Havens*.[187] In its unanimous opinion, the Court clarified that the "unusual" issue in *Havens* was that Havens provided the non-profit Black employees of Housing Opportunities Made Equal (HOME) with "false information about apartment availability—a practice known as racial steering," and that this practice "directly affected and interfered with HOME's core business activities," which were both advocacy and providing housing counseling.[188] In contrast, the Court stated that the FDA's actions have not "imposed any similar impediment to the medical associations' advocacy businesses," because the associations elected to divert their resources towards their own study of mifepristone, and this diversion did not prevent them from their advocacy mission.[189] The Court rejected the idea that an organization could "manufacture its own standing" by "expending money to gather information and advocate against the defendant's action."[190]

The Court acknowledged that there was one type of injury that the associational plaintiffs could have suffered: an informational injury due to the FDA's improper collection and dissemination of information about mifepristone.[191] Because the associations did not claim this kind of injury, however, and because the associations did not argue that the FDA would be required by law to disseminate this kind of information, the Court found that they failed to establish standing.[192]

As to the standing of individual doctors, the Court acknowledged that a conscience injury does constitute a concrete injury for purposes of Article III standing, but determined that the plaintiff doctors failed to show they would be

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[183] Jonathan H. Adler, *The Good and Bad of the Fifth Circuit's Abortion Pill Ruling*, REASON.COM (Apr. 13, 2023), https://reason.com/volokh/2023/04/13/the-good-and-bad-of-the-fifth-circuits-abortion-pill-ruling/ [https://perma.cc/UBX8-YPNG].

[184] Havens Realty Corp. v. Coleman, 455 U.S. 363, 363 (1982).

[185] Adler, *supra* note 183.

[186] *Havens*, 455 U.S. at 380–81 n.23 (noting that 42 U.S.C. § 3613 only describes suits that the Attorney General may bring and does not limit suits that private parties may bring under the Fair Housing Act § 812).

[187] *See* U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367, 370 (2024).

[188] *Id.* at 395.

[189] *Id.* at 396.

[190] *Id.*

[191] *See id.* at 395–96.

[192] *See id.*

forced to participate in an abortion against their moral objections.[193] Similarly, the Court recognized the legitimacy of monetary and diversionary injury in other cases, but found a lack of causation between the injuries the doctor-plaintiffs claim to have suffered and the FDA's actions.[194] The Supreme Court recognized the potential harm that could come from finding standing on such attenuated grounds, as this would allow "doctors or other healthcare providers to challenge general safety regulations as unlawfully lax," an "unprecedented and limitless approach" that would "allow doctors to sue in federal court to challenge almost any policy affecting public health."[195] The Court went further on this point, predicting that allowing such tenuous grounds for standing would be an "uncharted path" that would permit "virtually every citizen" to challenge government actions they do not like.[196]

Although the Supreme Court ruled that the plaintiffs in *AHM* did not establish standing, the Supreme Court provided more context to allow future litigants to obtain standing to challenge the approval of mifepristone and other FDA decisions. The legal organization behind the *AHM* plaintiffs indicated on the release day of the decision that they hope to continue the lawsuit with individual claims from Idaho, Missouri, and Kansas that rely on other grounds for standing.[197]

It can be expected that future litigants seeking judicial review of FDA decisions will learn from the standing errors in *AHM* to find plaintiffs with more concrete and direct causes of injury.

B. Risks from Judicial Imposition on the FDA Approval Process

The risks from judicial imposition on the FDA approval process through citizen petition review are significant, as a court could potentially reverse the science-based decisionmaking of the FDA. Prior to *AHM*, courts had not ventured into review of specific drug approvals, likely because these decisions are grounded so deeply in evaluation of the scientific evidence presented by manufacturers. The Supreme Court and courts of appeals have repeatedly explained that scientific agency decisionmaking, such as the review of technical documents related to a drug approval (or many other types of FDA determinations), should receive heightened deference on judicial review.[198]

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[193] *See id.* at 390.

[194] *See id.*

[195] *Id.* at 391.

[196] *Id.* at 391–92.

[197] Lawrence Hurley, *Supreme Court rejects bid to restrict access to abortion pill*, NBC NEWS (June 13, 2024), https://www.nbcnews.com/politics/supreme-court/supreme-court-rejects-bid-restrict-access-abortion-pill-rcna151308 [https://perma.cc/D5E9-R3GZ].

[198] *See, e.g.*, Balt. Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103 (1983); Zuni Pub. Sch. Dist. No. 89 v. Dep't of Educ., 550 U.S. 81, 90 (2007) (making a determination on a scientific or technical issue "is the kind of highly technical, specialized interstitial matter that Congress often does not decide itself, but delegates to specialized agencies," not courts); Kleppe v. Sierra Club, 427 U.S. 390, 412 (1976) (resolution of issues "requir[ing] a high level of technical expertise . . . is properly left to the informed discretion of responsible federal agencies"); Associated Fisheries of Maine, Inc. v. Daley, 127 F.3d 104, 110 (1st Cir. 1997) ("When an agency

Where "analysis of the relevant documents 'requires a high level of technical expertise,' we must defer to 'the informed discretion of the responsible federal agencies.'"[199] This deference holds even when specialists may have conflicting views on a topic, as "an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive."[200] The Supreme Court has noted that a court reviewing this type of scientific determination "must generally be at its most deferential;"[201] the D.C. Circuit has described this level of deference as "extreme."[202] Such deference has not been cleanly abrogated by *Loper Bright Enterprises v. Raimondo*,[203] which addressed the standard of deference that courts should give to agency interpretations of ambiguous statutes.

AHM serves as a test case for the significant substantive problems that can arise in the judicial review of citizen petitions. Had the plaintiffs had standing to bring their claims in *AHM*, the Fifth Circuit's ruling could be construed to substantively modify the FDA's conditions for mifepristone's approval and use. In its analysis of the 2016 Amendments, the Fifth Circuit

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is faced with conflicting scientific views and chooses among them, its decision cannot be termed arbitrary or capricious. Indeed, a reviewing court must afford special deference to an agency's scientific expertise where, as here, that expertise is applied in areas within the agency's specialized field of competence"); San Luis & Delta Mendota Water Auth. v. Jewell, 747 F.3d 581, 592–93 (9th Cir. 2014) (federal agencies are required to "employ the best scientific and commercial data available," but are "not required to support [their] finding[s] . . . with anything approaching scientific certainty"); *id.* at 610, 633 ("deference is greatest when the agency selects between scientific models," and courts "must respect the agency's judgment even in the face of uncertainty"); *see also* Katherine Renshaw, *Leaving the Fox to Guard the Henhouse: Bringing Accountability to Consultation Under the Endangered Species Act*, 32 COLUM. J. ENV'T L. 161, 206 (2007) ("explaining that "the extreme deference with which courts treats 'scientific' decisionmaking in the [Endangered Species Act] makes substantive challenge to those decisions nearly impossible despite the fact that mounting evidence calls into question the 'scientific' basis for many decisions").

