THE CONSERVATIVE COURT ON THE UNACCEPTABLE PERILS IN SECOND-GUESSING FDA SAFETY DECISIONS AND ITS COMING REVIEW OF *ALLIANCE FOR HIPPOCRATIC MEDICINE V. FDA* ("THE ABORTION PILL CASE")

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The August 2023 decision of the Fifth Circuit in Alliance for Hippocratic Medicine v. FDA *(hereinafter* AHM*) nullifying the changes the Food and Drug Administration (FDA) made in 2016 and 2021 to its Risk Evaluation and Mitigation Strategy (REMS) governing the use of mifepristone (the principal abortion medication in the United States) — sets up the most significant Supreme Court case on judicial review of an action by the FDA. The stakes are huge. If not reversed by the Supreme Court, the Fifth Circuit's ruling will severely restrict access to mifepristone, not only for women living in the seventeen states that effectively ban abortion within their borders, but also in the thirty or so others that want their residents to have the option of medicated abortion but whose doctors will be forced to obey restrictions the FDA has long determined are both unwarranted and unwise.*

When the Justices turn to decide AHM *this spring, they should recall a series of decisions in which the Court — and especially its more conservative members (Justices Roberts, Alito, Kavanaugh, and Thomas) — warned that no judge or Justice should "second-guess" such scientific judgments, which FDA experts make every day with respect to every drug the Agency regulates. Indeed, the Court applied that rule and repeated that warning only three years ago when it expressly deferred to a judgment the FDA had made with respect to the appropriate distribution of mifepristone.*

By contrast, the Fifth Circuit judges ignored that Supreme Court case law in upending the last seven years of FDA regulation with respect to mifepristone. And they did so without any regard for the FDA's reasoned analysis which sought to assure meaningful access to the drug — one of the specific obligations imposed on FDA by Congress.

This Article examines the Supreme Court warnings on the dangers of such judicial second-guessing of FDA drug safety determinations and details the history of the most important modifications FDA made to its mifepristone REMS in 2016 and 2021 by: (1) extending the deadline for using the drug (from seven weeks after gestation, which expired before most women confirm they are pregnant, to a more realistic ten weeks); and (2) eliminating the requirement for three separate, in-person office visits to obtain and use the drug, thus permitting telehealth

prescription that is now standard. The Article then parses the Fifth Circuit's rulings on those two critical issues, detailing how the panel failed to consider the controlling Supreme Court cases and to refute (or even acknowledge) the FDA's analysis of the relevant scientific and medical data.

The Article concludes by returning to the individual Justices who authored the contrary "deferential" case law and assesses the likelihood that they will apply those prior opinions in a consistent and intellectually honest manner to reverse the Fifth Circuit's profound intrusion on the authority and expertise of the FDA.

INTRODUCTION

The Fifth Circuit's recent decision in *Alliance for Hippocratic Medicine v. FDA*[1] ("*AHM*") — the lawsuit seeking to overturn FDA's approval and regulation of mifepristone, the primary abortion medication — has revived the national pastime of speculating on the most likely division of the Justices now that the case has reached the Supreme Court. Most commentators in the press, academia, and the world of politics have focused on the Justices' prior pronouncements with respect to abortion itself — most notably, their contradictory opinions in *Dobbs*.[2] And it is possible that, when the Court ultimately decides *AHM*, the political and religious views of one or more of the Justices may overwhelm the result they would have reached if they instead did what they have all sworn to do — "faithfully and impartially" decide cases without such personal bias.[3]

But if one assumes that intellectual honesty and respect for precedent still motivate a majority on the Court, it becomes important to review what the Justices have said on the overarching *legal* issue in *AHM* — the extent to which *any* judge or Justice should defer to the scientific and medical judgments that FDA makes *every* time it approves or regulates *any* drug. When that is done, one finds that the current Justices (*especially the more conservative ones*) have consistently insisted that such judicial deference is essential — both because that is what the Food, Drug and Cosmetic Act contemplates *and* because that makes good sense given the relative expertise of FDA scientists, who have devoted their entire careers to such questions, versus judges who, at most, may spend a few days every few years considering such issues.

It turns out that the most vocal champion of such judicial deference to the FDA is Justice Alito. And while it may take a true Pollyanna to believe he would vote to preserve any FDA action that makes an abortion medication more accessible, his opinions advocating virtually complete

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[1] All. for Hippocratic Med. v. FDA, 78 F.4th 210 (5th Cir. 2023), *cert. granted*, 144 S. Ct. 537 (2023) (No. 23-235).

[2] *See* Dobbs v. Jackson Women's Health Organization, 142 S. Ct. 2228 (2022).

[3] 28 U.S.C. § 453.

judicial deference to the FDA on matters of drug safety have been echoed by other conservative, Republican-appointed Justices — most notably, Chief Justice Roberts and Justice Kavanaugh. It would take only two of the conservative Justices — together with three pro-choice Justices (Justices Sotomayor, Kagan, and Jackson) — to reach the magic number five.

Although it is fashionable to assess such permutations by focusing on the political, philosophical, or personal views of the Justices, this Article takes the more traditional approach of recounting, in Part I, the specific judgments the FDA has made over the past twenty-five years on the benefits and risks of mifepristone; reviewing, in Part II, the Supreme Court case law on the proper approach to such FDA safety determinations; and then assessing, in Parts III-VI, the Fifth Circuit's decision under those two essential elements of any principled judicial review of FDA action. When that is done, it seems clear that *if* the Justices — most notably, two of those three "deferential" conservative Justices — *follow their own prior opinions*, the Fifth Circuit's decidedly *non-deferential* rulings should be reversed.[4]

I. FDA'S DEVELOPMENT OF THE MIFEPRISTONE REMS

From the "real-world" standpoint of doctors and their patients, the most significant rulings of the Fifth Circuit in *AHM* are its nullification of FDA decisions, from 2016 through 2021, in which the Agency revised its Risk Evaluation and Mitigation Strategy (REMS) for mifepristone by: (1) extending the period in which a patient can take the drug, from an often impractical seven weeks after gestation to a more reasonable ten weeks; and (2) allowing a patient to obtain the drug through "telehealth" means, without multiple in-person doctor visits. Taken together, those two rulings, if not reversed by the Supreme Court, will materially restrict the use of mifepristone — not only in the seventeen states that now effectively ban abortions within the ten weeks the FDA has set for the use of mifepristone, but also in the thirty or so others (which are home to about sixty percent

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[4] The Fifth Circuit's August 2023 decision presents other issues that could also warrant reversal, including the questionable standing of the plaintiffs, which the court of appeals found in the "conscience rights" of doctors who oppose abortion on religious grounds; the impact of the statute of limitations on some very stale claims; and the plaintiffs' failure to exhaust administrative remedies on more recent ones. Indeed, the majority opinion spent three times as many pages on those threshold issues as it did on the merits of the FDA actions that the court then overturned. *Compare All. for Hippocratic Med.,* 78 F.4th at 228-45, *with id.* at 246-51.

The Fifth Circuit's conclusion that those procedural problems did not preclude it from nullifying the FDA's decisions may well strike a classical conservative as unbridled "activism." That is for others to debate. We focus here on the more fundamental flaw in the Fifth Circuit's opinion — its disregard of the case law insisting on judicial deference to FDA safety decisions, even where they are *properly* before a reviewing court.

of all Americans) that do not ban abortions, at least during that ten-week period.[5]

We begin our discussion with a brief chronology of the twenty-five years it took the FDA to fashion the current REMS for mifepristone which (as Congress has mandated) balances reasonable access to the drug's benefits with appropriate safeguards for its use.

In the mid-1990's — after initially banning the importation of mifepristone (then known as RU-486) from Europe — the FDA began to evaluate the drug's suitability for American women. In 1996 the FDA submitted the available data on mifepristone's efficacy and safety to its Reproductive Health Drugs Advisory Committee — a panel of outside experts the Agency uses as part of its approval process. That panel concluded that mifepristone was "safe and effective" (the statutory requirement for all new drugs) when used to terminate a pregnancy.[6]

In 2000, the FDA formally approved mifepristone for that use under the brand name Mifeprex. The initial Mifeprex label, also approved by FDA, recommended that the drug be taken within seven weeks of gestation and that a patient make three separate visits to meet with the prescribing physician — the first to determine whether she was pregnant and to take the opening dose of mifepristone, the second to obtain and take a second drug, misoprostol, and the third to follow-up after the completion of the abortion.[7]

Danco Laboratories, the initial American supplier, then began to market the drug in 2002. That prompted various anti-abortion groups, including the American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG"), to file a citizen petition asking the FDA to suspend distribution on the grounds that the Agency's approval was invalid for a number

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[5] Although the state line-up is constantly changing as a result of legislation, referenda, and judicial rulings, at the moment Alabama, Arkansas, Georgia, Idaho, Indiana, Kentucky, Louisiana, Mississippi, Missouri, North Dakota, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, West Virginia, and Wisconsin effectively ban abortion in any form, either at gestation or at six weeks (which, as discussed below, typically makes securing a medication abortion impossible). Litigation is currently pending in six more states (Arizona, Florida, Iowa, Ohio, Utah, and Wyoming) where such a ban has been enacted but is temporarily enjoined. *Abortion in the United States Dashboard*, KAISER FAM. FOUND., https://www.kff.org/womens-health-policy/dashboard/abortion-in-the-u-s-dashboard/ (last visited Dec. 20, 2023).

[6] Food and Drug Administration ("FDA"), Reproductive Health Drugs Advisory Committee, Hearing on New Drug Application for Use of Mifepristone for Interruption of Early Pregnancy (July 19, 1996), Tr. 246-50.

[7] 2000 MIFEPREX LABEL. The initial dose of mifepristone prevents attachment to the patient's uterine wall; the misoprostol, taken a few days later, produces contractions which expel the uterine contents.

of reasons, including many of the same objections AAPLOG is now litigating in *AHM*.[8]

When the FDA did not respond promptly to AAPLOG's petition, it and other anti-abortion groups sought congressional review of *all* of FDA's prior decisions concerning mifepristone. In 2007, FDA's regulation of the drug became a focal point during Congress' enactment of amendments to the FDCA (the Food and Drug Administration Amendments Act ("FDAAA")). One of those amendments authorized the FDA to promulgate a REMS for a drug whenever the Agency concludes heightened regulation is necessary to insure its safe use, as assessed by a number of factors Congress also set forth in the legislation.[9] As discussed below, two of those statutory provisions direct the FDA to ensure that a REMS will not be "unduly burdensome on patient access to the drug" and, "to the extent practicable, minimize the burden on the healthcare delivery system."[10]

During the floor debate on the REMS legislation, Senator Jim DeMint (R-N.C.), an avowed abortion opponent, insisted that mifepristone be one of the first drugs subjected to such heightened restrictions.[11] And in 2011 the FDA issued its first REMS for the drug, which, *inter alia,* restated the prescription limits that the FDA had put in the initial Mifeprex label, including the seven-week deadline on its use and the requirement of three physician office visits.[12]

In 2015, Danco, following other provisions in the FDAAA, proposed a modification of the original mifepristone REMS based on the first thirteen years of American use, as well as more recent clinical studies establishing the drug's safety. After a year of review by a number of FDA teams, in March 2016 the Agency issued a new REMS, supported by eighty-nine single-spaced pages analyzing more than 100 clinical studies.[13]

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[8] American Association of Pro-Life Obstetricians and Gynecologists et al., *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*, (2002), https://aaplog.org/wp-content/uploads/2021/01/2002-Aug-Citizen-Petition_Mifeprex-8.20.02.pdf.

Although the first-named plaintiff in *AHM* is the Alliance for Hippocratic Medicine (a group incorporated in August 2022 within the Northern District of Texas, presumably to establish venue before a federal judge with a history of anti-abortion views), AAPLOG, the next-named plaintiff, appears to be the driving force in the case. As discussed below, many of the FDA's decisions on mifepristone responded to citizen petitions filed by AAPLOG and its executive director, Donna Harrison, M.D.

[9] 21 U.S.C. § 355-1(a)(1).

[10] 21 U.S.C. § 355-1(f)(5)(A).

[11] 153 CONG. REC. 5469, 5470 (2007).

[12] FDA, *Mifeprex Risk Evaluation and Mitigation Strategy* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf.

[13] FDA, Center for Drug Evaluation & Research, *Mifeprex Medical Review, Application Number: 020687Orig1s020* (2016) [hereinafter *2016 Medical*

As revised in 2016, the REMS extended the period of use to ten weeks. And, although the revised REMS continued to require healthcare providers to oversee the opening dose of mifepristone in their office, it no longer dictated where patients should subsequently take the misoprostol pills.[14]

Anti-abortion members of Congress then referred the FDA's actions to the Government Accountability Office (GAO), an investigatory agency under the control of Congress. Specifically, the House subcommittee overseeing the FDA "questioned whether the revised Mifeprex labeling has safety implications for women who use the drug."[15]

In 2018 GAO responded with a report focused on the FDA's decisions to extend the period for use to ten weeks and to eliminate the requirement that the misoprostol component be taken at a medical office. GAO found that those revisions were supported by "numerous" clinical studies of use by 45,000 women.[16]

In March 2019, AAPLOG filed another citizen petition, now requesting that the Agency reverse the 2016 REMS revisions, most notably by reducing the period of use back to seven weeks and reinstating the second (misoprostol) and third (post-abortion) office visits.[17] While FDA was reviewing that new petition, the COVID-19 pandemic prompted FDA to waive in-person office visits as to virtually all drugs. As detailed below, the Agency nevertheless maintained the initial office-visit requirement as to mifepristone. But, in April 2021, as the pandemic continued into its second year, the FDA announced that it was exercising "enforcement discretion" to waive that requirement as to mifepristone as well, at least during the public health emergency.[18]

Over the remainder of 2021, the FDA made another full review of the mifepristone REMS — now including the growing American data on telehealth prescription of the drug — in response to the 2019 AAPLOG citizen petition. Following that review, the FDA issued a forty-page denial of the AAPLOG petition, specifically rejecting their request to reduce the use period to seven weeks and to re-impose the second and third in-person

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Review], https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

[14] FDA, 2016 MIFEPREX LABEL, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020Lbl.pdf.

[15] U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-292, FOOD AND DRUG ADMINISTRATION: INFORMATION ON MIFEPREX LABELING CHANGES AND ONGOING MONITORING EFFORTS (Mar. 2018), https://www.gao.gov/assets/gao-18-292.pdf.

[16] *Id*. at 12-14.

[17] AAPLOG, *Citizen Petition,* AAPLOG (Mar. 29, 2019), https://aaplog.org/wp-content/uploads/2021/01/Citizen-Petition-Final-FDA-Mif-REMS.pdf.

[18] Janet Woodcock, *Letter from Janet Woodcock, M.D. to Maureen Phipps*, 1, at 2 (Apr. 12, 2021), https://www.aclu.org/sites/default/files/field_document/fda_acting_commissioner_letter_to_acog_april_12_2021.pdf.

visits.[19] Moreover, FDA announced that it had now decided that the initial office visit "was no longer necessary to assure the safe use of mifepristone," adding that "[r]emoving the in-person dispensing requirement will render the REMS less burdensome to health care providers and patients *and . . . will continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks*."[20]

Finally, on January 3, 2023, the FDA promulgated a revised REMS incorporating all of its prior decisions.[21] That current REMS adds a few new requirements which healthcare providers must satisfy to be certified to prescribe mifepristone.[22] But in-person office visits are no longer necessary.

II. THE SUPREME COURT CASE LAW ON THE IMPORTANCE OF JUDICIAL DEFERENCE TO FDA

In contrast to the Fifth Circuit's apparent belief that it was entitled to review and reverse the safety determinations of FDA virtually *de novo,* Supreme Court Justices, past and present, have repeatedly called for "reasoned deference" to the scientific and medical judgments of the Agency *and* have conversely warned against judicial "second-guessing" of FDA safety decisions by "non-expert" judges. [23]

With respect to the current members of the Court, those warnings began in 2009 in *Wyeth v. Levine*.[24] There the Court considered whether a tort lawsuit claiming inadequacies in a drug label had been preempted by FDA's apparent tolerance of the allegedly defective warning. Although a majority of the Court held that the drug manufacturer had not established the requirements of "conflict preemption" under the Supremacy Clause — because, in that particular case, the FDA had not taken any action on the label for many years — Justice Alito, writing in dissent for Justices Roberts and Scalia as well, argued at length that judicial deference to FDA safety determinations is essential.

Citing a review of the allegedly defective label by an FDA Advisory Committee (not the FDA itself) *24 years before the facts at issue in Levine*,

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[19] Patrizia Cavazzoni, *Letter from Patrizia Cavazzoni, M.D. to Donna Harrison, M.D.*, 1, at 6, 7-9, 12-18 (Dec. 16, 2021) [hereinafter *FDA Response to 2019 Citizen Petition*] (emphasis added), https://downloads.regulations.gov/FDA-2019-P-1534-0016/attachment_1.pdf.

[20] *Id*.

[21] *See* FDA, *Mifeprex Risk Evaluation and Mitigation Strategy* (Jan. 3, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf.

[22] *See id.* at 1-2.

[23] *See* Wyeth v. Levine*,* 555 U.S. 555, 609-12 (2009); Mutual Pharm. v. Bartlett*,* 570 U.S. 472 (2013); Merck Sharpe & Dohme v. Albrecht, 139 S. Ct. 1668, 1672 (2019); FDA v. Am. Coll. of Obstetricians*,* 141 S. Ct. 10 (2020); FDA v. Am. Coll. of Obstetricians, 141 S. Ct. 578 (2021) (Roberts, C.J., concurring).

[24] *Wyeth*, 555 U.S. at 609-12.

Justice Alito contended that even such sparse and dated administrative consideration preempted any "second-guessing" of FDA's position. In language that would certainly seem to apply to the ruling of a district judge upending repeated, and recent, FDA judgments on the appropriate use of a drug (e.g*.,* mifepristone), Justice Alito argued that such deference is warranted by the FDA's unique role in balancing the benefits and risks of all drugs — drugs which, as the FDA knows better than anyone, will heal many but harm (or even kill) some.[25]

As a predicate for his argument that the courts should defer to FDA on its safety determinations, Justice Alito provided a lengthy review of the FDA's extensive authority (and corresponding expertise) in approving and subsequently regulating all aspects of any drug. [26] That regulation begins with FDA's evaluation of each drug based on years of clinical testing. A company seeking FDA approval must follow a score of detailed regulations to obtain sufficient clinical evidence to establish the safety and efficacy of a proposed drug product,[27] which is then assembled in a New Drug Application (NDA) running thousands of pages.[28] The FDA evaluates that data (along with relevant public literature and often prior overseas use) through a wide range of disciplines including medicine, chemistry, statistics, risk assessment and labeling,[29] and then approves or disapproves the application.[30]

As Justice Alito also outlined in *Levine,*[31] the FDA must likewise approve every word, punctuation mark and typeface in the label that accompanies a drug product and thereby governs its use. Often, the FDA itself crafts the final language. Every approval letter from the FDA incorporates that label — and no deviations are permitted. Thereafter, the FDA requires manufacturers to modify their labels whenever there is even an "association" between the drug and some new hazard.[32]

The depth and breadth of this regulatory regime make clear that the FDA's control over pharmaceuticals is not a one-time, binary choice between approval or prohibition, but rather requires the Agency to impose nuanced regulation which is revised on a continual basis to take account of new data. And, to Justice Alito and his conservative colleagues in *Levine,* that was more than sufficient to convince them that courts should

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[25] *Id.* at 626 (Alito, J., dissenting).

[26] *Id.* at 607-08.

[27] FDA, *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* (May 1998), https://www.fda.gov/media/71655/download.

[28] FDA, *New Drug Application (NDA)*, FDA (Jan. 21, 2022), https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

[29] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 505(d)-505(e) (1938).

[30] 21 C.F.R. § 314.110 (2021).

[31] *Wyeth*, 555 U.S. at 608 (Alito, J. dissenting).

[32] 21 C.F.R. § 201.57(e) (2021).

defer to the FDA's scientific determinations rather than "second-guess" them.[33]

Four years later, in *Mutual Pharmaceutical v. Bartlett*,[34] that deference of the conservative Justices to the FDA's expertise grew to command a majority of the Court, in an opinion again written by Justice Alito. *Bartlett* involved the conflict between FDA drug approval and "design defect" law, which ostensibly permits a judge or jury to find that a drug is "unreasonably dangerous" because "the usefulness and desirability of the product to the public as a whole" is outweighed by its risks.[35]

Writing for the majority of the Court (and *all* of the other Republican-appointed Justices — Roberts, Thomas, Scalia, and Kennedy), Justice Alito detailed the extent to which the FDA regularly makes just such balances between the safety and efficacy of a drug and precludes manufacturers from making differing choices to satisfy subsequent courts.[36] Again Justice Alito and the other conservative Justices warned that second-guessing in the courts would undermine such FDA determinations in a way Congress never countenanced.[37]

In 2019 the Court again considered the appropriate deference to be accorded to FDA safety determinations in *Merck Sharpe & Dohme v. Albrecht*.[38] The discrete issue there was whether a judge or jury should be the one to decide whether a tort lawsuit conflicts with some prior FDA decision — in which case, the lawsuit is preempted. A unanimous Court held that procedural question was for judges to resolve.[39]

But, despite that unanimity on that narrow issue, Justice Alito — now writing a concurrence for Chief Justice Roberts and Justice Kavanaugh as well — felt compelled to warn once again that *any* second-guessing of FDA safety determinations is fundamentally wrong. Indeed, Justice Alito and his conservative colleagues argued that an FDA "decision" on how a drug should be regulated must be respected *even when the Agency took no specific action with respect to the risk at hand*.