[199] Marsh v. Oregon Nat. Res. Council, 490 U.S. 360, 377 (1989).

[200] *Id.* at 378.

[201] *Balt. Gas & Elec. Co.*, 462 U.S. at 103.

[202] City of Waukesha v. EPA, 320 F.3d 228, 247 (D.C. Cir. 2003) ("[W]e 'will give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise'" (first quoting Huls Am. Inc. v. Browner, 83 F.3d 445, 452 (D.C. Cir. 1996); then quoting Int'l Fabricare Inst. v. U.S. EPA, 972 F.2d 384, 389 (D.C. Cir. 1992); and then quoting Marsh v. Oregon Natural Res. Council, 490 U.S. 360, 377 (1989))).

[203] *See* Loper Bright Enters. v. Raimondo, 603 U.S. 369 (2024). To date, scholars and commentators have expressed different views on the likely impact of *Loper Bright* on review of agency scientific decisionmaking. Some commentators have argued that *Loper Bright* does not abrogate the "super deference" provided to agencies for factual and/or scientific decisionmaking in their areas of expertise. *See, e.g.*, Catherine Stetson, Susan Cook, Sean Marotta & Danielle Desaulniers Stempel, *What is NOT a Loper Bright Issue: A Practical Guide*, HOGAN LOVELLS (July 30, 2024), https://www.hoganlovells.com/en/publications/what-is-not-a-loper-bright-issue-a-practical-guide [https://perma.cc/HAS7-N6ZB]; Seth D. Jaffe, *Does Loper Bright Mean The End of Deference to Agency Expertise?*, FOLEY HOAG L. & THE ENV'T (July 31, 2024), https://foleyhoag.com/news-and-insights/blogs/law-and-the-environment/2024/july/does-loper-bright-mean-the-end-of-deference-to-agency-expertise/ [https://perma.cc/BE49-GFM7]. Other scholars and commentators argue that *Loper Bright* cannot help but disrupt scientific deference to agencies, because oftentimes agency decisions interconnect scientific decisionmaking and interpretation of potentially ambiguous statutes. *See, e.g.*, Sapna Kumar, *Scientific and Technical Expertise After* Loper Bright, 74 DUKE L.J. (forthcoming 2025).

critiqued the FDA for failing to "demonstrate the cumulative effect" of—or "offer an explanation for"—the 2016 Amendments, in its citizen petition response.[204] At the outset, when contending with a review of complex scientific decisionmaking, courts have other options beyond vacatur or injunctive relief. Instead of staying the 2016 Amendments, the Fifth Circuit could have ordered the FDA to provide further justification of its decision to adopt the 2016 Amendments, therein allowing the FDA to lend its scientific expertise to the court's decisionmaking process. Substantively, it also appears that the Fifth Circuit's decision does not comport with the substantial evidence review standard mandated under the APA. In briefing before the court, the FDA and Danco both noted that the APA gives agencies discretion to determine "whether a study is adequate and well controlled."[205] The FDA *did*, in fact, provide substantial evidence in support of the 2016 Amendments in the form of multiple studies that addressed the plaintiffs' challenges to these Amendments.[206] In its petition for certiorari, the FDA correctly noted that "neither the APA nor any other source of law required FDA to use the phrase 'as a whole' or otherwise 'incant magic words'"[207] to exercise its discretion in determining the legitimacy of a scientific study.

The Fifth Circuit's *AHM* opinion could be interpreted by future panels to mean that the Fifth Circuit requires *both* an explanation of agency action and that said agency action must comport with the court's perception of addressing "an important aspect of the problem."[208] The FDA's certiorari petition highlights this key issue—neither the APA, nor the FDCA, nor the FDA's regulations or guidance address specific requirements for clinical evidence to justify changes to a drug's approval.[209] This decision appears to have rewritten the rules for what must be shown to justify the FDA's decisionmaking on modification of drug approvals.

The Fifth Circuit's decision appears to greatly exceed the powers granted to courts for judicial review of agency action outlined under the APA. Under the APA, a court shall "hold unlawful and set aside agency action" if it is found to be "arbitrary" or "capricious."[210] As recently as 2021, a unanimous Supreme Court held that a court's role in reviewing agency action is only to ensure that

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[204] The 2016 Amendments included: increasing the gestational age from forty-nine days to seventy days; permitting non-physician prescribers; removing in-person administration and follow-up; eliminating prescriber's obligation to report non-fatal adverse events; switching administration of misoprostol from oral to buccal; and changing the dose of mifepristone to 200 mg and the dose of misoprostol to 800 mcg. *See* All. for Hippocratic Med. v. U.S. Food & Drug Admin., 78 F.4th 210, 225–26 (5th Cir. 2023).

[205] *Id.* at 152 (quoting Weinberger v. Hynson, Wescott & Dunning, Inc., 412 U.S. 609, 621 n.17 (1973)).

[206] *See id.*

[207] Petition for Writ of Certiorari at 23–24, U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367 (2024) (No. 23-235).

[208] Conditional Cross-Petition for Writ of Certiorari at 2, All. for Hippocratic Med v. U.S. Food & Drug Admin. and All. for Hippocratic Med v. Danco Lab. (2024) (Nos. 23-235, 23-236).

[209] Petition for Writ of Certiorari at 22–24, U.S. Food & Drug Admin. v. All. for Hippocratic Med., 602 U.S. 367 (2024) (No. 23-235).

[210] 5 U.S.C. § 706(2)(A).

an agency is acting "within a zone of reasonableness," and to affirm that the agency has "reasonably considered the relevant issues and reasonably explained the decision."[211] A court cannot "substitute its own policy judgment for that of the agency."[212] This is particularly true when examining factual findings made by scientific agencies on issues within their purview, which are entitled to significant deference.[213]

Applying these principles to the FDA's decisionmaking process in *AHM*, under the FDCA, a manufacturer can re-submit a new drug application or submit an efficacy supplement to a previously approved drug to revise a dose or dose regimen, provide for a new route of administration, and "incorporate other information based on at least one adequate and well-controlled clinical study."[214] By statute, these studies and articles were required to contain "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use."[215] In requesting the 2016 Amendments, Danco submitted sixty-two studies and articles to the FDA for agency review,[216] and the FDA accepted these documents as substantial evidence supporting the 2016 Amendments. No part of the governing statute for new drug approvals or supplements to the approval of an existing approved drug requires that all potential effects of proposed changes be considered in the aggregate. Rather, the FDA's regulations and policies merely require that the evaluation of an efficacy supplement show "evidence of effectiveness necessary for the traditional approval of a product . . . based on at least one adequate and well-controlled clinical study."[217] Scholars have commented on the FDA's practice in recent years of using fewer clinical studies to approve a drug and spending less time on the review of new drugs,[218] but there is no evidence that the FDA is acting outside of its statutory duties in approving new drugs or evaluating changes to approved drugs, nor that it did so in this case.