Justice Alito conceded that, although the FDA had been advised of the need for a revised label to warn of a newly discovered risk, the Agency had not approved any such revision prior to the injuries at issue. Nevertheless, Justice Alito insisted that even such "knowing *inaction*" by FDA cannot be questioned in a subsequent judicial proceeding: "[I]f the FDA declines to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified."[40] To buttress his argument

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[33] *Wyeth*, 555 U.S. at 608 (Alito, J., dissenting).
[34] Mutual Pharm. v. Bartlett, 570 U.S. 472 (2013).
[35] *Id*. at 483.
[36] *Id*. at 483-86.
[37] *Id*.
[38] Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019).
[39] *Id.*
[40] *Id*. at 1684 (Alito, J., concurring).

for such deference to FDA decisions (or even "knowing inaction"), Justice Alito quoted a much older Supreme Court case holding that, "[t]he presumption of regularity supports the official acts of public officers and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties."[41] Judicial "second-guessers" need not apply.

Last, but by no means least, we have the opinions and votes of all of the current Justices (save Justice Jackson) in the 2020 litigation over the initial in-person office visit requirement which FDA was then enforcing only as to mifepristone, once the COVID-19 pandemic had made clear such visits would be at least burdensome and perhaps dangerous. In *FDA v. American College of Obstetricians and Gynecologists* ("*ACOG*"), the medical board which sets the national standards for OB-GYN care sued to force the FDA to suspend that requirement in the then-existing (2016) mifepristone REMS. Judge Theodore Chuang of the District of Maryland initially ruled that the problems inherent in requiring in-person office visits justified an injunction to make mifepristone equally available for as long as the pandemic lasted. Judge Chuang came to that conclusion in large part because the FDA had offered no analysis at all to support its decision to treat mifepristone differently from all other drugs, where the Agency was actively encouraging "telehealth" prescriptions.[42] But, as discussed below, the Supreme Court reversed Judge Chuang, with the Justices — especially the more conservative ones — once again warning that federal judges must defer to FDA safety determinations (even when they are not supported by any published analysis).

Given that the Fifth Circuit's decision in *AHM* deals with the same office-visit requirement with mifepristone, *ACOG* deserves a closer look. In his initial July 2020 ruling on ACOG's motion for preliminary injunction, Judge Chuang held that the FDA's position maintaining the in-person office visits was entitled to only "limited deference"[43] because the Agency had not presented any analysis to show that it had considered the exigencies created by the pandemic when it came to the use of mifepristone (and mifepristone alone). In reaching that result, Judge Chuang did not reject the totality of FDA's prior analyses on the issue.[44] Instead he found that the FDA's REMS requiring the in-person visit was "dated and did not take account of intervening events," including the FDA's own 2016 finding that in-home use of misoprostol was safe.[45] Judge Chuang likewise stressed that the FDA had "acknowledged at the hearing on the [preliminary

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[41] *Id*. at 1684 (Alito. J., concurring) (quoting *United States v. Chemical Foundation, Inc.,* 272 U.S. 1, 14-15 (1926)).

[42] Am. Coll. of Obstetricians and Gynecologists v. FDA, 472 F.Supp.3d 183, 221 (D. Md. 2020).

[43] *Id.* at 219.

[44] *Id.*

[45] *Id*.

injunction] Motion, [that] . . . , FDA did not consider the use of telemedicine in any way, presumably because it was not frequently used at the time."[46]

Nor, as Judge Chuang noted, had the FDA provided any evidence to support the Agency's position during its subsequent presentations to the court. In contrast to the expert declarations submitted by ACOG, which had detailed the burdens and dangers of insisting on in-person office visits during the pandemic, the FDA

> offered no evidence demonstrating that telemedicine counseling sessions are ineffective or insufficient for communicating information about the risks or alternatives to medication abortion. The 2013 and 2016 FDA reviews do not address this issue. If anything, the 2016 [REMS] review revealed that . . . the Patient Agreement Form that is the subject of the In-Person Signature Requirement is "duplicative and no longer necessary to ensure that the benefits of the drug outweigh the risks."[47]

Judge Chuang therefore preliminarily enjoined the FDA from enforcing the in-person visit requirement as to mifepristone until the federal government declared the COVID-19 Emergency was over.[48]

The Government went directly to the Supreme Court, seeking a stay of Judge Chuang's injunction. In October 2020, the Court issued a brief, unsigned order advising that the Justices felt a more complete record should be compiled in light of the rapidly changing public health crisis (thus allowing FDA one more opportunity to provide *some* analysis or evidence justifying its refusal to waive the in-person requirement solely as to mifepristone).[49] The Supreme Court said it would hold the Government's motion against the district court's injunction "in abeyance" to give the parties and Judge Chuang an opportunity to "consider a motion by the Government to dissolve, modify, or stay the injunction."[50]

That initial Supreme Court order — postponing a ruling on the merits but maintaining the preliminary injunction for a few more weeks — drew a sharp rebuke from Justice Alito (joined by Justice Thomas). They were appalled that the other Justices were "refus[ing] to rule" in a manner that would defer to the FDA on an issue involving "the safety and health of the people."[51]

To support his position, Justice Alito quoted Chief Justice Roberts' concurrence a few months earlier in *South Bay United Pentecostal Church*

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[46] *Id*.
[47] *Id.* at 220.
[48] *Id*. at 232-33.
[49] FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 10 (2020).
[50] *Id.* at 11.
[51] *Id*. at 11-12.

v. Newsom,[52] where the Court had upheld a governor's decision to close places of worship during the pandemic, stressing the need for judicial deference to public health officials:

> Our Constitution principally entrusts "[t]he safety and the health of the people" to the politically accountable officials of the States . . . . When those officials "undertake to act in areas fraught with medical and scientific uncertainties," their latitude "must be especially broad." Where those broad limits are not exceeded, *they should not be subject to second-guessing by an "unelected federal judiciary" which lacks the background, competence, and expertise to assess public health and is not accountable to the people.*[53]

Justice Alito (with Justice Thomas) then argued, in their own words, that Judge Chuang was wrong in not deferring to the FDA's judgment on the safest way to prescribe mifepristone:

> [A] District Court Judge in Maryland took it upon himself to overrule FDA on a question of drug safety. Disregarding the Chief Justice's admonition against judicial second-guessing of officials with public health responsibilities, the judge concluded that requiring women seeking a medication abortion to pick up mifepristone in person during the COVID-19 pandemic constitutes an "undue burden" on the abortion right, and he therefore issued a nationwide injunction against enforcement of the FDA's requirement.[54]

After the case was remanded, Judge Chuang re-opened the record for any further evidence on the appropriateness of the FDA's insistence on office visits solely with mifepristone. But the Government still did not provide any analysis setting forth any scientific or medical grounds to treat mifepristone differently from other drugs. Instead, the FDA submitted declarations from various state officials asserting that the worst of the pandemic was over (as of December 2020).[55] Judge Chuang, however, relied on the CDC's most recent tally of new COVID cases, showing that the weekly count had actually tripled in the six months since his initial

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[52] S. Bay United Pentecostal Church v. Newsom, 140 S. Ct. 1613 (2020) (Roberts, C.J., concurring).

[53] *Id.* at 1613-1614 (quoting Jacobson v. Massachusetts*,* 197 U.S. 11, 38 (1905); Marshall v. United States*,* 414 U.S. 417, 427 (1974); Garcia v. San Antonio Metropolitan Transit Authority*,* 469 U.S. 528, 545 (1985) (emphasis added).

[54] Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. at 12.

[55] Am. Coll. of Obstetricians & Gynecologists v. FDA*,* 506 F.Supp.3d 328, 334-35 (D. Md. 2020).

decision.[56] He therefore issued a new order maintaining his preliminary injunction for the duration of the pandemic.

But despite the complete absence of any FDA analysis to justify treating mifepristone differently from other drugs, when the case returned to the Supreme Court, the Justices issued another unsigned order, this time staying (and thus effectively reversing) Judge Chuang's preliminary injunction. Chief Justice Roberts wrote a concurrence re-affirming the position he had taken in *South Bay Pentecostal* — but now specifically with respect to an FDA decision on the proper administration of mifepristone — that the "courts owe significant deference to the politically accountable entities with 'background, competence, and expertise to assess public health.'"[57] And the other conservative Justices (now including Justice Barrett) all likewise voted to reverse a federal district judge who had not so deferred to the FDA on how mifepristone should be prescribed and administered.

For their part, dissenting Justices Sotomayor and Kagan also agreed that "deference is due to reasoned decisions of public health officials grappling with a deadly pandemic."[58] But they concluded that such deference was not justified in *ACOG* because FDA had "not submitted a single declaration from an FDA or HHS official explaining why the Government believes women must continue to pick up mifepristone in person, even though it has exempted many other drugs from such a requirement given the health risks of COVID-19. *There simply is no reasoned decision here to which this Court can defer.*"[59]

III. THE PROCEEDINGS BELOW IN *AHM*

In contrast to the repeated pronouncements of the Supreme Court Justices on the importance of judicial deference to FDA safety determinations, the decisions of the lower courts in *AHM* have been decidedly non-deferential. In the space of four months, the safety judgments of the FDA were voided, not once, but three times — first by District Judge Matthew Kacsmaryk and then twice more by panels of the Fifth Circuit. None of those decisions acknowledged any of the Supreme Court opinions addressing the proper way FDA safety decisions are to be reviewed and respected.

In his initial April 7, 2023 ruling, which overturned *every one* of the FDA decisions challenged by the plaintiffs (from the Agency's initial approval of mifepristone in 2000 through the 2016 and 2021 REMS

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[56] *Id*. at 336.

[57] FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring) (quoting S. Bay United Pentecostal v. Newsom*,* 140 S. Ct. 1613,1614 (2020)).

[58] *Id*. at 584 (Sotomayor, J., dissenting).

[59] *Id*. at 584-85 (emphasis added). *See also id.* at 579 (Sotomayor, J., dissenting) ("Of the over 20,000 FDA-approved drugs, mifepristone is the only one that the FDA requires to be picked up in-person for patients to take at home.").

revisions), Judge Kacsmaryk did not mention any of those Supreme Court cases. The *only* case he cited on the ground-rules for judicial review of FDA safety determinations was a nearly forty-year-old decision of the Seventh Circuit which had *upheld* the FDA's judgment.[60]

To be sure, Judge Kacsmaryk at one point conceded that he was indeed "second-guessing" the FDA safety determinations and acknowledged that he should not do so "lightly."[61] But he nevertheless concluded that he was in a better position — after a month's review of a small fragment of the twenty-five-year administrative record — to decide that the balance the FDA had struck between access to, and safety of, mifepristone was "arbitrary and capricious" — and to enjoin those Agency decisions nationwide.[62]

The Fifth Circuit motions panel, which quickly issued a revised injunction, also nullifying the safety determinations the FDA had made from 2016 through 2021, said little more on the way courts should approach such scientific assessments by an expert agency. Like Judge Kacsmaryk, the motions panel ignored the "deferential" Supreme Court opinions which had addressed FDA safety decisions, relying instead on cases involving the actions of other agencies, such as the NTSB and EPA, which had completely ignored some important issue that was controlling under the operative statute.[63]

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[60] All. for Hippocratic Med. v. FDA, 668 F.Supp.3d 507, 550 (N.D. Tex.) (citing United States v. An Article of Device…Diapulse, 768 F.2d 826, 832-33 (7th Cir. 1985)).