Changing the FDA's statutory requirements for acceptable clinical trial parameters is the job of Congress, not the courts. Furthermore, evaluation of the scientific factors leading to drug approval or modification has been delegated expressly from Congress to the FDA. The Fifth Circuit's decision does not appear to be in line with precedent for judicial review of agency actions, or with the level of deference afforded to the FDA for these types of decisions. This case highlights the risk that a court may conduct similar, overly broad judicial review in the future.

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[211] FCC v. Prometheus Radio Project, 592 U.S. 414, 423 (2021).

[212] *Id.*

[213] See *supra* notes 198–202.

[214] 21 C.F.R. § 314.3 (2016).

[215] 21 U.S.C. § 355(b)(1)(A).

[216] *See* Information on Mifeprex Labeling, *supra* note 97, at 11.

[217] 21 C.F.R. § 314.126 (2016) (setting out the aims of clinical investigation and defining "[a]dequate and well-controlled studies"); U.S. FOOD & DRUG ADMIN., MAPP 6020.8 REV.1, NDAS/BLAS/EFFICACY SUPPLEMENTS: ACTION PACKAGES AND TAKING REGULATORY ACTIONS (2016).

[218] *See, e.g.*, Jonathan J. Darrow, Jerry Avorn & Aaron S. Kesselheim, *FDA Approval and Regulation of Pharmaceuticals, 1983-2018*, 323 JAMA 164, 173 (2020).

C. The FDA's Potential Responses to a Judicial Order Withdrawing Approval of a Drug

The Supreme Court did not reach the merits question on the FDA's approval of mifepristone, but in response to a court order withdrawing approval of a drug such as mifepristone, the FDA has two options—noncompliance or withdrawal of approval—each with significant drawbacks.

1. Noncompliance

First, the FDA could choose to ignore the court order and decline to enforce withdrawal of its approval of mifepristone.[219] Here, the enabling statute (the FDCA) provides no guidance as to how the FDA should proceed if judicially ordered to withdraw a drug approval. The FDCA only provides that if the agency determines that a drug is "withdrawn for safety or effectiveness reasons," it could potentially be removed from the list of approved drugs after approval is withdrawn, and later "relisted if the agency has evidence that . . . the withdrawal is not for safety or effectiveness reasons."[220] Thus, even if the FDA chooses to withdraw a drug following a judicial order for withdrawal, the FDA equally has the power to relist a drug if there is adequate evidence of safety and effectiveness.[221] Alternatively, the FDA could choose to withdraw approval for a particular drug but not remove the drug from the list of approved drugs (as listed in the FDA's Orange Book, a compilation of all approved drugs), meaning that generic versions of the drug could still be approved.

The FDA could still maintain mifepristone's approval even in the face of a court order, as the options to punish an agency actor for noncompliance are rarely invoked and often ineffective.[222] A 2018 Harvard Law Review study from Professor Nicholas Parrillo examines thousands of opinions to assess how federal courts respond to the federal government's disobedience.[223] Parrillo details how sanctions, such as fines, imprisonment, and adverse outcomes, can,

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[219] In *Heckler v. Chaney*, the Supreme Court concluded that "an agency's decision not to take enforcement action should be presumed immune from judicial review." 470 U.S. 821, 832 (1985). Although not directly relevant here, *Heckler* indicates that the Supreme Court is reticent to interfere with agency enforcement decisions. *See id.* at 848.

[220] 21 C.F.R § 314.161(a)(3) (2016); 21 C.F.R § 314.161(e) (2016).

[221] While the FDCA does not specifically lay out the process for relisting if a drug's approval has been withdrawn, the relisting process would likely proceed under 21 U.S.C. § 355(b), which governs new drug applications, and 21 U.S.C. § 355(e), which governs withdrawal of approval if "experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved."

[222] *See* Nicholas R. Parrillo, *The Endgame of Administrative Law: Governmental Disobedience and the Judicial Contempt Power*, 131 HARV. L. REV. 685, 696 (2018) (documenting the limits of the judicial power to punish administrative agencies).

[223] *Id.* at 685.

at least in theory, be employed against an offending agency.[224] Yet, as described below, these strategies are of nominal impact and are not likely to be effective in forcing the FDA to comply with a court order relating to mifepristone.

Fines against federal agencies can be used as compensatory contempt fines for the plaintiffs harmed by an agency's failure to follow a court order—imposing a direct penalty on an agency by taking fines from agency appropriations.[225] Fines have been generally ineffective, however, to deter administrative agencies, as historically such fines have been relatively modest.[226] Any fine that significantly decreased the FDA's appropriations would either (1) dip into the FDA's ability to approve and regulate other drugs, or (2) provide an incentive for the FDA to increase user fees from pharmaceutical firms, which already provide nearly three-quarters of funding for the FDA's drug division.[227] Therefore, in an attempt to leverage the APA against the FDA and rein in its ability to make decisions, a contempt fine could inadvertently give more control to lobbyists and private entities whose actions are further removed from the oversight of the judiciary.[228]

The remaining options Parrillo outlines are agency sanction, sanction of or action against individual agency officials, or reliance on the power of contempt itself.[229] Courts have sanctioned agencies only four times, which have generally only "imposed adverse outcomes on the agency within the lawsuit itself or within the particular agency proceeding . . . ."[230] Scholars have raised questions about whether such sanctions are even permissible, as per 18 U.S.C. § 401, courts may only sanction by "fine or imprisonment."[231] Furthermore, these types of sanctions seem inherently problematic, in that such sanctions usually involve a generalist court attempting to "force [a specialist] agency to do something complex that requires expertise . . . ."[232]

Action against agency officials is only an option if the non-compliant conduct can be attributed to an individual (or a small set of individuals). Although fining an agency official is perhaps an option, the judiciary has not availed itself of this option in a way that impacted agency operations.[233] In addition, such action is highly uncommon—Parrillo has found only four instances in which federal agency officials were threatened with imprisonment

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[224] *Id.* at 686, 763.

[225] *See id.* at 710, 736.

[226] *See id.* at 761–63.

[227] Christina Jewett, *F.D.A.'s Drug Industry Fees Fuel Concerns Over Influence*, N.Y. TIMES (Sep. 15, 2022), https://www.nytimes.com/2022/09/15/health/fda-drug-industry-fees.html [https://perma.cc/NQ74-X6R9].

[228] *See id.* (explaining the FDA's dependence on funding from the pharmaceutical industry).

[229] *See* Parrillo, *supra* note 222, at 764–65, 773.

[230] *Id.* at 763.

[231] *Id.* at 764 (first quoting 18 U.S.C. § 401 (2012); and then citing *Ex parte* Robinson, 86 U.S. (19 Wall.) 505, 512 (1874) (holding that these methods are exclusive)); *see also id.*, *supra* note 222, at 692 n.21 (clarifying the extent of the punitive power created by 18 U.S.C. § 401).

[232] *Id.* at 765.