[61] *Id.* at 554.

[62] *Id.* at 549, 560.

[63] *See* All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 2913725, at *16-17 (5th Cir. Apr. 12, 2023).

A review of the cases cited by Judge Kacsmaryk, and later the Fifth Circuit, plainly shows they do not support his admitted "second-guessing" on the scientific issues analyzed in detail by FDA in its decisions as to mifepristone).

In *Motor Vehicle Mfrs. Assn v. State Farm Mutual Auto Ins. Co.,* 463 U.S. 29 (1983), the principal case cited by the courts, the Supreme Court invalidated the Department of Transportation's (DOT) complete recission of an automotive passive restraint standard where DOT "apparently gave no consideration whatever to [the alternative of] modifying the [existing] Standard . . . ." *Id.* at 46. In arriving at that result, the Court took pains to hold (in a passage ignored by the courts below) that, "[t]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Id.* at 43. The *State Farm* Court expressly recognized that an agency is not subject to judicial reversal under the "arbitrary and capricious" standard where the agency has "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action . . . . " *Id.*

In *Michigan v. EPA*, 567 U.S. 743 (2015), the Court similarly held only that EPA's issuance of restrictions on power plant emissions, which "gave no . . . thought *at all*" to the cost of complying with the new standards, was arbitrary and capricious. *Id.* at 750-51 (emphasis in original).

The Government immediately took the motions panel's ruling to the Supreme Court. Nine days later, the Court issued an unsigned order staying the injunctions that had been issued by the two lower courts and remanding the matter to the Fifth Circuit for a decision on the merits of Judge Kacsmaryk's rulings. The Supreme Court's order added that any subsequent decision by the Court of Appeals would also be stayed (and the FDA's decisions on mifepristone would remain in effect) until the Supreme Court had an opportunity to consider, and resolve, any petitions for further review.[64]

There were two dissents to the Supreme Court's *de facto* reinstatement of the FDA's REMS determinations. Justice Alito wrote that he would not have stayed the lower court injunctions, leaving it to the FDA to use its "enforcement discretion" to deal with them during the time it would take for the Fifth Circuit to decide the case on the merits. Justice Alito added that his approach should "not express any view on the merits of the question whether FDA acted lawfully in any of its actions regarding mifepristone."[65] For his part, Justice Thomas announced, without any explanation, that he too would not have stayed the lower court orders.[66]

When *AHM* returned to the Fifth Circuit for a full review of Judge Kacsmaryk's rulings, the plaintiffs continued to challenge the FDA's decisions without regard to the deferential standard set by the Supreme Court. Indeed, in the opening words of their brief, plaintiffs complained that the FDA's argument that its drug safety determinations are entitled to judicial deference "reeks of hubris."[67]

That dismissive characterization resonated with the Fifth Circuit merits panel. At the very outset of the oral argument — when FDA's counsel noted that no court had ever before overturned an FDA drug approval and that "it's not a court's role to come in and second-guess that expertise" — Judge James Ho cut her off asking, "why not just focus on the facts of this case, rather than have this sort of FDA-can-do-no-wrong theme?"[68]

Judge Jennifer Elrod similarly criticized what she said were "inappropriate" statements in Danco's brief that a "non-expert" judge had "defied

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Most recently, in *FCC v. Prometheus Radio Project,* 592 U.S. 414 (2021), the other Supreme Court case cited by the courts below, the Court, in a unanimous opinion by Justice Kavanaugh, held that since the commission had substantiated its decision to change its prior rules limiting station ownership in a given market, that decision "was reasonable and reasonably explained for purposes of the APA's deferential arbitrary-and-capricious standard", and hence should not have been vacated by the Third Circuit. *Id.* at 417.

[64] Danco Lab'ys, LLC v. All. for Hippocratic Med., 143 S. Ct. 1075 (2023).

[65] *Id.* at 1075-77 (Alito, J., dissenting).

[66] *Id*. at 1075 (Thomas, J., dissenting).

[67] Brief of Appellees at 1, *All. for Hippocratic Med. v. FDA,* No. 23-10362 (5th Cir.).

[68] Oral Argument at 01:20-01:50, *All. for Hippocratic Med. v. FDA* (May 17, 2023) (No. 23-10362), https://www.c-span.org/video/?527646-1/circuit-court-hears-abortion-pill-case.

long-standing precedent" in a "judicial assault" on FDA safety determinations.[69] Judge Ho then returned to his critique of the Government's "FDA-can-do-no-wrong-theme," reciting claims by Agency critics (but no *judicial* statements) that FDA had "rushed" the approval of a different drug in a manner that "put speed over science"; had "unacceptable long-standing food safety failures"; and "is being blamed for the opioid crisis."[70]

It thus came as no surprise when the merits panel issued its August 2023 decision cutting a wide swath through FDA's determinations balancing the benefits and risks of mifepristone. Most notably, the Fifth Circuit judges agreed with Judge Kacsmaryk and the prior motions panel to turn the regulatory clock back to 2011 by nullifying the most important decisions made by the Agency from 2016 through 2021. Of greatest concern to those who want to preserve reasonable access to mifepristone, the Fifth Circuit's decision would reduce the period in which the drug can be used from ten to seven weeks *and* require three separate visits to the offices of doctor/prescribers, thereby eliminating telemedicine prescriptions. As detailed below, those rulings by the Fifth Circuit contradict the Supreme Court's insistence on judicial deference to FDA safety determinations in a number of ways.

First, the Fifth Circuit simply ignored the opinions in which the Court as a whole (and its conservative members in particular) have stressed the need for such deference — including the Court's decision in *ACOG*, where it specifically deferred to the FDA's expertise concerning the safe distribution of mifepristone. Those decisions are not even mentioned (although the Fifth Circuit *did* discuss the ruling by Judge Chuang in *ACOG*, with

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[69] *Id*. at 1:00:38 - 1:02:00.

[70] *Id*. at 1:03:20 - 1:05:20.

In his subsequent, written concurrence in *All. for Hippocratic Med. v. FDA*, 78 F.4th 210 (5th Cir. 2023), Judge Ho pursued his contention that "FDA has made plenty" of mistakes by referencing a few instances over the last eighty years when the Agency decided that drugs that it had initially approved should either be restricted or withdrawn. *Id.* at 270-71. Most notably, Judge Ho cited an article reporting that, of the 222 new drugs approved by the FDA from 2001 through 2010, "nearly *one-third* had safety issues." *Id.* at 271. But Judge Ho failed to add that the authors of that article had explained that those "safety issues" typically required only some change in the drug label, and that, in reality, *only 3 of the 222 were actually withdrawn. See* Nicholas S. Downing et al., *Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010,* 317 JAMA 1854, 1858 (2017) https://jamanetwork.com/journals/jama/fullarticle/2625319.

Indeed, the much more numerous label changes show the Agency is continually monitoring and, as necessary, modifying the way drugs are used — the very authority the Fifth Circuit panel would compromise with their own *ad hoc* rulings on the best way to evaluate scientific data.

the panel noting that that litigation had involved the same issue of in-person visits with mifepristone).[71]

Second, the Court of Appeals likewise did not follow other Supreme Court cases more generally concerning the deference that should be accorded the decisions of other administrative agencies. As noted above, those cases also hold that agency decisions are to be respected so long as they are accompanied by *some* reasoned analysis.[72]

Nor did any of the lower court decisions cited by the merits panel address the appropriate deference to be given to FDA safety decisions. The primary case the Fifth Circuit offered, *Southwestern Electric Power Co. v. EPA,*[73] involved a court's invalidation of an EPA rule which EPA *itself* conceded, had perpetuated an "outdated and ineffective technology" for wastewater treatment rather than pursue the "technology-forcing" mandate that had been set by Congress in the controlling Clean Water Act. In a passage omitted by the merits panel, the *Southwestern Electric* court made clear that its ruling on that "legal" issue did not "second-guess" any scientific judgment entrusted to the expertise of the agency — and, indeed, that it would be improper for a reviewing court to do so:

> We recognize that . . . EPA [is] entitled to special deference where its decision turns on "its evaluation of complex scientific data within its technical expertise . . . ." This case is different. *We do not question the scientific or statistical methodologies relied upon by EPA, nor second-guess its weighing of the statutory factors.* Instead, we rely on EPA's own scientific conclusions in the rule itself to conclude its choice of an outdated and ineffective technology . . . was unlawful under the [Clean Water] Act."[74]

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[71] *See* All. for Hippocratic Med. v. FDA, 78 F.4th 210, 240 (5th Cir. 2023), *cert. granted*, 144 S. Ct. 537 (2023) (No. 23-235).

[72] *See supra* note 50.

[73] 920 F.3d 999 (5th Cir. 2019).

[74] *Id.* at 1022 (quoting BCCA Appeal Grp. v. EPA, 355 F.3d 817, 824 (5th Cir. 2003)) (emphasis added).

Perhaps concerned that the majority had not cited any case discussing the deference to be accorded to *FDA* decisions, Judge Ho reported, in his partial concurrence, that he had found ten decisions over the last forty-five years where a court of appeals had reversed some FDA action. *See AHM*, *supra,* 78 F.4th at 271-72. But a review of those cases shows that, in each instance, the court was resolving a *legal* issue and not reversing FDA on any scientific or medical judgment.

Five of the ten opinions cited by Judge Ho involved the construction of *legal* requirements in the Hatch-Waxman Act, which extends drug patents under certain circumstances and directs FDA to take various *non-discretionary* steps to that end. *Am. Bioscience, Inc. v. Thompson,* 269 F.3d 1077 (D.C. Cir. 2001); *Teva Pharmaceuticals, Inc. v. Sebelius,* 595 F.3d 1303 (D.C. Cir. 2010); *Teva Pharmaceuticals, Inc. v. FDA,* 441 F3d 1 (D.C. Cir. 2006); *Purepac*

Third, as detailed below, the factual conclusions of the Fifth Circuit panel, which contradict the FDA's findings on the safest and most effective way to prescribe and administer mifepristone, rest on the panel's disagreement with the Agency over the proper way medical data should be evaluated — even though the FDA had followed the same approach it has long used. If not reversed by the Supreme Court, the Fifth Circuit's rejection of those established standards for reviewing clinical data will thus constitute a waiting snare for other drugs that have been studied and approved by FDA. To take one similar class of drugs — those related to human sexuality — one can readily imagine the same groups who filed *AHM* advancing future challenges to the benefit-risk analysis made by the FDA in approving and regulating oral contraceptives (which are associated with rare but serious risks such as strokes);[75] drugs used in gender-affirming care such as testosterone (known to cause polycythemia which again can produce strokes);[76] or sildenafil (Viagra) (which can cause a number of adverse effects including "permanent loss of vision",[77] but which the FDA permits to be distributed without any in-person doctor visits).