[233] *Id.* at 762.

or actually imprisoned.[234] Neither action would be particularly useful against the FDA, barring instances where an FDA official committed fraud or engaged in some other illegal conduct to force approval of a drug.

Finally, Parrillo indicates that the threat of a contempt finding could cause shame and thus influence agency action,[235] but in the mifepristone context (and indeed for the FDA at large) such threats are unconvincing. Parrillo cites a comment from the Environmental Law Institute demonstrating how contempt, even without sanctions, could be an effective way of compelling agency action at the EPA: "Top management [at the EPA] takes the threat of contempt quite seriously and personally, even though the threat is not real."[236] Nevertheless, Parrillo has few other examples of exactly how contempt is effective, and instead he posits only that contempt findings "give[] courts a face-saving way to allow agencies more latitude" by allowing agencies to negotiate compliance with a court while sparing the court from actually having to use contempt sanctions.[237] The threat of shame associated with a contempt finding might be impactful in the political sphere and among certain voting publics, but it is not clear how this norm would apply to the FDA, given that the agency is not directly responsive to the voting public. Contempt might, therefore, only be useful against the FDA if leveraged by members of Congress or other high-profile political officials, and even then, it is unclear how this "threat" would actually change FDA behavior.

For mifepristone in particular, public shame would likely be an ineffective tool to influence the FDA to withdraw related agency actions. Fifty percent of Americans think abortion should be legal under certain circumstances, and thirty-five percent believe it should be legal under any circumstances.[238] Sixty-nine percent of Americans think abortion should be legal in the first trimester, or up to thirteen weeks of gestation.[239] Under the 2016 Amendments, mifepristone is approved for use for up to ten weeks of gestation, and sixty-one percent of Americans believe it should be available in the U.S. as a prescription drug.[240] Judicial scrutiny of the FDA's inaction on mifepristone is not likely to impact the public's perception of the drug or abortion more generally. In the wake of the Northern District of Texas's *AHM* decision, multiple mainstream news outlets released headlines which stated that

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[234] *Id.* at 745.

[235] *Id.* at 770.

[236] *Id.* at 776 (quoting ENV'T & ENERGY STUDY INST. & ENV'T L. INST., STATUTORY DEADLINES IN ENVIRONMENTAL LEGISLATION: NECESSARY BUT NEED IMPROVEMENT, at v (1985)).

[237] *Id.*

[238] *Where Do Americans Stand on Abortion?*, GALLUP (July 7, 2023), https://news.gallup.com/poll/321143/americans-stand-abortion.aspx [https://perma.cc/QSU2-LQGN].

[239] *Id.*

[240] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN., (Feb. 11, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation [https://perma.cc/L2YV-GLWZ]; *Where Do Americans Stand on Abortion?*, GALLUP (July 7, 2023), https://news.gallup.com/poll/321143/americans-stand-abortion.aspx [https://perma.cc/QSU2-LQGN].

mifepristone's safety profile is on par with that of Tylenol and Viagra and questioned the court's assessment of the drug's safety profile.[241] If anything, the FDA's refusal to comply with a judicial order on mifepristone could increase public support for the FDA while simultaneously undermining the public's perception of the judiciary's impartiality. When the Supreme Court decision in *Dobbs v. Jackson Women's Health*[242] was issued in 2022, public support for abortion was at or near an all-time high, while public support of the Supreme Court reached a nearly twenty-year low.[243]

2. Compliance, Withdrawal, and Potential Relisting

Conversely, the FDA could comply with a judicial order and withdraw approval of mifepristone. In this scenario, manufacturers could later seek reapproval of their drug; although uncommon, the FDA can reapprove drugs after an earlier withdrawal in some scenarios.[244] Alternatively, if manufacturers did not seek relisting, doctors, manufacturers, and patients would need to use a misoprostol-only method of abortion[245] or turn to alternative abortion methods.[246] If the goal of the FDA is to protect the public health by ensuring the safety and efficacy of drugs, which it undoubtedly is, withdrawal without reintroduction should not be considered as a feasible "solution" to the challenges presented by *AHM*.

Should the FDA comply with a court order to withdraw mifepristone's approval, such withdrawal would not necessarily be permanent, nor would mifepristone become unavailable immediately in the United States market. Drugs can be withdrawn for a variety of reasons, including when post-market studies fail to verify clinical benefit, post-market studies are not performed with due diligence, a drug is not shown to be safe or effective under the conditions of

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[241] *See* Christine Fernando, *Mifepristone 'Safer than Tylenol,' Experts Say Amid Court Battle over Major Abortion Pill*, USA TODAY (Apr. 18, 2023), https://www.usatoday.com/story/news/nation/2023/04/18/mifepristone-case-abortion-pill-drug-tyenol-fda/11687403002/ [https://perma.cc/J95K-KNDF]; *see also* Annette Choi & Will Mullery, *How Safe is the Abortion Pill Compared with Other Common Drugs?*, CNN (Apr. 21, 2023), https://www.cnn.com/2023/03/15/health/abortion-pill-safety-dg/index.html [https://perma.cc/3KAC-EA7X].

[242] 597 U.S. 215 (2022).

[243] *See* Steven Shepard, *The Supreme Court Dramatically Changed Public Opinion on Abortion*, POLITICO (June 24, 2023), https://www.politico.com/news/2023/06/24/supreme-court-public-opinion-abortion-00103493 [https://perma.cc/K74T-EWGX].

[244] *See, e.g.*, 21 C.F.R. § 314.161(e) (explaining that a "drug may be relisted if the agency has evidence that marketing of the drug has resumed or that the withdrawal is not for safety or effectiveness reasons").

[245] *See, e.g.*, Ruvani Jayaweera, Ijeoma Egwuatu, Sybil Nmezi, Ika Ayu Kristianingrum, Ruth Zurbriggen, Belén Grosso, Chiara Bercu, Caitlin Gerdts & Heidi Moseson, *Medication Abortion Safety and Effectiveness with Misoprostol Alone*, 6 JAMA NETWORK OPEN 1 (2023). Although not approved for use by the FDA, there is some clinical evidence that misoprostol-only abortions may be efficacious.

[246] *See* Phillip G. Stubblefield, Sacheen Carr-Ellis & Lynn Borgatta, *Methods for Induced Abortion*, 104 OBSTETRICS & GYNECOLOGY 174, 174–85 (2004). Even if mifepristone were removed from the U.S. market, surgical methods (such as aspiration, dilation, evacuation/curettage, and induced labor) would remain available.

use, or when a second-generation drug is introduced and it is no longer feasible to continue manufacturing the first-generation drug (for business reasons or otherwise).[247] A withdrawal action is not the same as a recall—a withdrawal action is a "firm's removal or correction of a distributed product that would not be subject to legal action," and withdrawal is without prejudice to refiling.[248]

Recall means that a drug is in violation of the FDA's laws and will be seized and classified according to the relative degree of health hazard.[249] Recalls may involve effectiveness checks, where consignees are contacted by the firm or by the FDA to ensure that they have taken appropriate action.[250] Withdrawal does not compel the FDA to seize any withdrawn drug that remains at pharmacies or in doctors' offices (although states may choose to enforce seizures under their own laws). In 2023, the FDA recalled Makena (hydroxyprogesterone caproate injection), a drug that was approved in 2001 for reducing the risk of preterm birth. In post-market studies, Makena was found to be ineffective for reducing preterm birth and did not improve the health of babies born in this population. The FDA withdrew approval but conceded that a "limited supply of these drugs ha[d] already been distributed" and "acknowledge[d] that some health care providers might continue to prescribe or administer that limited remaining supply to their patients" so long as interstate commerce was not implicated.[251] With states stockpiling mifepristone after the district court ruling, there could still be a sizeable number of doses of mifepristone available in the United States even if a court ordered the withdrawal of its approval.

Although uncommon, withdrawn drugs have been subsequently reintroduced to the market with new indications and new controls. Actions can be taken to correct the conditions that led to a drug's withdrawal. As an example, the FDA approved and then subsequently withdrew approval for Lotronex (alosetron), a treatment for irritable bowel syndrome, within a period of ten months in 2000. Lotronex was reintroduced to the United States market in 2002 with different conditions for use to reduce the frequency of serious adverse events.[252] After studying the patients who were more likely to have adverse events, and upon finding no common element, the FDA required that patients

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[247] *See* 21 C.F.R. § 314.530(a) (2024). Drugs can also be withdrawn for business reasons, such as when a second-generation drug is introduced, and it is no longer feasible to continue manufacturing the first-generation drug.

[248] *See* 21 C.F.R. § 314.150(c) (2024); 21 C.F.R. § 7.3(j) (2024).

[249] *See* 21 C.F.R. § 7.3(g) (2024); *see also* 21 C.F.R. § 7.41(b) (2024). Assessment of health hazards includes whether disease or injuries have already occurred from the use of the product, whether existing conditions could contribute to a clinical situation that could expose humans to a health hazard, the degree of seriousness of the health hazard, the likelihood of the occurrence of the hazard, and assessment of the consequences of the occurrence of the hazard.

[250] *See* 21 C.F.R. § 7.42(a)(3) (2024).

[251] *See Makena (Hydroxyprogesterone Caproate Injection) Information*, U.S. FOOD & DRUG ADMIN. (Apr. 6, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information [https://perma.cc/Y9G2-9ZRV].

[252] U.S. FOOD & DRUG ADMIN., Approval Letter for Lotronex, NDA No. 21-107 (Feb. 11, 2000); U.S. FOOD & DRUG ADMIN., Approval Letter for Lotronex, NDA No. 21-107/S-005 (June 7, 2002); *see* Ray Moynihan, *Alosetron: A Case Study in Regulatory Capture, or a Victory for Patients' Rights?*, 325 BRIT. MED. J. 592 (2002).

start at a lower dose of Lotronex and that the treatment only be used for patients who had failed other treatment options.[253]

With mifepristone, as the Fifth Circuit's rationale in *AHM* relies heavily on hypothetical harm done to patients and the medical system, it is not clear what further evidence would allow the 2016 Amendments and the 2021 Actions to be reapproved under the standards set forth by that court. Given these challenges and the cost to conduct and review these studies, reapproval would be a daunting and costly task.

As explained in this Section, in contemplating its response to a judicial order withdrawing approval of a drug, the FDA faces a challenging choice. Noncompliance with the court order risks punishment for the agency, although this risk—as described above—may be less threatening in many potential situations. Withdrawal of mifepristone leaves open the option for reapproval and relisting of the drug in the future.

V. OPTIMIZING THE FDA'S PROCESSES TO PREVENT VEXATIOUS LITIGATION AND ADDRESS CITIZEN CONCERNS

Although the APA and FDCA require that judicial review remain available for redress of complaints against the FDA, improvements to the FDA's processes for addressing citizen feedback could mitigate many concerns leading to judicial intervention. This Part suggests two ways in which the FDA could improve its internal processes to create a more robust administrative record for review. First, the FDA should consider alternative methods to address citizen concerns within the agency, allowing agency and outside experts to contend with the intricacies of clinical trial data (and other complex scientific-based decisions) before turning the issue over to generalist courts. Second, this Part discusses suggestions to improve the completeness of responses, enhance the public's real-time knowledge, and track responses to bolster public confidence in the citizen petition process.

As previously demonstrated, significant risk still remains from judicial overreach into the FDA's science-based decisionmaking processes post-*AHM*. This risk is exacerbated in the wake of *Loper Bright*, as agencies can no longer expect deference to their interpretations of statutory language left ambiguous by Congress under the *Chevron* doctrine.[254] Certainly, administrative agencies seeking deference under *Skidmore v. Swift & Co.*[255] from reviewing courts will

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[253] *See* Moynihan, *supra* note 252, at 595.

[254] *See* Part IV.B *supra*; 467 U.S. 837 (1984); 603 U. S. 369 (2024).

[255] 323 U.S. 134 (1944). An agency is entitled to *Skidmore* deference to its determinations to the extent that such determinations are authorized by statute and based on the agency's expertise and informed judgment. *Skidmore* deference grants agencies deference where decisions have the "power to persuade," based on the decision's consistency with precedent, the formality of the decision, the agency's expertise in a space, the care that the agency took with the decision, and the overall persuasiveness of the agency's decision to a court. The Supreme Court seems to have preserved some form of *Skidmore* deference in the wake of *Loper Bright*, although the bounds of this deference are still in flux. *See, e.g.*, Christopher J. Walker, *Some Thoughts on* Skidmore *Weight After* Loper Bright, YALE J. ON REG.: NOTICE & COMMENT (Nov. 22, 2024), https://www.yalejreg.com/nc/some-thoughts-on-skidmore-weight-after-loper-bright/ [https://perma.cc/HYF5-6W85].

want to draft more robust descriptions and rationales for their decisionmaking. Additionally, wherever possible, agencies will want to ground their decisionmaking in scientific fact or technical analysis in seeking deference to the agency's scientific expertise.

The Fifth Circuit's criticism of the scientific determinations and legal interpretations in the *AHM* citizen petition response highlights the need for additional guardrails in the FDA's decisionmaking processes for citizen petitions. Part V.A reviews these potential options, including (1) reinstatement of the formal public hearing option, at least in complex cases; (2) creation of an expert panel review system to provide an additional level of analysis prior to judicial review; (3) creation of a science-focused "court," like the FDA's Public Boards of Inquiry held in the 1980s to delve deeply into complex scientific issues; and (4) creation of a quasi-adjudicatory court, to provide an additional level of review on both scientific and legal issues.

Part V.B explores potential options for enhancing real-time public knowledge of the citizen petition process, with the goal of improving public confidence in the FDA's review of petitions, curtailing potential concerns about politicization of decisions, and providing additional accountability to Congress.