Pharmaceutical Co. v. Thompson, 354 F.3d 877 (D.C. Cir. 2004); *Teva Pharmaceuticals v. FDA,* 182 F.3d 1003 (D.C. Cir. 1999). As explained in one of those decisions, "FDA has a longstanding policy not to get involved in patent disputes. It administers the Hatch-Waxman Amendments in a ministerial fashion simply following the intent of the parties that list patents." *Am. Biosciences, supra,* 269 F.3d at 1084.

The five other decisions proffered by Judge Ho likewise did not involve scientific judgments by FDA, but rather legal issues within the competence of reviewing courts. *See Zotos International, Inc. v. Young,* 830 F.2d 350, 352-53 (D.C. Cir. 1987) (construing the definition of a "trade secret" to be redacted from FDA documents by applying the tests in the Restatement of Torts); *Genus Medical Technologies, LLC v. FDA,* 994 F.3d 631, 644 (D.C. Cir. 2021) ("We emphasize the purely legal nature of the question before us," whether contrast agents (which FDA had conceded satisfied the statutory definition of "devices") could nevertheless be regulated under the statutory definition of "drugs"); *R.J. Reynolds Vapor Co. v. FDA,* 65 F.4th 182, 189-91 (5th Cir. 2023) (invalidating a new FDA rule on e-cigarettes because of *procedural* deficiencies in its issuance); *Rhodia, Inc. v. FDA,* 608 F.2d 1376, 1378-79 (D.C. Cir. 1979) (invalidating FDA's denial of an application for a veterinary product, on the grounds that adding one more supplier would increase the overall amount of the drug available, which was not one of the relevant statutory factors); *Natural Nutritional Foods Ass'n v. Mathews,* 557 F.2d 325, 336 (2d Cir. 1977) (invalidating a new rule classifying high-potency vitamins as "drugs" because that was "not relevant to the statutory definition of a drug").

[75] *See generally* 2023 FDA Label for Yasmin 5.1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021098s029lbl.pdf.

[76] *See generally* 2023 FDA Label for Testosterone 5.1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/216318s000lbl.pdf.

[77] *See generally* 2023 FDA Label for Viagra 5.3, https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/20895s039s042lbl.pdf.

Fourth, the Fifth Circuit judges likewise ignored the overall weight of the data on each of the issues on which they disagreed with the FDA. And the panel apparently did so without reading the studies they discounted, because Judge Kacsmaryk would not postpone his decision on plaintiffs' preliminary injunction motion to give the FDA the time it needed to compile and submit the administrative record. The extent of that procedural defect can be appreciated in one statistic: Of the thirty-four studies the FDA summarized in tabular form in its 2016 Cross-Discipline Team Leader Review to support the extension of the use period, the elimination of the second and third office visits, and the prescription by non-M.D. healthcare providers, only one (Winikoff 2012) was submitted to the record on appeal.[78]

That absence of the studies — and other evidence the FDA had used to support its REMS decisions — was no mere oversight. At oral argument, Judge Elrod questioned counsel at some length about the missing administrative record, noting that it "seems like something we would want to know about." Counsel for the FDA responded that the Government fully agreed that it was not appropriate for *any* court to rule on the issues presented in *AHM* without that record, but explained that Judge Kacsmaryk had nevertheless decided to proceed without it. Judge Elrod then suggested that the panel might look into possible solutions to obtain the absent record. But no further record submissions were made; and the panel's decision ignores the problem.[79] The net result is that the Fifth Circuit judges had no opportunity to read, much less weigh, the studies they have now decided to discount, reducing their "review" of FDA's safety determinations to a game of blind-man's-bluff.[80]

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[78] *See* All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 2913725 (5th Cir. April 12, 2023), Record on Appeal, ROA. 726, 2320-24, 2327-35; *See* Cross Discipline Team Leader Review, *020687Orig1s020*, FDA CENTER FOR DRUG EVALUATION AND RESEARCH (March 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020CrossR.pdf.

[79] Oral Argument at 22:24-24:44, All. for Hippocratic Med. v. FDA, 78 F.4th 210, 240 (5th Cir. 2023), *cert. granted*, 144 S. Ct. 537 (2023) (No. 23-235), https://www.ca5.uscourts.gov/OralArgRecordings/23/23-10362_5-17-2023.mp3. *See also* All. for Hippocratic Med. v. FDA, 668 F.Supp.3d 507 (N.D. Tex.), Defendants' Response to Order Proposing Advancement of Trial on the Merits and Consolidation with Preliminary Injunction Motion (Feb. 10, 2023) at 7-10 (explaining that the administrative record was "tens if not hundreds of thousands of pages," and therefore requesting that Judge Kacsmaryk postpone consideration of the preliminary injunction motion until the record could be submitted). A few days later, he declined to do so.

[80] By contrast, on the same day Judge Kacsmaryk issued his order invalidating the FDA's liberalizations of the mifepristone REMS, Judge Thomas Rice of the Eastern District of Washington — who is presiding over a lawsuit filed by seventeen states seeking to guarantee *greater* access to mifepristone — issued an order maintaining the *status quo* (at least in those states). *Washington v. FDA,* 2023 WL 2825861 (E.D. Wash. Apr. 7, 2023). Judge Rice then gave the FDA the

Finally, the Fifth Circuit's nullification of the FDA's revisions to the mifepristone REMS was profoundly anachronistic. As detailed below, the panel judges concluded that the data supporting FDA's modifications was inadequate, first as of 2016 and then again as of December 2021. But the panel simply ignored the data that came to the Agency over the next 12 months, before the FDA issued the current January 2023 REMS, which reaffirmed those earlier decisions — most notably, the "real-world" results from telehealth prescriptions after COVID changed the way *all* drugs are prescribed. Such a dated judicial review would likely be invalid on most scientific issues, where facts obviously change over time. But it was especially inappropriate here, where the Fifth Circuit nullified the superseded 2016 and 2021 REMS without discussing the prevailing January 2023 REMS or the more recent data on which it is based.

IV. THE FIFTH CIRCUIT'S RULING ACCELERATING THE DEADLINE FOR USING MIFEPRISTONE

The Fifth Circuit's decision to nullify the FDA's extension of the period in which mifepristone can be used, from seven to ten weeks after gestation, exhibits each of the analytical errors listed above. That ruling will effectively deny mifepristone's benefits to the majority of American women, who, on average, do not learn they have unintentionally become pregnant until only a few days before that seven-week deadline — and especially to teens fifteen to nineteen years old who, on average, do not realize it until week seven and beyond.[81]

Unless checked by the Supreme Court, the panel's ruling will thus undoubtedly reverse the increase in the number of women who were able to access mifepristone since FDA's 2016 extension of the use period: In 2014 medication abortions constituted thirty-one percent of total abortions; by 2020, that percentage had increased to fifty-three percent.[82] And the practical denial of mifepristone's benefits as a result of the earlier

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time to provide the relevant administrative record of FDA REMS decisions and the evidence on which they were based.

On September 1, 2023, the FDA lodged approximately 6000 pages of that record — many of which were the full texts of the studies the FDA had considered in developing the REMS that the Fifth Circuit has now overturned. *See* Case 1:23-cv-030205-TOR, ECF Entry No. 127.

[81] According to the leading study published by NIH, in 2013 (the most recent year then reported), the mean time for American women to become aware of an unintended pregnancy was 6.6 weeks; for those fifteen to nineteen, 7.4 weeks. Amy M. Branum & Katherine A. Aherns, *Trends in Timing of Pregnancy Awareness Among U.S. Women,* 21 MATERNAL CHILD HEALTH J. 715, 719 tbl.2 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5269518/.

[82] Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All U.S. Abortions,* GUTTMACHER INSTITUTE (Feb. 24, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

seven-week deadline will likely be even more pronounced post-*Dobbs*, as women in the seventeen states that effectively prohibit abortions will need to travel to other states to obtain such care.

The Fifth Circuit decision to reimpose the shorter deadline is problematic on both legal and scientific grounds. Clearly (to quote Justices Alito and Thomas in *ACOG,* who in turn were quoting Chief Justice Roberts), the panel judges — members of "an 'unelected federal judiciary' which lacks the background competence, and expertise to assess public health and is not accountable to the people" — flatly overruled "officials with public health responsibilities."[83]

Nor does the panel's second-guess on the appropriate period for safe use satisfy the limited exception to judicial deference articulated in such cases as *State Farm* or *Michigan v. EPA,* where an administrative agency "apparently gave no consideration whatever" or "no thought *at all*" to factors Congress had mandated in the agency's authorizing legislation.[84] Here, it is undisputed that FDA *did* review the voluminous data on the proposed extension from seven to ten weeks, and then explained its decision to do so *in detail*.

Specifically, the FDA's 2016 Clinical Review found that the extension was supported by no less than twenty-two clinical studies (seven American and fifteen foreign), involving 35,000 patients — all showing remarkable efficacy, in the range of ninety-four to ninety-eight percent, with only "rare" side effects of any kind.[85] That much clinical data would be more than sufficient to support even the *de novo* approval of a new drug (which the FDA usually predicates on studies involving only "several hundred to several thousand" patients);[86] it was certainly enough to support an extension in the period for recommended use.

The Agency carefully parsed those studies for any evidence that adverse events increased with use from fifty to seventy days. Listing the percentage of adverse events reported in each study, the FDA found that, with use through nine weeks, "[s]erious adverse events including death, hospitalization, serious infection, bleeding requiring transfusion and ectopic pregnancy with the proposed regimen are rarely reported in the literature. The rates when noted are exceedingly rare, with rates generally far below one percent for any individual adverse event."[87] And then — while conceding the data in 2016 was somewhat less robust as to the final, tenth week — the FDA cited one additional study showing that, even in that last week, the same categories of adverse events were "no higher than in the

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[83] FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 10, 12 (2020).

[84] *State Farm*, 463 U.S. 29, 46 (1983); Michigan v. EPA, 576 U.S. 743, 750-51 (2015) (emphasis in original).

[85] 2016 Medical Review, *supra* note 13*,* at 28-38.

[86] 21 C.F.R. § 312.21(c).

[87] 2016 Medical Review, *supra* note 13*,* at 56.

lower gestational ranges."[88] Yet none of that clinical data analyzed by the FDA is mentioned by the Fifth Circuit.

The Fifth Circuit's decision also ignored the fact that, five years later (2021), the FDA re-examined and re-affirmed the extension to ten weeks when it rejected AAPLOG's citizen petition seeking a return to the seven-week deadline. In denying that petition, the Agency explained that the clinical studies and adverse event data, before, and after especially after, the 2016 extension, completely outweighed the results of one small study in Finland (from 2003 to 2006), which had included use well into the second trimester (i.e., weeks thirteen to twenty), rather than the ten-week limit FDA had adopted.[89]

FDA likewise reported that in 2021 it had made a multi-faceted review of adverse event data following the 2016 changes and had not found "any new safety concerns":

> For our recent review of the REMS, we searched our FAERS database, reviewed the published medical literature for postmarketing adverse event reports for mifepristone for medical termination of pregnancy, and requested that the [manufacturers] submit a summary and analysis of certain adverse events. *Our review of this postmarketing data indicates that there have not been any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days gestation* . . . .[90]

Neither that express finding by the FDA nor the results of the clinical studies (and other supporting data on which it was based) is disputed (much less refuted) in the Fifth Circuit's opinion. Again, of the nineteen studies set forth by the FDA in a comprehensive table to support its conclusions, only one was even in the record before the district court and court of appeals.[91] Instead, the panel judges accepted the plaintiffs' novel theory that FDA's analysis and supporting data in its 2016 REMS modification were insufficient because the Agency did not cite studies that had "examined the effect of implementing all of the changes together."[92]

Remarkably, the panel announced, and then applied, that novel all-in-one study approach without reference to any such requirement in the FDCA or FDAAA; any judicial decision concerning a proper review of scientific studies; any FDA or HHS regulation; any scientific treatise or article; or any review by another official body (such as the GAO which,

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[88] *Id.* at 57.