A. Reforming Internal Review of Citizen Petitions

To avoid unnecessary litigation based on delayed or contentious citizen petition responses, the FDA and Congress should carefully consider implementing more guardrails for the FDA's internal review of citizen petitions. Additionally, or alternatively, the FDA should provide more opportunities for members of the public to challenge FDA responses to citizen petitions before FDA presiding officers, before resorting to judicial review.

Petitioners already have several procedures available to seek reconsideration of a citizen petition decision. The procedures available under 21 C.F.R. § 10.33[256] (for administrative reconsideration of an action) or 21 C.F.R. § 10.35[257] (for administrative stay of an action) are available in the citizen petition context to request reconsideration of an action.[258] Additionally, the FDA still retains the procedures for holding formal evidentiary public hearings and could elect to reinstate those procedures. More specifically, the FDA could offer review of a decision by a presiding officer before a petition response becomes final. Prior to the establishment of the current citizen petition procedure in 1979, the FDA would reach an initial decision and then allow for public hearing with a presiding officer before publishing its final response to a citizen petition in the Federal Register.[259] The FDA could reinstate a similar process, which would provide additional opportunity for public input before a petition response is finalized. Similarly, the FDA could institute procedures similar to those used in the early 2020s by the Director of the USPTO for Director Review of institution

[256] 21 C.F.R. § 10.33 (2024).

[257] 21 C.F.R. § 10.35 (2024).

[258] *See* Administrative Reconsideration of Action, 21 C.F.R. § 10.33 (2024); Administrative Stay of Action, 21 C.F.R. § 10.35 (2024) (applying to FDA actions such as citizen petitions).

[259] 21 C.F.R. § 2.66 (1968).

or final decisions of the Patent Trial and Appeal Board in proceedings where a party believes that an issue has been misapprehended or overlooked by the Board.[260] As internal review procedures by agency leadership are likely to be subject to concerns about bias, Congress could instead categorize the hearings as part of the agency exhaustion process rather than allow these procedures to substitute for proceedings at the district court level. Given the length and administrative burden that such hearings create, reinstitution of these procedures on a regular basis is unlikely.[261] However, public hearings in cases of high technical complexity or public interest might be a useful tool to bolster the administrative record.

The FDA could also consider adding expert review to its reconsideration or secondary-stage procedures. To this end, the FDA could look to procedures at other science-focused agencies that use multiple levels of review in responding to public inquiries, including panel review upon a request for reconsideration. For example, among other forms of public comments, the EPA handles requests for corrections of information (RFCs).[262] RFCs allow affected parties to obtain a correction or clarification of information disseminated by the EPA that they believe does not follow the EPA's quality of information guidelines.[263] EPA RFCs are the closest analogous requests to FDA citizen petitions.

The EPA uses multiple levels of review to handle its requests for correction. The EPA's Office of Environmental Information (OEI) confirms that RFCs have satisfied the required formalities and then circulates RFCs to the

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[260] U.S. PATENT & TRADEMARK OFF., *Revised Interim Director Review Process*, https://www.uspto.gov/patents/ptab/decisions/revised-interim-director-review-process [https://perma.cc/FQQ9-Q2SC]. This suggestion discusses the procedures for Director Review instituted at the USPTO by Director Kathi Vidal during the Biden administration. The USPTO made some attempt to codify this process (s*ee Director Review Process*, 89 Fed. Reg. 79751 (effective Oct. 31, 2024) (to be codified at 37 C.F.R. § 42.75)), but during the early days of the second Trump Administration, many Vidal-era procedures have been revoked including the interim Director Review process.

[261] *See, e.g.*, Todd R. Smyth, *The FDA's Public Board of Inquiry and the Aspartame Decision*, 58 IND. L.J. 627, 627 (1983) (describing hearings leading to an "eight-year approval process," and stating that these "[h]earings were perceived to be burdensome").

[262] The EPA handles two forms of public comments: (1) public comments on proposed policy changes, submitted in response to the EPA's publication of proposed policies or reports in the Federal Register; and (2) requests for corrections of information. As to the first form of public comment, as is common for many federal agencies, when addressing public comments in response to the EPA's publication of proposed policies or reports, the EPA aggregates public comments; summarizes each significant argument or question raised across all comments; and provides a single response to each argument or question. *See, e.g.*, Public Comment Process, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/superfund/public-comment-process [https://perma.cc/A4VU-7WWD]; U.S. ENV'T PROT. AGENCY, EPA's Response to Public Comments, Volume 1: General Approach to the Science and Other Technical Issues, https://19january2017snapshot.epa.gov/climatechange/epas-response-public-comments-volume-1-general-approach-science-and-other-technical.html [https://perma.cc/Q962-MTPN].

[263] U.S. ENV'T PROT. AGENCY, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, § 8, "Administrative Mechanisms for Correction of Information" (Oct. 2002), https://www.epa.gov/sites/default/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf [https://perma.cc/U9AY-X48Z].

appropriate "information owner" (program offices, regions, laboratories, or field offices).[264] Requests for reconsideration are processed through OEI in the same manner through the information owner, but a top official at the information owner (the Assistant Administrator or Regional Administrator of the Program Office or Region of the information owner) must present its proposed response to an executive panel comprised of the Science Advisor for the Office of Research and Development, the Chief Information Officer for OEI, and the Economics Advisor for the Office of Policy, Economics, and Innovation.[265] The panel must make its final decision within ninety days or explain why it will require more time.[266]

The EPA executive panel example indicates that the FDA could benefit from enhanced internal procedures for review of petitions, including through expert panel review. Panel review of petition responses, using a group of FDA or outside experts with relevant previous experience in clinical research and the life sciences, would allow the FDA to consider additional expert scientific perspectives before finalizing a decision. For example, professionals in clinical research consistently engage in debate over appropriate study design, measurement methods, and minimizing bias.[267] There is no single rule that can be used to determine whether a drug is safe or whether a study has been conducted with appropriate controls—instead, Congress has delegated determinations on safety and appropriate study design to the FDA to make reasonable determinations. Enhancements from a secondary review, thereby bringing additional perspectives to the decisionmaking process, could be extremely helpful to judges. In this type of review, the FDA could build the science-based record, make explicit factual findings, and allow for challenge by interested third parties while in front of agency experts. For this reason, allowing the FDA to have a secondary period of review before turning matters over to a generalist court will result in a better use of judicial resources and quicker resolution of issues.

There are a variety of mechanisms that could be used to provide this secondary review. Parties could request secondary review of a citizen petition response after an initial decision has been reached by the FDA. To avoid vexatious use of the process, the FDA could have the Commissioner (or a designee from the Commissioner) evaluate these requests to determine whether secondary review would be helpful to expand the administrative record, or overly burdensome. The FDA could look to its advisory committee structure for support and potential experts—the FDA has at least fifty advisory committees, which provide advice on technical issues in the new drug approval and clinical adequacy processes.[268]

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[264] *Id.* at §§ 5.3–5.4, 8.1.

[265] *Id.* at § 8.7. If the information request is directed to one of these offices, an alternate administrator will replace the affected administrator on the executive panel. *Id.*

[266] *Id.*

[267] *See generally* Glenn T. Clark & Roseann Mulligan, *Fifteen Common Mistakes Encountered in Clinical Research*, 55 J. PROSTHODONTIC RSCH. 1 (Jan. 2011).

[268] 21 C.F.R. § 14.160 (2024); *see Advisory Committee Research, Reports, and Announcements*, U.S. FOOD & DRUG ADMIN. (Jan. 15, 2025),

As an alternative approach to bringing secondary expert review to scientific issues, the FDA has experimented with a "science court" in the past, through instituting the Public Board of Inquiry (PBOI) in 1975.[269] Under this approach, the FDA conducted an informal public hearing as a means for scientific inquiry, rather than as a trial-like formal evidentiary hearing. This approach was only used twice in the 1980s,[270] but Professor Sidney Shapiro has argued that the PBOI "process offers the FDA a unique option with several important advantages over the agency's advisory committee system."[271] Shapiro explains that the PBOI is typically conducted post-approval, and thus its review "can serve as an independent check on the validity of [the agency's] decision" and supply a more fully developed record. This feature would be highly useful for judicial review in cases like *AHM*, where the PBOI's review of the facts could provide a highly persuasive decision for courts to review under *Skidmore*. Second, Shapiro notes that, as opposed to advisory committees, the PBOI "emphasizes data analysis and is more accountable than other processes for its conclusions."[272] This feature is important because it "increase[s] the accuracy of the decisionmaking process, even if the panel can offer no particular assistance to the agency on issues of regulatory judgment."[273] The PBOI's independence thus could enhance the perceived legitimacy of the FDA's decisionmaking.[274]

Ultimately, mechanisms for obtaining additional deference to both scientific and legal decisionmaking by the FDA may be needed to prevent a repeat of *AHM*. If additional deference to legal decisionmaking that relies heavily on scientific fact finding is sought, Congress could look to the solution it crafted for review of patent validity challenges at the USPTO's Patent Trial and Appeal Board (PTAB): using administrative judges with expertise in relevant technical areas to decide these legal challenges. In 2011, recognizing the harm that non-meritorious patents had on the federal court system, Congress passed the America Invents Act (AIA) to revitalize the patent system.[275] The AIA created the PTAB, a quasi-adjudicative body within the USPTO consisting of the Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and Administrative Patent Judges (APJs) who

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https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm165313.htm [https://perma.cc/96WC-Y5XV] ("[T]o assist in its mission to protect and promote the public health, [the FDA] uses 50 committees and panels to obtain independent expert advice on scientific, technical, and policy matters").

[269] *See* 21 C.F.R. § 13.1 (2024).

[270] *See* Sidney A. Shapiro, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry*, 1986 DUKE L.J. 288, 307–18 (1986).

[271] *Id.* at 342.

[272] *Id.*

[273] *Id.* at 323.

[274] *Id.*

[275] H.R. REP. NO. 112-98, pt. 1, at 38–40 (2011); *Patent Reform in the 111th Congress: Legislation and Recent Court Decisions, Hearing Before the S. Comm. on the Judiciary*, 111th Cong. 181–87, 210 (2009) (statement of David J. Kappos, Vice President and Assistant General Counsel, Intellectual Property Law and Strategy, IBM Corp., and testimony of Professor Mark A. Lemley, Stanford Law School); *see generally Committee Print Regarding Patent Quality Improvement: Hearing before the Subcomm. on Cts., the Internet, and Intell. Prop.*, 109th Cong. (2005); *Patent Trolls: Fact or Fiction?, Hearing before the Subcomm. on Cts., the Internet, and Intell. Prop.*, 109th Cong. (2006).

are appointed by the Secretary of Commerce.[276] The Director or a delegated panel of APJs can decide to institute the most common type of administrative proceeding post-patent grant (an inter partes review proceeding)[277] on limited validity grounds (novelty and non-obviousness of the challenged patent claims) based on whether there is a reasonable likelihood the petitioner would prevail with respect to at least one of the challenged claims.[278] The Director assigns APJs to a panel based on their preferred technology disciplines and a judge's prior experience.[279] Once instituted, a proceeding is held before a panel of three or more APJs. The proceeding is not a formal trial like those held in district court, but both petitioner and patent owner may file affidavits, declarations, written memoranda, undergo limited discovery, and have an oral hearing before the PTAB.[280] Importantly, these proceedings are popular as they cost less and generally take less time to complete than district court litigation, there is no presumption that a patent is valid, and petitioners are more likely to succeed compared to suits in district court.[281] Decisions made at the PTAB receive judicial review through appeal to the United States Court of Appeals for the Federal Circuit.[282]

These types of concerns could be mitigated in the FDA context by providing express guidance on the composition and size of expert review panels. Other concerns about APJs have stemmed from their relative inexperience compared to district court judges in patent-heavy courts.[283] For FDA review, panels could be structured to provide expertise directly relevant to the scientific or rulemaking question at hand.

B. Enhancing Real-Time Public Knowledge of the Citizen Petition Process: Reporting and Tracking of Responses

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[276] Patrick Lavery, *Does the Patent Trial and Appeals Board's Precedential Opinion Comport with Due Process?*, 89 FORDHAM L. REV. 731, 736 (2020).

[277] There are two types of proceedings at the PTAB: post-grant review (PGR) and inter partes review proceeding (IPR). PGR proceedings may be brought within nine months of a patent's issue and allow a third party to request to cancel a patent on any ground. *Post Grant Review*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/ptab/trials/post-grant-review [https://perma.cc/BNF7-33FN]. IPR proceedings can be filed nine months after a patent's issue and allow a third party to challenge the validity of a patent only on two specific grounds. IPR proceedings only allow challenges on the grounds that a patent covers a non-novel invention or that an invention that would have been obvious to a person having ordinary skill in the art. *Inter Partes Review*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/ptab/trials/inter-partes-review [https://perma.cc/J29W-V2KL].

[278] 35 U.S.C. § 314(b).

[279] U.S. PAT. & TRADEMARK OFF., PAT. TRIAL & APPEAL BD. *Standard Operating Procedure 1 (Revision 15): Assignment of Judges to Panels* (2018), https://www.uspto.gov/sites/default/files/documents/SOP%201%20R15%20FINAL.pdf [https://perma.cc/4FKY-THBB].

[280] 35 U.S.C. §§ 316(a)(5)–(10); *see* U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 1202 (2024).

[281] Lavery, *supra* note 276, at 738.

[282] 35 U.S.C. § 737.

[283] *See* Gene Quinn, *PTAB Judges Shockingly Inexperienced Compared to District Court Judges* (Mar. 6, 2018), https://ipwatchdog.com/2018/03/06/ptab-judges-shockingly-inexperienced/id=94438/ [https://perma.cc/FPP8-EMGP].