[89] FDA Response to 2019 Citizen Petition, *supra* note 19*,* at 8.

[90] *Id.* at 26 (emphasis added).

[91] *See* Transcript of Record at 2327-32, All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 2913725 (5th Cir. April 12, 2023) .

[92] All. for Hippocratic Med. v. FDA, 78 F.4th 210, 246 (5th Cir. 2023), *cert. granted*, 144 S. Ct. 537 (2023) (No. 23-235).

as noted above, had investigated and endorsed the 2016 REMS changes).[93] In fact, the Fifth Circuit's "second-guess" of the FDA's evaluation of the data supporting the 2016 modifications was wrong, as a matter of both the congressional mandates in the FDCA and long-standing FDA practice.

First, the panel judges were incorrect in assuming that clinical studies are even necessary for a REMS modification (in the same way they are necessary for the *de novo* approval of a *new* drug). The 2007Amendments to the FDCA provide that a proposed REMS change need only set forth an "adequate rationale",[94] and that the Agency is then to make an "assessment" of the modification.[95] Nowhere does the REMS statute limit the type of data FDA can consider (much less require that it be an all-in-one clinical study that mimics every aspect of the way a drug will be used if the proposed changes are adopted).[96]

To the contrary, such a limitation on the data the FDA may "assess" when modifying a REMS would be inconsistent with the comprehensive approach on appropriate data set forth by Congress in the portion of the 2007 Amendments empowering FDA to impose a REMS in the first place. That portion of the Amendments states that the FDA may impose a REMS on the basis of any "new safety information" — which is then broadly defined to include "information derived from a clinical trial, an adverse event report, a post approval study . . . , or peer-reviewed biomedical literature; data derived from the post market risk identification and analysis system . . . ; or other scientific data deemed appropriate by the [HHS] Secretary" (who, by law, is the official who issues FDA actions).[97]

It would be absurd — indeed, dangerous — to suggest that a REMS which had been issued on the basis of such data from the real-world use of a drug (rather than only clinical studies) could not be modified (either to be more restrictive as safety concerns may demand or to be less restrictive to fulfill Congress' directive that REMS not be unnecessarily "burdensome") when that real-world data justifies such a change. Nor can one reasonably contend that it would be "arbitrary and capricious" for the FDA to rely in a REMS modification on the same broad range of data that Congress provided should be used to create a REMS *ab initio.*

It is thus not surprising that the FDA's long-standing practice on REMS modifications likewise does not limit the Agency to clinical study data. The FDA's official Guidance states that the requisite "adequate rationale" for a REMS modification "may include" a wide range of information on "the reason(s) why the proposed modification is necessary; the

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[93] *Id.*

[94] 21 U.S.C. § 355-1(g)(4).

[95] 21 U.S.C. § 355-1(h)(1).

[96] By contrast, when Congress wants to require a particular type of data be used in some FDA decision, it so specifies in the FDCA. *See, e.g.*, 21 U.S.C. § 355(d) (requiring "adequate and well-controlled clinical investigations" to establish the efficacy of a drug in the initial approval process).

[97] 21 U.S.C. §§ 355-1(a)(2)(A) and (b)(3).

potential effect of the proposed modification on how the REMS addresses the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on healthcare delivery system; and other appropriate evidence or data to support the proposed change."[98]

Again, the FDA's Guidance on initially designing a REMS is equally broad, stating that the Agency should consider "*[a]ny information demonstrating the effectiveness of the proposed strategy in mitigating the risk* (e.g., results from premarket testing with stakeholders, effectiveness demonstrated during clinical trials or from the published literature, findings from qualitative or quantitative human factors studies, [or] previous experience with similar REMS programs."[99] The Guidance then lists various types of relevant evidence, including "[a]pplicant's REMS data" collected from providers operating under the existing REMS; "surveys"; "drug utilization data"; "postmarketing adverse event data"; "observational/epidemiological data"; and "data from stakeholder outreach."[100] Again, none of these statutory provisions or agency regulations is mentioned in the Fifth Circuit's decision. In short, the Fifth Circuit panel had no basis for its all-in-one study demand other than its own second-guess of decades of contrary FDA decisions, where no such requirement was ever imposed on the scope of clinical studies and other data which, in their totality, amply supported a set of regulatory modifications.

The Fifth Circuit's other rationale for voiding the 2016 REMS changes — that the FDA simultaneously erred in removing an unusual provision in the 2011 REMS that had required doctors to report *any* adverse event following the use of mifepristone directly to FDA's Adverse Event Reporting System (FAERS) — was also an unsupported "second-guess" of a long-standing FDA policy. Again, the Fifth Circuit judges overruled the FDA scientists on that particular change without citing any support for their position in any statute, regulation, or prior FDA decision.

The panel judges began their discussion of that FAERS issue by acknowledging that FDA had expressly addressed that change in its 2016 REMS decision.[101] The court quoted the finding of the FDA review officer that the change was appropriate because "after 15 years of reporting serious adverse events, the safety profile for Mifeprex is essentially unchanged."[102]

But the Fifth Circuit judges then posed the same Catch-22 objection they had advanced with the clinical studies, speculating that the *other*

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[98] FDA, *Risk Evaluation and Mitigation Strategies: Modifications and Revisions, Guidance for Industry* 1, 12 (June 2020), https://bit.ly/46KpZkY (emphasis added).

[99] FDA, *REMS Assessment: Planning and Reporting, Draft Guidance for Industry* 1, 4 (Jan. 2019), https://bit.ly/3FcmUOM, (emphasis added).

[100] *Id.* at 8-12 (emphasis added).

[101] All. for Hippocratic Med. v. FDA, 78 F.4th 210, 246 (5th Cir. 2023), *cert. granted*, 144 S. Ct. 537 (2023) (No. 23-235).

[102] *Id.* at 246-47 (quoting FDA 2016 Summary Review at 26).

changes made in the 2016 REMS (most notably, the extension of the use period and the removal of one of the three office visits) "might alter the risk profile."[103] Yet, again, the panel judges did not offer any factual support for their speculation as to a scientific issue the FDA had been monitoring for fifteen years; nor did they cite anything in any statute, regulation, or prior decision to justify such a concern.

In reality (and in law), the FDA's decision in 2016 to reduce the obligation of doctors to report ADRs with mifepristone directly to the FDA was entirely consistent with the approach taken with virtually all other drugs. For decades, the FDA MedWatch and FAERS programs have been founded on voluntary reporting by physicians. Those doctors may submit such reports as they see fit to manufacturers, distributors, or (again as they see fit) directly to the FDA. And if the doctors chose to report the event to a manufacturer, other FDA regulations (still in effect as to mifepristone) require that those reports be passed along to the FDA, within timeframes related to their severity.[104] Despite all that, the Fifth Circuit panel concluded that when the FDA (expressly relying on fifteen years of mandatory physician reporting) made mifepristone subject to the same type and level of adverse event reporting used with other drugs, the Agency violated the APA.[105]

In sum, the Fifth Circuit's ruling that the FDA's extension of the use period was "arbitrary and capricious" because the Agency relied, in part, on clinical studies and adverse event data that did not each evaluate the "cumulative" effect of other changes, rests on nothing more than the panel's assumption that they know better than the FDA which data should be considered in a REMS modification — even though the court's view (1) was not consistent with the REMS statute and (2) was contrary to the

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[103] *Id.* at 247.

[104] In 2007, around the time of the initial mifepristone REMS, the National Institutes of Health described the MedWatch system as follows: "MedWatch . . . offers a choice between a *voluntary reporting form, designed primarily for healthcare professionals, and the general public*, and a mandatory AERS available to manufacturers . . . ." Valeri Craigle, *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*, 95 J. MED. LIBR. ASSOC. 224 (April 2007) (emphasis added), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1852611/?report=reader#!po=70.0000.

And that approach continues today: "FDA receives *voluntary* reports directly from healthcare professionals (such as physicians, pharmacists, nurses, and others) and consumers . . . . Healthcare professionals and consumers may also report to the products' manufacturers. If a manufacturer receives a report from a healthcare professional or consumer, it is required to send the report to FDA as specified by regulations." *Questions and Answers on FDA's Adverse Event Reporting System (FAERS)*, FDA, https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers (last visited August 25, 2023) (emphasis added).

[105] All. for Hippocratic Med. v. FDA, 78 F.4th 210, 247 (5th Cir. 2023), *cert. granted*, 144 S. Ct. 537 (2023) (No. 23-235).

FDA's general practice with all other drugs. That was hardly the "reasoned deference" to FDA expertise that the Supreme Court Justices (especially the Court's more conservative members) have previously demanded.

V. THE FIFTH CIRCUIT'S RULING REIMPOSING THREE OFFICE VISITS

The Fifth Circuit's nullification of the FDA's phased decisions in 2016 and 2021 reducing, and then eliminating, required in-person office visits by patients using mifepristone suffers from the same analytical problems. And again, the conflict between the approach of the court of appeals panel and the judicial deference to FDA judgments espoused by the Supreme Court could not be more clear.

The first problem with the Fifth's Circuit's reimposition of the office visit requirements is that it involved precisely the same "public health" question that the *ACOG* Court held must be left to FDA's expertise. To be sure, in *ACOG* the Court insisted on such deference when FDA had decided (without any articulated analysis) to maintain such visits, even as the Agency was counseling against them as to all other drugs during the pandemic.[106]

Now, in accord with hundreds of thousands of safe telehealth prescriptions of mifepristone over the last two years without such in-person visits, the FDA has explained, in three comprehensive decisions, that such visits are unnecessary.[107] It would take an unabashed cynic to presume that the Justices who argued and voted in favor of judicial deference to the expertise of FDA in *ACOG* will now reverse themselves in *AHM* simply because they personally may not favor abortion medications.

Plainly there would be no principled basis for such an about-face by those Justices. The Supreme Court case law (along with common sense) recognizes that administrative agencies may properly reverse their prior decisions to meet "changing circumstances."[108] And that is precisely what the FDA did, from 2016 through 2021, as the benefits of telehealth prescriptions were demonstrated, first in general and then super-charged during the pandemic — a "changing circumstance" if ever there was. Yet now the Fifth Circuit has decided to reimpose the physician office visit requirements set twenty years ago and reject the FDA's expert analysis that they are no longer necessary (just as office visits now are not required for patients to obtain almost any other drug).