As explained earlier, significant evidence indicates that the citizen petition process has been inefficient for at least twenty years.[284] A 1998 OIG investigation into the citizen petition process found that the FDA's response delays resulted from limited resources, a lack of written policy and procedures for addressing citizen petitions, ineffective screening and prioritizing, and lack of central monitoring.[285]

Modifications to the citizen petition process designed to enhance real-time public knowledge on the status of citizen petitions will improve public confidence in the FDA's review of petitions, curtail potential concerns about politicization of decisions, and provide additional accountability to Congress. These reforms will also help to engage third parties in the citizen petition process at the agency level, therein hopefully allowing citizens to provide additional useful information to the FDA for decisionmaking prior to any judicial review. The reforms suggested in this section address two key issues: (1) increasing public accessibility through developing a centralized location for petition information (including current status and information about the FDA's rationale for delaying a response); and (2) submitting annual reports to Congress, who ultimately has the responsibility to oversee the FDA's citizen petition process.

First, reforms should be made to address the FDA's common practice of delaying a citizen petition response until it takes other agency action. When Congress implemented the FDAAA to prevent brand firms from unjustly delaying a generic's approval, it inadvertently incentivized the FDA to use simultaneous approval and petition responses as a way of avoiding judicial review. It is common for the FDA to provide its response to a citizen petition the same day that it takes another agency action on the subject, particularly when the FDA has delayed its response beyond the 180-day statutory deadline. In the case of mifepristone, the FDA replied to the 2002 Petition and the 2019 Petition on the same date it announced the 2016 Amendments and the 2021 Actions, respectively.[286] This strategy is not reserved for responses to more politically contentious petitions—for 505(q) petitions, the FDA will also often deny a manufacturer's petition on the same day that it grants generic approval. Although this strategy may be efficient from the FDA's perspective, it leads to improperly delayed responses with no public-facing explanation for the delay. To combat arguments that the FDA has intentionally and improperly delayed its responses, where the FDA intends to make such a simultaneous decision, it should be required to justify why the decisions were released on the same day with an explanation other than convenience.[287] Professor Michael Carrier has posited that simultaneous rulings are a tactic employed by the FDA to reduce the likelihood it is sued; if the FDA denies a 505(q) petition before a generic is approved, the petitioner could seek judicial review of the decision.[288] Although it is understandable why the FDA would seek to minimize litigation, the FDA should not intentionally delay petition responses to do so without explanation.

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[284] *See* OIG July 1998 Review, *supra* note 57.

[285] *Id.* at 4–8.

[286] *See* All. for Hippocratic Med. v. U.S. Food & Drug Admin., 668 F. Supp. 3d 507, 520–31 (N.D. Tex. 2023).

[287] *Id.*

[288] Carrier, *supra* note 46, at 343.

The FDA could make significant strides in public accessibility of the citizen petition process without additional congressional action by creating a centralized location where all citizen petition dockets can be viewed. A public-facing display of this data is authorized by current regulations and could be accomplished without further action from Congress, though additional funding to complete such a project might be required. Currently, only two FDA centers publish aggregate citizen petition data on their webpages.[289] As part of these records, the FDA should also provide information on the current status of petitions (a publicly accessible record of delayed petitions), and where possible, provide petitioners with a justification for any delays. To better communicate with petitioners, Congress should require the FDA to write petitioners if the petition is still outstanding 180 days after submission, to provide a substantive justification for the delay and an approximate time frame for when the petitioner will receive a response.[290]

Further action from Congress may be needed, however, to make additional, more permanent improvements to the timeliness of the citizen petition process (as the FDA's internal processes are subject to change with leadership changes). One reasonable proposal could involve requiring the FDA to submit annual reports to Congress detailing the volume and status of citizen petitions before the agency. A similar mechanism, involving 505(q) petitions filed by innovator manufacturers to challenge ANDA applications from their generic manufacturer competitors, has been met with great success. To address concerns about how citizen petitions might lead to delays in new drug approvals, Congress amended the FDCA in 2007 to require the FDA to submit an annual report to Congress including the total number of ANDAs, the number of ANDAs delayed by 505(q) citizen petitions, the number of days by which ANDAs were delayed, and the number of 505(q) petitions that were submitted during the reporting year.[291] Following enactment of this requirement, the FDA has substantially met the statutory deadlines for its responses to 505(q) petitions by responding to all petitions that were not withdrawn by the end of a fiscal year

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[289] The Center for Tobacco Products and the Center for Devices and Radiological Health both have public-facing displays of citizen petitions. *See CDRH Petitions*, U.S. FOOD & DRUG ADMIN. (Feb. 16, 2025), https://www.fda.gov/about-fda/cdrh-foia-how-get-records-cdrh/cdrh-petitions [https://perma.cc/M2CK-4F2C]; *Tobacco Products-Related Citizen Petitions*, U.S. FOOD & DRUG ADMIN. (Feb. 16, 2025), https://www.fda.gov/tobacco-products/products-guidance-regulations/tobacco-products-related-citizen-petitions [https://perma.cc/73SK-AGFG].

[290] *See generally* Michael A. Carrier, *Five Actions to Stop Citizen Petition Abuse*, 124 COLUM. L. REV. F. 1 (2024), https://columbialawreview.org/content/five-actions-to-stop-citizen-petition-abuse-2/ [https://perma.cc/5BZ9-WU6Y]. Carrier discusses the need for more transparent measures to reduce abuse of 505(q) petitions that contribute to potential delays in generic drugs. Similar measures would be beneficial in improving understanding of the citizen petition process for all types of citizen petitions.

[291] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 957 (codified in scattered sections of 5, 18, 21, and 42 U.S.C.); U.S. FOOD & DRUG ADMIN., Fifteenth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action, *supra* note 61.

and by replying to "generally" all of the petitions within the requisite 150 days.[292]

Instituting a similar mechanism for *all* citizen petitions could be highly effective in both improving timeliness of responses and increasing transparency to Congress on petitions received in a year. Although the 505(q) amendments have been effective in improving the timeliness of the FDA's responses, the FDA has noted that completing 505(q) petitions on this schedule has taken resources away from other agency actions.[293] Therefore, in order to receive similar success with a larger program, increased funding (and an OIG review of how each center allocates their funding) may be required.

VI. CONCLUSION

Alliance for Hippocratic Medicine revealed longstanding flaws in the FDA's citizen petition process that must be remedied. The inefficiencies and delays in the current system not only undermine the trust of petitioners in the FDA, but also create an opportunity for activists or competitors to use judicial review to their advantage. Although ultimately mifepristone's approval was not withdrawn as a result of this judicial review, it is likely that future parties will attempt similar strategies to challenge FDA decisions and drug approvals. Noncompliance is certainly an option, but the FDA and Congress should instead be proactive in improving the citizen petition process, the FDA's internal processes, and judge shopping considerations so citizen concerns can be heard and addressed by those who are best equipped to assess them.

[292] *See id.* at 5. The FDA has not released data on how many of these petitions were responded to within 150 days, and only states that it has "generally" met its statutory deadlines vis-à-vis 505(q) petitions.

[293] *See id.*