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[106] *See supra* at text accompanying notes 42-59.

[107] *See supra* at text accompanying notes 13-20.

[108] "[W]e fully recognize that '[r]egulatory agencies do not establish rules of conduct to last forever' and that an agency must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'" Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 (1983) (quoting American Trucking Assns., Inc. v. Atchison, T. & S. F.R. Co., 387 U.S. 397, 416 (1967) and Permian Basin Area Rate Cases, 390 U.S. 747, 784 (1968)).

As outlined above, that phased change began with the 2016 REMS revisions, after the FDA had spent a year reviewing the most recent data showing that the second (misoprostol) and third (follow-up) office visits were not necessary. With respect to the second visit, the FDA relied on two 2015 studies, involving "large numbers of women in the U.S. who took misoprostol at home," which found "rates of common adverse events comparable to those in the studies of clinic [office] administration . . . ."[109] The FDA explained that it had also considered other studies involving a total of 45,000 women — half of whom had taken the misoprostol dose without visiting their doctors — which likewise showed "there is no clinical reason to restrict the location in which misoprostol may be taken."[110]

The Agency then articulated an additional reason why self-administration of misoprostol at home is actually *safer* than requiring patients to take the dose at a doctor's office: "Given the onset of bleeding and cramping after misoprostol, allowing dosing at home increases the likelihood that a woman will be in an appropriate and safe location when the pregnancy termination process begins."[111]

Turning to the third, "follow-up" office visit, the FDA similarly found that several clinical studies and one "systematic article" surveying the literature established that "there were no significant differences in adverse outcomes between women who underwent self-assessment of health compared to those who had a clinic visit" after the abortion.[112] The FDA's review team likewise outlined eleven studies, involving more than 50,000 patients, in support of the Agency's decision to eliminate the third, follow-up visit.[113] (Once again, only one of those eleven studies was in the record available to the Fifth Circuit.)

Over the next four years (March 2016 to March 2020), physicians following the revised REMS met with patients before initially prescribing the mifepristone/misoprostol combination, but did not insist on a second or third visit. Then came COVID. In the spring of 2020, the FDA (along with the entire medical profession) worked to arrange for the prescription of all drugs without in-person office visits. In a series of highly-publicized actions in March and April 2020, the FDA announced that it would not

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[109] FDA, Center for Drug Evaluation and Research, *Summary Review of Application Number: 020687Orig1s020* at 15 (Mar. 29, 2016) [hereinafter *2016 REMS Decision*], https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf. As with its extension of the use period, the FDA's elimination of the second office visit was further supported by an analysis of the relevant studies in a simultaneously-released review of the Agency staff. *See* 2016 Medical Review, *supra* note 13*,* at 38-41, 44.

[110] *2016 REMS Decision*, *supra* note 109*,* at 15.

[111] *Id.* at 16.

[112] *Id.*

[113] *See* Cross Discipline Team Leader Review, *Application Number: 020687Orig1s020*, FDA CENTER FOR DRUG EVALUATION AND RESEARCH (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020CrossR.pdf at 55-58.

enforce requirements for office visits prior to the prescription of other drugs subject to a REMS — even opioids — and generally "acted to advance the use of telehealth during the pandemic."[114]

But, as discussed above, the FDA initially refused the requests of healthcare providers to waive the same requirement as to mifepristone.[115] And that disparity prompted the *ACOG* litigation — with the Supreme Court's ultimate ruling, in January 2021, that the FDA could not be "second-guessed" by any court on such an issue of "public health."

A few months later, the FDA decided that mifepristone should no longer be the sole exception to its general policy allowing telehealth prescriptions during the pandemic. In April 2021, Acting Commissioner Janet Woodcock announced that the Agency "intend[ed] to exercise enforcement discretion during the COVID-19 PHE with respect to the in-person dispensing requirement . . . ."[116]

In contrast to the FDA's prior unexplained refusal to waive the requirement solely as to mifepristone, Dr. Woodcock's April 2021 decision cited four new studies, following 32,000 women who had used mifepristone through various telehealth programs which did not entail any physician visits.[117] Those studies found no "increases in safety concerns (such as hemorrhage, ectopic pregnancy, or surgical interventions) occurring with medical abortion as a result of modifying the in-person dispensing requirement during the COVID-19 pandemic."[118] Significantly (given the Fifth Circuit's subsequent suggestion that a study must involve every element of a revised REMS), each of the four studies cited by the FDA involved the dispensation of *the reduced 200 milligram dose, up to ten weeks gestation, and without any physical office visits.*[119]

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[114] *See* American Coll. of Obstetricians and Gynecologists v. Food and Drug Administration, 472 F.Supp.3d 183, 193-95 (2020).

[115] Letter from Maureen Phipps, M.D., Chief Exec. Officer, American College of Obstetricians and Gynecologists, to Stephen M. Hahn, M.D., Comm'r, U.S. Food and Drug Admin. (Apr. 20, 2020), https://s3.amazonaws.com/cdn.smfm.org/media/2345/ACOG_SMFM_letter_to_FDA.pdf.

[116] Letter from Janet Woodcock, M.D. Acting Comm'r, Food and Drug Administration, to Maureen Phipps, M.D., Chief Exec Officer, American Coll. of Obstetricians and Gynecologists (Apr. 12, 2021).

[117] *Id.*

[118] *Id.*

[119] *Id.* (citing Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 CONTRACEPTION 43, 43-48 (2021), https://www.contraceptionjournal.org/action/showPdf?pii=S0010-7824%2821%2900091-3; Courtney Kerestes et al., *Provision of Medication Abortion in Hawai'i During COVID-19*, 104 CONTRACEPTION 49, 49-53 (2021), https://www.contraceptionjournal.org/action/showPdf?pii=S0010-7824%2821%2900097-4; ARA Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion Provided Via Telemedicine: A National Cohort Study*, BJOG 1464-74 (2021), https://obgyn.onlinelibrary.wiley.com/doi/pdf/10.1111/1471-0528.16668; John J.

The FDA then monitored the use of mifepristone without in-person office visits for the remainder of 2021, while simultaneously considering AAPLOG's citizen petition seeking to reinstate the requirement for *all three* visits. In December 2021, the FDA rejected that petition with a detailed analysis re-examining and affirming the 2016 modifications — now with an additional review of adverse event data from the widespread telehealth prescription of the drug, with no office visits at all. The FDA reported that that adverse event data through the fall of 2021 "indicates there have not been any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days gestation, *including during the time when in-person dispensing was not enforced."*[120]

All of these Agency decisions — and the data they reviewed — were then re-evaluated by the FDA one more time in a December 2022 decision, which further modified the mifepristone REMS by requiring that those prescribing the drug (directly or through a telehealth program) be specially trained and certified to do so — requirements the FDA then set forth in a new REMS in January 2023.[121] In that December 2022 decision, the FDA concluded, on the basis of both published literature and a new review of the adverse event data, that those measures would insure the safe and effective use of mifepristone while, at the same time, meeting the congressional directive to promote patient access and minimize burdens on the healthcare system.[122]

None of that last year of data and Agency analysis was refuted by the Fifth Circuit judges. Instead, the merits panel — accepting plaintiffs' tactical decision not to challenge those more recent evaluations of the safety data[123] — limited its review to the superseded agency actions in 2016 and

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Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: A prospective observational cohort study during the COVID-19 pandemic*, 47 BMJ SEXUAL & REPRODUCTIVE HEALTH 246-51 (2021) https://srh.bmj.com/content/familyplanning/47/4/246.full.pdf.

As was the case with the studies relied upon by the FDA in the 2016 Decision, none of these studies (or the dozen more used by FDA to eliminate the initial visit in its December 2021 Decision) were included in the record before the Fifth Circuit. Nevertheless, the court ruled that they were so inadequate that the FDA's reliance on them was "arbitrary and capricious." All. for Hippocratic Med. v. FDA, 78 F.4th 210, 249 (5th Cir. 2023), *cert. granted*, 144 S. Ct. 537 (2023) (No. 23-235).

[120] FDA Response to 2019 Citizen Petition, *supra* note 19*,* at 26 (emphasis added).

[121] FDA, Summary Review, Application Number: 020687Orig1so25 (Dec. 19, 2022); Revised Mifeprex REMS (Jan. 3, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/summary_review/2023/020687Orig1s025SumR.pdf.

[122] *Id*. at 19-21.

[123] The filing of the *AHM* Complaint on November 18, 2022 — just before FDA was scheduled to rule on the latest REMS modification — may have been timed to try an end-run around that most recent review by the Agency. And

2021. And, once again, none of the studies cited by the FDA in either its 2021 or 2022 decisions concerning the elimination of the initial office visit was in the record before the Fifth Circuit.

In the face of all of this data evaluated by the FDA on three separate occasions over six years, the Fifth Circuit rested its reimposition of the office-visit requirement on the fact that, in its December 2021 rejection of AAPOG's 2019 citizen petition, the FDA acknowledged that mifepristone's adverse event profile *at that time* was based *in part* on studies which varied somewhat in their design. The Fifth Circuit quoted the FDA's comment at some length.[124] But the panel judges then failed to add that, *in the next seven single-spaced pages of the same decision letter, the FDA went on to detail the results of 10 of those studies, involving thousands of patients, which demonstrated the safety of mifepristone when dispensed in a wide range of settings (e.g., retail pharmacies, mail-order pharmacies, couriers, Internet providers) — all without in-person doctor office visits*.[125] In this instance, then, the Fifth Circuit panel did not so much "second-guess" an FDA analysis as pretend it simply did not exist.

VI. THE FIFTH CIRCUIT'S FAILURE TO FOLLOW CONGRESS' DIRECTIVE TO ASSURE PATIENT ACCESS AND MINIMIZE HEALTHCARE BURDENS IN ALL REMS MODIFICATIONS

In the final pages of its opinion, the Fifth Circuit turned to "the remaining steps of the preliminary-injunction analysis" in which, the judges noted, they were required to assess whether the plaintiff doctors were "likely to sustain irreparable injury absent an injunction" and, "if so, then balance the equities and consider whether the injunction serves the public interest."[126] Significantly, the panel judges turned to that topic only *after* they had concluded that the plaintiffs were "likely to succeed in showing that [the 2016 and 2021 REMS modifications] violated the APA" because FDA had failed to convince the panel that those changes would not adversely affect patient safety.[127]

Of paramount importance, the Fifth Circuit judges reached that conclusion without any mention — much less any consideration — of the countervailing benefits of the modifications in assuring meaningful patient access and minimizing burden on the healthcare system. That was clear legal error because Congress has mandated that precisely those factors must be weighed by the FDA in any REMS decision (and hence by a

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plaintiffs did not thereafter amend their complaint to cover FDA's December 2022 affirmance that office visits were not necessary or the current 2023 REMS which adopts different safety procedures. As a result, the courts below enjoined the *superseded* 2016 REMS as if the current 2023 version does not exist.

[124] *All. for Hippocratic Med*., 78 F.4th at 250 (explaining the FDA's Response to the 2019 Citizen Petition).

[125] FDA Response to 2019 Citizen Petition, *supra* note 19, at 29-35.

[126] All. for Hippocratic Med., 78 F.4th at 251.

[127] *Id.*

reviewing court assessing whether such a REMS determination was "arbitrary and capricious".)

Specifically, in the 2007 Amendments to the FDCA, Congress directed that a REMS not be "unduly burdensome on patient access to the drug" and, "to the extent practicable minimize the burden on the healthcare delivery system."[128] In the related statutory provision authorizing the FDA to implement its REMS decisions by promulgating specific Elements to Assure Safe Use (ETASU) — as the FDA did in the case of mifepristone — Congress likewise insisted that such ETSAU "not be unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas) . . . ."[129]

The FDA satisfied those statutory requirements in both its 2016 and 2021 modifications. In its 2016 Decision, the FDA specifically found that eliminating the requirement for a second visit to a physician office to take misoprostol in his/her presence "would avoid . . . the time, transportation, loss of work, inconvenience, etc. that such a visit would involve," in addition to ensuring that the patient "be in a convenient, safe place (home or at a support person's location)," instead of being on a return trip home, "when the uterine cramping and vaginal bleeding . . . occur."[130]

The FDA made the same sort of burden analysis as to the third, "follow-up" visit:

> One strong argument for flexibility in follow-up timing, location and method is to avoid placing an undue burden on either the provider or the patient, while maintaining the ability to identify incomplete terminations. The currently approved [2011] labeling specifies three visits (two for dosing, one for follow-up) at fairly rigid times that are often not practical, convenient or necessary.[131]

Five years later, the FDA struck the same balance in eliminating the initial office visit as well. In the Agency's response to AAPLOG's citizen petition seeking to re-instate all three office visits — the "relief" the Fifth Circuit has now granted — the FDA explained that "[r]emoving the in-person dispensing requirement will render the REMS less burdensome to healthcare providers and patients"; and the Agency therefore concluded that remaining office-visit requirement should also be eliminated from the mifepristone ETSAU.[132]

The Fifth Circuit never cited any of these statutory provisions which Congress set forth as the touchstone of an appropriate REMS or ETSAU; and the court of appeals likewise never mentioned the express findings of

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[128] 21 U.S.C. § 355-1(f)(2)(C)-(D).
[129] 21 U.S.C. § 355-1(f)(2)(C)(ii), (iii).
[130] 2016 Medical Review, *supra* note 13, at 41.
[131] *Id*. at 44.
[132] Response to 2019 Citizen Petition, *supra* note 19, at 35.

the FDA striking that balance in its REMS modifications. The panel thus held that the FDA acted arbitrarily when it followed specific congressional mandates the court *itself* ignored.

Even if one were willing to excuse the Fifth Circuit for failing to consider Congress' mandate that any REMS modification must be assessed in terms of patient access and healthcare burden in the court's review of the substance of plaintiffs' APA claims — and looked instead for such an analysis in the panel's discussion of "competing interests" under the procedural factors for a preliminary injunction — one would be sorely disappointed. To be sure, the Fifth Circuit judges began their discussion of the "competing interests" by noting that public health groups had explained "that 'disrupting access to mifepristone' would unduly burden state and local health-care systems" — concerns the panel conceded were "not insignificant."[133] But the panel then decided that they could ignore those issues because the prior motions panel had asserted that those concerns "center on the district court's removal of mifepristone from the market," which the court of appeals was not ordering.[134] *The merits panel then said nothing more on the issues of patient access or burden on the healthcare system.*

The Fifth Circuit judges thus wasted their last opportunity to address the statutory requirement governing every REMS change in terms of patient access and healthcare burden. But the FDA made those assessments in its REMS decisions*;* and those assessments now stand as the unrefuted findings of the expert agency entrusted by Congress with such safety determinations.

To sum up: The Fifth Circuit did not even attempt to argue, much less establish, that the FDA was incorrect when it decided that patient access to mifepristone would not be "assured" by returning to a forty-nine-day deadline which runs before most women confirm an unintended pregnancy *or* that the healthcare system should not be "burdened" by 1.5 million unnecessary patient encounters each year (three separate visits for each of those 500,000 patients). Far from deferring to the FDA's experience and expertise in deciding such public health issues, the Fifth Circuit judges ignored those issues entirely.

VII. THE PROSPECTS FOR REVERSAL IN THE COMING SUPREME COURT REVIEW

How then may the Supreme Court's case law on the need for judicial deference to FDA safety determinations impact the quest for a five-Justice majority when the Court decides *AHM* this spring? Most obviously, it shows that the Court's conservative members — especially Chief Justice Roberts and Justices Alito and Kavanaugh — have consistently argued

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[133] All. for Hippocratic Med. v. FDA, 78 F.4th 210, 253 (5th Cir. 2023), *cert. granted*, 144 S. Ct. 537 (2023) (No. 23-235).

[134] *Id*.

and voted in favor of "reasoned deference" to the FDA's judgments, rather than permit "second-guessing by an unelected federal judiciary which lacks the background, competence, and expertise to assess public health and is not accountable to the people."[135]

That was their view whether the drugs at issue were used to treat migraines (*Levine*), sore shoulders (*Bartlett*), or osteoporosis (*Albrecht*) — even though the documented risks of those drugs were, respectively, the amputation of gangrenous arms, the decomposition of most of a patient's skin, or serious femoral fractures. Moreover, we know from *ACOG* that Chief Justice Roberts and Justice Alito (again with Justice Kavanaugh concurring) have insisted on such judicial deference to the FDA where the Agency's decisions concerned the measures necessary to assure the safe use of mifepristone itself.

Focusing on those three Justices seems appropriate as they most likely will decide *AHM*. On the one hand, many assume that Justice Barrett may follow her career-long opposition to abortion in any form;[136] that Justice Thomas' announcement that he would have maintained the Fifth Circuit's prior injunction in *AHM* signals a similar intent on the merits; and that Justice Gorsuch (who did not issue any opinions in the two FDA-deference cases on which he sat *(Albrecht* and *ACOG)*) may vote to affirm the Fifth Circuit because of his general antipathy towards the "regulatory state".[137] But then, on the other hand, most assume Justices Sotomayor, Kagan, and Jackson will defer to the FDA's decisions which increase access to mifepristone — in accord with their statement in *ACOG* that they will so defer to the FDA so long as the Agency has provided some "reasoned decision" to support its position — a standard that is certainly met by the hundreds of pages of analysis that are now under attack in *AHM*.

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[135] FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 10, 13 (2021) (Alito & Thomas, JJ., dissenting) (quoting Garcia v. San Antonio Metro. Transit Auth., 469 U.S. 528, 545 (1985)).

[136] In an article co-authored at the start of her career, Justice Barrett considered the issues presented when a Catholic judge is involved in a capital case — concluding that, at times, judges who feel bound by the Church's teachings should recuse themselves. She then added that recusal in such cases may not always be necessary because the Church's teachings on capital punishment are "not flat prohibitions like the ban on abortion, which (properly defined) is always immoral." John H. Garvey & Amy V. Coney, *Catholic Judges in Capital Cases*, 81 MARQ. L. REV. 303, 316 (1998).

[137] Unlike some of Justice Gorsuch's opinions voiding administrative actions, *AHM* is not a case where there should be any argument that FDA's authority to regulate abortion medications is a "major question" Congress has never addressed. At various times from 1997 to 2006, Congress specifically debated whether to exclude mifepristone from the FDA's jurisdiction, but repeatedly declined to do so. For a complete discussion, *see* Peter Grossi & Daphne O'Connor, *FDA Preemption of Conflicting State Drug Regulation and the Looming Battle Over Abortion Medications*, 10 J.L. & BIOSCIENCES 42-44 (2023).

Such a 3-3 split of those six Justices would thus again bring the ultimate decision back to Justices Alito, Roberts, and Kavanaugh. Justice Alito will need to decide whether he will follow his own opinions in *Levine, Bartlett, Albrecht,* and *ACOG,* which all argued forcefully for judicial deference to FDA safety determinations. Perhaps he will. Or perhaps his announced opposition to the stay the other Justices issued in *AHM* [138] portends an attempt to walk away from his repeated insistence on judicial deference to FDA decisions, now that one of them increases, rather than restricts, access to an abortion medication.

Chief Justice Roberts may be more likely to vote against the Fifth Circuit's "second-guessing", given his respect for precedent, his concurrences in Justice Alito's opinions stressing the need for judicial deference to FDA safety determinations, *and* his own concurring opinion in *ACOG* extending that deference to the Agency's judgments on mifepristone. He may conclude that the deference to the FDA that he has consistently endorsed in the past should not be abandoned simply because, in *AHM*, that would uphold FDA decisions to treat mifepristone like other medications. Moreover, since the use of mifepristone is still limited to ten weeks from gestation, that method avoids some of the controversy surrounding late-term, surgical abortions which, Justice Roberts suggested in *Dobbs,* causes the most fractious debate.[139]

If Justices Alito and Roberts in fact split their votes in that manner, that could well give Justice Kavanaugh the deciding vote in *AHM* — just as he was in *Dobbs*. And that would raise other, but related, issues. For it must be remembered that, in addition to his repeated concurrences with the other conservative Justices on the importance of judicial deference to the FDA, Justice Kavanaugh has repeatedly insisted that his decisive vote in *Dobbs* was grounded in his belief that the courts should not be involved in setting abortion policy, but rather should "leave[] the issue for the people and their elected representatives to resolve through the democratic process in the States or Congress."[140]

Those "democratic processes" obviously include the decisions of the FDA which is ultimately responsible to the voters who elect the President (who appoints the FDA Commissioner) and Congress (which provides the Agency's authority). The FDA's balance between the benefits and risks of any drug may thus change over time (within the bounds of a reasoned analysis of data) without being "arbitrary" or "capricious". Rather that evolving balance may reflect the "will of the voters" — precisely what

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[138] Danco Laboratories, LLC v. All. for Hippocratic Med., 143 S. Ct. 1075, 1075-1077 (2023) (Alito, J., dissenting).

[139] *See* Dobbs v. Jackson Women's Health Organization, 597 U.S. 215, 351 (2022) (Roberts, C.J., concurring).

[140] *Id.* at 338.

Justice Kavanaugh, and the other Justices who signed on to *Dobbs,* said they both desired and intended.[141]

All that said, it remains to be seen whether two of the conservative Justices will honor their own prior opinions when they review the Fifth Circuit's decision to second-guess the most significant portions of the FDA's regulation of mifepristone. We shall see.

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[141] A vote by Justice Kavanaugh in favor of judicial deference to FDA in *AHM* would also be consistent with his opinion for the Court in *FCC v. Prometheus Radio,* 141 S. Ct. 1150 (2021)*,* and with his earlier opinion, as a judge on the D.C. Circuit, upholding an FDA ruling on the proper classification of a medical device — where he warned "[a] court is ill-equipped to second-guess that kind of agency scientific judgment under the guise of APA's arbitrary and capricious standard." Cytori Therapeutics, Inc. v. FDA, 715 F.3d 922, 927 (D.C. Cir. 2013).